Policy Guideline
High Risk Medicines Management Policy Guideline

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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 Guideline is designed to support SA Health services comply with the accompanying Policy Directive, and 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. It provides guidance on formulating an organisational management strategy for high risk medicines including: identifying high risk medicines; identifying and assessing risks associated with high risk medicines; and implementing and evaluating risk reduction strategies.

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

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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
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High Risk Medicines Management Policy Guideline
Document control information

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High Risk Medicines Management Policy Guideline

1. Objective

The High Risk Medicines Management Policy Guideline is designed to support SA Health hospitals and health care services comply with the High Risk Medicines Management Policy Directive. It provides guidance on formulating an organisational management strategy for high risk medicines including: identification of high risk medicines and development of a high risk medicines list; identification and assessment of risks associated with use of high risk medicines; and implementation and evaluation of risk reduction strategies.

This policy guideline is to be read in conjunction with the High Risk Medicines Management Policy Directive.

2. Scope

All SA Health employees, and persons who provide services on behalf of SA Health, who are involved in medication management should be aware of this policy guideline. Those involved in formulating an organisational high risk medicines list, performing risk assessments of use of medicines and medication management processes, and/or implementing or evaluating risk reduction strategies for management of high risk medicines should refer to this guideline.

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 inadvertently 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 step of the medication management pathway, in accordance with the National Safety and Quality Health Service Standards
- information is available from Australian and international safety organisations to assist health services implement strategies to identify and improve safe use of high risk medicines.

4. Detail

4.1 Development of an organisational high risk medicines list

Health services should develop their own high risk medicines list through reference to existing high risk medicines lists, the published literature, and the organisation’s own medication incident data.
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) APINCH taxonomy.

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<th>Category</th>
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<tr>
<td>A</td>
<td>Anti-infectives</td>
<td>Refers to amphotericin, vancomycin, and aminoglycosides, but may also include others.</td>
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<tr>
<td>P</td>
<td>Potassium and other electrolytes</td>
<td>Refers to injectable electrolyte preparations, e.g. potassium chloride and magnesium sulfate, but may also include other medicines.</td>
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<td>I</td>
<td>Insulin</td>
<td>Refers to all insulins.</td>
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<td>N</td>
<td>Narcotics and other sedatives</td>
<td>Refers to all opioids; sedatives may include benzodiazepines and other sedating agents.</td>
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<tr>
<td>C</td>
<td>Chemotherapeutic agents</td>
<td>Refers to cytotoxic chemotherapy.</td>
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<tr>
<td>H</td>
<td>Heparin and anticoagulants</td>
<td>Refers to heparins and all anticoagulants, including the New Oral Anticoagulants.</td>
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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 is not 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.

Other lists of medicines considered to be universally acknowledged as high risk have been developed by international organisations.

The UK National Patient Safety Agency (NPSA) 2009 report ‘Safety in Doses’ found the groups of medicines most frequently associated with the most severe harms (as reported to the National Reporting and Learning Service (NRLS) in 2007) to include cardiovascular, anti-infective, opioid, anticoagulant and anti-platelet medicines. This is followed by chemotherapy, anaesthetics and insulin. No incidents of death or severe harm related to potassium chloride injection or oral methotrexate were reported; this follows earlier guidance from the NPSA on the safe use of these medicines.

The Institute for Safe Medication Practices (ISMP) has created, and periodically updates, a list of High-Alert Medications identified in the USA which has formed the basis of similar high risk medicines lists worldwide and within Australia. The list, consisting of medicine groups and individual medicines, is based on error reports submitted to the ISMP National Medication Errors Reporting Program, reports of harmful errors in the literature, and input from practitioners and safety experts. This list reflects the collective thinking of all who provided input. The list for institutional and inpatient healthcare settings can be accessed at https://www.ismp.org/Tools/highAlertMedicationLists.asp.
A separate list for community and ambulatory healthcare settings is also available from ISMP.

Whilst the types of medicines used and patients treated may vary between and within healthcare settings, the ISMP believes that the evidence suggests there is a core group of medicines that should be considered high risk and that every hospital’s list should include (when used):

- concentrated electrolytes
- neuromuscular blocking agents
- opioids
- anticoagulants
- insulin
- epidural or intrathecal medications
- chemotherapy.

Individual organisations may use additional or different medicines that present as a risk to patient safety. Health services may customise their high risk medicines list to better suit their own organisation and patient population, and are encouraged to identify those high risk medicines which pose the greatest threat to patient safety. Multiple high risk medicines lists may be required within an organisation, for example for different wards or services, due to differences in patient populations and the medicines used.

To develop an organisational high risk medicines list, the following steps can be taken:

- form a multidisciplinary working group to develop the list
- review and consider the acronym APINCH medicines
- review and consider the ISMP’s List of High-Alert Medications
- review and consider current published literature to identify specific medicines and/or medicine groups that bear a heightened risk of causing significant patient harm when used in error
- review incident reporting data in South Australia relating to prevalence and severity of medication incidents
- review incident reporting data in the organisation relating to prevalence and severity of medication incidents
- review incident reporting data in specific services or wards of the organisation relating to prevalence and severity of medication incidents
- conduct a risk assessment in the organisation to obtain specific data related to medication incidents with respect to prevalence, severity, potential for harm, and contributing factors for error
- consider all data reviewed to identify and define the medicines and/or medicine groups to be included on the high risk medicines list
- after development of an agreed upon high risk medicines list, submit the list to the Drug and Therapeutics Committee or equivalent in your organisation for approval.

4.2 Reference to and review of the high risk medicines list

Once a high risk medicines list has been established it should be reviewed regularly for relevance and completeness, known by staff, and referred to by staff involved in management of high risk medicines.

Recommended processes to support regular review include:

- ensuring an appropriate review date for the list
- review of the list as a regular item on the appropriate committee agenda.

Recommended processes to support staff knowledge of the high risk medicines list include:
ensuring processes are in place and adhered to in order to enable health service wide distribution and promotion of the list
ensuring processes are in place and adhered to in order to provide continued and easy access to the list by all staff involved in the management of medicines.

The Institute for Safe Medication Practices (ISMP) suggests updating a high risk medicines list as needed and reviewing the list at least every two years. 

Reference to, and review of, the high risk medicines list is recommended when considering formulary applications or individual patient use applications for medicines in a health service. This is part of the 'purchasing for safety' approach to medicines management which should be implemented in all SA Health services. If a medicine to be added to the formulary or used on an individual patient basis is considered to have potential to be high risk, a risk analysis can be undertaken to determine whether the medicine presents a risk to the organisation.

4.3 Identification and assessment of risks associated with high risk medicines

4.3.1 Assessment of medication management processes

As part of the safe management of high risk medicines, assessment of medication management processes should be regularly undertaken.

Recommended tools available to assist hospitals in assessing their medication safety practices and identify opportunities for improvement include:

- The Medication Safety Self Assessment® for Australian Hospitals (MSSA)  
- The Medication Safety Self Assessment® for Antithrombotic Therapy in Australian Hospitals (MSSA-AT)
- 2012 ISMP International Medication Safety Self Assessment® for Oncology

Using these assessment tools helps hospitals meet their obligations for accreditation. The ACSQHC recommends assessment of the medication management system every three years.

4.3.2 Medication incident reporting and review

Medication incidents, including those associated with high risk medicines should be reported by staff to the SA Health Safety Learning System (SLS) as per the SA Health Incident Monitoring Directive and Guideline.

Reporting medication incidents to SLS allows important information about incidents and contributing factors to errors to be available for further analysis, sharing of learning, and implementation of safety strategies for the use of medicines. Identification of system processes that may contribute to error may be identified and new issues with medicines may be discovered.

Encouraging staff to report medication incidents to the incident monitoring system will assist in focussing high risk medicines safety efforts to those areas where they are most needed.

SA Health has a Safety Learning System (SLS) Incidents User Guide which provides information about how to report incidents into the Safety Learning System.
Governance arrangements should be in place to ensure medication incidents, including ‘near misses’, involving high risk medicines are regularly reported to and reviewed by the appropriate committees at a Local Health Network and hospital level (e.g. Medication Safety Committee, Drug and Therapeutics Committee).

4.3.3 Risk assessment

For any risks associated with high risk medicines identified through assessment of medication management processes, review of incident monitoring data or other mechanisms, a risk assessment should be undertaken.

SA Health has a Risk Management Policy Directive, and accompanying Risk Assessment Framework, which contains a Risk Assessment Matrix. These documents can be referred to when assessing processes involved in the management of all medicines, including those considered high risk.

Action to address any identified risks should be implemented and evaluated.

4.4 Risk Reduction Strategies

Once established, a high risk medicines list needs to be current, known by staff, and accompanied by robust evidence-based risk reduction strategies. The primary goals of implementing risk-reduction strategies are to:

- prevent errors
- make errors visible, and
- mitigate harm. ^5

The medication management system is sometimes described as a medication management pathway or cycle (Figure 1), with a clear emphasis on the consumer as the central focus. For each consumer, the decision to prescribe a medicine is individualised, with the choice of medicine the most appropriate, safe and cost-effective for them.^10

Safe management of high risk medicines requires a multidisciplinary and organisation-wide approach, addressing all stages of the medication management pathway, including system processes such as medicines procurement and materials management.
Strategies may be implemented at any, or all, of the steps of the medication management system. A single risk-reduction strategy for each high risk medicine is rarely sufficient to prevent errors and harm from errors. Actions should thus be comprehensive and ISMP recommends:

- using numerous risk reduction strategies together
- using strategies that have impact on as many steps of the medication management system as possible
- using high-leverage risk reduction strategies, such as forcing functions and standardisation, together with low-leverage strategies such as staff education and passive information dissemination
- strategies should be sustainable.

Any strategies that are implemented should be evaluated for effectiveness using both outcome and process measures. Results should be discussed regularly at the appropriate committee meetings, such as the Medication Safety Committee or Drug and Therapeutics Committee meetings.

Information is available from Australian and international safety organisations to assist health services implement appropriate strategies to identify and improve safe use of medicines, including high risk medicines.

Details of available information and strategies are provided below for reference. This is not an exhaustive list; organisations should ensure they keep up to date and informed of national and international initiatives and strategies designed to enhance safe use of high risk medicines.

### 4.4.1 National Medication Safety Alerts for High Risk Medicines

In Australia, the former Australian Council for Safety and Quality in Health Care developed a national alert system for high risk medicines to:
• warn health leaders and professionals about serious known medication hazards;
• provide tools to effectively ensure action to reduce the hazards; and
• set out responsibilities for system change.

All hospitals and health care services should evaluate their safety controls against the alert recommendations. Compliance with the recommendations of the alerts is a requirement of accreditation to the National Safety and Quality Health Service Standards.

Currently, the ACSQHC provides two national high risk medication safety alerts which are available on their website:

**Intravenous potassium chloride can be fatal if given inappropriately** 11

- Released in October 2003 in response to reports of fatalities and significant patient harm from the improper administration of intravenous potassium chloride, the alert contains recommendations to improve patient safety by implementing strategies such as the removal of potassium ampoules from ward areas.

**Vincristine can be fatal if administered by the intrathecal route** 12

- Released in December 2005, this alert draws on international and Australian work to make a range of recommendations.
- Vincristine, a medicine commonly used in the treatment of leukaemias and lymphomas, is neurotoxic and must only be administered intravenously.
- Sentinel events associated with the inadvertent intrathecal administration of vincristine have been repeatedly reported in Australia and overseas. This error results in a fatal outcome in 85% of cases with devastating neurological effects in the few survivors.

### 4.4.2 South Australian Medication Safety Alerts

**South Australian Medication Safety Alerts** provide important safety information to healthcare professionals and services across the South Australian health system.

Information from local, national and international sources is utilised to provide health services with warnings, advice and guidance on medicine related safety issues. The alerts also serve to ensure learnings relevant to enhancing safe use of medicines may be shared across the South Australian health system in an active manner.

Medication Safety Alerts are distributed by the SA Health Safety Alert Broadcast System (SABS).

Each alert specifies action to be taken by health services, the timeframe in which such action must occur, and responsibility for the actions. For more information on this, refer to the SA Health **Safety Alert Broadcast System webpage**.

### 4.4.3 National and state recommendations

The Australian Commission on Safety and Quality in Health Care website provides information on a range of national recommendations relevant to medication safety and safe use of medicines. Although not specific to high risk medicines, they are relevant to the safe management of all medicines. SA Health policies regarding implementation of these recommendations at a state level are also available in some cases.

- **National Inpatient Medication Chart (NIMC)** 13
The NIMC is a suite of nationally standardised medication charts, both paper and electronic, that present and communicate information consistently between healthcare professionals providing care to patients on the intended use of medicines for an individual patient.

Use of the NIMC is mandatory and a requirement for accreditation to National Safety and Quality Health Service Standard 4 Medication Safety. Its purpose is to reduce the risk of prescribing, dispensing and administration error by health professionals through standardised presentation of information on the intended use of medicines for an individual patient, and through standardised presentation of medicines information in all high risk healthcare settings.

To promote safe prescribing and monitoring, the NIMC has designated sections for prescribing warfarin and venous thromboembolism prophylaxis. Participation in local and nationally coordinated auditing of the NIMC is encouraged.

SA Health provides information on the [NIMC for South Australia](#).

- **National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines**  
  SA Health provides a policy directive, associated resources and an e-learning module, 'Labelling for Safety – injectable medicines, fluids and lines', for SA Health employees. The module can be accessed via the [SA Health Medicines and Technology Policy and Programs website](#).

- **Recommendations for Terminology, Abbreviations and Symbols used in Prescribing and Administering of Medicines**  
  SA Health provides information on safe medication terminology including the [Spell It Out policy](#).

- **Australia’s National Tall Man Lettering List**  
  Tall Man lettering uses a combination of lower and upper case letters to highlight the differences between look-alike drug names, like fluOXETine and fluVOXAMine, helping to make them more easily distinguishable.

  Tall Man lettering is designed for use in electronic medication management systems including prescribing and dispensing systems, on printed labels used for inpatient dispensing shelving in pharmacies and ward medicines cupboards, and in smart pump drug libraries. It reduces error by warning health care professionals about the risk of confusing a particular medicine name and by helping health professionals to select the right product in electronic systems or from shelves.

  Use of the national standard for Tall Man lettering:
  - prevents the proliferation of various lists of Tall Man names, which may lead to inconsistency in the application of the technique and result in confusion;
  - ensures the best available scientific evidence is used to support the development of Tall Man names; and
  - provides credibility to the technique as a tool that can be used to help reduce the risks associated with look-alike, sound-alike drug names.
• **Electronic Medication Management**


### 4.4.4 Other strategies for organisations

Strategies to reduce errors with high risk medicines may be particular to the medicine or medicine group, such as those suggested for implementation in the National Medication Safety Alerts, or may be more generic strategies that can be applied to all medicines.

The Australian Commission on Safety and Quality in Health Care provides examples of strategies that can be implemented to safely manage high risk medicines in their Safety and Quality Improvement Guide Standard 4: Medication Safety. The ACSQHC also provides links to safety alerts and other guidance. The list provided is not exhaustive.

The Institute for Safe Medication Practices provides information about high risk medications and risk reduction strategies.

### 5. Roles and Responsibilities

For information regarding roles and responsibilities associated with this guideline refer to the High Risk Medicines Management Policy Directive.

### 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:


SA Health hospitals and health services are required to report against a set of APAC key performance indicators 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.

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. Associated Policy Directives / Policy Guidelines (if applicable)

Associated SA Health directives and guidelines

- Accreditation Policy Directive
- Aminoglycosides: recommendations for use, dosing and monitoring Policy Clinical 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 Directive
- 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
9. 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. Australian Commission on Safety and Quality in Health Care, ACSQHC High Risk Medicines webpage, including Medication Safety Alerts and Notices
6. Clinical Excellence Commission, Medication Safety Self Assessment for Australian Hospitals (MSSA),
10. Australian Pharmaceutical Advisory Council, Guiding principles to achieve continuity in medication management, Commonwealth of Australia, July 2005
11. Safety and Quality Council Medication Alert, Medication Alert! Intravenous POTASSIUM CHLORIDE can be fatal if given inappropriately, Alert 1, October 2003, Medication Safety Taskforce of the Australian Council for Safety and Quality in Health Care
12. Safety and Quality Council Medication Alert, Medication Alert! VINCristINE can be fatal if administered by the intrathecal route, Alert 2, December 2005, Australian Council for Safety and Quality in Health Care
13. Australian Commission on Safety and Quality in Health Care, National Inpatient Medication Chart, ACSQHC, Sydney
15. Australian Commission on Safety and Quality in Health Care, Recommendations for Terminology, Abbreviations and Symbols used in the Prescribing and Administration of Medicines, January 2011, ACSQHC, Sydney
19. Indicators for Quality Use of Medicines in Australian Hospitals, NSW Therapeutic Advisory Group, 2007

Resources and Related Documents

- SA Health Medication Safety internet site, including High Risk Medicines page
- Controlled Substances Act 1984
- Controlled substances legislation
- SHPA Standards of Practice for Medication Safety
- The ‘How to Guide’ for Reducing Harm from High Risk Medicines available at www.patientsafetyfirst.nhs.uk
- The Institute for Healthcare Improvement (IHI) resources including a How-to Guide: Prevent Harm from High-Alert Medications’ and associated tools (log-in required)
- ‘Medication Safety’ series, Journal of Pharmacy Practice and Research. Provides up-to-date information about medication safety issues and strategies to prevent medication errors. Incidents reported are drawn from Australian experience and from the Institute for Safe Medication Practices, USA.

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

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<td>Recognising &amp; Responding to Clinical Deterioration</td>
<td>Preventing Falls &amp; Harm from Falls</td>
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11. Other

N/A

12. Evaluation

Implementation of the High Risk Medicines Management Policy Guideline will be evaluated by the Medicines and Technology Policy and Programs Branch through Local Health Network (LHN) reporting to the South Australian Medication Safety Advisory Group (SAMSAG). Trends in high risk medicines incident reporting across SA Health are reviewed at meetings of the SAMSAG, with recommendations for improved high risk medicines management made where appropriate. LHNs are to report identified risks.
associated with high risk medicines and results of implemented improvement strategies on a regular basis.

SA Health hospitals and health services can evaluate the safety of their high risk medicines management using the following:

- **Australian Commission on Safety and Quality National Medication Safety Alerts for High Risk Medicines**¹¹,¹²
- **Medication Safety Self Assessments**
  - The Medication Safety Self Assessment® for Australian Hospitals (MSSA)⁶
  - The Medication Safety Self Assessment® for Antithrombotic Therapy in Australian Hospitals⁷
  - The 2012 ISMP International Medication Safety Assessment® for Oncology⁸
- **SA Health Australian Pharmaceutical Advisory Council (APAC) Key Performance Indicators**¹⁸
- **Indicators for Quality Use of Medicines in Australian Hospitals**¹⁹
- **National Inpatient Medication Chart (NIMC) Auditing**¹³

### 13. Attachments

N/A

### 14. 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.¹⁷

- **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.²⁰

- **High risk medicine** means: any medicine which has a heightened risk of causing significant patient harm when used in error.⁴

- **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.²⁰

- **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 systems failures.²⁰

- **Medication incident** means: potential or actual patient harm that comes from errors or system failures associated with the preparation, prescribing, dispensing, distribution or administration of medicines.²⁰
• medication sentinel event means: medication error leading to the death of a patient reasonably believed to be due to incorrect administration of drugs

• medication management pathway means: the cognitive and physical steps involved in the use of medicines, with a focus on the consumer.  

• 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. 

• risk means: the chance of something happening that will have a negative impact. It is measured by consequence and likelihood.

• Safety Learning System (SLS) means: an electronic system for the reporting and management of incidents and consumer feedback across SA Health.