AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Principles for the safe selection and storage of medicines

Guidance on the principles and survey tool

July 2020

Published by the Australian Commission on Safety and Quality in Health Care

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ISBN: 978-1-925948-71-4

The Commission's preference is that you attribute this publication (and any material sourced from it) using the following citation:

Principles for the safe selection and storage of medicines – Guidance on the principles and survey tool. Sydney: ACSQHC; 2020.

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13. Reduce the risk of medicine selection error through standardisation of processes, systems and technology.
14. Eliminate unnecessary steps in systems for the selection and storage of medicines.

Background

The Australian Commission on Safety and Quality in Health Care (the Commission) works in partnership with patients, carers, clinicians, the Australian, state and territory health systems, the private sector, managers and healthcare organisations to achieve a safe, high-quality and sustainable health system.

Key functions of the Commission include: developing national safety and quality standards, developing clinical care standards to improve the implementation of evidence-based health care, coordinating work in specific areas to improve outcomes for patients, and providing information, publications and resources about safety and quality.

The Commission works in four priority areas:

- Safe delivery of health care
- Partnering with consumers
- Partnering with healthcare professionals
- Quality, value and outcomes.

The Commission identified a need to develop guidance for the safe selection and storage of medicines, with a focus on look-alike, sound-alike (LASA) medicines.

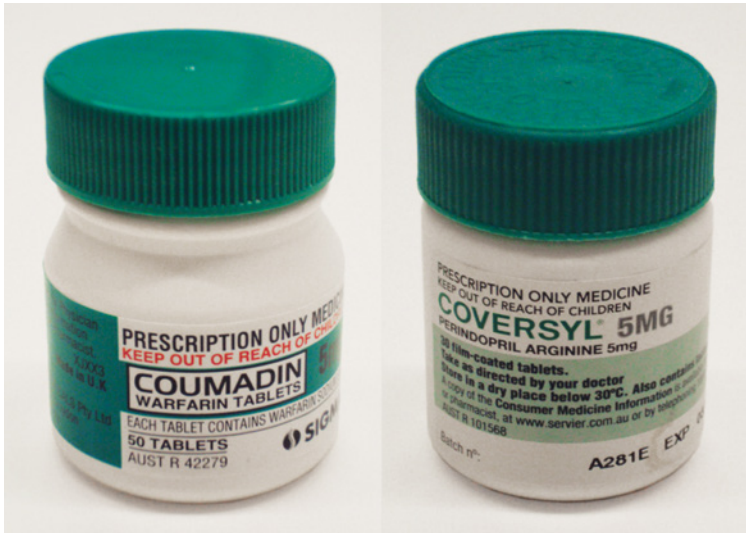
Medication incidents related to LASA medicine names are one of the most common type of medication error.[1,2,3]

The Commission supports a multi-faceted approach to help clinicians reduce the risk of selection errors. This includes the use of Tall Man lettering to reduce the risk of selection errors by health professionals associated with LASA medicines. The Commission is responsible for the development and stewardship of the *National Tall Man Lettering List* which is available for use by health service organisations. The List comprises LASA medicine name pairs (generic and brand name pairs) known and predicted to pose the greatest risks to patient safety.

Over recent years, concerns have been raised regarding the risk of selection errors due to the increasing availability of generic medicines and the similarities in medicine labelling and packaging.

In addition to LASA medicine names, the consultation identified other factors that increase the potential for risk of confusion and subsequent medicine selection error, for example, medicine packaging similarities (see Figure 1).

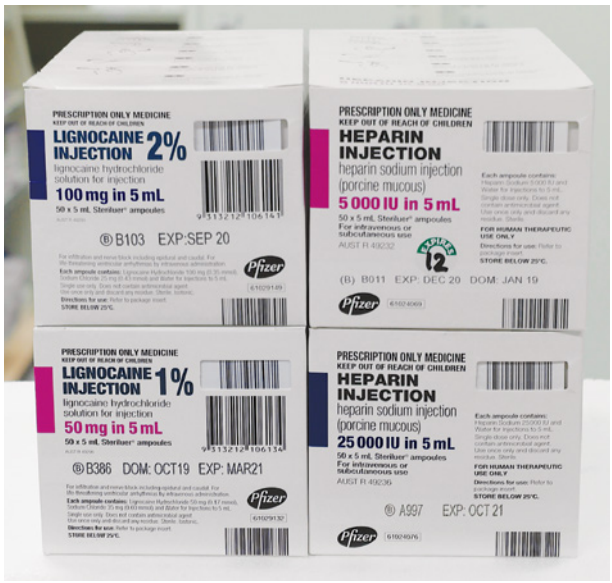
Figure 1: Examples of name and/or packaging similarities



Coumadin versus Coversyl

Invanz versus Primaxin

Solavert 80 mg versus Solavert 160 mg



Lignocaine versus heparin

Heparin 5000 IU in 5 mL versus heparin 25,000 IU in 5 mL

Therefore, this guidance has been broadened to address all aspects of medicine selection and storage that can affect the likelihood of medication error, including:

- Human factors (system design and behaviours that can impact safety)[4]
- Labelling (for example, font size for shelf labels)
- Organising medicines (for instance, lack of order or system)
- Storage of multiple strengths
- Storage of medicines with LASA names
- Storage of medicines with similar packaging
- Formulary decisions and procurement.

In 2013, the Institute for Safe Medication Practices (ISMP) published a list of risk-reduction strategies that could be used alone or in combination to target medication risks[5], including those associated with high risk medicines. These strategies aim to mitigate risk along the medication management pathway.[6] This includes the areas of procuring, storing, selecting, prescribing, compounding (or preparing), dispensing and administering medicines; as well as patient monitoring; and recovery preparedness.

The ISMP strategies align with the second edition of the National Safety and Quality Health Service (NSQHS) Standards[7], in particular Action 4.14 of the Medication Safety Standard.[8] The Medication Safety Standard requires organisations to implement 'strategies for safe and secure storage and selection of medicines, including high-risk medicines'.

NSQHS Standards Medication Safety Standard logo

This guidance aims to further articulate strategies and principles for the safe and secure selection and storage of medicines, with examples, supported by a survey tool for use by health service organisations (HSOs).

Intended audience

This document is intended for use in hospitals by all clinicians involved in the medication management pathway, including those with governance responsibilities within the health service. The guidance is also intended to be applied within pharmacy and ward storage environments.

Scope

This guidance comprises strategies and principles developed to address safe selection and storage of all medicines, including LASA medicines, which will have additional considerations given their greater potential for confusion.

The principles are broad and closely aligned with the NSQHS Clinical governance[9] and Partnering with consumer standards[10]. They also consider the impact of a clinician's work environment.

Purpose

Strategies proven to improve medication safety at selection include a mix of high leverage and low leverage strategies, which are summarised below:

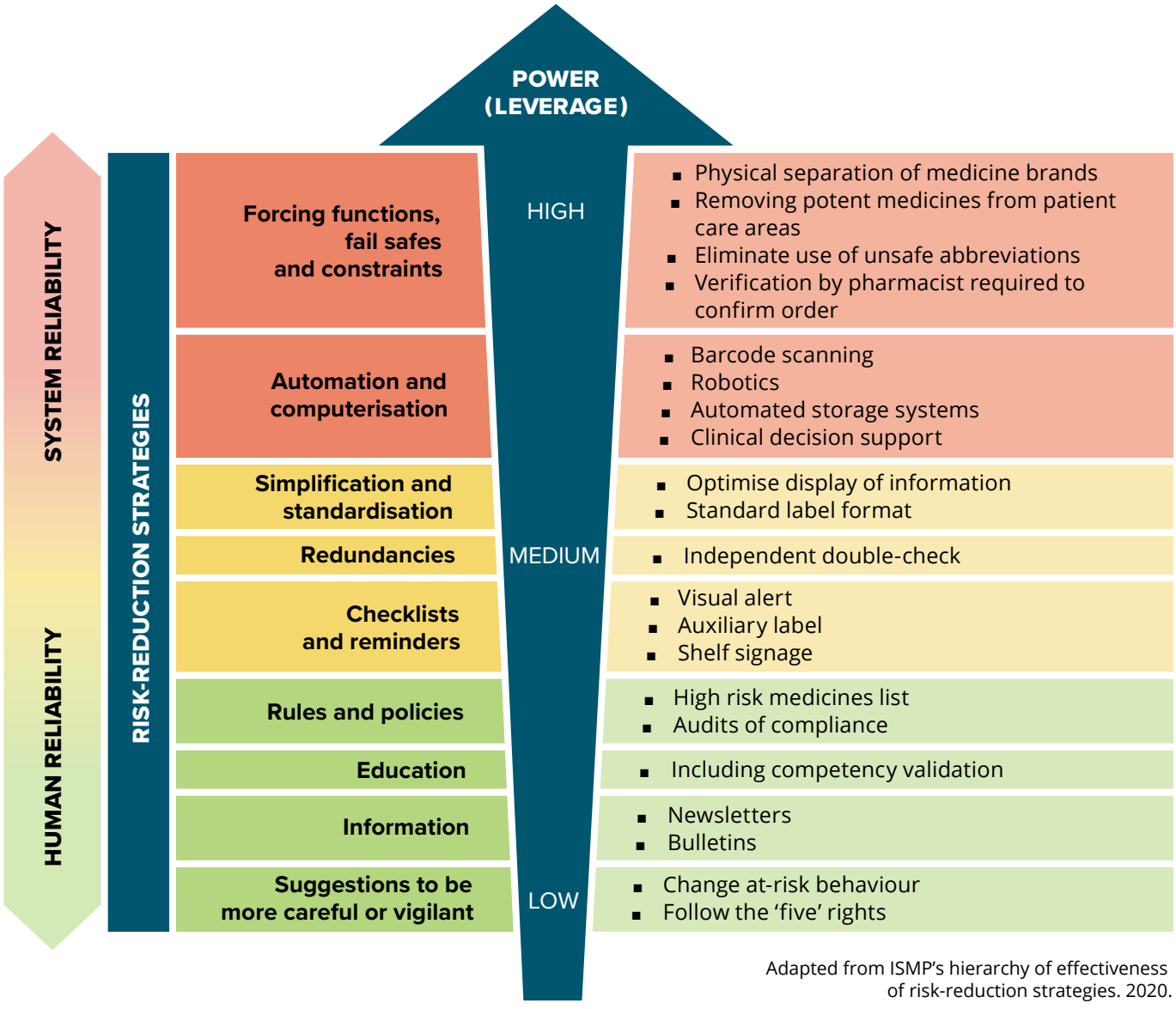
- Tall Man lettering of LASA name pairs
- Physical separation of different brands or strengths of medicines
- Special shelf signage – for example, alert stickers
- Technology solutions – bar code scanning; automation. For example, automated dispensing or storage cabinets
- Procurement/formulary strategies[11,12] – limiting range of concentrations, strengths or forms; involvement in product tender evaluations; local site product review using a checklist; feedback from ward staff
- Audits and medication safety walk rounds in hospital wards – use of local, national or international audit tools[13] for assessment and/or compliance with labelling and storage.

In developing this guidance the Commission has referenced risk-reduction strategies detailed in Table 1 of the ISMP's 2009 Medication Safety Alerts.[14] These have been adapted for use in the Australian context.

HSOs need to consider all options when implementing risk-reduction strategies. Lower leverage solutions may be used at first. However, these will often need to be supplemented by other strategies that focus on system as well as human factor issues to improve medication safety. For instance, the medication management system includes the workspace as well as the individuals and groups of clinicians that work in the system. Changes in system design or practices will make a difference to how well clinicians will work within it.[15] Organisations need to identify potential hazards, find ways to design-out these hazards, incorporate effective risk controls measures and design-in efficiencies.[16] For instance, assessing the risk of look-alike medicine packaging confusion or how the medicines information is displayed within an electronic medication management (EMM) system, will assist organisations to identify the best risk-reduction interventions to implement.

It will be important for organisations to routinely monitor the medication management pathway and evaluate risk-reduction strategies that have been implemented. Depending upon the results of this assessment, more powerful strategies may need to be considered to further enhance medication safety (see Figure 2).[17]

Figure 2: Hierarchy (power) of risk-reduction strategies



Adapted from ISMP's hierarchy of effectiveness of risk-reduction strategies. 2020.

Survey tool pilot[18]

During 2019, the Commission developed and tested a survey tool based upon an initial set of 17 principles for the safe selection and storage of medicines.

The survey tool in development was piloted over a 4 week period commencing 23 April until 20 May 2019. The pilot comprised of two parts:

1. completion of a survey of risk-reduction strategies for implementation; and
2. feedback on the clarity of these strategies.

Eighteen valid survey responses were available for analysis, representing every state and territory along with a mix of public and private, large metropolitan and small regional hospitals. A mix of clinical areas were selected for survey including emergency; medical and surgical wards; as well as a multi-purpose service.

Results of the survey indicated a majority of the strategies were either 'partially' or 'fully implemented' within pharmacy or clinical areas and respondents found the majority of listed strategies clear (>85%).

The pilot supported the usefulness of the set of principles, accompanying risk reduction strategies and survey tool in assessing hospitals' medicine selection and storage risks.

Sites were able to identify where they have implemented risk reduction strategies along the medication management pathway and/or where additional strategies could be implemented to further enhance medication safety.

Following feedback, the revision resulted in two overarching, organisation-wide principles and an additional 14 principles supported by 91 risk reduction strategies (see Figure 3).

The revised guidance now comprises:

- Introduction, target audience, scope, purpose, background, survey pilot and developing an action plan as well as a glossary of terms and a hierarchy of risk-reduction strategies
- Two overarching organisation-wide Principles:
  - Governance
  - Consumer participation
- An additional 14 principles supported by a total of 91 risk reduction strategies
- Practical examples to assist HSOs when assessing their medicine selection and storage risks
- A **survey tool** reflecting the additional principles and strategies.

Further work is required to progress development of an online version of the survey tool for access and use by HSOs to assess the safety of the selection and storage of medicines within the organisation's pharmacy and clinical areas.

Figure 3: Development pathway of the principles for safe selection and storage of medicines

The survey tool

The **survey tool** comprises:

- Four implementation ratings to assess risk reduction strategies for safe storage and selection
- Practical examples of risk reduction strategies
- An action plan to inform quality improvement.

The four ratings are based upon the structure used within ISMP's Medication Safety Self Assessment® (MSSA) program:[13]

- Implemented everywhere
- Partially implemented
- Considered but not implemented
- Not considered or implemented.

The survey tool is intended for use by HSOs to conduct gap analysis on the safe storage and selection of medicines in their health service. The information collected should assist the HSO to identify where risk reduction strategies have, or have not, been assessed against the four ratings. HSOs should seek input from relevant stakeholders including (but not limited to) representatives from pharmacy, medical and nursing. This combined approach can be used by HSOs to develop an action plan based upon any perceived gaps or identification of risk reduction strategies.

Numerous practical evidence examples that HSOs may find useful for assessing various risk reduction strategies have been included. These examples are not exhaustive and the HSO may have alternative local examples, or evidence of alternative risk reduction strategies, that improve the safety and effectiveness of the HSO's selection and storage systems.

Developing an action plan

The action plan should include assessment of the effectiveness of any risk reduction strategies or interventions aimed at improving and ensuring the safe selection and storage of medicines. The HSO's medicines governance group should be involved in monitoring their implementation and evaluation. This includes being alert to introduction of any unintended consequence or unforeseen risk.

Ideally an action plan (electronic or hardcopy) would include:

- well-defined action(s)
- all the steps/tasks involved
- what resources are required
- who is responsible – overall and for each step/task
- assignment of priority and timeframe for completion
- status or indicator of progress (on schedule; behind schedule; complete)
- additional information (or commentary) to assist the HSO to monitor progress.

The HSO's action plan should be dynamic and accessible for information and status updates, and in a format that allows presentation or tabling at governance group meetings.

Resources are available on the Commission's website that HSOs may find useful when developing an action plan. A sample **Implementation action plan template** is available along with other tools which are included in the Commission's **Implementation toolkit for clinical handover improvement**.

The Agency for Healthcare Research and Quality (AHRQ) in the US provides **guidance** (including an action plan template) on what to consider when developing an action plan: **Action Planning Tool for the AHRQ Surveys on Patient Safety Culture.**

Electronic project management tools may also provide a useful mechanism to develop, maintain and monitor the HSO's implementation of selected risk reduction strategies. For example, Smartsheet™ provide a selection of **action plan templates** that can be downloaded and set up within Excel or similar.

Organisation-wide principles — in detail

Governance

Suitable governance is in place for safe procurement of medicines (including look-alike sound-alike (LASA) medicines) and formulary decision-making.

Governance responsibility is required for safe medicines procurement and formulary decision-making. Procurement and formulary decision-making are important aspects to managing risks associated with medication management.

Overarching governance could be achieved via state-wide oversight or locally, via a drug and therapeutics committee (D&TC) or equivalent, in line with guiding principles for *Achieving effective medicines governance*.[19]

Policies and procedures for medication management need to describe processes for safe procurement, selection and storage requirements for all new or alternative medicines, for instance, during a medicines shortage. This would include the requirements for and the conduct of a risk assessment. For example, Australian[11] or international[12] checklists for product assessment and audits to monitor uptake and ongoing compliance with risk-reduction strategies; and Victorian procedure and compliance audit for high risk medicines distribution restrictions, alerts and stickers[20]; storage and assessment of neuromuscular blocking agents.[21,22]

Governance oversight also includes the development and implementation of quality improvement initiatives. Results of any risk assessments (for instance, FMEA[23] or similar) should be used to develop an action plan (or quality improvement plan) to mitigate risks associated with LASA error potential of a new or alternative medicine. For example, include a strategy for alerting clinicians of a new/alternative brand or formulation. Strategies for assessing and decreasing the risk of LASA selection errors need to be employed, for example, procurement of a different brand or pack size.

Including LASA medicines within high risk medicines lists will assist HSOs by highlighting which medicines require special risk reduction strategies in accordance with national[24] or international guidance.[25] For example, a local or state-wide list which includes LASA medicines of local concern should also include information about a suitable escalation process for active review as a result of an incident or risk assessment.

Safe procurement, selection and storage requirements for medicines must also be considered and built into contracts with external pharmacy service providers.

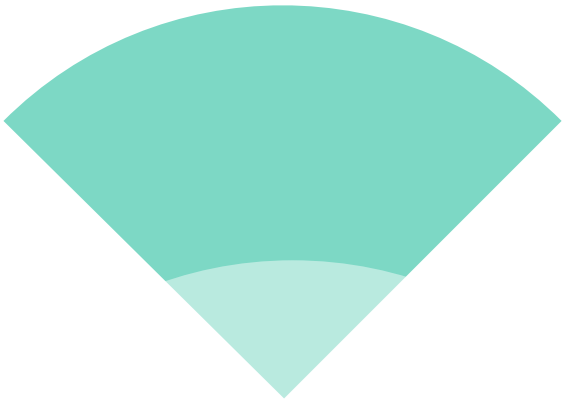
Consumer participation

Patients (and their carers) are included when considering the risks and benefits of taking medicines (including LASA medicines) and are informed and educated about these risks.

Patients (and their carers) can be empowered by informing and educating them about the risks associated with confusing medicines and how these risks can be avoided. This can happen at the time of taking a best possible medication history, medication review, medication reconciliation and during counselling (includes transition of care, i.e. at time of discharge).

A range of strategies includes:

- Encouraging patients (and their carers) to know active ingredient name(s) of their medicine (including non-prescription and over-the counter (OTC) medicines) and why they are taking it.[26]
- Emphasising the need to read the medicine name and strength rather than rely on package recognition, particularly for patients taking medicines within the same brand range.
- Encouraging patient (and carer) feedback on concerns about their medicines (for instance, appearance of their medicine), or if they experience unexpected symptoms. This is a mechanism to alert clinicians to take action, for instance, to review, respond to and report this feedback.
- Encouraging consumers (and their carers) to ask questions if their medicines look different than usual or expected. This ensures an ability to safely recognise similarities and differences between brands of a medicine.[26]
- Clinicians asking patients (and their carers) how they usually take their medicines, if they have any concerns, or if they are satisfied with the outcomes from their medicines, or if they need help with their medicines, or if they have experienced unexpected symptoms. This will assist in developing a personalised medication management plan that is tailored to address individual adherence barriers.[27] Understanding patients' medicines-taking behaviours and preferences is essential to encouraging safe and effective medicine use and in promoting adherence to treatment regimens.[28]
- Ensuring patients taking multiple medicines are able to differentiate their medicines particularly when new medicines are introduced to a complex regimen.



Principles for application within pharmacy and clinical areas — in detail

Application within pharmacy and clinical areas

Principle		Description	Examples of strategies
1	**Risk assessment**	**Conduct proactive assessment of the risks associated with the selection and storage of medicines**	Use of international or nationally or locally developed and endorsed assessment tools to conduct audits or self-assessments or perform risk assessment. For example, Failure Mode Effects Analysis (FMEA)[23] or similar, and pay particular attention to LASA selection risk.
2	**Checklists and reminders**	**Include assessment of LASA medicine risk in checklists and when applying labels or alerts**	Apply the Commission's *National standard for user-applied labelling of injectable medicines, fluids and lines*.[29] Use of procurement checklists or assessments in facilities and/or tender evaluations that consider medication safety and risk of medicine selection errors.
3	**Positive performance shaping factors**	**Provide a work environment that reduces the risks associated with the selection and storage of medicines**	Use of 'Do not interrupt' interventions consistent with the Commission's Evidence Briefing on *Interventions to reduce interruptions during medication preparation and administration*.[30] For example, quarantining medication administration rounds by using 'do not disturb' vests or signage; noise reduction via designated quiet zones; checklists; task allocation/responsibility for non-medication related enquiries via telephone. The physical design, layout and choice of medicine storage equipment and technology is conducive to safe selection, storage and preparation of LASA medicines.
4	**Education and competency validation**	**Ensure clinician awareness and competency on the risks associated with incorrect selection and storage of medicines**	Inform and educate clinicians involved in prescribing, dispensing and administering (and monitoring effects of) medicines about the consequences of confusing different formulations or medicine potency.

Principle		Description	Examples of strategies
5	**Situational awareness and critical thinking**	**Use simulation when informing and educating clinicians about risks associated with incorrect selection and storage of medicines**	Use of simulation to expose and educate clinicians involved in prescribing, dispensing and administering LASA and high risk medicines about the potential risks and risk-reduction strategies.
6	**Recovery and harm mitigation**	**Monitor medicine use and related alerts or triggers for patient deterioration**	Patient monitoring, alerts or triggers used to detect irregularities or deterioration. For example, therapeutic drug monitoring; naloxone administration in response to opioid overdose; or unexplained respiratory depression due to the administration of an incorrect medicine or fluid.
7	**Limit access or use**	**Apply and communicate formulary restrictions related to medicines**	Restrict stock (imprest) of certain concentrations, strengths or formulations in clinical or ward storage locations.
8	**Constraints, barriers and forcing functions**	**Physically separate look-alike medicines that present risks associated with selection and storage**	Employ automated storage technology in pharmacy, or clinical/ward storage locations. For example, consistent with the Commission's Evidence Briefing on *Automated dispensing systems*.[31] If not automated, physically separate different brands and strengths of medicines by using shelf dividers or positioning on separate shelves.
9	**Differentiate items**	**Alter the appearance of packaging and/or labelling to emphasise the difference between look-alike medicines**	Alter the appearance of LASA medicine names on shelving and stock containers, For example, using Tall Man lettering[32]; colour; font size; or bolding.
10	**Add redundancy**	**Implement practices (manual) or design features or warnings (electronic) to detect and prevent medicine selection errors**	Employ independent second check (manual) for high risk or LASA medicines, or high risk techniques involving medicines. For example, consistent with the Commission's Evidence Briefing on *Double-checking medication administration*.[33] Employ technology to conduct checks. For example, use machine-readable (for instance, a linear barcode) scanning[34]; electronic approval; electronic prescribing; electronic administration.[35]
11	**Optimise display of medicines information**	**Display medicines information in a consistent manner including medicine names and instructions for use**	Adopt the Commission's *Guidelines for on-screen display of medicines information*[36] in all digital technology for medication management (in particular, prescribing, dispensing, administration and automated storage systems).

Principle	Description	Examples of strategies
12 **Use of affordances**	**Apply visual design technology to reduce the need for interpretation and risk of medicine selection errors**	Medicine labels present the medicines information in the same manner as the on-screen order. For example, the pharmacy dispensing label on the medicine container matches the presentation of the EMM medicine order that a clinician refers to when selecting a medicine for administration.
13 **Standardise**	**Reduce risk of medicine selection error through standardisation of processes, systems or technology**	Use evidence-based and standardised order sets within electronic medication management (EMM) systems.[37] Source commercially available products in the most ready-to-use formulation (according to TGA[38] and Pharmacy Board of Australia (PBA) codes, guidelines and policies[39]).
14 **Simplify**	**Eliminate unnecessary steps in systems for the selection and storage of medicines**	Use integrated EMM systems to eliminate risk of transcription errors.

Safe selection and storage of medicines

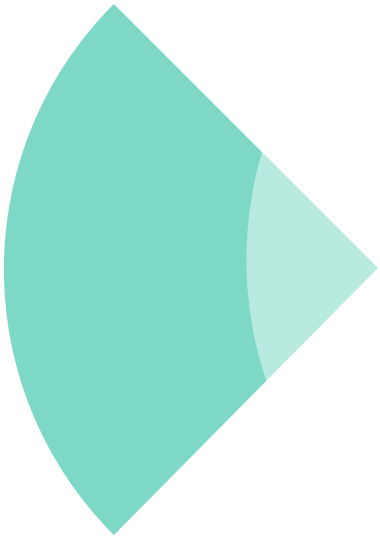
Principle		Risk reduction strategies for safe selection and storage
1 Risk assessment	**1.1**	Perform proactive risk assessment on any or all of the following: ▪ new medicines for high risk, including LASA risk (for example, name and/or packaging similarity), before use ▪ new technology – for example, infusion pumps ▪ high risk processes involving medicines ▪ use of alternative medicines in the event of a medicine's shortage, including Special Access Scheme (SAS). For example, FMEA[23] or similar. See various related principles and strategies.
	1.2	Use of **international or nationally developed and endorsed** assessment tools to assess or audit the safety of prescribing, dispensing, administration and storage systems for high risk medicines, including LASA medicines. For example, ensuring that Core Characteristics[40] that consider LASA medicines names, technology used, medicines standardisation, storage and distribution are assessed and implemented as relevant and applicable.
	1.3	Use of **locally developed and endorsed** assessment tools to assess the safety of storage systems for high risk medicines, including LASA medicines. For example, assessment of the storage of neuromuscular blocking agents (NMBAs).[22]
	1.4	Perform regular inspection of medicine storage to ensure pharmacy and ward storage systems comply with the risk reduction approach and strategies that have been implemented, for instance policy/procedure compliance. For example, separation/ segregation; access restrictions; alert labels; Tall Man lettering.[32] **Note**: This may include audit of inventory (pharmacy and/or ward) that may prompt removal or deletion of a medicine.

Principle		Risk reduction strategies for safe selection and storage
2 Checklists and reminders	**2.1**	Apply the Commission's *National standard for user-applied labelling of injectable medicines, fluids and lines*.[29]
	2.2	Use of a 'time out' checklist prior to a procedure that involves selection of a medicine, or to ensure the correct medicine has been administered. For example, use a cancer chemotherapy time out checklist, for instance, the eviQ *Antineoplastic drug time out checklist*[41]; apply the WHO (or ANZ edition) *Surgical Safety Checklist.*[42]
	2.3	Reminders for patient monitoring built into EMM standard order sets and/or medicine treatment protocols.
	2.4	Visual or audible alarms. For example, an alert generated by scanning a machine-readable code (for instance, a linear barcode) when a medicine is selected in error.
	2.5	Allergy records are available and considered in medicine selection and matching the correct medicine to avoid risk of patient harm from selection error. For example, completion of the Allergy/ADR box on the NSMC; allergy/ADR status recorded in EMM or alerted via red patient identification bracelets; allergy recording and documentation meets NSQHS Medication Safety Standard requirements – Actions 4.7 and 4.8.[8]
	2.6	Allergy and medicine duplication alerts are integrated into all electronic systems in use. For example, automated dispensing cabinets (ADCs); EMM; dispensing software and patient identification bracelets enabled with a machine-readable code (QR or linear barcode).
	2.7	Use of procurement checklists or assessments in facilities and/or tender evaluations that consider medication safety and risk of medicine selection errors and application of best practice labelling guidance.[43] For example, consider implications of: ▪ LASA medicine names with suffixes that denote a modified release instead of an existing or listed immediate release medicine ▪ differing indications for different brands of the same active ingredient ▪ storage requirements for ready-made injectable solutions that could be mixed up, for instance, 100 mL minibags of 10 mmol potassium chloride to be differentiated from 100 mL minibags of sodium chloride 0.9% ▪ the similar appearance of pre-filled syringes of a high risk medicine that could have devastating consequences if administered via the wrong route for example, vincristine for intravenous administration ONLY ▪ storage requirements for ready-made epidural infusions.
	2.8	Use of a checklist or assessment process (similar to that described above) in procurement and evaluation of replacement stock when a **medicine shortage** occurs. For example, this may occur locally or via a state-wide process.
	2.9	Apply restrictive practices within prescribing, dispensing and administration of replacement stock **in response to a medicine shortage**. For example, as part of a local or state-wide medicine-shortage management strategy.
	2.10	Use of communication tools or resources (electronic or hard copy) as a ready reference for clinicians. For example, bulletins, posters or safety alerts on avoiding specific medicine formulation mix-ups, or prompts for differentiation, including LASA medicines.

Principle	Risk reduction strategies for safe selection and storage
 **Positive performance shaping factors**	**3.1** The physical design, layout and choice of medicine storage equipment and technology is conducive to safe selection, storage and preparation of medicines. For example, is uncluttered and well organised.[44] *Also refer to* Standardisation.
	3.2 Use of 'Do not interrupt' interventions consistent with the Commission's Evidence Briefing on *Interventions to reduce interruptions during medication preparation and administration*.[30] For example, quarantining medication administration rounds by using 'do not disturb' vests or signage; noise reduction via designated quiet zones; checklists; task allocation/ responsibility for non-medication related enquiries, for example, phone calls.[45] **Note**: There is limited evidence of the effectiveness if interventions to significantly reduce interruptions.[46] A 2017 Australian study reported on the evaluation of using 'do not disturb' signage to reduce non-medication related interruptions during medication administration.[47] Whilst the intervention was shown to be statistically significant the authors noted that the impact on error rates should be considered relative to the effectiveness of alternative interventions. *Also refer to* Standardisation.
	3.3 Provide hands-on experience and competence assessment for clinicians involved in medication management in line with the role, authority and level of skill required.
	3.4 Invite clinicians involved in prescribing, dispensing, preparing (compounding) and administering (and monitoring the effects of) medicines to inform educational and interventional campaigns about potential risks and risk-reduction strategies. For example, informed by clinicians' experience with LASA and/or high risk medicines and how to influence practice change.
	3.5 A positive organisational safety culture with ability to recognise, respond to, give feedback, and learn from adverse events (NSQHS Standards: Clinical governance standard[9]). For example, a culture that supports and empowers staff to recognise and challenge an illegible, ambiguous or conflicting medicine order that could result in patient harm.
 **Education and competency validation**	**4.1** Educate clinicians about how selection errors can happen, the steps that the organisation is taking to avoid these types of errors and clinicians' role in error-reduction. For example, potential for LASA errors if handwritten orders are not legible; all illegible orders are potential medication errors; emphasising the need to read the medicine name and strength rather than rely on package recognition. **Note**: Education needs to identify and address barriers to understanding, and highlight the need for clinicians to change practice.
	4.2 Inform and educate clinicians involved in prescribing, dispensing and administering (and monitoring effects of) medicines about the consequences of confusing different formulations or medicine potency. For example, includes a focus on LASA and high risk medicines: lipid versus conventional parenteral formulation of amphotericin; morphine versus HYDROmorphone).
	4.3 Alert, inform and educate clinicians involved in prescribing, dispensing and administering medicines when a new or alternative medicine has been added to the formulary and has been assessed as having a LASA selection risk.
	4.4 Assess clinician competency and use results of competency assessment to identify and address barriers to understanding and need for a change in practice. For example, mandate essential medication safety training at intern orientation; conduct annual calculation assessments for nurses; random quizzes on strategies for safe selection and storage of medicines.

Principle	Risk reduction strategies for safe selection and storage
5 Situational awareness and critical thinking	**5.1** Use simulation to expose and educate clinicians involved in prescribing, dispensing and administering LASA and high risk medicines about the potential risks and risk-reduction strategies.
	5.2 Coach or instruct clinicians on specific techniques involved with the prescribing, dispensing, compounding or administration of LASA and high risk medicines.
	5.3 Teach and encourage clinicians to be vigilant and seek advice on LASA risks prior to undertaking critical tasks involving high risk medicines or high risk techniques. For example, prescribing or selecting a high risk medicine; taking 'time out' prior to administration of intrathecal chemotherapy; responding to acute unexplained clinical deterioration.
	5.4 Clinicians are involved in team 'huddles'[46,47] that include a focus on the potential risks and risk-reduction strategies associated with prescribing, dispensing, compounding or administration of medicines. For example, when a new or alternative LASA or high-risk medicine is added to formulary.
	5.5 Analyse and use system/technology 'override' data to identify potential risk from human factor tendencies and inform clinician education and/or simulation. For example, workarounds or alert fatigue.[48]
	5.6 Record and trend incidents and near misses involving LASA medicines, including 'override' data, associated with automated storage systems; EMM systems; infusion pumps.
	5.7 Investigate trends in incident reports involving medicine selection or storage errors and take action. For example, where LASA and high risk medicines are implicated.
	5.8 Monitor and respond to safety alerts and the environment (for instance, learning from others' reported experience[49]), for new medication safety warnings and use to inform educational and interventional campaigns. For example, new studies or literature; newsletters; quality improvement initiatives; medicine use or incident evaluation. *Also refer to* Education and competency validation.
6 Recovery and harm mitigation	**6.1** Resuscitation (or reversal) protocols in place to guide clinicians for a range of high risk medicines or high risk techniques involving medicines. For example, how to recognise and treat local anaesthetic toxicity, for instance, if lignocaine 1% injection is mistaken for 0.9% sodium chloride; how to manage a wrong route administration of a medicine – intrathecal versus intravenous.
	6.2 Patient monitoring, alerts or triggers used to detect irregularities or deterioration. For example, therapeutic drug monitoring; naloxone administration in response to opioid overdose; or unexplained respiratory depression due to administration of the wrong medicine or fluid.
	6.3 Action taken if the patient expresses concern about a medicine or experiences unexpected symptoms. For example, include assessment of a LASA selection error to help determine causality and appropriate patient recovery.
	6.4 Patients (and their carers) speak up, ask questions, are listened to and informed about the medicine's indication or purpose, potential risks and how these risks can be avoided, for instance, at the time of taking a best possible medication history, medication review and medication reconciliation (includes transition of care, i.e. at discharge). For example, to learn how to avoid potential medicine brand mix-ups (Coversyl versus Coumadin[50]); or how to recognise duplicated medicines (two different brands of same active ingredient). *Also refer to* Consumer participation.

Principle		Risk reduction strategies for safe selection and storage
7 Limit access or use	**7.1**	Restrict stock (imprest) of certain medicine concentrations, strengths, formulations in wards or clinical areas. For example, concentrated potassium salt ampoules are only available in ICU; neuromuscular blocking agents are only available in perioperative settings; individually dispense immediate release verapamil or diltiazem.
	7.2	Individually dispense restricted or high risk medicines (concentrations, strengths, or formulations). For example, warfarin (Coumadin), which has been implicated in look-alike packaging-related dispensing errors[50]; special access scheme (SAS) medicines.
	7.3	Restrict stock of liquid oral opioid medicines to certain clinical/ward locations. For example, individual doses of methadone liquid or single bottles of codeine phosphate solution.
	7.4	Limit the use to a single medicine or strength of a medicine. For example, 10 mmol potassium chloride in 100 mL minibags for intravenous administration.
	7.5	Limit the range of stock (imprest) in clinical or ward locations. For example, imprest list of medicines is tailored to the specialty; only stock HYDROmorphone in specialist pain management or palliative care areas.
	7.6	Place neuromuscular blocking agents (NMBAs) in separate containers or a locked lidded compartment/cubie in an automated storage system and only within limited clinical locations (for instance, operating theatre; anaesthetic bay; other perioperative settings).
	7.7	Prevent purchase of medicines with similar (look-alike) packaging or appearance. **Note**: This may not always be possible, for instance during a medicine shortage, and will require use of other strategies to avoid risk selection risk. *Also refer to* Risk assessment.
	7.8	Criteria for limiting quantities of high risk medicines stocked in automated storage systems. For example, restocking at frequent, monitored intervals.
	7.9	Prevent clinicians from returning unused medicine to automated storage systems.
	7.10	Access controls on drawers, bins and compartments, including software restrictions and use of location lights or locks, are activated on automated storage systems.



Principle		Risk reduction strategies for safe selection and storage
8 Constraints, barriers and forcing functions	**8.1**	Physically separate different brands and strengths of medicines **in pharmacy**. For example, use shelf dividers; position on separate shelves.
	8.2	Employ automated storage and dispensing technology **in pharmacy**. For example, automated dispensing systems or robotics.
	8.3	Stock different strengths of known and potentially confusable medicines where a selection error could lead to significant patient harm. For example, morphine versus **HYDRO**morphone which is 5 to 7 times more potent than morphine. **Note**: This may not always be possible, for instance during a medicine shortage, and will require use of other strategies to avoid risk selection risk. *Also refer to* Risk assessment.
	8.4	Physically separate different brands and strengths of medicines in clinical or ward storage locations (imprest).
	8.5	Physically separate different concentrations, strengths and formulations (including immediate and delayed release).
	8.6	Physically separate LASA medicines with the same indication or clinical use.
	8.7	Employ automated storage technology **in clinical or ward storage locations**. For example, automated storage systems consistent with the Commission's Evidence Briefing on *Automated dispensing systems*[31] and adhere to storage safety.[51,52]
	8.8	Use algorithms to load automated storage systems to ensure look-alike medicines are separated.
	8.9	Use automated storage systems that limit the access to selection of one medicine and a single strength and formulation.
	8.10	Avoid placement of look-alike medicines within the same multiple-compartment/cubie (open matrix) drawer.

Principle	Risk reduction strategies for safe selection and storage
 **Differentiate items**	**9.1** Adopt the Commission's *Guidelines for on-screen display of medicines information*[36] in all digital technology for medication management (in particular, prescribing, dispensing, administration and automated storage systems). For example, use Tall man lettering[32] or configure EMM systems to separate LASA medicine names with a space in drop down selection menu. *Also refer to* Optimise display of medicines information.
	9.2 Alter the appearance of LASA medicine names **on shelving and stock containers**. For example, using Tall Man lettering[32]; colour; font size or bolding.
	9.3 Alter the appearance of LASA medicine names **on dispensing labels**. For example, using Tall Man lettering[32]; colour; font size or bolding.
	9.4 For LASA medicines alter the appearance by giving the active ingredient (approved or generic) name more prominence than the brand name on dispensing labels.[53,54]
	9.5 Apply ancillary labels, alerting clinicians of high risk and potential selection error, to the original look-alike medicine packaging and dispensed medicines. For example, apply cautionary advisory labels[55]; or apply locally designed labels to differentiate various strengths of a single medicine.
	9.6 Use standardised storage/signage labels or alerts to itemise/organise medicine storage areas. For example, uniquely labelled storage bins; designated and standardised trolleys and layout for resuscitation medicines.
	9.7 Medicines remain in original containers/packaging. For example, avoid potential for look-alike selection error of tablets or capsules in identical foil packaging; or mix-up of ampoules/vials of similar size and volume. **Note**: Original containers include important storage information, for instance, whether the medicine needs to be protected from light.
	9.8 Use equipment that will differentiate a medicine and help to ensure it is administered via the correct route: orally versus intravenous, or intravenous versus intrathecal/epidural. For example, use of oral dispensers/syringes to support delivery of oral medicines via the oral route and prevent accidental parenteral administration; use of neural connector devices that comply with ISO 80369-6:2016 to support appropriate administration of neural medicines).[56]
	9.9 Prescribe LASA medicines using both the active ingredient (approved or generic) and brand names. For example, consistent with active ingredient prescribing requirements.[53,54]

Principle		Risk reduction strategies for safe selection and storage
 **Add redundancy**	**10.1**	Employ independent second check (manual) for high risk or LASA medicines, or high risk techniques involving medicines. For example, consistent with the Commission's Evidence Briefing on *Double-checking medication administration*.[33] Note: There are various approaches to double-checking. Clarity is required in health service procedures.[57,58,59]
	10.2	Employ technology to conduct checks; to restrict access; or to provide decision-support. For example, use machine-readable (for instance, a linear barcode) scanning[34]; electronic approval; electronic prescribing; electronic administration.[35]
	10.3	Process for verbal or telephone orders (which should be limited) includes a second check. For example, by repeating the order to another clinician; by incorporating spelling the medicine name (for sound-alike names in particular) and stating the indication.
	10.4	Employ technology to conduct checks to verify the selection of the correct medicine during dispensing according to the Pharmacy Board of Australia Guidelines for Dispensing of Medicines.[39] For example, use machine-readable (for instance, a linear barcode) scanning.[34]
	10.5	Employ technology to conduct checks during administration to prevent wrong medicine selection or administration (including wrong route) errors. For example, use machine-readable (for instance, a linear barcode) scanning.[34]
	10.6	Employ technology to conduct checks when restocking automated storage systems. For example, use machine-readable (for instance, a linear barcode) scanning.[34]
	10.7	Use of a witness 'signature' in an automated storage system to allow access to restricted medicines. For example, schedule 8 medicines.
	10.8	Check of appropriateness of dose (and indication) when dispensing a high risk or LASA medicine, for instance, when dispensing a monoclonal antibody. For example, application of the Commission's Evidence Briefing on *Double-checking medication administration*.[33]
	10.9	Print instructions on medicine dispensing labels for LASA medicines that prompt a second check. For example, 'PLEASE CHECK CAREFULLY – medicine with similar name or appearance'.
	10.10	Require the indication for a medicine to be on the national standard medication chart(s) and included within EMM or electronic prescribing systems, **ensuring visibility** at time of dispensing and administration. *Also refer to* Optimise display of medicines information.

Principle		Risk reduction strategies for safe selection and storage
11 Optimise display of medicines information	**11.1**	Adopt the Commission's *Guidelines for on-screen display of medicines information*[36] in all digital technology for medication management (in particular, prescribing, dispensing, administration and automated storage systems). *Also refer to* Differentiate items.
	11.2	Document all the details required on the national standard medication chart(s) or prescription when prescribing. This includes where EMM or electronic prescribing systems are implemented.
	11.3	Include medication safety considerations in the procurement process, including the risk of LASA confusion with the appearance of medicines already listed on formulary. For example, for name and/or packaging similarity.
	11.4	Use alerts within digital systems (for instance EMM) to remind prescribers, dispensers and those administering medicines of potential LASA risks.
	11.5	Consider potential alert fatigue (as well as override potential) when developing criteria for LASA medicine alerts that focus on greater risk of patient harm.[48]
12 Use of affordances	**12.1**	Medicine labels present the medicines information in the same manner as the on-screen order. For example, the pharmacy dispensing label on the medicine container matches the presentation of the EMM medicine order that a clinician refers to when selecting a medicine for administration.
	12.2	Medicine storage systems (for instance, shelving, labelling and stock organisation) are purpose-designed, incorporate consistent features and layout, and are replicated within each ward location. For example, anaesthetic trolleys are set up in an identical and systematic manner to promote familiarity, safe selection and access to high risk and look-alike medicines.[60]

Principle		Risk reduction strategies for safe selection and storage
 **Standardise**	**13.1**	Use evidence-based and standardised order sets within electronic medication management (EMM) systems.[37] For example, adoption of EviQ protocols[61,62] within chemotherapy-related EMM systems.
	13.2	Standardise the available medicine formulations in ready-to-use concentrations and quantities that are condition-specific. For example, pack sizes of opioids that reflect expected dosing and duration of treatment; pre-mix isotonic fluid containing 10 mmol potassium chloride per 100 mL for peripheral electrolyte replacement in diabetic ketoacidosis.
	13.3	Apply a standardised format for dispense labelling.[63]
	13.4	Standardised procedures for restocking imprest storage, including automated storage systems that limit process variation and include a requirement for labels on medicine packaging to be clearly visible. For example, face forward on shelves or face up in drawers; use machine-readable (for instance, a linear barcode) technology to scan every individual pack of a look-alike medicine when loading automated storage systems.
	13.5	A standardised approach to the medicines storage system(s) and preparation areas is employed throughout clinical and ward locations. The approach is consistent with requirements of MSSA[40] Core Characteristic 12: that medicines are prescribed, prepared, dispensed and administered within a safe workflow and physical environment that offers adequate space and lighting to allow clinicians to remain focused without distraction. For example, space and layout for medicines that is uncluttered and a dedicated work area that is free of distraction and noise.
	13.6	Procedures for dispensing medicines (including LASA and high risk medicines) are defined and disciplined and afford a sequential process for selection, matching, dispensing and labelling, and include redundancy measures. *Also refer to* Add redundancy.
	13.7	Source commercially available products in the most ready-to-use formulation (according to TGA[38] and Pharmacy Board of Australia (PBA) codes, guidelines and policies[39]). For example, specialised and complex sterile products that are manufactured in a TGA-approved or licenced facility.
 **Simplify**	**14.1**	Dispense commercially available products or compounded medicine(s) in the most ready-to-use formulation (according to TGA[38] and Pharmacy Board of Australia (PBA) codes, guidelines and policies[39]). For example, total parenteral nutrition solutions that do not require any further manipulation in pharmacy OR by clinicians who administer.
	14.2	Use integrated electronic medication management (EMM) systems to eliminate risk of transcription errors.
	14.3	Use or apply 'closed-loop' strategies within the medication management system. For example, seamless integration of EMM, dispensing and automated storage systems.[64,65]

Glossary

Affordances[5,14]: Generally held knowledge about how things work, thereby suggesting how to interface with the object. For instance, copying a standard approach used elsewhere reduces the need for interpretation.

Best practice labelling[43]: Therapeutic Goods Order (TGO) 91 and 92 in the current Australian labelling regulations do not cover packaging. However, confusion still exists around packaging including for consumers taking a number of generic branded medicines. This risk of error is highlighted and has been retained by TGA in their best practice guidance for the labelling legislation. Section 3.1: *Design principles*, contains suggestions for use of colour, font and limited use of capitalisation. The FDA regulations are also referenced.[66]

Clinician[7]: A healthcare provider, trained as a health professional, including registered and nonregistered practitioners. Clinicians may provide care within a health service organisation as an employee, a contractor or a credentialed healthcare provider, or under other working arrangements. They include nurses, midwives, medical practitioners, allied health practitioners, technicians, scientists and other clinicians who provide health care, and students who provide health care under supervision.

'Closed-loop' medication management[64]: A process that integrates automated and intelligent systems to completely close the inpatient medication management and administration loop. This enhances medication safety and improves efficiency of the entire medication management process, from prescription ordering and supply to the administration of a medicine.

Constraints and barriers[5]: Use of special equipment or environmental conditions to prevent a hazard from reaching a target. For example, use of personal protective equipment (PPE) to reduce risk of exposure.

Use constraints to restrict access to certain medicines or error-prone processes; require special education or conditions for prescribing, dispensing or administration of a medicine; require special authorisation for participation in certain tasks.

Consumer participation: A baseline strategy intended to impart upon patients specific knowledge (what they know) and skills (the ability to apply the knowledge) about medicines and their safe use and verifying the knowledge and skills. For instance, advise patients taking LASA medicines about the risk of mix-ups and how to avoid them.

Core characteristics[40]: The Medication safety self-assessment (MSSA) tool is divided into key elements that significantly influence safe medicine use. Each element is defined by one or more core characteristics that further define a safe medication system. Each core characteristic contains individual self-assessment items to help evaluate implementation success. Some of the self-assessment items relate to the safe storage of medicines. MSSA tools are specifically designed to help take an active and system-based approach to medication safety.

Differentiation: Can be achieved by altering the appearance of medicine names, their original containers or delivery devices. The aim is to unambiguously differentiate, for instance, by using Tall Man lettering or use of distinctive labels or labelling reminders (or alerts) on drug containers. For example, the application of the Commission's *National standard for user-applied labelling of injectable medicines, fluids and lines*.[29] *See also* Differentiation using colour coding or labelling alerts.

Differentiation using colour coding or labelling alerts[67]: Colour coding is the systematic application of colour to aid in classification and identification. It tends to be the focus of brand identity with potential for all forms and strengths of the same medicine to be presented in boxes of the same colour and shape. Use of opposing or colour contrast may be a useful for product differentiation provided consideration is given to individuals with limited colour perception (for example, colour-blindness). For instance, Vision Australia has a colour contrast analyser on their website.[68] *See also* Differentiation.

Judicious and standardised colour coding can assist with identification or matching, for example, the Commission's *National standard for user-applied labelling of injectable medicines, fluids and lines*.[29] However, using colour alone for differentiation can lead to selection error, so that the written word remains the primary identifier with colour as the secondary identifier.

FMEA[23]: Failure Mode Effects Analysis: a systematic method to identify the parts of the process that are most in need of change. Proactive identification of the ways that processes or medicine-related equipment can fail, why it might fail, how it might affect patients, and how it can be made safer; assessment of current systems and practices against best practice.

Forcing functions and fail safes[5]: Employ procedures or equipment design features that will:

- Prevent something from happening until certain conditions are met, i.e. a barrier that allows correct performance only (forcing function)
- Prevent malfunctioning or unintended operation by reverting back to a predetermined safe state if a failure occurs (fail safe).

High leverage and low leverage risk reduction strategies[17]: Forcing functions, fail-safes, constraints and barriers are among the most powerful and effective high leverage strategies. Education and information, along with policies and checklists rely on memory, and are considered low leverage strategies. Use of low leverage strategies alone, does not significantly reduce the risk of errors. Refer to Figure 3: Hierarchy (power) of risk-reduction strategies.

Huddles or 'safety' huddles[69,70]: Brief (<10 minutes) and focused exchange of information about potential or existing safety risks which may affect patients, staff and any person accessing the healthcare environment. Collective multidisciplinary awareness of a situation promotes a culture of safety and in turn can reduces the potential for causing preventable harm. Huddles support shared situational awareness by providing team members with the opportunity to share vital information about patients or the environment. Huddles are typically stand-up meetings held once a day, for instance, at the commencement of a shift. Refer Situational awareness and critical thinking.

Human factors[4,15,16,71]: Ergonomics (or human factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimise human well-being and overall system performance. Organisational, individual, environmental and job characteristics can influence behaviour in ways that impact safety in clinical and healthcare contexts that means lives are at stake. In healthcare, the organisation, environment and culture can either support or obstruct delivery of safe, effective and person-centred care. This includes the design and use of equipment; the quality of the healthcare team interaction; work flows in practice, and process/ procedure design.

Independent double-check[33,57,58,59]: Also referred to as double-checking and double-person checking, independent double-checking is a 'redundancy' strategy that has been used to reduce medication administration errors. For instance, checking that the 'rights' of medication administration have been adhered to: the right patient, right drug, right dose, right route and right time. Its effectiveness continues to be disputed. However, if used, organisations should conduct a thorough evaluation to ensure that manual independent double checks, of high risk medicines in particular, are used judiciously and properly, are designed for success, and that they are the best risk-reduction strategy to use. Refer to Figure 3: Hierarchy (power) of risk-reduction strategies.

Positive performance shaping[5,14]: An aspect of humans' individual characteristics, environment, task or organisation that specifically improves human performance, thus reducing the likelihood of error (for example, task complexity; workflow; workload; time availability/urgency; process design; experience; training; fatigue; stress; culture). For instance, limit distractions in the environment when carrying out complex tasks. Human error investigation should uncover any pre-existing performance shaping factors.

Recovery: Harm minimisation. Recognise that despite efforts, an error might occur; enhance the ability to detect the initiating event and correct it before significant patient harm can occur.

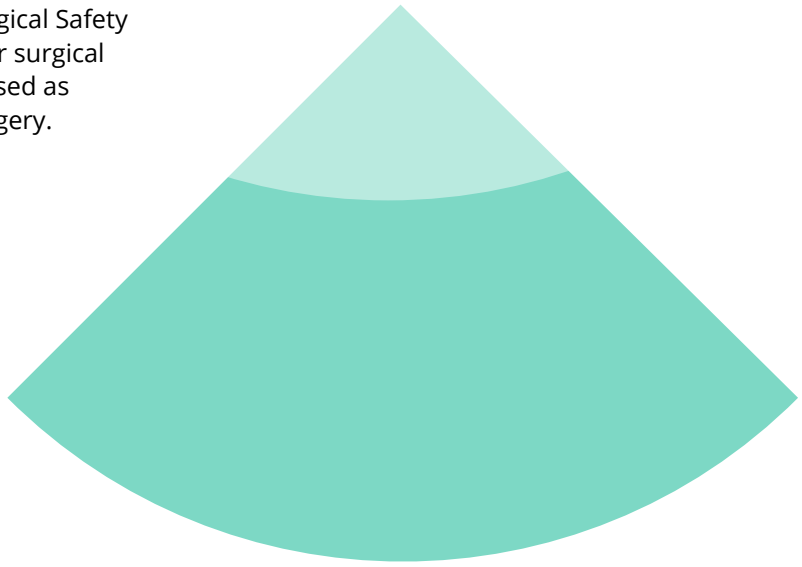
Redundancy[5,14]: Implementing multiple pathways so that if the first pathway fails, a second pathway may detect the error and be successful, for instance, use of an independent double-check before administration of an intravenous dose of a medicine; barcode scanning during the dispensing or administration process; time-out procedure; two step verification for patient identification.

Safe procurement: An Australian study has demonstrated that it is possible to decrease the risk of selection error by conducting a medication safety review during the procurement process.[11]

Safety alerts, warnings and visual cues: Safety alerts can take the form of a label or sticker applied to a medicine (for example, an auxiliary label) or on the shelf where the medicine is stored, and will usually contain key or succinct information as a visual cue intended to warn about a particular risk or provide additional instructions. These alerts or warnings can also be included as safety features or visual cues within electronic medication management systems (clinical decision support). For instance, interactive warnings such as duplicate medicine checking, or visual cues used to distinguish multiple concentrations of the same medicine, may include an order entry alert for verification of the selected medicine or concentration.

Situational awareness[5,14]: To enhance the accurate understanding of the environment in order to understand how information, events, and ones' own actions will impact patient safety and other goals both immediately and in the near future; a strategy used to reduce drifting into unsafe practice habits. Use of simulations to expose staff to common risk and to teach them to identify and manage the risks.

Surgical safety checklist[42]: The World Health Organization Surgical Safety Checklist has been demonstrated to improve patient safety and is now widely used in Australia. In 2009 Health Ministers endorsed the World Health Organization Surgical Safety Checklist as the nationally agreed strategy for surgical safety in Australia. This checklist should be used as patient/procedure matching protocol for surgery.



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