INTRODUCTION
Medication safety is a fundamental patient right and is not optional. Every patient has the right to receive effective medicine in the safest possible manner.1

Promoting medication safety is the core component of the quality use of medicines (QUM). Therefore, medication safety is integral to every pharmacist’s practice and one of the core functions of a hospital pharmacy.

Medication safety systems are fundamental to every organisation’s risk management strategy, which should be supported by targeted programs and led by pharmacists as part of a multidisciplinary team.

Medication safety principles apply to all parts of, and all people involved in, the medication management pathway: prescribing, storage and distribution, dispensing, administering and monitoring of medicines.2 Medication safety requires the involvement of a multidisciplinary team with leadership, sponsorship and governance from the organisation’s management. Medical, nursing and pharmacy staff, as well as patients, should be actively encouraged to participate in medication safety programs.

Pharmacists specialising in this area of practice coordinate medication safety activities and promote QUM more broadly. The terminology used in these standards of practice assumes that there is an individual within the organisation with the responsibility for overseeing a medication safety program. Depending on the structure and size of the pharmacy this may be a dedicated position or shared between a number of staff.

There should be a peak committee within the organisation responsible for governance and systems for medication safety.3 This may be the drug and therapeutics committee (or equivalent), a separate medication safety committee or medication safety may be incorporated into another committee’s role, e.g. patient care, quality and risk.4

OBJECTIVE AND DEFINITIONS
Medication safety systems and strategies aim to ensure medicines are used in a manner which reduces the risk of avoidable adverse outcomes and enhances positive outcomes.

Medication safety describes the systems and strategies necessary to ensure clinicians safely prescribe, dispense and administer appropriate medicines to informed patients and/or carers.3

QUM includes the judicious, appropriate and safe use of medicines.5 Australia’s National Medicines Policy defines QUM as:

- selecting management options wisely
- choosing suitable medicines if a medicine is considered necessary
- using medicines safely and effectively.6

This definition applies equally to decisions about medicines use by individuals and decisions that affect the health of the population.7 For other definitions relating to medication safety and QUM refer to the Glossary.

EXTENT AND OPERATION
Pharmacists must recognise that medication safety is fundamental to an organisation’s risk management strategy. Medication safety activities must be supported and promoted by all pharmacy staff. Medication safety programs conducted within and external to a hospital pharmacy may be led by a pharmacist supported by other pharmacists, technicians and other staff within the department or health service organisation.

Medication safety activities involve a multidisciplinary team supported by the organisation’s management.

CORE ROLES
The primary goal of a medication safety role or program is to ensure systems are in place to reduce the risk of preventable harm from adverse medicines events for patients, using an evidence-based approach to achieve system improvements. Medication safety activities should have a patient-centred focus. Pharmacists leading a medication safety program must provide strong, influential and persuasive leadership within the organisation to achieve this goal. The core tasks are ensuring systems are in place for:

- Leading the governance of medication safety committees. This includes ensuring medication safety messages are considered in the organisational clinical governance programs.
- Leading the development and implementation of improvement initiatives using change management techniques.
- Promoting a ‘just culture’ and ‘open disclosure’ in developing safety systems for medication use.
- Sharing knowledge with other health professionals.
- Leading the development and review of policies to enhance medication use.
- Reporting and reviewing errors, near misses and adverse medicines events (AMEs).
- Reporting and monitoring adverse drug reactions (ADRs).
- Monitoring trends and reviewing work practices and systems to identify risks or gaps in practice, e.g. drug use audit, chart review.
- Introducing evidence-based medication safety initiatives and programs that can be monitored against accreditation standards.
- Educating pharmacy and other clinical staff about medication safety.
Leading in the Governance of Medication Safety
Pharmacists involved in medication safety should be able to access the latest evidence for medication safety initiatives and review these for applicability to their area of practice. They should be familiar with the local, state, national and international health quality agendas. This includes, but is not limited to, the national strategy for QUM and the emerging use of electronic health records and electronic medication management systems.

Organisations should have robust clinical governance, medication safety and/or risk management committees and the pharmacist member of these groups should raise emerging agendas, as relevant. Pharmacists leading or involved in medication safety programs may also fulfil a governance or advocacy role at state and/or national level.

Developing and Implementing Improvement Initiatives
Reviewing incidents and emerging risks identifies where safety or quality improvement strategies are needed to reduce these risks. This is a major focus of any medication safety role or program. An understanding of the principles of change management, resistance to change, human factors and criteria for sustainable change are used when leading this work. Pharmacists involved in medication safety should take a lead role in the strategic planning, setting the direction and focus of medication safety programs for the health service organisation.

Activities to improve medication safety can be targeted at all steps of the medication management pathway. Medication safety activities should also link with other programs, such as venous thromboembolism prevention and antimicrobial stewardship, to achieve synergies through collaboration. Pharmacists involved in medication safety may participate in evaluating and promoting appropriate use of technology and other innovative solutions, e.g. automated dispensing, electronic medication management, electronic prescribing, smart pump technology. Pharmacists involved in medication safety have a role in advocating for and integrating these innovations and evaluating them.

Pharmacists involved in medication safety should advise and provide clinical input into the procurement process to ensure that safety and quality issues are considered when medicines and related products are purchased. They should provide advice when medicines are in short supply or are recalled. They should have a role in evaluating and planning the storage and distribution arrangements for medicines in newly planned wards, services or refurbishments.

Promoting a ‘Just Culture’ in Developing Safe Systems for Medication Use
Promoting a culture of reporting, ‘open disclosure’ and ‘no blame’ is an important safety initiative. A ‘just culture’ indicates there is shared accountability within the organisation (see Glossary). This includes the organisation being accountable for the systems they design and for how they respond to the behaviours of staff and issues/errors that may occur. Such a culture promotes staff accountability for reporting their own errors and vulnerabilities of systems, and for their own actions.

A just culture is fair and open and recognises that adverse events can be opportunities for learning and reflecting on systems issues and lead to designing safer systems. Staff are supported and encouraged to report risks, errors and hazards. A just culture also requires a clear understanding of what is acceptable and unacceptable behaviour.

Open disclosure is used to facilitate consistent and effective communication with patients following adverse events.8

Sharing Knowledge
Pharmacists involved in medication safety should present their work at conferences and publish results of innovations and processes that have had a positive impact on patient safety. Publications may include: letters to the editor, case histories or descriptions of audits undertaken to inform improvement. Work should be undertaken by a multidisciplinary team, presented in a multidisciplinary forum and reported internally.

Leading Policy Development and Review
Pharmacists involved in medication safety should participate in developing, reviewing and implementing guidelines and policies that enhance the safe and effective use of medications.

Reporting and Reviewing Errors, Near Misses and Adverse Medicines Events
Pharmacists involved in medication safety must participate in reviewing medication errors, incidents and near misses within the pharmacy and across the health service organisation. They must also be involved in the development of recommendations and action plans to prevent recurrence of similar incidents, such as compiling, documenting and analysing AMEs, and providing regular reports to relevant committees. These reports might have a particular focus, e.g. high-risk medicines.

Pharmacists involved in medication safety should participate in the review and root cause analysis (RCA) of serious medication-related errors and incidents (see Glossary). Benchmarking of incident rates with other organisations is not recommended.9 Incidents reported in voluntary systems represent a fraction of actual incidents. A decrease in incident reports does not necessarily mean a decrease in the number of incidents occurring. Higher numbers of incident reporting may reflect a safety culture in which staff feel supported and are encouraged to report incidents and near misses with a view to informing improvement activities.10

Pharmacists and others involved in the investigation of serious medication-related errors and incidents need to be aware that the caregivers, health professionals and other staff involved in the incident may also require help and support as the second victim of the error. Pharmacists need to be aware of support structures that can be offered immediately after an incident, during the investigation and follow-up.

Reporting and Monitoring Adverse Drug Reactions
Monitoring ADRs includes encouraging reporting of ADRs, reviewing cases for preventability and causality, reporting findings and developing solutions to prevent ADRs.

Healthcare staff and patients should be encouraged to report ADRs. Pharmacists involved in medication safety should review each report, preferably with pharmacology or relevant medical input, e.g. immunologist, general medical, infectious diseases. Input can be sought from a medicines information service. The patient affected should be counselled about managing the ADR and how to prevent recurrence or future problems. They should also be given
Identifying Risks or Gaps in Practice

Pharmacists involved in medication safety should monitor trends and review work practices and systems in order to identify risks or gaps in practice, e.g. drug use audit. Managing risk requires proactive and reactive measures that take into account system-wide risks as well as those associated with human factors. Pharmacist’s involvement in risk management encompasses reviewing current and emerging risks, e.g. evaluating new brands or products introduced to the purchasing contract for look-alike sound-alike potential. Systems such as failure mode and effects analysis (FMEA) can be used to assess new procedures and processes (see Glossary).

Reviewing Improvement Initiatives

Regular audits should be undertaken to identify risks, ensure safety strategies are effective and monitor compliance and quality assurance for existing procedures and new initiatives, e.g. retrospective chart review, direct observational audit. Medication safety programs are integral to the hospital accreditation process and a detailed understanding of organisational accreditation requirements, e.g. National Safety and Quality Health Service Standards and EQuIP5,10

Drug use evaluation (DUE) activities within the organisation should support medication safety programs.

Audit results are required as evidence for organisational accreditation and should be part of routine data collection, along with key performance indicators for medication use and medication use systems. Tools and datasets include:

- medication safety self assessment for Australian hospitals12
- incident management and reporting systems
- pharmacist intervention reports
- ADR reporting
- DUE activities
- medication storage system audits and monitoring
- National Inpatient Medication Chart audit13
- indicators, e.g. Indicators for QUM in Australian hospitals14
- trigger tools, e.g. Global Trigger Tool for Measuring Adverse Events15

Educating Staff

There needs to be systems within the organisation to ensure regular education for all staff. A key role for pharmacists involved in medication safety is educating pharmacy and clinical staff, and patients about reducing the risks of medicines, raising awareness of medication safety issues and QUM. Programs should include early education for new staff, continuous professional development for all staff and feedback on internal issues and areas for improvement identified by medication safety activities.

Educating patients on medication safety issues empowers them to participate in their medication management.

Programs should include multi-faceted approaches with multiple channels and reminder systems, such as talks, newsletters, campaigns and social media. In addition, there is a wealth of material and short courses available online. A key role for pharmacists is the awareness and promotion of these courses to prevent duplication of effort.

DOCUMENTATION

Documentation of medication safety policies and details of quality improvement activities and actions implemented to prevent future incidents is critical to a robust governance system. A mechanism should be in place so that data supporting medication safety is easily accessible by all staff involved in medicines management and governance. Keeping electronic records on a secure shared drive is essential for project continuity if personnel change.

Quality Improvement

Documenting the results of projects and audits is an important component of a medication safety system. A running record of projects should be kept as they progress and are completed. Copies of project plans, audit criteria, agreed guidelines, data collection tools, memoranda and correspondence, tabulated data, feedback reports, committee meeting minutes, intervention plans, project reports and publications must be maintained and regularly updated. Projects may have special requirements, such as ethics approval and storage of all data for several years.

Quality Indicators

Quality indicators are measures of processes and outcomes of health care and assist in the continuous improvement process. They can be used to indicate trends and help to gauge how well the organisation achieves medication safety. The indicators help to identify areas for improvement and assist to embed changes within the system.

It is important to document the indicators used, how data are collected and to whom the information is reported. So that subsequent data are collected in a consistent manner and trends can be monitored over time. It is preferable that organisation-wide reporting systems incorporate both medication incident and medication safety audit data.

Reporting

Projects and audits may require regular reports to the organisation’s committees or project sponsor, e.g. brief monthly updates including progress of all current projects. Wider sharing of project and audit results may be achieved through publication in peer-reviewed journals, presentations, development of action plans and newsletters to the professional community and the public.

STAFF STRUCTURE AND LEVELS

Staffing levels should be adequate to achieve the medication safety program’s goals and objectives. Medical, nursing, quality and pharmacy staff should be involved in all aspects of medication safety activities. Suitably-trained personnel within organisations should be available to lead medication safety activities.

All pharmacists should take responsibility for implementing medication safety systems as part of the organisation’s risk management strategy. Specifically trained pharmacists should be allocated to lead medication safety activities. Many aspects of data collection, monitoring, intervention and education
may be incorporated into the work of other health professionals. Non-professional staff, e.g. pharmacy technicians or assistants, research associates and students may be recruited for prescription or chart screening, data collection and collation, and conduct and monitor audits. Review, interpretation and analysis of medication safety data will generally require health professional input, and may require a statistician or IT assistance.

RESOURCES
Resources for pharmacists involved in medication safety should be adequate to ensure that program goals can be achieved. These include access to reference texts, journals and information sources, data retrieval resources, office space, furniture and space for storing documentation. Computer hardware, peripherals and software, including Internet access, must be available and appropriate for management of data entry, analysis and reporting by project personnel. Relevant occupational health and safety regulations must be observed. In addition to physical resources, pharmacists must have access to local incident data, membership of multidisciplinary committees and organisational support for networking and attendance at professional meetings.

A medication safety tool kit with resources is available on the SHPA eCPD web site.

EVALUATION
To demonstrate that the medication safety program is successful, it should achieve measurable outcomes.\(^4\) The impacts and outcomes of a medication safety program should be monitored from a patient outcome perspective. The program should advocate for changes that strive to provide continuous healthcare improvement.

Acknowledging and understanding the success of a medication safety program can be achieved by measuring processes, objective outcomes or defined performance indicators. Some examples of process indicators include:
- guidelines produced or reviewed and in date
- new procedures or processes implemented
- presentations delivered
- audit reports
- outcomes of changes and implementation of safety and quality initiatives
- medication safety self-assessment completed and the results used to develop and implement a medication safety action plan and risk register.\(^5\)

It is important to choose indicators appropriately and wherever possible use indicators that measure outcomes rather than process.

Process indicators like those listed above can provide an interim measure but should be linked to clinical outcomes. Many indicators are process rather than outcome measures, as process measures are easier to collect (i.e. measure the degree to which healthcare providers perform processes to achieve desired aims). Process indicators may be related to clinical outcomes (e.g. number of medication incidents acted on) or workload (e.g. number of guidelines reviewed).

Measures must be meaningful and valid. Outcome measures are more difficult to collect and are usually multi-factorial requiring risk adjustment and defined populations, or measure rare events or events occurring over time, e.g. mortality data, readmission rate.\(^6\)

Measures can also be developed for specific high-risk initiatives and/or policies that will require evidence of compliance via auditing.

EDUCATION, EXPERIENCE AND TRAINING
Pharmacists involved in medication safety require a wide range of clinical, data management, incident analysis, RCA and communication skills. These pharmacists require:
- influential and persuasive communication (written and verbal), interpersonal and project management skills
- skills in change management, building sustainable change and human factors engineering
- leadership skills
- wide ranging clinical knowledge, supported by several years post-registration experience
- skills in literature retrieval and interpretation
- computer skills necessary for data management
- ability to work within a multidisciplinary team
- postgraduate qualifications in pharmacoepidemiology, change management, adult education or other relevant areas is desirable.

It is desirable that pharmacists commencing in these positions are:
- Competent in project management, research method/ skills and develop expertise in presentation skills as well as undergo training in data management, incident analysis and RCA
- Familiar with relevant state and national policies that facilitate medication safety and QUM. For example policies about whistle blowing, open disclosure, reporting policies, RCA, second victim of medical errors, FMEA and accreditation, e.g. National Safety and Quality Health Service Standards.\(^3\)
- Familiar with other tools vital to medication safety and QUM, e.g. medication safety self-assessment.\(^12\)
- Familiar with quality improvement techniques, such as the Plan, Do, Study, Act (PDSA) cycle.

References
Glossary

Adverse drug reaction (ADR). A drug response that is noxious and unintended, and that occurs at doses normally used or tested in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.

Adverse medicines event (AME). An adverse event due to a medicine. This includes the harm that results from the medicine (an adverse drug reaction) and the potential or actual patient harm that comes from errors or system failures associated with the preparation, prescribing, dispensing, distribution or administration of medicines.

Change management. When new systems are introduced there can be resistance to implementing the new system. Sometimes people return to the old system, i.e. the change was not sustainable. Change management describes some approaches that are likely to lead to the changed system being implemented and the implementation sustained.

Continuous improvement. A systematic, ongoing effort to raise an organisation’s performance against a set of standards or indicators. It is a planned activity in which the quality cycle (Plan, Do, Study, Act) may be used as a decision-making process. For the improvement to be sustained, it is important not just to focus on process or design but to also engage and involve participants. Communication and positive feedback are important for staff engagement and commitment to sustaining the change.

Drug use evaluation (DUE). Authorised, structured, ongoing system for improving the quality of medicine use within a health care organisation. Medicine use is evaluated using pre-determined standards, and efforts are initiated to correct patterns of use which are not consistent with these standards. It includes a mechanism for measuring the effectiveness of these corrective actions.

Failure mode and effects analysis (FMEA). Ongoing quality improvement process that is carried out in healthcare organisations by a multidisciplinary team. It can be used to examine the use of new products and the design of new services and processes to determine points of potential failure and what their effect would be before any error happens. In this regard, FMEA differs from root cause analysis (RCA). RCA is a reactive process, deployed after an error occurs, to identify the underlying causes. While FMEA is a proactive process used to look carefully and systematically at vulnerable areas or processes. FMEA can be used before purchase and implementation of new services, processes or products to identify potential failure modes so that steps can be taken to avoid errors before they occur.

Human factors engineering (HFE). System concerned with the design of tools, machines and systems that take into account human capabilities, limitations and characteristics.

Incident. Event or circumstance which could have resulted, or did result, in unintended or unnecessary harm to a person and/or a complaint, loss or damage.

Just culture. Culture of no blame where an atmosphere of trust is present and people are encouraged or even rewarded for providing essential safety-related information, but where there is also a clear line between acceptable and unacceptable behavior. Engineering a just culture is an essential early step in creating a safe culture.

Medication error. Any preventable event that may cause or lead to inappropriate medication use or patient harm while medication is in control of the health professional, patient or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

Near miss. Incident that did not cause harm, but had the potential to do so. This can be described as either an event that did occur but harm did not eventuate or an event that would otherwise have led to harm if it were not intercepted.

Open disclosure. Open discussion with a patient about an incident that resulted in harm to that patient while receiving healthcare. The criteria of open disclosure are an expression of regret and a factual explanation of what happened, the potential consequences and the steps being taken to manage the event and prevent recurrence.

Plan, Do, Study, Act (PDCA) cycle. Four steps for carrying out change. The cycle should be repeated to ensure continuous change.

Risk. Chance of something happening that will have a negative impact. It is measured by consequence and likelihood.

Risk management. Design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the institution.

Root cause analysis (RCA). Structured method used to analyse serious adverse events. Initially developed to analyse industrial accidents, RCA is now widely deployed as an error analysis tool in health care. A central tenet of RCA is to identify underlying problems that increase the likelihood of errors while avoiding the trap of focusing on mistakes by individuals. The goal of RCA is to identify both active errors (occurring at the point of interface between humans and a complex system) and latent errors (hidden problems within health systems that contribute to adverse events). An RCA does not include investigating the professional competence of a person in relation to the event or finding out who is to blame for the happening or event.

Second victim of medical errors. Health professional who makes a medical error and also suffers as a consequence of the error.

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