Pharmaceutical Defence Limited

Owned by our pharmacist members for over 110 years

PDL Risk Management Guide for Pharmacists

Disclaimer

The contents of this document provide general information and recommendations of its authors and should not be considered as definitive or exclusive advice on risk management. PDL is not the interpreter or arbiter of legislation but rather provides a perspective on how to most professionally and ethically apply the appropriate references for a particular activity.

The document is intended to complement, not replace, existing policies, procedures or regulations set by regulatory bodies or accepted references by professional associations. It aims to provide guidance on minimising risk for pharmacists and their patients.

The case scenarios used throughout the document are not specific to any pharmacist or pharmacy, but are a combination of common scenarios to illustrate common themes encountered in pharmacy.

PDL encourages pharmacists to exercise their professional judgment and discretion when applying the information contained in this document in specific situations and always consider the laws, regulations and professional practice standards. The authors, contributors and issuing organisation do not assume responsibility for any actions taken based on the recommendations or in relation to the materials contained herein.

Always seek advice from PDL Professional Officers should you need guidance and advice specific to your circumstances.

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Acknowledgement of Country

In the spirit of reconciliation, PDL acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples reading this document.

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Executive summary

Introduction

Pharmacists work within a diverse range of care settings that are rapidly evolving and often operate in demanding, highly complex and busy environments.

These challenging settings require management of patient expectations and need, widening of pharmacists' scope of practice and integration of new technologies. Additionally, the profession may be impacted by natural disasters, cybersecurity threats and workforce shortages.

Through the broad and expanding range of services that pharmacists provide and contemporary settings in which they work, pharmacists must identify, address and manage many risks. This is important for assuring the safety of patients, the integrity of pharmacy operations, compliance with legal and regulatory standards and a reduction of the risk to the pharmacist's reputation and registration.

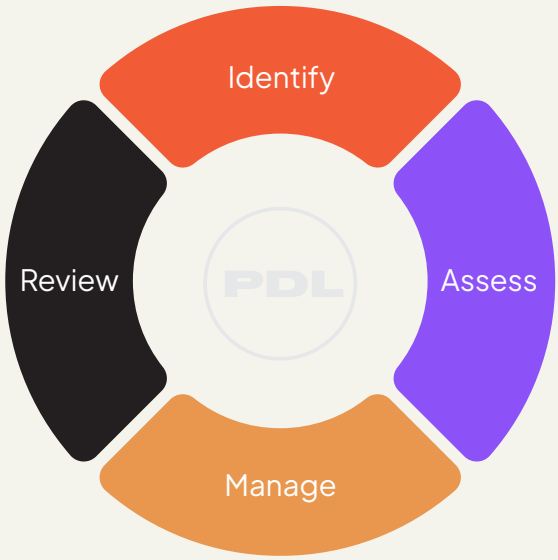
Purpose

Every pharmacist has faced a moment of doubt or realisation during their practice that might have led to a near miss or incident. If you have ever been worried about an event that may compromise patient safety or put your registration at risk, you're not alone. In today's complex and highly visible healthcare environment, where pharmacists are balancing a fast-paced environment, patient needs, compliance obligations and constant scrutiny, managing risk is not optional — it's essential.

This guide is designed not just to inform, but to empower. Through real-world case scenarios, practical tools and reflective activities, it is demonstrated how proactive risk management can become second nature — and why it is critical to both patient safety and professional confidence.

Risk Management Cycle

1. IDENTIFY	Pinpoint areas within your practice where potential risks or harm may occur.
2. ASSESS	Evaluate the severity and urgency of required actions, using the tools outlined in the Guide.
3. MANAGE	Implement and maintain effective systems and processes within your practice.
4. REVIEW	Reflect upon and evaluate outcomes from implemented changes.



PDL's vision to be the leading organisation for pharmacists' professional risk management includes supporting pharmacists to build capacity in managing their own systems and processes more safely and effectively, regardless of role. The PDL Risk Management Guide for Pharmacists offers a structured approach to mitigating risk in practice, by addressing four key objectives that make up a Risk Management Cycle.

This **Risk Management Cycle** will be referenced throughout the document, helping pharmacists to foster professional accountability and develop an ongoing Continuous Quality Improvement (CQI) process in their daily activities. The principles in this document offer practical guidance to pharmacists in any practice setting.

Intended audience

This publication is widely applicable and may be relevant to pharmacists in various roles. The following categories are matched with potential learning opportunities to help readers identify how this document can align with professional needs.

Audience	How they may benefit
Pharmacy students and provisionally registered (intern) pharmacists	• Use it as a professional development resource to build risk management skills and clinical acumen. • To prepare for safer and considered practice.
Early career pharmacists	• Use it as a professional development resource to enhance critical thinking and problem-solving skills.
Experienced professionals	• Incorporate it into CQI efforts, such as addressing skill gaps, updating staff training, or ensuring compliance with qualifications.
Pharmacists post-incident	• Employ it as a reflective practice activity to review incidents and demonstrate commitment to remedial action.
Managers and pharmacy owners	• Use it to identify and mitigate risk as part of robust clinical and business governance frameworks.
Banner groups	• Implement and standardise its use across pharmacies to ensure consistent delivery of safe and effective professional services.

Using the guide

Each module consists of the following components.

INTRODUCTION & LEARNING OBJECTIVES

Each module will outline the intended objectives and the anticipated outcomes for the user.

FOUNDATIONS

This part constitutes the main content of each section, focusing on the key principles and theories.

CASE STUDIES

These case studies are not specific to any pharmacist or pharmacy but are a combination of common scenarios reported to PDL. These real-world examples are designed to provide you with context and insights into how to improve practice.

KEY TAKEAWAYS

These handy bullet points at the end of each section offer concise takeaway messages that summarise key content. They highlight the key points from the section.

ACTIVITY

Certain sections include a practical, hands-on exercise that demonstrates how the concepts can be applied in the workplace.

RECOMMENDED READING

Additional resources are provided for PDL members who wish to further explore and expand their knowledge on specific topics.

PDL resources may be accessed via the Appendix section on page 87.

PDL recommends reading the modules in sequence, but readers can select and focus on those most relevant to achieving their personal learning goals.

Module 1: Understanding risk in pharmacy practice

This module is designed to equip you with basic knowledge and concepts to begin fostering a risk mindset. It addresses the IDENTIFY and ASSESS components of the Risk Management Cycle.

Accreditation Number: A2507PDL1

This activity has been accredited for 1.5 hours of Group 1 CPD (or 1.5 CPD credits) suitable for inclusion in an individual pharmacist's CPD plan.

The 2016 Competency Standards addressed by this activity include: 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 2.2, 2.3, 2.4, 3.1, 4.1, 4.2, 4.3, 4.7

Accreditation expires: 30/6/2027

Module 2: Applying risk principles in practice

This module builds upon the foundational concepts introduced in Module 1, helping readers to develop a more holistic approach to assessing risk and providing a structure to support the implementation of effective systems and processes. It addresses the ASSESS and MANAGE components of the Risk Management Cycle.

Accreditation Number: A2507PDL2

This activity has been accredited for 1.5 hours of Group 1 CPD (or 1.5 CPD credits) suitable for inclusion in an individual pharmacist's CPD plan.

The 2016 Competency Standards addressed by this activity include: 1.3, 1.6, 2.1, 2.2, 2.3, 2.4, 3.1, 4.2, 4.3, 4.5, 4.6, 4.7

Accreditation expires: 30/6/2027

Module 3: Managing incidents

This module will guide you through the steps that follow a near miss or incident in your practice. It will help you understand the processes following an incident, implement measures for yourself and others to minimise risk of further adverse events, and develop effective reflective practices to support continuous learning and improvement. It addresses the MANAGE and REVIEW components of the Risk Management Cycle.

Accreditation Number: A2507PDL3

This activity has been accredited for 1.0 hour of Group 1 CPD (or 1.0 CPD credit) suitable for inclusion in an individual pharmacist's CPD plan.

The 2016 Competency Standards addressed by this activity include: 1.3, 1.6, 2.1, 2.3, 2.4, 4.1, 4.2, 4.3, 4.6

Accreditation expires: 30/6/2027

Module 4: Managing high-risk areas

This module brings together all four components of the Risk Management Cycle, illustrating how each stage could be applied in real-world practice. It targets five key risk areas commonly associated with incidents. Readers will also be encouraged to recognise the risk principles in this document and apply them to emergent areas in pharmacy, to minimise the impact of potential risks.

Accreditation Number: A2507PDL4

This activity has been accredited for 1.5 hours of Group 1 CPD (or 1.5 CPD credits) suitable for inclusion in an individual pharmacist's CPD plan.

The 2016 Competency Standards addressed by this activity include: 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 2.3, 2.4, 3.1, 4.2, 4.3, 4.4, 4.7

Accreditation expires: 30/6/2027

Introducing the Guide

The **PDL Risk Management Guide for Pharmacists** offers a structured approach to achieving four key objectives:

OBJECTIVE 1

IDENTIFY

Pinpoint areas within your practice where potential risks or harm may occur.

To proactively assess potential risks during all professional activities

To demonstrate leadership and accountability as part of your role in good clinical governance

OBJECTIVE 2

ASSESS

Evaluate the severity and urgency of required actions, using the tools outlined in the Guide.

To contribute toward a culture of continuous learning (selecting relevant CPD activities)

To leverage incidents and near misses as opportunities for practice improvement

To consider appropriate ways to mitigate and control risk in practice

OBJECTIVE 3

MANAGE

Implement and maintain effective systems and processes within your practice.

To work independently and collaboratively to maintain governance systems to prevent and address incidents

To confidently engage in handling and resolving incidents

OBJECTIVE 4

REVIEW

Reflect upon and evaluate outcomes from implemented changes.

To develop reflective practice and self-directed learning to minimise risk of incidents and repeat incidents

To review and adjust your own practices, following near misses or incidents

Together, these four elements form an ongoing **Risk Management Cycle**.

Risk Management Cycle

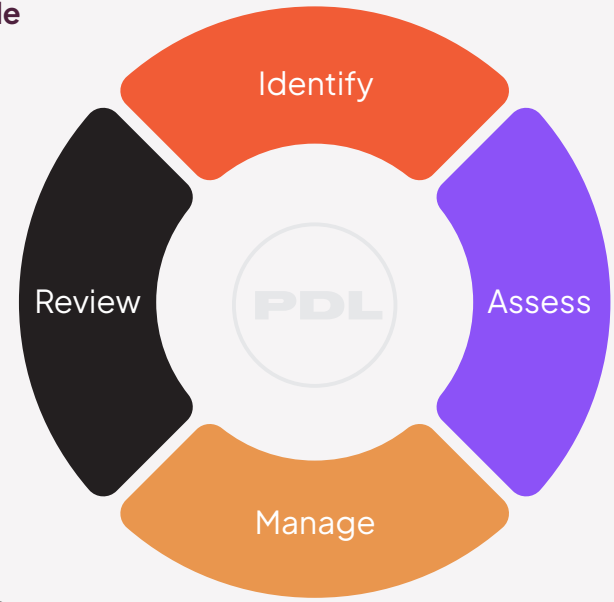


Figure 1: *Risk Management Cycle*

This simple process ensures that the pharmacist "takes responsibility and is accountable for their own actions and decisions, and for the team they manage"[1], as depicted in the PSA Professional Practice Standards. Having a Continuous Quality Improvement (CQI) process front-of-mind helps to achieve this.

Following these steps can help pharmacists to foster professional accountability, ensure ongoing compliance and enhance operational efficiency — essential components in delivering high-quality, person-centred care.

Background and purpose

About PDL

PDL is Australia's largest member-based pharmacist organisation and was established in 1912. The organisation is independent, member-owned and the most preferred professional indemnity insurance provider for Australia's pharmacists.

Our vision is to be the organisation of choice for pharmacists' professional risk management, and we are continually seeking ways to give pharmacists security and peace of mind throughout their professional life.

Our values

Dependable	Reliable and useful
Responsive	Anticipating; reacting quickly and positively
Supportive	Helping each other, without judgement
Integrity	Independent, respectful and trustworthy
Member centric	Unique and high-quality service, with members at the core of what we do

We aim to help pharmacists build capability in effectively managing their own systems and processes, regardless of their role, and demonstrate strong self-leadership and governance to recognise and mitigate risk in practice.

Our five core values are the driving force behind all that we do.

The PDL Risk Management Guide for Pharmacists has been created to align with our vision and purpose of supporting pharmacists to cultivate a strong mindset for risk awareness and reporting. As the leading provider of professional indemnity insurance and a trusted authority in risk management for the profession, we are committed to equipping our members with the knowledge they need to practise confidently and safely.

The Australian healthcare system

The Australian healthcare system faces complex challenges that can influence patient experiences and expectations, the delivery of services and the quality of care provided.[2]

Some examples of the challenges include[2,3]:

- **Changing consumer behaviour**: reduced loyalty to organisations and service providers, increased expectations to have personalised services, increased digital literacy and heightened awareness of individual rights and public health stances.
- **Digital health technologies**: innovative, new technologies have the power to strengthen shared data systems and improve healthcare delivery, but not all healthcare providers and patients have the same level of access and experience with digital technologies.
- **Ageing population and chronic conditions**: life expectancy in Australia continues to grow, and the proportion of people living with at least two chronic conditions rises. This increases the demand for services from multiple healthcare providers and requires an understanding of the diversity of healthcare needs and the burden of disease on the lives of patients.

The pharmacy workforce exists within this broader system to facilitate and improve health outcomes for Australian communities through the implementation and delivery of pharmaceutical knowledge and systems within their practice. [4] Pharmacists and pharmacy staff can deliver healthcare within a diverse range of primary, secondary and tertiary care settings, often operating in demanding, highly complex and busy environments. While medication dispensing is a core activity for many pharmacists, the use of their medication management expertise is not limited to just a dispensing function. Pharmacists delivering primary health care offer a wide range of professional services within their continually expanding scope of practice.

Well-known examples of pharmacist scope of practice activities include services such as administering vaccines and other medicines by injection, preparing dose administration aids, compounding medicines, working collaboratively as part of an allied healthcare team, assessment and treatment of minor ailment and supply of certain Schedule 4 medicines via protocol-based prescribing. Pharmacists undertake these activities while having the highest regard for patient safety and promoting quality use of medicines.

Recognising the challenges facing the Australian healthcare system — and, by extension, the pharmacy profession — underlines the need to evolve models of care and the nature by which pharmacists practise.

Clinical governance and the responsibility of the individual

The pharmacy landscape poses many potential risks which pharmacists must navigate and balance as healthcare providers. These include patient safety issues, medication-related errors, operational issues, and legal and ethical obligations.

As such, effective risk management is a non-negotiable component of pharmacy practice. The PDL Risk Management Guide for Pharmacists offers a structured means to support pharmacists in mitigating risk in practice as best they can, thereby improving patient safety, the integrity of pharmacy operations, compliance with legal and regulatory standards, and reducing professional and reputational risk to the individual practitioner.

There are governance systems in place, existing as part of a large and complex healthcare system, to ensure that patients and consumers receive safe and quality health care.[5] Pharmacists' individual responsibility to identify, assess, and manage risk falls within one such governance system; a clinical governance framework, and applies to the scope of services that each pharmacist provides.

The National Model Clinical Governance Framework, developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC)[6] defines **Clinical Governance** as:

"…a complex set of leadership behaviours, policies, procedures, and monitoring and improvement mechanisms that are directed towards ensuring good clinical outcomes."

National Model Clinical Governance Framework

Figure 2: *National Model Clinical Governance Framework, Australian Commission on Safety and Quality in Health Care (ACSQHC)*

The principles of clinical governance hold an expectation from staff members at all levels of employment within a health service organisation to maintain accountability for their individual roles to continuously improve the quality of health services provided and safeguarding high standards of care. [7] This ensures that everyone — from the newest frontline pharmacy staff (students, interns) to members of governing bodies and boards — utilises their skills and expertise within their capacity to meet these accountabilities.

Clinical risk management is part of an overall good clinical governance system. The overarching focus of a good clinical governance system is to minimise risks and harm to patients. As such, pharmacists need to ask the following questions as a first step to developing a risk mindset:[7]

1. What can and does go wrong?
2. What factors influence this?
3. What are you doing to prevent risks or recurrence of adverse events?
4. What is the outcome of an adverse event, and what have you learned?
5. How are you monitoring risks?

The table below provides an overview of some key roles in the pharmacy and their contributions to clinical governance. Additional roles and their responsibilities will be examined in detail later in *Module 2*.

Table 1: *Actions that can be taken in the pharmacy to address clinical governance, as adapted from the PSA Clinical Governance Principles for Pharmacy Services*[8]

Role	Accountabilities
Pharmacy owner or manager	• Oversight of activities of employee pharmacists, provisionally registered pharmacists (interns) and assistants • A strong and safe culture instilled from owners and management to all staff • Business professional indemnity insurance and business continuity plans are in place • Suitably qualified staff are present and available to meet service needs • Resources to allow the team to provide all services in a safe and efficient manner • Occupational health and safety protocols in place to ensure a safe environment for staff and patients • Consulting rooms meet professional standards for the services being offered
Pharmacist or provisionally registered (intern) pharmacist *providing clinical services*	• The use of evidence-based information in your patient interactions • Identify and act on opportunities for quality improvement in the provision of health services and one's own professional development • Uphold pharmacist standards, codes and guidelines applicable to their scope of practice • Reporting to management when technology or any part of a process fails • Adhere to organisational policies, procedures and systems • Report and monitor any incidents and near misses • Reporting and documentation obligations are met

Module 1:

Understanding risk in pharmacy practice

australian pharmacy council ACCREDITED CPD

1.5 CPD credits Group One

Accreditation Number: A2507PDL1

This activity has been accredited for 1.5 hours of Group 1 CPD (or 1.5 CPD credits) suitable for inclusion in an individual pharmacist's CPD plan.

Pharmacist competencies: 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 2.2, 2.3, 2.4, 3.1, 4.1, 4.2, 4.3, 4.7

Accreditation expires: 30/6/2027

OBJECTIVE 1

IDENTIFY

Pinpoint areas within your practice where potential risks or harm may occur.

To proactively assess potential risks during all professional activities

To demonstrate leadership and accountability as part of your role in good clinical governance

OBJECTIVE 2

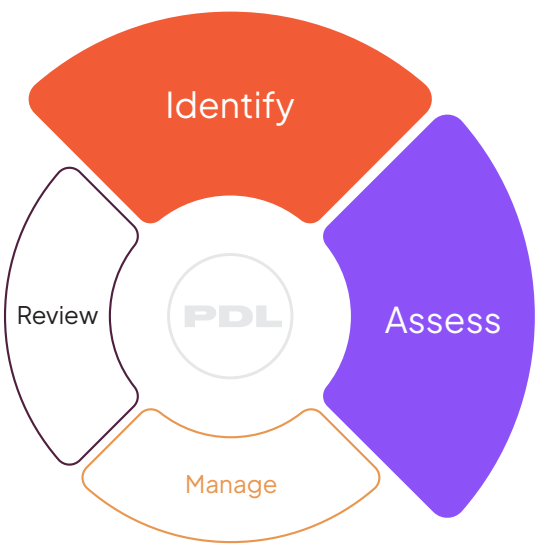
ASSESS

Evaluate the severity and urgency of required actions, using the tools outlined in the Guide.

To contribute toward a culture of continuous learning (selecting relevant CPD activities)

To leverage incidents and near misses as opportunities for practice improvement

To consider appropriate ways to mitigate and control risk in practice



Risk Management Cycle

This module is designed to equip you with basic knowledge and concepts to begin fostering a risk mindset.

After completing this module, pharmacists should be able to:

- Explain the importance of having a proactive risk management mindset.
- Describe the fundamental elements that comprise a pharmacist risk mindset and how each translates into practice.
- Recognise your own approach to risk and how that affects your practice.
- Describe the five predominant risk categories encountered in pharmacy practice and appreciate the intersection between them in many cases.

What is risk?

Risk is an effect that is "a deviation from the expected" which can be "positive, negative, or both"; and uncertainty is the root cause of risk and specifically "any kind of deficiency of information".[9]

For pharmacists, risk often means anything that could compromise the safety, quality or legality of care – whether related to clinical decisions, medicines management, communication, workflow or business operations.

As the range and complexity of pharmacists' scope of practice continues to change, new risks constantly emerge and are now an inherent part of clinical and business operations. By proactively increasing their awareness of potential risks in daily practice, pharmacists can navigate evolving expectations and requirements through more informed decision-making, adaptability, innovative thinking and strategic problem-solving.

Why is risk management important?

In many instances, the workday proceeds without incident, as individuals follow routine processes, complete their tasks and conclude the day without any major event. However, there can be occasions when a consequence can occur for a patient, perhaps without any obvious lapse or on other occasions because of a lack of planning and foresight.

Adopting a proactive approach is more effective than reacting to issues as they arise. There are several reasons why identifying and addressing challenges earlier can be beneficial for the practitioner, the organisation, the workforce around them and above all, the patients. Practical benefits of adopting proactive behaviour include:[10]

- De-escalation of aggressive interactions before they become dangerous.
- Better decision-making and ability to handle uncertainties because of strengthened internal systems and processes.
- Minimisation of losses in time, resources and costs.
- Reduced likelihood of adverse patient outcomes, e.g. hospitalisations.
- Reduced likelihood of regulatory action taken against a pharmacist.
- Stronger team culture and morale — possibly leading to enhanced staff retention.
- Encouragement of innovation and growth by evaluating and treating, not ignoring, near misses.
- Protection of the pharmacist's and pharmacy's reputation.

Being proactive in considering and identifying risk in pharmacy practice can lead to positive empowerment of staff members and patients. Importantly, that person does not necessarily have to hold a senior position in the team.

Having a risk management plan is easier than it may sound. Risk management is simply "coordinated activities to direct and control an organisation with regard to risk"[9]; entailing having a framework in place to specify "the approach, the management components (includes procedures, practices, assignment of responsibilities, timing of activities), and resources to be applied" to manage the issue.

What is the Swiss Cheese Effect?

The Swiss Cheese model of accident causation was originally proposed by James Reason, a professor of psychology at the University of Manchester. He used this model to explain the occurrence of system failures as a series of barriers, represented as slices of the cheese. The holes in each cheese slice illustrate individual weaknesses in individual parts of a system or process, or absent or failed barriers. An accident – or in a pharmacy sense, an adverse incident – occurs when a failure slips through all holes and allow "a trajectory of accident opportunity".[11]

In practice, the more 'holes' we identify at each level of a system or process, or at least look for them, the more opportunities we have to improve upon safety.[11,12] Risk management entails examining each slice to minimise the number of holes thereby reducing the likelihood of an event not being stopped somewhere along the patient journey.

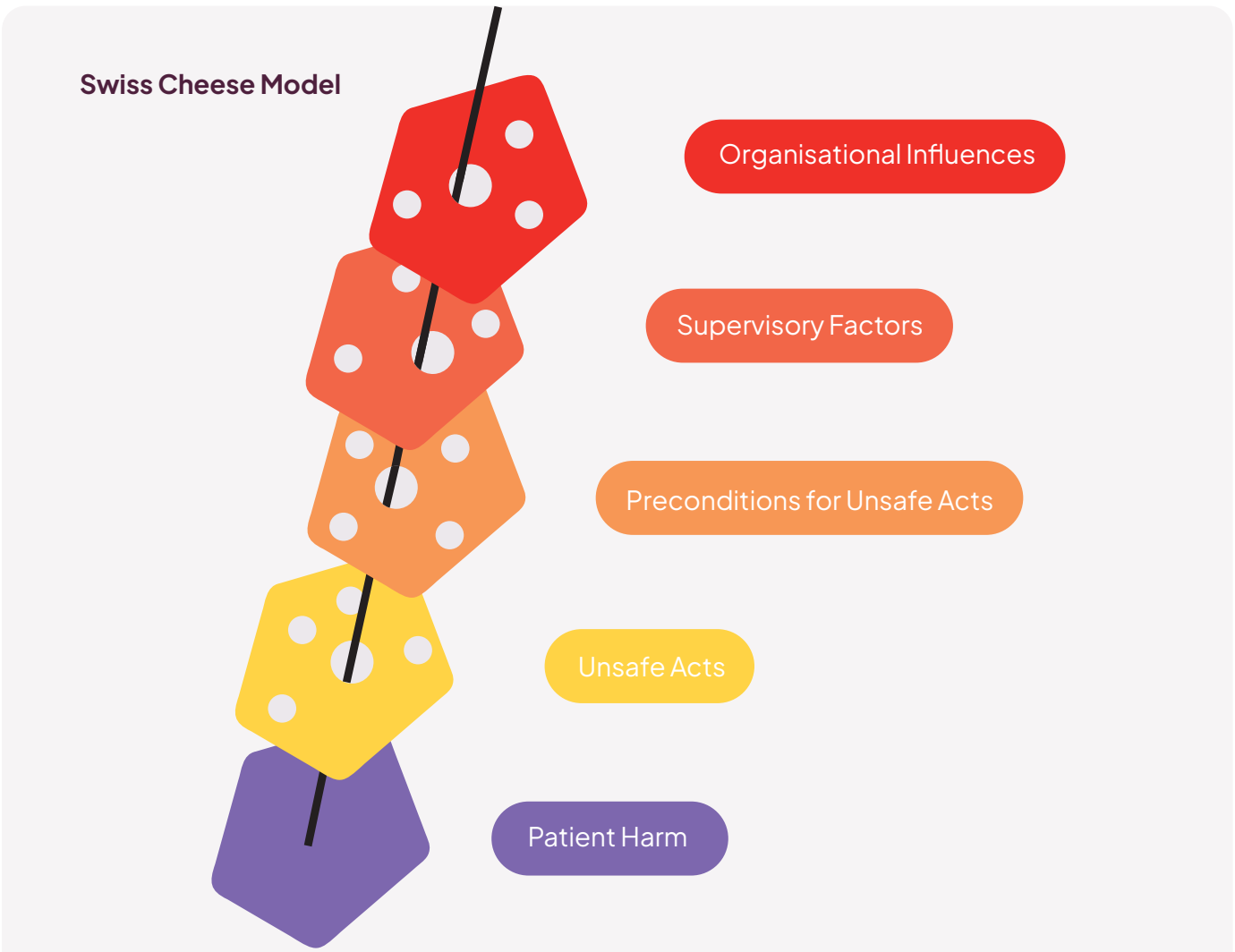


Figure 1: *The Swiss Cheese Model (adapted from the Journal of Patient Safety, 2022)* [12]

Case Study 1 explores the Swiss Cheese Effect and provides an example of how the absence of barriers or checks can lead to significant consequences.

CASE STUDY 1: Communication lapses

It was January and the pharmacy was bustling as always. The pharmacy serviced many residents at the local aged care facility across the road and pharmacy staff had a good relationship with the staff at the facility. The new managing pharmacist thought the existing team managed themselves quite well and he would have an easy time in his new role. The managing pharmacist didn't believe in micromanagement and allowed his team to do their own thing each day, so long as the work got done in the end.

It came as a surprise to the managing pharmacist when he received a call from the GP regarding an elderly resident from the facility, questioning why the patient had been dispensed denosumab one month after the previous dispensing. The GP says the patient has been administered two doses of denosumab by nursing staff, one month apart. The GP asks how the second supply could have been dispensed so soon after the previous supply.

The managing pharmacist discovered that a nurse at the facility had administered denosumab to the resident in December, and one of their nursing staff phoned the pharmacy to advise of the administration. The managing pharmacist wasn't sure who took the call and whether that message was relayed to any pharmacists on duty (as there were no notes in the system or no record of the interaction). When a new prescription for denosumab was provided to the pharmacy for the next dose, the denosumab was dispensed along with the other medicines required for the patient. The dispensary technician did not detect or relay the 'early dispensing' pop-up alert in the dispensing software to the pharmacist on duty. The nursing staff did not identify the short interval since the previous dose was administered.

Points to consider:

- What went wrong in this case?
- What are some of the potential consequences (consider all stakeholders involved)?
- What are some checkpoints that, if implemented along the process, could have prevented this?
- What are some systems the managing pharmacist can implement to better manage communication, both internally, with the nursing staff and with the prescriber?

Fundamentals of a risk mindset

What is a risk mindset?

A risk mindset is the cognitive ability to proactively recognise, assess and manage potential threats in a systematic way. It involves being aware of risks, making informed decisions and thinking ahead to minimise potential harm.

The scenario on page 18 demonstrated the potential consequences when pharmacists and pharmacies do not continually apply a professional risk mindset.

Importance for pharmacists

A risk mindset in a healthcare profession is essential to ensure patient safety is paramount. Pharmacists continually encounter complex situations requiring critical decision-making with significant patient implications. The foundations of safe and high-quality patient care are the application of a professional risk mindset.

This approach can enable pharmacists to identify potential risks early and prevent adverse patient outcomes, improve decision-making through a structured approach to risk assessment, adapt to unexpected challenges and promote innovation and continuous improvement in practice procedures and healthcare delivery outcomes.

In the previous case study, having a more cautious and practised approach could help the pharmacist prevent adverse outcomes like the one described. The pharmacist can use this experience as a learning opportunity — by reviewing and improving the systems around him and appreciating his importance in the clinical journey of every patient. The pharmacist should share the reasons for the implementation of new processes with the wider team. Demonstrating that mistakes (no matter whose) can be met with humility, transparency and a blame-free culture will give other team members the confidence to report incidents and near misses.

Developing a risk mindset

Developing a risk mindset starts with understanding these five fundamental principles and integrating them into your thought process.

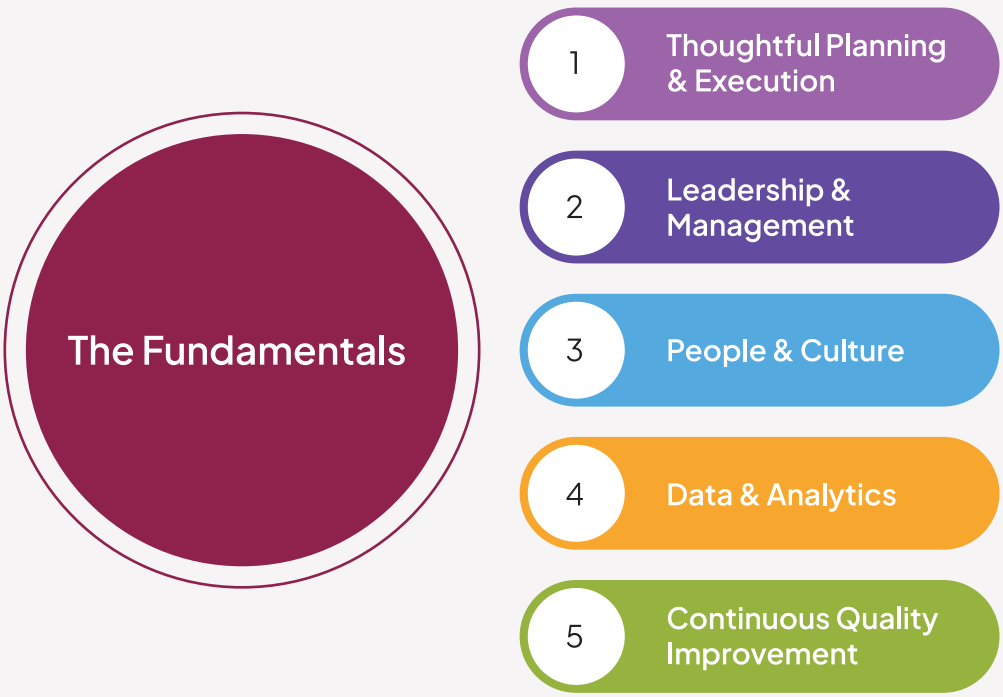


Figure 2: *Fundamentals of a risk mindset*

1. Thoughtful Planning & Execution

- **You are intentionally preparing for the delivery of professional services.**
- **You are coordinating the day's activities — including core duties (dispensing, counselling) as well as any services/activities on offer that day.**
- **You are assessing our available staff and determining if you can meet the day's responsibilities or if adjustments are necessary.**
- **Do you need to take a break before you make a mistake?**
- **Is it fact, or assumption?**

As the range of pharmacist activities continues to expand, so does the risk of adverse events and negative consequences for everyone involved in the service delivery. Pharmacists have become more comfortable undertaking professional activities outside of traditional roles and should recognise the expansion of risk that comes with these activities.

Attempts to provide a new service or undertake a new activity without thorough contemplation, planning and risk mitigation strategies increases the risk of consequence for the patient, the pharmacist, the pharmacy owner or management and potentially the profession.

Pharmacists need to consciously plan for how they prepare for any new service or activity by developing a comprehensive understanding and check of aspects including:

- Competence
- Premises
- Occupational Health and Safety
- Workflow around the service and other duties

The **PDL Scope of Practice Checklist** (access appendix, pg. 87) can offer further guidance.

Once risk has been considered, actions can be taken to minimise those risks to a level acceptable for all involved.

Thoughtful planning includes being present-minded. The acronym HALT (Hungry, Angry, Late, Tired) is a good reminder for pharmacists of four common stressors that can introduce risk into your practice. Be proactive about planning your tasks, your rostering and your workload to pre-empt the HALT factors. If you are feeling like you're not able to practice to the level expected of a pharmacist, seek to take yourself out of frontline services, take a break if possible or ensure another pharmacist can be conducting final checks and critical activities.

In pharmacy practice, assumptions due to misunderstanding or miscommunication, lack of comprehension of the patient's needs or inattention to the detail of the communication can have a detrimental consequence for patients and pharmacists. Assumptions may lead to an error, incorrect advice, a lack of relevant information being provided or negative consequences for the patient.

The unsatisfactory outcome for a patient can negatively impact the relationship with the patient, damage the reputation of the pharmacy and possibly lead to a formal complaint about the pharmacist to a regulatory agency.

2. Leadership & Management

- **You are maintaining awareness of the organisation's policies and procedures.**
- **You understand when to escalate issues to senior staff members and are familiar with the reporting structures available for support.**
- **You work collaboratively with all team members, sharing accountability while maintaining clarity about your own role.**

Planning and execution of risk management strategies are unlikely to be successful without guidance and support from individuals and teams responsible for ensuring safe and quality healthcare in a pharmacy service. Pharmacists are often accustomed to working independently and may not always engage with leaders, colleagues and the broader team to discuss and strategise the implementation of new services or changes to processes. When leadership from owners, management and senior staff members is present, then service delivery is more likely to be positive and effective with broad engagement from all team members.

- **Are you error-wise? Is your workplace error-wise?**

Making sure you are approaching every task with consideration of the potential risk of consequence for a patient. Being error-wise enables you to take a proactive approach to thinking about how you can reduce this risk for the patient and how you can have relevant risk discussions.

3. People & Culture

- **You actively contribute to a team environment and clearly recognise your role and its expectations and behaviours.**
- **You ensure collective success by supporting all members of the team.**

Understanding risk from the perspective of person-centred care is a strong foundation to building a healthy approach to risk management in the workplace.

A blame-free culture plays a crucial role in Continuous Quality Improvement (CQI), benefitting every pharmacy staff member. Without it, valuable learning opportunities are lost, as staff may feel reluctant to report mistakes, preventing errors from being identified and addressed.

A positive reporting culture is built on key attributes including:

- Clear and supportive leadership that empowers staff to report issues without fear of repercussions, with guaranteed follow-up.
- A workplace environment where staff feel safe and encouraged to report concerns.
- Open communication and follow-up to ensure reported issues are effectively managed.

By collaboratively planning, implementing and regularly reviewing policies and procedures, pharmacy owners, management and employees can build confidence in the organisation's systems — benefitting the entire team. Strong connections between staff and management contribute to reducing risk for all parties involved.

As reporting culture strengthens over time, the quality of reports improves, reinforcing a commitment to better patient care and continuous improvement.

- **You are committed to practising with caution and care while being forgiving of yourself and others when errors arise. You practise with humility and transparency.**

An extension of the above thought process is the acceptance of the fallibility of humans. Everyone makes mistakes. Restoring professional confidence and maintaining positive morale is more likely to occur when all pharmacy staff work with humility and transparency. All staff members should feel comfortable reporting incidents and near miss events.

4. Data & Analytics

- **You recognise the importance of identifying and reporting near misses, incidents and their contributing factors, to improve patient safety and workflow efficiency.**

An understanding of past and current practices and outcomes for pharmacy services, whether in a pharmacist's current setting or through feedback and insights from others in the profession, is a vital consideration when seeking to assess risk in any pharmacy activity.

It is mentioned in **People & Culture** that a good reporting culture can lead to CQI (next point). The collection and analysis of data such as patient, employee and pharmacy outcomes and feedback to those involved in service provision is necessary to assess and improve upon new and existing services and activities.

For example, when considering expansion of your scope of services offered to the community, you could consider data not only specific to your pharmacy but also relating to the wider profession.

For instance, if a pharmacist new to providing vaccination services is seeking to offer this service at a pharmacy they may choose to consider data such as: range and quantity of vaccination services provided by other pharmacists, patient feedback, the level and range of demand for vaccination services, analysis of times when vaccination services have been or are more or less likely to be requested, review of existing and newly included vaccines in subsidised vaccination programs and analysis of patient demographics and cross referencing to the recommended vaccines for that patient cohort.

5. Continuous Quality Improvement (CQI)

- **You take a proactive approach by identifying practical steps that can be implemented immediately to improve patient safety, enhance processes and promote person-centred care.**

A set-and-forget approach to instituting pharmacy services is not acceptable and increases the risk of negative consequences for patients, pharmacists, owners and management. Continuous Quality Improvement (CQI) activities must be built into any organisation's standard operating procedures with formal, planned reviews occurring regularly.

Reporting in line with agreed protocols and assessment of reported outcomes can help to detect emerging areas of risk leading to prompt action and any required practice change and remediation. Leadership within an organisation must support CQI and utilise a non-judgemental approach to encourage reporting of issues to management so that genuine review of services and activities can be undertaken.

The PDL Risk Management Cycle helps to underpin the basic steps and how REVIEW is always included as part of the process.

Table 2: *Actions that can be taken in the pharmacy to embed CQI, if a near miss or incident has occurred:*

Role	Examples
Pharmacy owner or manager	• Have you given your team enough support and resources to manage any new processes? • What were the contributing factors? • Have you got effective reporting structures in place? If not, what are the barriers?
Individual practitioners — any pharmacist or provisionally registered pharmacist (intern) providing clinical services	• What were some contributing factors? • How did you feel at the time? • What can you do differently next time? • Where can you go for support? • Do you need more training, mentoring or targeted learning (can be clinical or otherwise, e.g. leadership skills, communication skills)? NB: The PDL Reflective Practice Activity (access appendix, pg. 87) can support here.

REVISITED CASE STUDY 1: Communication lapses

What went wrong in this case?

The pharmacist was entering into a pre-established team of competent and able staff members and a system that had been working so far.

Should the pharmacist have taken any extra measures to review existing processes and procedures?

What are some of the potential consequences? Consider all stakeholders involved.

Risk of adverse health outcome

Damage of relationship between pharmacy and aged care facility — could lose rapport and business with them

Ignoring this incident allows for future similar events to occur

What are some checkpoints that, if implemented along the process, could have prevented this?

Management of communications involving the aged care facility — emails, calls, verbal messages. Who takes these? How are messages relayed? Who should they be relayed to? What happens if that person is away?

Dispensing process — who dispenses, who is responsible for checking history and important pop-ups or alerts? How can the checking pharmacist exercise clinical judgement when it comes to assessment of patients and their medical history? Refer to the PDL Guide to Good Dispensing for a refresher suitable for the whole dispensary team.

Final check and patient collection — are there any measures in place as a final checkpoint? Refer to the PDL Supplement to Guide to Good Dispensing for important points to consider at this final stage of interaction with a patient.

What are some systems the pharmacist manager can implement to better manage communication, both internally, with the nursing staff and with the prescriber?

The primary message is to appreciate the situation in which the pharmacist found himself in; as a manager, he could be exercising some reflective thought to measure out the inherent risk in the workflow the pharmacy has with the nursing home. Once he puts in some controls, he and the pharmacy may find that the remaining residual risk is far less than if he had done nothing at all. He cannot predict and prevent everything, but he can take reasonable measures to mitigate risk in foreseeable circumstances.

Some controls that the pharmacist manager can put into place might include:

- Having a communication system titled “Aged Care Facility Comms” where all staff members are trained to put notes in there, e.g. when they take phone calls, emails, verbal messages, etc. — and pharmacists on duty must read this daily.
- Refreshing on some good dispensing processes — reinforcing at team meetings the importance of reading all pop-up notes and referring to the pharmacist if it is a technician dispensing.
- Manager can undertake some CPD training on leadership skills or management training.
- Never skip counselling. Check with the patient at the point of collection of medicine, even if you have checked in the dispensing software and all seems well.
- If unsure, consult with patient’s doctor.

Where the definitions are:[9]

Inherent risk: the risk without considering internal controls or “a raw risk that has no mitigation factors or treatments applied to it”.

Controls: a measure that is applied to address risk. Controls include any process, policy, device, practice or other actions that modify risk. Controls may not always exert the intended or assumed modifying effect.

Residual risk: risk remaining after risk treatment. Residual risk can contain unidentified risk.

The pharmacist could establish appropriate controls to address anticipated risks, however it must be noted that it is not possible to eliminate all risks entirely. Some elements of risk are unidentified and unable to be prevented.

Understanding YOUR approach to risk…and why it matters

Every individual has a personal level of comfort when it comes to taking risks and a certain level of acceptance around risk.

This next case study introduces the concepts of individual approaches to risk and why understanding these within oneself can help practitioners operate with better intent and lend to more considered outcomes.

CASE STUDY 2: That doesn't seem right!

A community pharmacist was dispensing a hospital prescription for a 43yo male patient new to the pharmacy:

Morphine oral liquid, 2mg/mL
2.5mg q4–6h PRN
For suppression of cough

The pharmacist was a highly risk averse individual and believed herself to be very thorough and evidence-based in her practice. She was surprised to see a potent pain-relieving medicine being prescribed for a common cough. She checked her AMH and eMIMS and being unable to find helpful information, she was sure that this was a prescriber error — maybe it was meant for Rikodeine (dihydrocodeine) liquid.

Hence, she hastily approached the patient and enquired with the man what he was using the medicine for, because "we don't normally see this prescribed for cough". The man was a bit taken back and reluctant to disclose any information. He bluntly stated that he did not want to talk about it, as the hospital had already gone through it with him. The pharmacist was feeling extremely uncomfortable about the whole situation and told the man she was not going to dispense the prescription, and that she would need to double-check with his doctor.

The prescriber she contacted was a senior oncologist at the hospital. He conveyed that he had correctly prescribed the morphine liquid for cough suppression, as the patient was in palliative stages of cancer and coughing up lung tissue. He also cited his informed prescribing decision as coming from a reputable evidence-based Australian online resource providing cancer treatment protocols and point of care information.

The pharmacist dispensed the medication and provided counselling, whilst feeling rather sheepish that she had not considered a broader spectrum of indications and possibilities before rushing to conclusions.

Why manage risk?

Once a proactive, risk-aware mindset is established, the next step is effective risk management. This should be an integral component of core practice, valued equally alongside the technical aspects of the role.

Poor dispensing processes can lead to the same poor outcomes as poor risk management strategies. Both directly affect patient safety, quality of care, professional reputation and the profession's long-term success.

Embedding risk management and well-considered reasoning into core practice can help pharmacists to proactively anticipate and prevent errors and inefficiencies. In doing so, pharmacists can safeguard their practice and contribute towards a higher, safer standard of care for the Australian community.

Cultivating a risk mindset shifts the focus from a "compliance checklist" to a more balanced way of thinking, so that managing risk becomes a part of the core values of who we are, not just something we "do".

Risk appetite and risk tolerance

Risk appetite refers to the amount of risk an individual is willing to pursue to achieve their objectives. A higher risk appetite might mean one is more likely to adopt new practices, while a lower risk appetite might mean one would prioritise safety and compliance over venturing into unknown territory. A related term is risk tolerance. This is a subjective and psychological term relating to an individual's comfort levels, based on their personal experiences and preferences. In other words, risk tolerance is the specific limits that an individual is prepared to accept, i.e. it represents the thresholds within which one perceives risks to be manageable and acceptable.

Example of risk appetite: "Patient safety is your top priority. However, you accept that there will be times when ensuring patient safety requires extra time, which can come at the expense of prompt service. This is where you must balance risk vs benefit."

Example of risk tolerance: "You plan to advise each patient awaiting a prescription that there is a 15–minute wait. However, you recognise that there can be unexpected circumstances in the day that cause delays, in which case you accept that sometimes patients may be asked to wait for up to 2 hours."

A key takeaway message is that:

Each individual will have a different approach to risk.

There is no level of risk tolerance or aversion that is "safer" than the other; both come with a mindset that manages risk in context and will be portrayed in our actions, behaviours and responses at work. At times, individuals must balance risk and benefit, to determine and justify the most appropriate way forward.

An individual's risk appetite and risk tolerance help define the boundaries within which each pharmacist can safely operate while managing uncertainty. Understanding these can help pharmacists make more informed decisions about which risks can be mitigated, accepted or avoided.
Be mindful that others may work differently, and that is okay, therefore lending to more balanced verbal communication, actions and behaviours.

Understanding your approach to risk

Although risk is natural to life and inherent to the pharmacy (and health) professions, it is understood that individuals have different capacities for risk, often referred to as an "internal risk dial". This will be influenced by unique personalities, cultural and moral beliefs, as well as the role or level of experience held by the individual.

Pharmacists often work in environments that are clearly defined and "black and white" with decision-making based on legislation and straightforward "yes or no" pathways, which provide comfort and certainty. PDL note that many pharmacists seeking advice expect fully informed and clear-cut answers.

However, much of the time in the profession is spent navigating the "grey areas", where there are multiple possible approaches, each with their own outcomes and consequences.

A pharmacist with a mature risk mindset and capacity is often more prepared to accept that some degree of risk is always involved. They develop strategies that allow them to address risk to the best of their ability while engaging the consumer in the process.

REVISITED CASE STUDY 2: That doesn't seem right!

The pharmacist understands that she is a risk-averse individual. While she has relied on a few key resources, the deviation from situations outside of the ordinary (in this case, a dose and indication that she has not regularly had exposure to) has challenged her personal risk tolerance. She believes that she has acted within her professional obligations to exercise caution, check references and consult the prescriber. But as she develops her risk mindset and self-awareness, her communication skills will also evolve. She will be able to extend herself to think of alternate options before making decisions based on perceptions of risk without being fully informed.

From this, the pharmacist may be able to express her reservations with the patient in a more productive manner, without causing unnecessary alarm or distress and work alongside others with curiosity and emotional intelligence, without accidentally conveying judgement and blame.

Is there a problem here?

Perceived risk vs actual risk

There is a distinct difference between perceived and actual risk. Perceived risk[9] refers to a person's view on a risk. Risk perception reflects the stakeholder's needs, issues, knowledge, beliefs and values. By contrast, actual risk refers to the quantifiable aspects of risk. It includes aspects such as the likelihood, the impact and the severity of the risk.[9]

While pharmacy practice poses many known risks that can be managed through well-informed, educated decisions, there will be situations where unforeseen circumstances come into play.

Perceived threats can generate unhelpful anxiety, leading to inappropriate actions or responses in the workplace.

For example, responding to an upset patient by yelling is unlikely to result in a favourable outcome for either party. A balanced, measured response to challenging situations is achievable with a mature risk mindset.

Types of risk in pharmacy practice

The following scenario helps to prompt awareness of various types of risk and how they may arise in day-to-day practice.

CASE STUDY 3: The multifaceted nature of risk

An elderly Dose Administration Aid (DAA) patient was receiving multiple medications via a DAA blister pack, which included apixaban. A decision was made by treating practitioners that the patient should cease the apixaban and commence warfarin.

The patient's daughter brought in a prescription for warfarin 1mg & 2mg. The daughter advised the assistant taking the prescription that the warfarin was not to be packed in the DAA as the patient would be administering the warfarin according to the pathology results and GPs direction. The medicine was dispensed and at the time of dispensing there was no recognition of the currently packed apixaban. The packing technician continued to pack apixaban as per the patient profile on hand and since there was insufficient apixaban to complete filling the DAA and there were no apixaban repeats remaining, the technician dispensed an "owing" prescription for the apixaban, which the pharmacist checked and packing continued.

It was only 2 weeks later when the patient had a fall and extensive internal bleeding that the error was identified, and management of the anticoagulants was addressed.

Points to consider:

- What are some of the contributing factors to this incident?
- Where was the communication lapse and how could this be addressed for future?
- Who is in charge of DAA processes and improving them? What can pharmacists and assistants do to support any changes needed?
- What resources are available to support you with best practice guidance on the delivery of DAA services?
- What types of risks do you think are present in this case? What actions therefore need to be taken?

Five types of risk in pharmacy practice

An element of risk exists in every human activity and pharmacy practice is no exception. Drawing from the experience of PDL Professional Officers and their interactions with pharmacists over the years, the following are the five predominant risk categories seen in pharmacy practice:

#1 REGULATORY & COMPLIANCE RISK

This type of risk is listed as #1 because it is a non-negotiable aspect for individual practitioners. Legislation is black and white; it clearly defines the legal activities of a pharmacist. Lapses or intentional breaches of legislative requirements are more likely to lead to a negative outcome for a pharmacist if brought before a regulatory agency and more likely to incur a penalty for the pharmacist. Examples of this type of risk include:

- **Non-compliance with laws and regulations**
- **Inadequate record keeping**
- **Failure to meet accreditation standards**
- **Controlled substance handling violations**

#2 CLINICAL RISK

These types of risks are associated with clinical functions and always involve patient safety. This relates to pharmacists' duty of care and ensuring the clinical risk for the public is mitigated to the greatest extent. Examples include:

- **Prescribing errors**
- **Dispensing errors**
- **Inadequate or lack of patient counselling**
- **Transitions of care/interprofessional communication errors**

#3 PROFESSIONAL RISK

These refer to situations where a pharmacist's actions, decisions or practices can lead to legal, ethical or reputational consequences. Pharmacists must practice within their clinical expertise and legal framework. However, navigating professional expectations can be challenging in grey areas, where no clear answer exists and each outcome uniquely impacts the patient, pharmacist, pharmacy setting and other factors in different ways. These professional risks highlight the need for diligence, ethical conduct and adherence to pharmacy standards. Examples include:

- **Breaches of confidentiality**
- **Unethical behaviour**
- **Poor clinical judgement**
- **Non-compliance with legislation or regulations**
- **Neglecting CPD requirements, potentially leading to reduced competence or inability to meet standards of care**
- **Inadequate record keeping**

#4 ETHICAL RISK

There may be times where a pharmacist's actions may conflict with their moral or ethical principles, leading to a compromise in their professional conduct (either intentionally or unintentionally). This can cause significant moral distress and may have legal or professional ramifications. PDL often receive calls from members who are worried about themselves, their practice and their patients — and this clearly weighs on them personally and ethically as a practitioner. Examples include:

- **Inadequate or lack of patient counselling**
- **Conflicts of interest, e.g. prioritisation of financial, personal or commercial interests over patient care**
- **Patient autonomy and informed consent, e.g. intentional or unintentional withholding of critical information**
- **Refusal to dispense medications based on personal beliefs**
- **Bias or discrimination**

#5 OPERATIONAL RISK

The potential for disruptions or inefficiencies in the day-to-day running of a pharmacy can negatively impact service delivery, patient care or the business itself. These risks often arise from internal processes, systems or human factors. Poor planning, governance, training and support are key contributing factors in incidents and their subsequent consequences. Examples include:

- **Workflow inefficiencies**
- **Inadequately trained staff or shortages in staff**
- **Supply chain disruptions**
- **Inventory management issues**
- **Data breaches involving patient records**
- **System downtimes and failures**
- **Occupational health and safety hazards**
- **Poor communication or coordination between staff or other stakeholders (patients, GPs, specialists, aged care facility staff, etc.)**

KEY TAKEAWAYS

- A proactive approach is more effective than a reactive approach.
- A strong risk mindset enables more informed decision-making, allowing for better planning and safeguarding of future events.
- Understanding and building your risk approach comes with time and experience.
- Understanding the types of risks affected in any given scenario can help you make more considered and longer-term action plans and solutions, as opposed to a quick fix.

Activity

Now it's your turn to take a closer look at Case Study 3.

REVISITED CASE STUDY 3: The multifaceted nature of risk

There are several contributing factors to this scenario. These include: a lack of communication between the daughter, assistant and pharmacist about the new medicines, a lack of clinical acumen by the pharmacist when checking the warfarin and the patient profile, the lack of a new profile being sent by the GP and a reliance that the daughter would explain the changes to the pharmacy staff, the dispensing of the apixaban without a prescription, the lack of addition of the warfarin to the patient DAA profile which may have alerted the DAA checking pharmacist to the double up of anticoagulants and lack of holistic clinical review.

Consider yourself the pharmacist in this scenario. Before taking remedial action, please review the **five types of risk in pharmacy practice (pg. 27)** to assist in determining which areas of risk are at play and hence what can be done to address them from a holistic and long-term perspective. Answer the following questions to demonstrate your understanding of risk types in pharmacy practice:

1) Regulatory & Compliance Risk

What legal options exist to allow for continuity of therapy? (Options to consider include verbal instructions, faxed or emailed prescription, continued dispensing arrangements in some cases, emergency supply laws, etc.)

2) Clinical Risk

What clinical considerations do you need to make? Think about all stakeholders involved.

3) Professional Risk

What professional practice risks are relevant in this case? Think back to the pillars of clinical governance.

4) Ethical Risk

Consider pharmacists' duty of care to the patient and their families, the prescriber and the psychological impact for all people involved in the incident.

5) Operational Risk

Again, consider what lapses have occurred from a governance perspective, e.g. procedures, trainings, oversight from management.

RECOMMENDED READING

PDL Scope of Practice Checklist

PDL Guide to Good Dispensing

PDL Supplement to Guide to Good Dispensing

Access appendix on pg. 87

Module 2:

Applying risk principles to practice

australian pharmacy council ACCREDITED CPD

1.5 CPD credits Group One

Accreditation Number: A2507PDL2

This activity has been accredited for 1.5 hours of Group 1 CPD (or 1.5 CPD credits) suitable for inclusion in an individual pharmacist's CPD plan.

Pharmacist Competencies: 1.3, 1.6, 2.1, 2.2, 2.3, 2.4, 3.1, 4.2, 4.3, 4.5, 4.6, 4.7

Accreditation expires: 30/6/2027

OBJECTIVE 2

ASSESS

Evaluate the severity and urgency of required actions, using the tools outlined in the Guide.

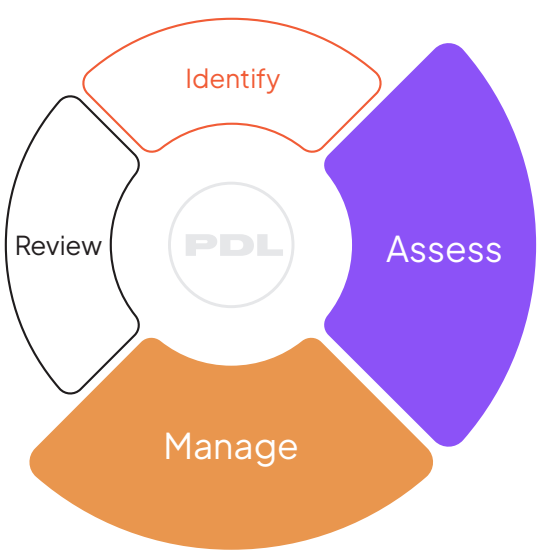
- To contribute toward a culture of continuous learning (selecting relevant CPD activities)
- To leverage incidents and near misses as opportunities for practice improvement
- To consider appropriate ways to mitigate and control risk in practice

OBJECTIVE 3

MANAGE

Implement and maintain effective systems and processes within your practice.

- To work independently and collaboratively to maintain governance systems to prevent and address incidents
- To confidently engage in handling and resolving incidents



Risk Management Cycle

This module builds upon the foundational concepts introduced in Module 1, helping readers develop a more holistic approach to assessing risk and providing a structure to support the implementation of effective systems and processes.

After completing this module, pharmacists should be able to:

- Identify three key risk factors in practice and how their relationship collectively contributes to overall risk.
- Apply the PDL Risk Assessment Tool to clearly define a specific area of risk in your pharmacy and implement appropriate measures to address and mitigate that risk.

Turning awareness into action

"When should you worry about an error?"
"When does a near miss become an incident?"
"What is considered an adverse event?"
"What should you do in each situation?"

Pharmacists understandably may be more aware of clinical risk as they are health professionals trained to focus on a patient's health and wellbeing from a medicines safety perspective. However, there are many areas of risk for patients and pharmacists, apart from clinical risks. For example, other areas where situations may cause risk for patients and pharmacists include general counselling and healthcare advice, privacy and confidentiality responsibilities, physical and psychological consequences from pharmacists' activities, financial impacts from pharmacists' actions and advice and challenges to the reputation of the profession.

There are divergent views as to the classification of a near miss event and an incident. Some references classify a near miss as an event where a person is aware of an error, but there has been no clinical consequence for a patient. However, it is PDL's view that such a situation is an incident, as the person is aware of an error or lapse in expected practice. While there may not have been a consequence for the patient, the error or lapse has the potential to cause consequence and therefore should be treated as an incident.

PDL would categorise a near miss as a situation where an error or lapse has occurred, but it has been rectified before the medicine or advice is provided to the patient or carer.

An adverse event is some form of negative consequence including a physical effect, a psychological, financial or perceptive impact.

PDL would encourage reporting within an organisation of any near miss event, incident or adverse event as these situations can inform practice review and reflective practice change. Furthermore, PDL recommends that incidents and adverse events are reported to the professional indemnity insurance provider as this is a requirement of a pharmacist's or pharmacy owner's insurance policy. Apart from the benefit of prompt reporting to the insurance provider, the reporting data can be analysed to assess the frequency of error, consider contributing factors and provide pharmacists with insights into areas of risk that may only become apparent from larger scale data analysis.

These first two case studies address the ASSESS and MANAGE learning objectives by encouraging readers to evaluate the situation in front of them, identifying potential risks and thinking through some possible outcomes with a process-improvement lens.

CASE STUDY 1: Should you really be doing that?

A 46-year-old patient has been prescribed fremanezumab (Ajovy®) by her specialist. She presents to your pharmacy with the new prescription. After you have provided counselling and covered how to self-administer, she remains very uncomfortable about the idea of self-injecting.

The patient asks if you can show her how to do the injection while she is present. You take her to the consultation room and watch the "How To Use the Autoinjector" video together and you talk her through the process as she self-administers the injection.

The following month, the patient returns to the pharmacy and asks if you can please just give her monthly injection ongoing, because "it's just easier".

Points to consider:

- Is the administration of a medicine by subcutaneous injection within your scope of practice?
- Do you have the knowledge and competence to do this?
- Do you have the authority to do this? Is it the same in every state?
- Will your professional indemnity insurance cover you if the patient has an adverse consequence following the administration of the medicine by you?

CASE STUDY 2: Tirzepatide strength and dose confusion

Tirzepatide (Mounjaro®) is an injectable medicine approved for Type 2 diabetes and weight loss. It comes in many strengths and sometimes selection can be confusing while dispensing.

The pharmacist-on-duty receives an electronic prescription for:
Tirzepatide 12.5mg/mL
administer 7.5mg weekly for 4 weeks

The pharmacist examines the tirzepatide listings in the dispensing software. The pharmacist selects the product containing 12.5mg from the multiple listings available. The pharmacist did not recognise this listing relates to a dose of 12.5mg per 0.6mL. This strength was selected rather than the 12.5mg/mL product which offers the prescribed dose of 7.5mg per 0.6mL.

The pharmacist includes the instruction on the dispensing label to "administer 7.5mg weekly" as per Doctor's orders.

The pharmacist placed a note in the script basket so the assistant could advise the pharmacist when the patient returned to collect the prescription and an explanation could be provided about using the "click method" to measure the prescribed dose.

A few weeks later, the pharmacist received an angry call from the patient's GP, letting him know that on their check-up appointment, the patient revealed they had been administering 12.5mg rather than 7.5mg. The GP said he was "very clear" on his instruction and will be making a complaint to Ahpra regarding this incident.

Points to consider:

- What could be the contributing factors leading to the selection error?
- What other steps could you have taken to support your decision-making?
- What other examples can you think of where selection error may be possible due to confusion in strength/dose/combination medicines/etc.?
- What actions/steps could be taken to prevent a similar incident occurring again?

How areas of risk overlap

In the dynamic environment of pharmacy practice, risks often interact and influence each other. Being mindful of the fact that risk rarely occurs in isolation is important because of the compound impact; one risk factor can amplify the effects of another.

Targeting a single risk may not be enough if others are reinforcing it. By understanding how risks are linked, pharmacists may be able to better predict potential outcomes and make more informed and accurate decisions in risk assessment and management.

The following scenarios provide examples of how the pharmacist's role, the patient and the practice setting can all affect the other.

Transitions of care — incomplete sharing of patient information when a patient is discharged from hospital or leaves their home to live in an aged care facility.

Updated DAA chart — the doctor changes an anticoagulant medicine in a patient's DAA and provides the patient with an updated profile however the profile is not provided to the pharmacy.

Insufficient or inaccurate record-keeping — forgetting to enter a patient's vaccination onto the Australian Immunisation Register (AIR).

Unexpected needle-stick injury — a patient brings her 2-year-old into the vaccination room and during the consultation the child reaches into the sharps container and accidentally stabs himself with a discarded needle in the sharps bin.

Poor communication — from a professional perspective, if communication and collaboration skills are not strong, this can increase the likelihood of errors occurring, which affects patients and can be worsened by an environmental element (e.g. inefficiencies in workflow or resourcing inadequacies).

A component of risk assessment is to consider the potential impact to various stakeholders in any activity or service. For instance, from a patient perspective those impacted can include family members, carers and treating health practitioners. From the pharmacist perspective, those impacted may include pharmacy owners, management and staff, colleagues, the reputation of the profession and the regulatory agencies that might become involved.

The following Figure 1 provides a way to visualise the interconnected nature of risk factors. In understanding this, pharmacists can take a holistic approach to risk management, as they better anticipate potential problems and their flow-on effects.

(Please note this has been simplified to highlight key focus areas, though other aspects of practice may also contribute to overall risk.)

Figure 1: *Interconnected Risk Factors: Patient, Professional role and Practice setting*

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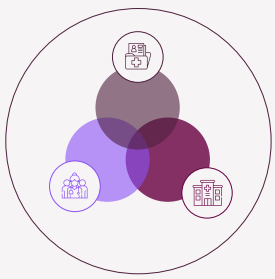


Effective risk mitigation strategies should be integrated across all aspects of practice to ensure that patient safety, regulatory compliance and professional integrity are continuously balanced and maintained.

The PSA Clinical Governance Principles for Pharmacy Services[8] describes clinical governance, in the context of Australian pharmacy practice as:

- Governance arrangements within a community pharmacy, pharmacy department or other pharmacy business to ensure clinical accountability of pharmacists and management.
- Relationships between pharmacists, clinicians and a clinical governance unit and/or leaders within a hospital.
- Partnerships between pharmacies and commissioning bodies (such as Primary Health Networks (PHNs)).
- Clinical accountability within a general practice environment where pharmacists contribute to quality use of medicines.
- Professional responsibilities of accredited pharmacists in undertaking medication reviews.
- Accountabilities of pharmacists working in shared care arrangements (e.g. within a mental health team).

These points address the three predominant risk factors in **Figure 1**; evaluating professional activities or services through this lens increases the likelihood of comprehensive risk identification and mitigation.

Your professional role

Roles and responsibilities

Risk management is a **shared responsibility**. Effective risk management requires everyone in the team to be accountable to patients and the community for ensuring the delivery and continuous improvement of safe, effective, integrated and high-quality health services. This accountability extends from pharmacy assistants and dispensary technicians to pharmacists, pharmacist managers and proprietors.

Pharmacy owners

National and local pharmacy regulatory agencies have expectations and resources for pharmacy owners to meet minimum expected standards of practice to mitigate the risk of harm for the public.

These obligations generally include having an awareness of the manner in which the pharmacy business is being conducted and intervening to address potential risks and implement service improvements in alignment with applicable guidelines.

Some of these obligations include:

- Developing and maintaining protocols and resources that facilitate risk identification and management
- Adequately resourcing their workforce with appropriately trained staff
- Remaining up to date with information provided by regulators/peak bodies/other stakeholders
- Communicating clear reporting and auditing protocols
- Promoting Continuous Quality Improvement (CQI)

Owners are encouraged to take the lead in fostering a culture that supports safe and transparent reporting within their organisation. Establishing an environment where team members feel confident raising issues or concerns can help enhance education and continuous improvement in practice.

Proprietors should consider developing and maintaining protocols and resources that facilitate risk identification and management and promote CQI.

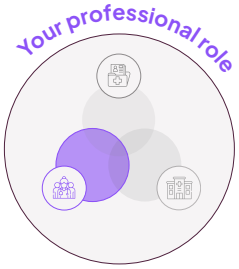
Pharmacists employed in management roles

Pharmacists with an elevated level of responsibility work in tandem with owners or other senior team members to implement standard operating procedures (SOPs) and staff training protocols. They also play an important role in risk identification and management and developing strategies to improve service provision where required.

They play a crucial role in supporting and empowering staff in the workplace through education, training and supervision. They are often a conduit for communication between staff and owners/senior management. Effective communication and exchange of ideas, issues or concerns is essential to ensuring effective clinical governance can be achieved for the organisation.

These pharmacists play a key role in:

- Maintaining a high standard of service provision
- CQI
- Modelling good pharmacy practice
- Staff management, education and training
- Reporting areas of risk, incidents and near misses via the appropriate channel
- Building a healthy workplace culture
- Engaging with the profession to stay up to date with legislative and practice change



Refer to page 33 for Interconnected Risk Factors

Pharmacists (including provisionally registered pharmacists)

Risk management is often thought of as the responsibility of proprietors, senior pharmacists or management. However, pharmacists assigned to direct service provision are often the first people within an organisation to identify actual or potential risks and opportunities for improvement.

Pharmacists are autonomous healthcare practitioners and are expected by regulators and the public to be aware of and understand legislation and follow best practice guidelines, if applicable, for the services they provide.

Pharmacists contribute to risk management by ensuring they practise according to the appropriate legislation, standards and guidelines and should have their own systems and self-assessment in place to maintain their knowledge and skillset to the expected level.

All pharmacists, including locum pharmacists, can contribute to the organisation's approach to risk management. The pharmacist provides feedback on procedures and processes that could be improved, identifies risks and manages services to ensure all incidents and near misses are reported to owners or senior management as soon as possible.

Pharmacists play a crucial role in risk management through:

- Self-assessment and maintaining knowledge and skills
- Engaging with the profession to stay up to date with legislative and practice change
- Following standard operating procedures (SOPs), legislation and best practice guidelines
- Providing a safe and quality healthcare service
- Communicating areas of risk, incidents and near misses via the appropriate channel

Non-pharmacist staff

All pharmacy staff from dispensary technicians, pharmacy assistants or third-party contractors (e.g. delivery service providers, cleaners) have a role to play in the patient's health journey and are part of a robust clinical governance framework.

Non-pharmacist staff can contribute to clinical governance by:

- Understanding their roles and responsibilities
- Engaging with training and education opportunities
- Following SOPs
- Passing on customer or patient feedback
- Raising issues or concerns with senior staff

Clinical judgement

A key professional responsibility of any practising pharmacist is to apply sound clinical judgement. Clinical judgement is the process of sound decision-making and is developed through evidence-based knowledge, practice and experience.

Development of clinical judgement is an ongoing learning process. Throughout a pharmacist's career, there will be many situations where the 'right' answer is unclear, with multiple possible actions and outcomes. In those cases, good clinical judgement can help pharmacists make well-informed decisions to determine the best course of action.

Consideration of how risk can present itself in daily activities can help when trying to decide on the best clinical approach, and then the response can be appropriately matched to the perceived risk.

Thinking about risk can improve clinical judgement and decisions.

Scenario A
Repeat prescription for atorvastatin 20mg 1 d

60yo male patient

History of dispensing this medication for 2 years from the same prescriber at appropriate intervals

Action:

- Discussion with the patient confirms their adherence to the treatment, regular pathology testing as ordered and absence of adverse effects from the medicine

Risk assessment:

- Long term medication
- Dose sits within therapeutic guidelines

LOW risk

Scenario B
New prescription for fluoxetine 20mg

23yo female patient

No prior history of SSRIs

Action:

- History taking and discussion with patient required to understand indication and past history to better assess risk

Risk assessment:

- New medication
- No medical history at this pharmacy

MILD risk

Scenario C
New prescription for prednisolone 5mg/mL, 13mg d for 3 days only

Father presenting with the child

Action:

- History taking and discussion with patient required to understand indication and past history to better assess risk
- Confirm child's weight
- Dose calculation and confirmation it is within recommended range for the child's weight

Risk assessment:

- Paediatric patients may raise the level of risk
- Directions must be provided in a logical and applicable manner for the parent/carer, i.e. in mLs rather than in mg

MODERATE risk

Scenario D
Emailed prescription for fentanyl patches 75mcg Qty 20, 1 patch every 48 hours

Patient and prescriber not known to the pharmacy

Action:

- Regulatory requirements for prescribing and supplying Schedule 8 medicines must be satisfied
- Patient not known to pharmacists or pharmacy (confirmation of identity may be required)
- Prescriber not known to pharmacists or pharmacy (confirmation of identity and authority to prescribe may be required)
- Dose outside accepted therapeutic guidelines may need to be confirmed

Risk assessment:

- Further investigation required with patient and prescriber before considering supply

HIGH risk

Documentation and reporting

Extensive and accurate documentation and timely reporting are critical in healthcare professions. The Australian Commission on Safety and Quality in Health Care[13] says:

"Good documentation contributes to better patient outcomes by enabling information exchange and continuity of care by all members of the healthcare team."

Well-documented records should be accurate, current, relevant, available and accessible. They support clinicians by:[13]

- Making safer clinical decisions
- Facilitating effective communication across transitions with other healthcare providers
- Maintain continuity of care
- Communicate and partner with patients and other healthcare providers
- Acting favourably as evidence of care, in the event of an incident, regulatory notification and/or liability claim

Key examples of documentation include clinical notes, near miss and incident reports (for internal purposes and your professional indemnity insurance provider), and handovers as part of good workflow processes. Other formal recording processes include Real Time Prescription Monitoring, Australian Immunisation Register, clozapine monitoring and formal adverse drug reaction reporting.

Managing systemic factors

The environment in which pharmacists work is a series of complex, interconnected systems. Having that broader view of these systems around us is crucial for effective management of unanticipated events or uncontrollable situations.

An example is the management of time. There will be peak periods that can be predicted but also times when workload is higher than anticipated. Some activities will require a pharmacist's attention for longer than anticipated, delaying engagement in other activities. Time constraints are unavoidable, and this is where workflow and process efficiencies are paramount. Rushed consultations may lead to incomplete clinical assessments, inadequate patient comprehension and increased risks.

Continuity of care should always be at the forefront of pharmacists' minds to avoid fragmented care when healthcare access may be limited. This is particularly important in rural or remote settings, where alternative care or referral to another healthcare provider is not easily accessible. Patients with limited transportation options or financial restraints are some other possible considerations.

Your patient

Each patient is an individual, shaped by their own beliefs, level of health literacy and personal responses to care. Recognising and respecting these differences is essential for pharmacists, who should avoid a one-size-fits-all approach to patient care. By tailoring their interactions and decisions to the specific needs and contexts of each patient, pharmacists can reduce the potential for harm and contribute to safer, more effective healthcare outcomes.

Reducing risk for patients and pharmacists

Throughout the various stages of a patient encounter — from the initial point of contact to their departure from the pharmacy — multiple opportunities for potential risk can arise, each with the capacity to compromise patient safety.

PDL has noted several factors that repeatedly come up in incident reports and therefore play a significant role in patient safety: communication issues, consent, privacy, storage, and factors that are specific and unique to each patient.

Communication and consent

Communication is a core component of providing a safe and high-quality health service and is a skill that can take time to develop and improve. PDL incident reports often indicate that communication misunderstandings or lapses are contributing factors in the incident. While the misunderstanding may not be attributed to the pharmacist in some of these cases, there are many occasions when communication could have been improved and tailored to the specific patient and their circumstances.

The Australian Commission on Safety and Quality in Health Care define informed consent as "a person's decision, given voluntarily, to agree to a healthcare treatment, procedure or other intervention" and is a "legal, ethical and professional requirement of all treating health professionals".[14]

Informed consent is an important part of the pharmacist-patient interaction, and some pharmacists may not have adequately considered how to best engage with their patients to achieve consent. While many interactions between pharmacists and patients are low risk for patient consequence, the expanding scope of practice, the greater volume of off-label prescribing and non-TGA approved medicines means that informed consent is of greater importance for patients and pharmacists.

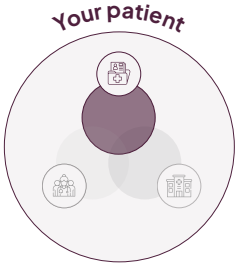
Clear communication and patient consent are also important in situations such as active ingredient prescribing and generic substitution. Pharmacists frequently provide generic substitutes and different brands of medicines in line with legislation and professional guidelines. However, it may be easy to become a little complacent in the communication to patients so that each patient clearly understands the reasons for substitution and continues the therapy as intended.

Similarly, if a pharmacist has a conscientious objection to supply a medicine, then communication needs to be appropriate to explain the situation and alternatives available to patients, without stigmatising or discriminating against the patient or impacting the timely provision of therapy.

Privacy

The pharmacy or facility should have a privacy and confidentiality policy and a professional approach to always ensuring privacy. This includes the availability of an area suitable for conducting private conversations and the avoidance of holding patient conversations in a public area.

Pharmacy staff should avoid assumptions about the privacy expectations of an individual patient but rather have a process to allow a patient to explain their preferred level of privacy and work with the patient to meet that level.



Refer to page 33 for Interconnected Risk Factors

Storage of medicines

Pharmacists understand their own clinical, regulatory and professional expectations for the correct storage of medicines.

But patients also expect to be informed of appropriate storage requirements for their medicines — yet sometimes this important counselling point may be overlooked or miscommunicated. PDL is aware of a variety of cases where misunderstanding or miscommunication has led to inappropriate medicine storage, causing impact for patients and pharmacists.

Such cases have included the following aspects:

- The storage of vaccines in home refrigerators rather than immediately transferring the product to a GP clinic.
- Management of other temperature-sensitive drugs (e.g. insulin, biologics).
- Storing heat-sensitive medicines in inappropriate locations.
- Storing potent sedating medicines within reach of children.
- Being unaware of short expiry dates upon opening products or due to national supply shortages.
- Poor home organisation, which sometimes leads to confusion between medications, particularly in vulnerable patient groups. Consider Dose Administration Aids as one option in these scenarios.
- Hazardous drugs such as cytotoxics or hormones. Advice should include things like the need for any form of protection, risks of contact with the medicine or the patient after the medicine has been administered/taken, and safe disposal of that medicine.

Extra consideration should be given to these points during the counselling process.

Patient-specific factors

The role of communication in patient care

Effective and appropriate communication is a core component of professional pharmacy practice and an area where pharmacists will continue to learn, reflect and adapt across their career. Assumptions should not be made about a patient's ability to understand and respond accurately to questions and requests for relevant information, or their ability to comprehend and apply the information provided. PDL has many examples of incidents where there was a disconnect in the communication between the pharmacist and patient with lapses, assumptions or misunderstandings from either or both parties. Challenges within communication between pharmacists and patients are noted to occur in the following areas.

Factors such as limited English proficiency, limited health literacy, hearing impairment and health conditions such as cognitive impairment can all affect a patient's ability to understand a pharmacist's questions or advice, potentially leading to mismanagement of their condition(s).

Even in the absence of obvious communication barriers, there can be instances where communication lapses occur. For instance, if a patient is distressed or distracted, if a pharmacist couldn't express the intent appropriately or assumed their communications were well received as the patient had limited engagement.

In some situations, patients may withhold important health information due to personal reasons such as stigma, fear or embarrassment, due to perceived power imbalance such as an older pharmacist dealing with a younger patient, gender such as a young women seeking an emergency contraceptive and being assisted by a male pharmacist, or due to concerns that the information provided may be passed on to other people or agencies.

Professional and appropriate communication can be impacted when a third party is involved in the supply of medicines or when responding to pharmacist enquiries on behalf of a patient. This could be when the third party is not formally recognised as the patient's guardian or carer, or when the third party might be related but does not have the authority to act on behalf of the patient, such as in the case of separated parents with one parent having custody or medical rights for the child while the other parent does not have such recognition.

In the examples above, and the myriads of communications a pharmacist may have with patients and others, it is important for the pharmacist to explain the purpose of the questions being asked, provide the person with context to assure them the enquiries are relevant to patient safety and wellbeing, and the discussions are confidential and non-judgemental. PDL has many reports where the context for questions may not have been provided to a patient, and responses are not clear or complete.

Furthermore, if a patient or third party is allowed to ask questions and demonstrate an understanding of the advice provided, then the risk of misunderstanding or error is greatly reduced. The use of open questions with patients engages the person in the conversation and confirms understanding or flags a misunderstanding or error.

Pharmacists indicate to PDL that time may not have been available to allow for thorough history taking or counselling; however, the consequences for patients and pharmacists can be significantly disproportionate to the small effort that may have been required to ensure the communication was clear.

Patient expectations

Changing consumer behaviours and expectations can influence the pharmacist-patient encounter. A people-pleasing culture that is omnipresent in community pharmacy sets unrealistic expectations — consider cannabis supply as an example. This is where communication with the patient and prescriber is essential. Pharmacists should ensure they provide an appropriate explanation to patients and stakeholders to reduce disappointment or distress. Set time aside to raise awareness across the pharmacy team of issues in certain practice areas, to ensure a united front and positive outcomes.

Your practice setting

Gesme and Wiseman, authors of the article **Reduce risks to patients in your practice**, state that:[15]

"In a culture of patient safety, people understand that underlying system flaws, not individuals, are the source of most errors. Developing well-designed systems for safe patient care requires a team approach in which assigning blame has no part.

Physicians have a key leadership role and can champion patient safety by fostering a team culture and initiating risk-reduction strategies."

Optimising workflow with physical layout

The space in which you work is crucial to optimising workflow.

A well-planned, structured and consistent workflow helps pharmacists and pharmacy staff to fulfil their tasks efficiently and effectively, improving staff productivity and morale, and resulting in a better patient experience.

A well-planned workspace is one that ensures staff and patient safety, maintains privacy and confidentiality, is adequately resourced (staffing requirements), and meets legislative requirements and best practice guidelines. The physical layout of the pharmacy or pharmacist workspace encompasses not only the fixed infrastructure but also fixtures and fittings. Workspaces should be suitable for expected tasks and support a logical workflow that minimises barriers to safe and efficient practice for all using the space.

At times, you may grow so familiar with a workplace that you stop noticing areas for improvement. In such cases, it's helpful to step into the patient's shoes and reflect on their physical and psychological experience when they receive a service from a pharmacist.

Some useful things to consider:

- Are the entrances and exits accessible and clear to reduce risk of injury to the patient? Consider those with a pram, wheelchair or crutches.
- Is there an obvious path and signage to direct patients to a professional services area or to access the pharmacist?
- How many people can the waiting area accommodate? Are the chairs positioned in a safe manner, or are they cluttered and creating barriers?
- Does the pharmacist have enough visibility of the clinical services area? If not, what can be moved around to ensure they can oversee what is happening at all times?
- Where do bottlenecks exist, and what impact are they having?
- How are you using the layout to minimise disruptions to the pharmacist?
- Do you have sufficient computers to perform all duties — dispensing, checking/logging information onto national registers, scanning barcodes, scanning e-prescriptions? Are they stationed in a sequential manner to minimise having to walk back and forth?

Please refer to references developed for your field of practice for further information. For instance, community pharmacy settings could access the Quality Care Pharmacy Program (QCPP) for support and guidance to meet the **AS 85000:2024 Australian Community Pharmacy Standard.**

A review of the workspace should be conducted at regular intervals to ensure it continues to be fit for purpose. This becomes especially important when a new service is being considered. If pharmacists are unsure about legislative requirements for the provision of certain professional services, they could contact the local authority for the regulation of pharmacy premises in your state or territory.

To enhance daily productivity and reduce risk of errors, implement measures that streamline daily processes:[16]

- Manage interruptions so you can focus on core tasks, e.g. train and delegate pharmacy staff to support the pharmacist in non-clinical tasks (e.g. taking phone calls, taking a message for non-urgent cases).
- Spend some time each morning to prioritise daily tasks and manage workload.
- Ensure adequate staffing ratios to meet the fluctuating demands of the day to help reduce stress and fatigue.
- Identify and address physical and resource bottlenecks and barriers that hinder smooth workflow.
- Create standard operating procedures (SOPs) to eliminate ambiguity during busy times.
- Don't skip breaks. They are essential to maintain focus, sustain performance, and mental and physical wellbeing.

Refer to page 33 for Interconnected Risk Factors

As outlined in the ACSQHC Clinical Governance Principles, continuous workplace improvement is a shared responsibility among all team members. This begins with having open communication and empowering staff to voice any challenges or inefficiencies they encounter in their daily tasks. By identifying barriers and bottlenecks, the team can collaboratively develop solutions to enhance overall workflow and optimise pharmacy processes.

Workplace culture

A strong characteristic of a workplace with a positive risk culture is one where:[17]

"...staff at every level appropriately manage risk as an intrinsic part of their day-to-day work, and [everyone] is encouraged to express concerns, and maintains processes to elevate concerns to appropriate levels."

Of course, the culture of any organisation is complex and affected by many factors. But there are some typical modes through which people are influenced and pick up cultural messages: [17]

- Role models — these people can be management or staff at any level, and they demonstrate accepted behaviours that eventually become core beliefs.
- Explicit messages — through organisational policies and procedures.
- Incentives — recognition and rewards for displaying good risk management behaviours, e.g. reporting.
- Symbolic actions — similar to role models, but these refer to the daily actions of senior team members, which can take on wider importance and can spread values across the team.
- There are many strategies, some very small and easy to achieve, that can improve risk culture in the pharmacy.
- Talk about it. The more risk management vocabulary becomes common, the more the message becomes clarified.
- Reporting language and terminology that reduces the stigma of reporting. PDL refers to the spectrum of issues as incidents in preference to errors and mistakes; this reduces the implication of judgement.
- Remember H.A.L.T. and self-check regularly.
- Set clear boundaries and expectations, e.g. for wait times, fees for service. Ensure these are established to all staff.
- Identify high-risk times and manage accordingly, e.g. peak hours, end of day when staff are transitioning, over lunch breaks.
- Minimise distractions to the pharmacist.
- Hold yourself accountable for your actions.
- Integrate lessons learned from incidents/near misses into team communications, education and training. These mishaps are an important tool in governance.
- Assess when more time is needed and manage accordingly, e.g. prescriptions that require additional time for clinical assessment or validation, legislative compliance checking, record-keeping.

Now that the three Interconnected Risk Factors have been discussed, please see Table 1 on page 42, which outlines key areas to consider when assessing risk in pharmacy practice. Readers will notice that each sector is covered, sometimes appearing multiple times across different activities, which shows the interconnected nature of these risks. While each specialised field of pharmacy has its own unique risks, this table serves as a starting point for risk awareness and critical thinking.

(Please note that the PDL Risk Management Guide for Pharmacists is not intended to cover clinical aspects of medicine supply and pharmacist practice, as these are covered in resources provided by other organisations.)

Table 1: Examples of risk considerations in common pharmacist daily activities

Type of pharmacist activity	Risk considerations
Assessing appropriateness of medicines or treatment (includes both prescription and non-prescription items)	• Clinical assessment, e.g. indication, route, dose, age, polypharmacy, vulnerable patient groups • Compliance with legislation, e.g. special requirements such as for Schedule 8 prescriptions • Active ingredient prescribing • Dosages outside therapeutic guidelines • Review of Real Time Prescription Monitoring platform
Dispensing	• Clinical assessment, e.g. interval between dispensing, dose suitability, off-label indications, drug interactions, change in therapy/strength/ dose, combination medicines such as statin/ ezetimibe, oral contraceptives • Patient assessment and individual considerations
Counselling	• Risk of patient, e.g. paediatrics, elderly, polypharmacy, low health literacy, drug dependence, disability • Individual scope of pharmacist • New or changed therapy/brand • Device demonstration • Documentation
Liaising with doctors and other healthcare professionals	• Personal risk tolerance and awareness • Miscommunication • Differing protocols and preferred references

Recall the Interconnected Risk Factors

*(**Figure 1**: Interconnected Risk Factors: Patient, Professional role and Practice setting) on page 33, and consider the following case study.*

CASE STUDY 3: An ethical dilemma

You are the owner of a community pharmacy working with an early career employee pharmacist.

You have recently developed some chronic pain and associated anxiety and your GP has prescribed diazepam 2mg up to tds prn. It helps quite a bit and allows you to work without the pain distracting you, and you don't believe it impairs your ability to practise.

For transparency, you usually have the diazepam dispensed at another pharmacy as you and the owner are friends, and you feel comfortable they are empathetic to your situation. However, you have run out of the diazepam and are considering dispensing it yourself, in your pharmacy, today.

While you're unsure, you feel it might be more appropriate to ask your employee pharmacist to dispense the medicine for you.

Taking the three Interconnected Risk Factors into consideration:

1. Professional role

- Consider if there are any legal obligations that apply when dispensing monitored medicines for a colleague. Would it be professionally and ethically appropriate to do so? Think about what information or resources are available to assist you in your decision.
- If the roles were reversed and you were the pharmacist asked to dispense this medicine, what would be your considerations and concerns? What if the request came from a local GP who had prescribed it for himself, would that change your decision?
- Consider also if additional documentation is required.

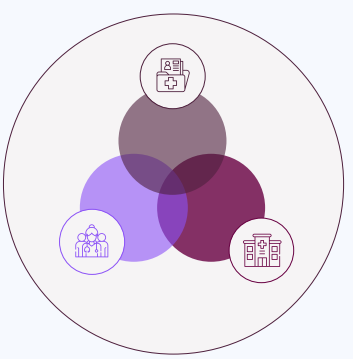
2. Patient

- In this case, how do you separate yourself as the patient from the role as the pharmacist and the pharmacy owner/employer?
- There may be concerns about practising while taking a benzodiazepine. What strategies do you have in place to ensure you have reduced any risk to the public from some unrecognised impact or impairment?

3. Practice setting and workplace culture

- What happens if you were involved in an incident or error while you were taking the diazepam? Would you report your benzodiazepine usage as a contributing factor?

This scenario poses various ethical considerations — none with a clear black and white answer. Most depend on your personal level of comfort and acceptance of potential risk (see Module 1 for more detail). PDL reminds pharmacists that every case is individual, and risk versus benefit must be weighed up each time.



Refer to page 33 for Interconnected Risk Factors

Introducing the PDL Risk Assessment Tool

A guide to identifying and addressing risk areas in your pharmacy

Consideration of the three Interconnected Risk Factors and the interplay between them is a great start to building a proactive risk mindset.

But how can you ensure that any actions you're planning to take not only addresses an issue in the short term, but has a sustainable impact in minimising the same risk in future?

The PDL Risk Assessment Tool

The PDL Risk Assessment Tool (RAT) uses a simple traffic light system to categorise risks and thereby allowing users to identify necessary behavioural or process changes to manage risks more effectively, based on their priority and urgency.

By enabling self-assessment, this tool helps pharmacists gain a more holistic understanding of the risk environment around them. By having a more comprehensive approach to risk management, pharmacists may be able to implement protective strategies that sustain positive practice change in the long run.

Risk can arise in many aspects of pharmacy practice. While some risks, such as meeting legal requirements, may have obvious solutions, the PDL RAT is designed to promote a comprehensive approach to risk management. It encourages pharmacists to explore areas that might otherwise go unnoticed.

In Module 1, we outlined the five types of risk in pharmacy practice:

1. REGULATORY & COMPLIANCE RISK
2. CLINICAL RISK
3. PROFESSIONAL RISK
4. ETHICAL RISK
5. OPERATIONAL RISK

The PDL RAT categorises potential risks within these categories based on their likelihood and severity, using a colour-coded scale from green (low risk) to red (critical risk). The goal is to help pharmacists take actionable steps to reduce risk levels, moving from red toward green, to ensure effective management and provide assurance to themselves, their organisations and regulatory bodies.

Who can benefit from this tool?

These questions help to explore how different pharmacists can gain benefits from the PDL RAT, based on their individual needs:

- *Have you introduced any new professional services in your pharmacy lately?*
- *Are you thinking of expanding your scope of practice?*
- *Have you (or a colleague) had any recent incidents or near misses?*
- *As an employee pharmacist, how do you monitor and address risk areas in the pharmacy?*
- *As a pharmacy owner, do you have sufficient oversight of the pharmacy's operations?*

Understanding your risk level

As pharmacists, the imperative is to minimise risks to yourself and your patients, to the lowest possible level.

The risk rating colours serve as a guide only. Ultimately, the onus of responsibility is on the individual practitioner to understand and consider what level of risk they deem to be acceptable for each situation. Please work through the PDL RAT honestly and thoughtfully for the best outcome.

Risk rating	
CRITICAL	Red – This is a **CRITICAL** risk area that requires **immediate action** before proceeding further. Address this as a top priority to ensure safety and compliance.
HIGH	Orange – This indicates a **HIGH** risk level that could escalate to CRITICAL without timely intervention. Take proactive measures to mitigate the risk. Consider what steps you can take individually, whether to involve your team, or if escalation to senior management is necessary to address the issue effectively.
MODERATE	Yellow – The risk is **MODERATE** and generally represents an acceptable level of safety. Reflect on how you can maintain this standard. There may be opportunities to improve further, or to upskill others in the team to enhance overall capabilities. Distributing expertise across the team supports workload balance, contingency planning and a higher-quality service delivery.
LOW	Green – The risk is **LOW**, which is a positive outcome. Consider what has contributed to this success. Can these practices be applied to other areas of the pharmacy? Use this opportunity to explore Continuous Quality Improvement (CQI). Are there other neglected areas where attention can now be redirected?

PDL Risk Assessment Tool

A guide to identifying and addressing risk areas in your pharmacy.

How do I use it?

Step 1: Define your risk question

Analyse your question(s) against each of the five risk categories (refer to next page). Sometimes there is overlap between the definitions of each category and that is fine.

Examples of a 'risk question':

- "I am considering adding a new service to my pharmacy (e.g. dispensing medicinal cannabis). What regulatory considerations do I need to be aware of and how can these be managed?"
- "Mr BY is a regular patient of mine, and I have been dispensing his insulin (new medication). He is having difficulty and asked me to administer it to him in our consult room. Should I be doing that?"
- "Our daily vaccination volumes are increasing; are we managing staff/resources appropriately around this service delivery (and other service obligations)?"
- "Is the medication shortage of drug XXX becoming a bigger issue that I need to address?"

Step 2: Assess risk level by using the 'Indicators for determining risk level' column

Compare current practices in the pharmacy with the indicators for each risk level. The indicators identify potential impacts for your consideration.

Step 3: Enter the identified risk level under the 'Current risk status' column

While this tool helps to provide some parameters around what constitutes each risk level, sometimes it may be unclear which level you fall under. Simply enter all that apply. This is a self-assessment and there is no right or wrong answer.

Step 4: Enter the 'Date of next review' and any observations or planned actions in the 'Actions/notes' section

This step helps you develop action plans to address areas that require attention, and having a firm date for ongoing review will keep you on track and accountable.

If your risk question relates to undertaking a certain activity/service in the pharmacy, you may wish to use the PDL Scope of Practice Checklist to help map out necessary actions.

Step 5: Regularly review and update

Schedule regular assessments, especially in high-risk areas, to update the PDL RAT and ensure Continuous Quality Improvement (CQI).

Understanding your risk level

As pharmacists, our imperative is to minimise risks to ourselves and our patients, to the lowest possible level. The onus of responsibility is on the individual practitioner to understand and consider what level of risk they deem to be acceptable.

Risk rating	Recommended action
CRITICAL	Do not execute service/ activity or proceed until immediate action is taken.
HIGH	Some extra measures may be required. Identify the steps you can take, or can be delegated to others, to address necessary change.
MODERATE	Foreseeable risks have been addressed. Consideration should now be given to maintain or improve this safety level and/or service efficiency.
LOW	Continuous Quality Improvement (CQI) measures — such as annual audits or reviews — are required to help you maintain this risk level, or improve the service area. Consideration should be given to apply the aspects that are working well, in this case, to other service areas.

TODAY'S DATE:	STAFF INITIALS:
Your risk question:	

Risk category	Indicators for determining risk level (suggestions only)				Current risk status
	CRITICAL	HIGH	MODERATE	LOW	
1. Regulatory & Compliance (relating to legislation and regulations)	There are significant compliance gaps. Mandatory qualifications have not been met. The pharmacy has been provided warning by regulatory bodies.	There have been recurrent compliance lapses. Audits have flagged that corrective actions are needed.	There have been minor compliance issues noted internally or via audits.	All necessary qualifications and certifications are current, for all pharmacists undertaking this service/activity. All recent regulatory audits have been passed without issues.	
2. Clinical (involving patient safety)	There has been a recent incident(s) that may have resulted in significant consequence (patient harm, regulatory notification). Critical errors have regularly occurred in a given service area.	There has been a recently reported incident. There is confusion or disconnect amongst the team around procedures/ responsibilities/etc.	An isolated near miss event has occurred. Patient counselling or other service provision requires review and/or re-training.	Little or no recent incidents or errors.	
3. Professional (risks associated with your professional actions, decisions or practices)	There has been a serious lapse of professional standards and possible remedial actions yet to occur.	There have been occasions of professional lapses impacting the team or patients.	There have been occasional lapses in professional conduct, that were resolved promptly. There are minor gaps detected in adherence to professional standards.	Professional standards and behaviours are maintained. All interactions with patients and colleagues are respectful and ethical.	
4. Ethical (conflicts with moral or ethical principles or professional conduct)	There has been a serious ethical lapse (e.g. breach of confidentiality). There is evidence that ethical guidelines are being consistently disregarded.	There are significant ethical concerns affecting patient trust and satisfaction.	There are minor ethical concerns or potential conflicts of interest. There has been a need to reinforce ethical policies among the team.	The pharmacy has established a set of rules and principles to encourage ethical behaviour and integrity.	
5. Operational (day-to-day running of pharmacy, including staffing)	There are significant delays, frequent errors or complaints by either staff or patients. Operational efficiency is impacting patient care.	Workflow issues (time, staffing, etc.) are impacting the overall patient experience and staff morale.	There are occasional delays or service inefficiencies, warranting minor workflow adjustments.	Workflow is efficient, when considering the daily operation of all staff members, and the overall patient experience.	
Other					

Actions/notes: **Date of next review:**_____

This activity is general in nature and designed only to highlight issues for your consideration and action. Please consider your individual circumstances and needs. If you require professional advice and incident support, call PDL on 1300 854 838 to speak with one of our Professional Officers.

Example

TODAY'S DATE: 5/5/25 **STAFF INITIALS:** A.Z

Your risk question:
Is injecting a patients' Ajory to them within my scope of practice?

Risk category	Indicators for determining risk level (suggestions only)				Current risk status
	CRITICAL	HIGH	MODERATE	LOW	
1. Regulatory & Compliance (relating to legislation and regulations)	There are significant compliance gaps. Mandatory qualifications have not been met. The pharmacy has been provided warning by regulatory bodies.	There have been recurrent compliance lapses. Audits have flagged that corrective actions are needed.	There have been minor compliance issues noted internally or via audits.	All necessary qualifications and certifications are current, for all pharmacists undertaking this service/activity. All recent regulatory audits have been passed without issues.	Critical
2. Clinical (involving patient safety)	There has been a recent incident(s) that may have resulted in significant consequence (patient harm, regulatory notification). Critical errors have regularly occurred in a given service area.	There has been a recently reported incident. There is confusion or disconnect amongst the team around procedures/ responsibilities/etc.	An isolated near miss event has occurred. Patient counselling or other service provision requires review and/or re-training.	Little or no recent incidents or errors.	Moderate
3. Professional (risks associated with your professional actions, decisions or practices)	There has been a serious lapse of professional standards and possible remedial actions yet to occur.	There have been occasions of professional lapses impacting the team or patients.	There have been occasional lapses in professional conduct, that were resolved promptly. There are minor gaps detected in adherence to professional standards.	Professional standards and behaviours are maintained. All interactions with patients and colleagues are respectful and ethical.	Low
4. Ethical (conflicts with moral or ethical principles or professional conduct)	There has been a serious ethical lapse (e.g. breach of confidentiality). There is evidence that ethical guidelines are being consistently disregarded.	There are significant ethical concerns affecting patient trust and satisfaction.	There are minor ethical concerns or potential conflicts of interest. There has been a need to reinforce ethical policies among the team.	The pharmacy has established a set of rules and principles to encourage ethical behaviour and integrity.	Low
5. Operational (day-to-day running of pharmacy, including staffing)	There are significant delays, frequent errors or complaints by either staff or patients. Operational efficiency is impacting patient care.	Workflow issues (time, staffing, etc.) are impacting the overall patient experience and staff morale.	There are occasional delays or service inefficiencies, warranting minor workflow adjustments.	Workflow is efficient, when considering the daily operation of all staff members, and the overall patient experience.	Moderate
Other					

Actions/notes:
Regulatory & Compliance
- Refer to PDL Scope of Practice Checklist (6/5/25)
- Check legislation
- Check with colleagues
- Any mandatory training needs? check with manufacturer, PSA, PDL

Clinical, Professional - (As Above)

Date of next review: 6/5/25 (1 month)

This activity is general in nature and designed only to highlight issues for your consideration and action. Please consider your individual circumstances and needs. If you require professional advice and incident support, call PDL on 1300 854 838 to speak with one of our Professional Officers.

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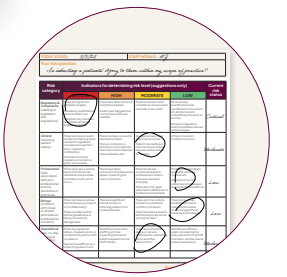


Now we will revisit Case Study 1 and demonstrate how the PDL RAT can be applied in conjunction with a pharmacist's clinical judgement in professional practice, to help decide whether to proceed with an activity (or not).

Remember: such a decision is subjective to a particular situation and while the PDL RAT may help to come to a final decision the tool is only an aid. The ultimate responsibility will be that of the pharmacist as the autonomous practitioner.

REVISITED CASE STUDY 1: Should I really be doing that?

Recall the case challenged you to consider how you might respond to a patient's request for you to administer their Ajovy (fremaznezumab) — and whether such a service is within your scope of practice.

Step 1: Define your risk question

The pharmacist has defined the risk question as: "Is injecting a patient's Ajovy to them within my scope of practice? Should I be doing that?"

Step 2: Assess risk level by using the 'Indicators for determining risk level' column

After carefully reading each risk category, the pharmacist assesses the risk level for each category as follows:

Regulatory & Compliance – CRITICAL

If the pharmacist is unsure whether there is a mandatory qualification required to perform a service, and hence whether they have fulfilled this obligation, then the risk should be viewed as CRITICAL and addressed before proceeding. They also need to check whether the state/territory they practice in allows for pharmacists to do this.

Clinical – MODERATE

There has been no near miss or incident involving patient safety as yet — but the reason for the MODERATE rating is because this service provision does require some review and/or training before proceeding.

Professional – LOW

By pausing and doing this exercise before administering a new service they are unsure of, the pharmacist is maintaining professional standards and behaviours.

Ethical – LOW

There is no moral or ethical dilemma in this scenario.

Operational – MODERATE

If the pharmacist decides to proceed with this service, there may be workflow considerations that need to occur.

Step 3: Enter the identified risk level under 'Current risk status' column

The pharmacist records the above risk statuses into the final column of the table 'Current risk status'.

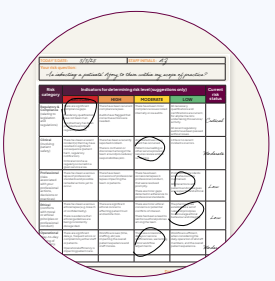
Refer to page 48 for how to use the RAT.

Step 4: Enter date of next review and any observations or planned actions in the 'Actions/notes' section

He records the following planned actions and date to check in and follow-up on changes made:

Actions/notes:	Date of next review:
Regulatory & Compliance • Refer to the PDL Scope of Practice Checklist (access appendix, pg. 87) to ascertain further whether this is something I should be doing • Check legislation allowing a pharmacist to administer a prescribed S4 medicine by the subcutaneous route • Check with colleagues — what are other pharmacists doing? What works or doesn't work? • Check whether any mandatory training needs to be completed before going ahead; could try manufacturer as well as peak body, e.g. PSA for advice, PDL for guidance **Clinical** • As above **Professional** • As above **Ethical** • No action **Operational** • Consider workflow processes to accommodate the time required to conduct this new service • Who will be doing the other dispensary tasks while they are occupied? • What if other patients request this service, how can this be managed? • Should we be advertising that we now do this? What if the patient tells their friends?	1 month

Refer to page 48 for how to use the RAT.



REVISITED CASE STUDY 2: Tirzepatide strength and dose confusion

The pharmacist can use the PDL RAT to work out the multiple ways in which risk can appear in this scenario and put in a thorough plan to minimise this type of error from occurring in future.

Using the PDL RAT step-by-step:

Step 1: Define your risk question

The pharmacist has defined the risk question as: "How can I reduce selection errors for Mounjaro (tirzepatide)?" and included today's date as 5/5/25.

Step 2: Assess risk level by using the 'Indicators for determining risk level' column

After carefully reading each risk category, the pharmacist assesses the risk level for each category as follows:

Regulatory & Compliance – **MODERATE**

While there hasn't been a legal compliance lapse, part of a pharmacists' Professional Practice Standards dictates they need to be collaborative and respectful of the person's needs and maintain responsibility and accountability for actions and decisions.

Clinical – **CRITICAL**

If there is patient harm or even a threat of patient harm, then this risk category should be viewed as CRITICAL. The patient has taken twice their recommended dosage and there is a risk of a severe health consequence.

Professional – **HIGH**

Same reason as for Regulatory & Compliance but from a professional perspective, this is a higher risk level.

Ethical – **LOW**

There hasn't been any moral or ethical breaches in this scenario.

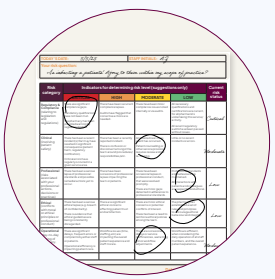
Operational – **HIGH**

This incident has arisen from poor operational practices that have impacted a patient's health and drawn attention from the GP clinic that works closely with the pharmacy. Serious consideration needs to be given to workflows (including staffing levels, delegation of duties, pivoting when unexpected peak times arise, and everyone knowing when to disturb the pharmacist).

Step 3: Enter the identified risk level under 'Current risk status' column

He records the above risk statuses into the final column of the table 'Current risk status'.

Refer to page 48 for how to use the RAT.



Step 4: Enter date of next review and any observations or planned actions in the 'Actions/notes' section

The pharmacist records the following planned actions and date to check in and follow-up on changes made:

Actions/notes:	Date of next review:
Regulatory & Compliance • Review all the options for tirzepatide in our dispensing software and understand each of the selections • Talk to manager about lodging a report to our software provider about this incident and ask if they can put in any measures (like pop-ups?) to alert all future dispensers of this potential selection error **Clinical** • Lodge an incident report with PDL as soon as possible, seek guidance from PDL Professional Officers about how I should proceed next • Manage patient/GP interactions as advised by PDL **Professional** • Acknowledge my oversight in dispensing processes • Read the PDL Guide to Good Dispensing and Supplement to Guide to Good Dispensing: Final Check & Supply of Medicine • Share learnings with team **Ethical** • No action **Operational** • Work with management about how to manage distractions and interruptions during peak periods • Work with management to implement a risk management policy for when incidents occur • Team training on above — use PDL Practice Alerts • Dispensary team noted that this error most likely occurs with 12.5mg item line, as other strengths don't have cross over between strength and standard weekly dose — we will put note to check for any regular patients on this medication and a sticky note on dispensary bench • Talk to Head Office about adding a session on Common Dispensing Errors at next monthly Pharmacist Training Day	2 months from now, an approximate length of time for repeats to have been dispensed again

KEY TAKEAWAYS

- By understanding how risks are linked, pharmacists may be able to better predict potential outcomes and make more informed and accurate decisions in risk assessment and management.
- Risk management is a collective responsibility, with each pharmacist playing a vital role.
- Each patient is a unique individual, and therefore pharmacists should tailor their interactions and decisions to the specific needs and contexts of each one, rather than adopt a uniform approach for everyone.
- A well-planned workspace and workflow help pharmacists fulfil their tasks efficiently and effectively.
- The PDL RAT is a useful guide to identifying and addressing risk areas in your pharmacy, e.g. after recent near misses/incidents, initiating new services, having greater oversight of certain areas of the pharmacy.

Activity

Apply the concepts in this module to critically analyse this scenario and answer the following questions with what you would do in practice.

Please use the PDL RAT and its breakdown of the five risk categories to support your thinking and address different areas that would be important not to miss.

Navigating transitions of care

A patient, known to you, has been diagnosed with myeloma and has been commenced on lenalidomide from their recent hospital stay. She brings in a packet of lenalidomide with a valid PBS repeat for lenalidomide 15mg D1–21 of a 28–day cycle, with 1 repeat.

Your community pharmacy, located in a rural town, is registered to dispense the medication. You dispense 21 capsules, as directed. As this is a new medication, you counsel the patient with the Consumer Medicines Information leaflet, as well as information on dosing. The patient informs you that she has just moved into a nursing home nearby and asks if you can make up a weekly Dose Administration Aid for her, to be delivered. She also requests to hold onto her prescription repeats.

How will you ensure all medications have been accurately reviewed and reconciled between different care settings (i.e. when she self–manages at home)? Has she changed GPs now that she has relocated?

Can a cytotoxic, or other high–risk medicine, be packed in a DAA? What are the risks?

If lenalidomide is not to be packed in the DAA, how can you help the patient manage this?

What are the requirements for a pharmacy to be registered to dispense lenalidomide? If the patient opted to take their repeat prescription and have it dispensed elsewhere, will there be potential supply limitations? What is our duty of care?

Five risk categories

1. REGULATORY & COMPLIANCE RISK
2. CLINICAL RISK
3. PROFESSIONAL RISK
4. ETHICAL RISK
5. OPERATIONAL RISK

RECOMMENDED READING

PDL Guide to Incident Reporting

PDL Supplement to Guide to Good Dispensing – Final Check & Supply of Medicine

PDL Scope of Practice Checklist

Access appendix on pg. 87

Module 3:

Managing incidents

Guiding pharmacists through the post-incident process

australian pharmacy council ACCREDITED CPD

1.0 CPD credits Group One

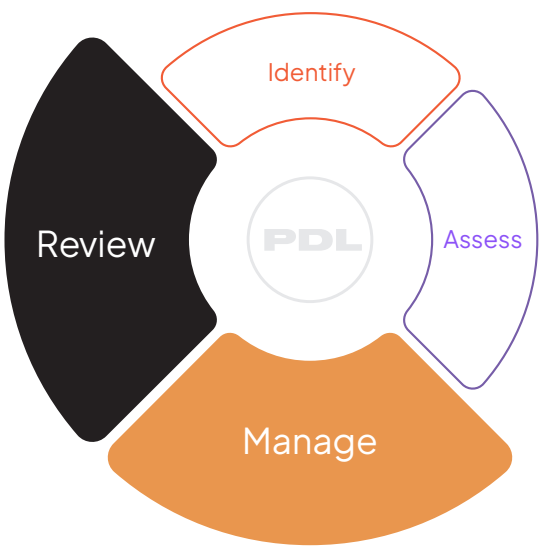
Accreditation Number: A2507PDL3

This activity has been accredited for 1.0 hour of Group 1 CPD (or 1.0 CPD credit) suitable for inclusion in an individual pharmacist's CPD plan.

Pharmacist Competencies: 1.3, 1.6, 2.1, 2.3, 2.4, 4.1, 4.2, 4.3, 4.6

Accreditation expires: 30/6/2027

OBJECTIVE 3	OBJECTIVE 4
MANAGE	REVIEW
Implement and maintain effective systems and processes within your practice.	**Reflect upon and evaluate outcomes from implemented changes.**
To work independently and collaboratively to maintain governance systems to prevent and address incidents	To develop reflective practice and self-directed learning to minimise risk of incidents and repeat incidents
To confidently engage in handling and resolving incidents	To review and adjust your own practices, following near misses or incidents



Risk Management Cycle

This module is designed to guide you through the steps that follow a near miss or incident in your practice. It will help you understand how to navigate regulatory processes, implement safety measures for yourself and others, demonstrate your commitment to minimising future risks, and develop effective reflective practices to support continuous learning and improvement.

After completing this module, pharmacists should be able to:

- Discuss features of good incident management.
- Explain some possible consequences of near misses and incidents.
- Identify psychosocial hazards following incidents that may affect pharmacists, understand their impact and learn strategies for self-care.
- Review and adjust practices following near misses or incidents.

Let's begin with a case study about a pharmacist experiencing an incident during work that turned into a regulatory notification.

CASE STUDY: When an incident turns into a regulatory notification

Lee, one of your regular patients has been taking mycophenolate for the last 10 years since his kidney transplant. One day, he presents to the pharmacy and shows you a box of mycophenolate that is 6 months past the expiry. Upon investigation, it became clear that the expired medicine had been dispensed to him during his previous visit. You apologise for what had occurred and offered a replacement at no charge. Lee appeared satisfied with the resolution and left the pharmacy.

Three months later, you receive a regulatory notification. You learn that Lee's wife is deeply upset about the oversight and the anxiety it has caused the family about the potential for harm.

The fallibility of humans

Pharmacists are human and fallible, so despite their best efforts, adverse events and mistakes can still occur.[18]

Recognising the importance of transparency in pharmacy practice and acknowledging human fallibility creates open communication in healthcare — and is crucial for recovery when incidents occur. Ifrim R et al[19] agree that:

"Communication is the basis of all interpersonal actions; optimal and efficient communication needs permanent awareness and training in order to learn these skills."

Demonstrating high levels of care towards patients after an incident can assist in the early resolution of grievances and sometimes eliminate the likelihood of complaints. A work culture that encourages incident reporting and process improvement are those that are best equipped to handle difficult situations.

The art of saying sorry

Pharmacists may be concerned that making an apology may be construed as an admission of guilt. Contrary to this, apology laws in Australia aim to dissociate the act of making an apology from an admission of liability and are designed to enable the natural 'human response' of apologising.[18]

It is widely accepted that apologies can have psychological benefits to a concerned or irate patient. It is also in line with Ahpra's Shared Code of Conduct[25], which requires health practitioners to be open and honest in communication with patients who have been harmed by adverse events, apply the principles of open disclosure, listen to a patient's concerns and acknowledge any distress.

An apology that acknowledges distress, even without accepting fault when the pharmacist is adamant there is none, can be useful to de-escalate situations — for example, "I'm sorry that you are upset about this situation."

Apologising also demonstrates insight and good reflection and is valued by the regulators (such as the Pharmacy Board of Australia or healthcare complaints agencies).

The action of an apology and open disclosure is considered favourable to a practitioner in the event of a regulatory notification.

The following describes some practical guidance on making an apology:[18]

- Try to avoid delays, as a prompt response can help to quickly de-escalate and resolve a situation.
- Use the word 'sorry', e.g. "I am very sorry that this happened. Please be assured that we take these matters seriously and your health and wellbeing are our priority. We will investigate this matter promptly so that we can understand how this happened and take steps to avoid any recurrence" or "I'm sorry you are upset, but the law does not allow me to do what you are asking."
- Express genuine empathy to recognise the patient's concern, even if you feel there hasn't been an error made by yourself or the organisation.
- Use active listening and open questions to allow the patient or third party an opportunity to explain how the incident is affecting them.
- Gather relevant information, offer to provide follow-up contact if accepted by the person and ensure efforts to follow up have been documented.
- Do NOT make offers or mention of potential outcomes such as offers of compensation or legal action.
- Inform senior staff, management or owners, and follow advice and directions provided.
- Document any matter in the organisation's incident reporting system and make notes in the patient profile in a manner that allows colleagues to readily see or access the information.
- Notify your professional indemnity insurance provider as soon as possible to get appropriate advice.

How to say 'no' or 'not yet'

Pharmacists are dedicated to help patients with their healthcare needs, but there are times when they are unable to fulfil a request for a particular medicine or service, based on professional opinions, and legal or ethical obligations. It is important to do so in a way that maintains patient trust while confidently asserting boundaries.

There are some essential skills that can be used to ensure your response is understood and well-received by the patient:[28]

- Move the conversation to a more private area.
- Actively listening to the patient, allowing them an opportunity to explain their experience and/or concerns.
- Convey sincere apologies and demonstrate empathy.
- Communicate clearly and honestly.
- Offering an alternative product or service, which may be by your organisation or through direction to another provider.
- Maintaining your own composure and professionalism.
- Seek to work with the patient to explain or clarify the situation, the pharmacist's role and limitations.
- Documentation after deferral or declining a service.

Aggression in the pharmacy

Pharmacists and pharmacy support staff are often the first point of contact for patients, regardless of their practice setting. Unfortunately, work-related violence and aggression is reported in the pharmacy sector, as they are in other industries where staff interact directly with the public.[20]

As pharmacists strive to deliver high-quality care, it is essential that they feel safe and protect their own physical and psychological wellbeing. Pharmacies are usually publicly accessible settings, leading to an inability to control all situations and interactions.

The Queensland Government classify workplace violence and aggression as "any incident or behaviour in which a person is abused, threatened or assaulted in circumstances relating to their work".[21] Distinguishing the difference between someone who is merely angry/frustrated or experiencing a mental health crisis to someone who is truly aggressive is crucial.

The PDL CLASHED Action Plan (access appendix, pg. 87) is a useful resource to assist pharmacists and their teams to understand the nature of an irate person's behaviour and provide measures to manage and hopefully de-escalate the situation:

- Remain CALM
- Actively LISTEN without interrupting
- Having an AUDIENCE is not helpful
- Do not enter a person's physical SPACE
- Call for HELP if your/others' safety is at risk

If the situation escalates

- Ask the person to EXIT the premises
- DISCONTINUE discussions

If a traumatic event has occurred or in other times of stress, it could be helpful to contact Pharmacists' Support Service (PSS), other support organisations such as Lifeline or access an Employee Assistance Program that may be available through your employer.

On an organisational or management level, the incident should be discussed and clear strategies implemented going forward. These could include whether the current policies and procedures require amendment, whether staff require refresher training, or if further safeguards could be implemented for the future.

If a team is able to identify practice change, then it is possible to transform what was a negative experience into a positive internal change with greater protection for pharmacy staff and their community going forward.

A blame-free culture

In *Module 2*, it was discussed how the practice setting and the culture upheld by individuals contribute greatly to the overall management of risk in practice. It was also discussed that continuous workplace improvement is a shared responsibility among all team members.

Having a positive risk culture in the pharmacy — by having open communication, empowering staff to voice any challenges or inefficiencies they encounter and identifying barriers and bottlenecks — can be one of the most effective tools the pharmacy team can have to proactively develop solutions to optimise workflow, minimise adverse outcomes, and positively manage distressing situations together.

Managing incidents

Overview

In pharmacy practice, incidents can occur despite the best efforts of practitioners. Incidents can have significant consequences for patient safety, therefore, a structured yet compassionate approach to incident management should be applied.

Incidents should not be seen as failures but as valuable opportunities for professional development.

Incident management is a subset of overall management and is an important feature of good clinical governance. The ACSQHC states that:[22] "a well-designed incident management system will assist patients, carers, families and the workforce to identify, report, manage and learn from incidents".

Effective incident management requires a holistic approach and collective effort across all levels of the organisation. In other words, it is a shared responsibility of all staff members. This collective responsibility is crucial for creating a safe and supportive environment for patients and healthcare staff alike. The process of risk assessment and management should be viewed as dynamic rather than fixed, as risks and best practices evolve over time.

Table 1 on page 59 shares insights into some key features of good practice in incident management. The PDL Guide to Incident Management (access appendix, pg. 87) provides further insights that can be helpful in the event of an incident.

Table 1: Key features of good incident management

Key feature	Examples in practice
Saying sorry	• It was mentioned earlier that apologising will generally not constitute an admission of liability and will often calm the situation before it escalates into demands or regulatory notifications. Be empathetic and give the individual an opportunity to express their feelings. • Examples of apologising without admitting liability: **"I'm sorry this situation has caused you concern/distress"** **"I am sorry this has happened"**
Reporting and documentation processes	• Having clear incident reporting processes, outlining WHO should report, WHEN, WHERE and HOW to report. • Records should be contemporaneous, comprehensive, accurate and retrievable. It is essential for tracking incidents, identifying trends and implementing necessary improvements. • Ensure all stakeholders are considered. **Internal reporting:** • Inform management and relevant team members, medication safety pharmacists and risk management teams. • Internal review processes to assess, find root cause and potential solutions. **External reporting:** • Stakeholders may include other healthcare providers involved in the patient's care, Therapeutic Goods Administration (TGA), individual indemnity provider, business insurer or other professional organisations. • Having good clinical documentation, e.g. for provision of a prescribing service such as OCP supply.
Confidentiality and privacy	• If an incident involves a breach of privacy or confidentiality, address the breach to limit any future impact for the people involved, e.g. retrieval of any materials or information involved in the breach and any reporting that is mandated or recommended. Not all privacy breaches reach a reportable threshold to agencies such as the Office of the Australian Information Commissioner (OAIC) or the Australian Digital Health Agency (ADHA), however advice should be sought from these agencies as to what should be reported.
Workplace culture	• Everyone can contribute to a non-punitive, resolution-focused culture that encourages staff to report incidents or near misses without fear of blame.
Continuous Quality Improvement (and prevention) strategies	• Review nature of incident, assess causative and contributing factors, and undertake remedial actions to prevent such an incident occurring again. • Identifying knowledge gaps and investing time into upskilling, training and education to address deficiencies. • Regularly review, refine and adjust processes/procedures. Individuals need to move beyond initiatives such as Quality Care Pharmacy Program (QCPP) and strive for ongoing commitment to Continuous Quality Improvement, raising standards beyond regulatory compliance. • Pharmacists should stay informed with best practices and evolving risks to stay ahead of potential challenges and remain adaptable. • Having clear, existing protocols in place for managing incidents but also effectively communicating these to all staff — to build trust and a strong reporting culture and minimising further harm.

Common pitfalls

Vulnerabilities in pharmacy practice can be broadly categorised into systemic factors (workload and technology), as well as behavioural and cultural issues:

Heavy workloads and **inadequate staffing** can significantly increase the likelihood of an incident. Stress, time pressure and mental fatigue can contribute to poor decision making. Decreased attention to detail can lead to an inability to perform necessary safety checks.

Technology assists with automation and efficiency, however overreliance on technology can result in incidents. Relying heavily on automated systems without adequate verification, neglecting the critical role of human oversight is a common pitfall. The interoperability of digital systems remains a challenge. Poor integration between multiple software can result in incomplete patient information, affecting clinical decisions.

Behavioural or cultural issues include **defensiveness**. When an individual or organisation becomes defensive in the face of an incident, it can hinder discussions and prevent lessons from being learned. Patients generally do not appreciate a defensive response when a mistake has been made. Defensiveness can create an impression that the healthcare service is avoiding responsibility or not taking the error seriously. Patients may feel unheard, which can erode their confidence in the pharmacy's ability to provide safe and reliable care. A productive and open dialogue is essential to maintain trust, promote transparency and ensure incidents are addressed constructively.

Making light of the incident. Offering excuses for why an incident occurred rather than taking full responsibility is a common defence mechanism. Lack of accountability can result in systemic problems being left unaddressed.

Failure to provide an apology can be detrimental to the therapeutic relationship.

Lack of awareness of reporting obligations can undermine opportunities for broader system-wide improvements.

Repercussions/consequences

The consequences of pharmacy errors can be far-reaching, affecting patients, the practitioner, pharmacy practice and the wider healthcare system. When making clinical decisions, it's essential to consider all stakeholders, as each may be impacted differently.

Potential repercussions include:

1. **Patient harm**
   The most direct consequence of an incident is physical harm to the patient. Errors can also cause emotional impact such as distress, anxiety or loss of trust, affecting the patient's wellbeing.
2. **Legal and financial consequences**
   A pharmacy or pharmacist may face legal action or financial compensation claims. There may be significant financial repercussions for the pharmacy.
3. **Reputational damage**
   Incidents can tarnish the reputation of the pharmacy. This could result in patient attrition and damage to professional credibility.
4. **Regulatory scrutiny and action**
   Regulatory bodies may conduct investigations and pharmacists may receive a regulatory notification. The primary focus of regulatory bodies is to ensure public safety. It is important to acknowledge that complaints can be made based on potential harm, even if no actual harm came to the patient. There are multiple reasons as to why someone may choose to lodge a complaint about you. Patients have the right to complain about healthcare services they receive. It is important for pharmacists to recognise the importance of patient feedback in improving care. While some complaints may lack basis, others are crucial for identifying potential risks to public safety.
5. **Impact on colleagues**
   Incidents can have a ripple effect on the entire team, creating a negative work environment and affecting morale. Other staff members involved in the incident can become 'second victims'. There may be impacts on their mental health, job performance and overall wellbeing. Providing support for these individuals is crucial to help them cope and recover.

Practitioner distress and managing the aftermath

Many pharmacists receive a regulatory notification at some point in their career, as patient-facing roles inherently involve the possibility of complaints. PDL states: [23] "Regulatory notifications are a mechanism for the public to raise any concerns about their healthcare experience and are an integral part of the regulatory framework".

PDL acknowledges that a notification from the Pharmacy Board or another regulator can be distressing. It can be a shock to receive a notification, but it is not uncommon. It is not always possible to meet everyone's expectations — and sometimes a complaint may be lodged even when all legal, ethical, and best practice guidelines were followed. It is very important to note that most regulators are looking for the practitioner to reflect and treat the incident that led to the notification as a learning opportunity. Their focus is not to punish but rather promote patient safety.

The Australian Commission on Safety and Quality in Health Care describes healthcare professionals to sometimes be "deeply affected by harmful incidents, even if they played only a small role".[24] Pharmacists can become the second victim of incidents when their confidence is compromised.[25] The 'second victim' in this context is the pharmacist, when they feel some of the same emotions and feelings that the affected patient and family members may feel. Following an incident, some patients (and pharmacists) will feel numbness, detachment from work and the incident, depersonalisation, confusion, anxiety, grief and depression, withdrawal, agitation and they can also re-experience the event upon returning to work.

But even when understanding that errors are inevitable, they can still lead to significant emotional distress for the practitioner involved. Maintaining one's own health and wellbeing as a practitioner is clearly listed as part of the Ahpra Shared Code of Conduct.[26]

In an AJP article, Holding your head up high: restoring professional confidence after experiencing an incident, it is stated that:[27]

> Since pharmacists have a duty of care to patients, there is great professional responsibility to maintain their own psychological health and remain professionally confident to prevent patients experiencing harm.

The PDL Returning to Practice: A 7-step toolkit for pharmacists (access appendix, pg. 87) can help to address the emotional wellbeing of the practitioner and manage the aftermath of an incident, and includes the following recommendations:

1. **Acknowledge the incident and reflect**
2. **Seek support and guidance**
3. **Prioritise self-care**
4. **Develop a habit of reflective practice**
5. **Compose a written action plan for yourself**
6. **Commit to a learning mindset**
7. **Implement risk management strategies**

Pharmacists are not alone. As part of point two above, PDL strongly recommends relying on colleagues or mentors in pharmacy for support, as well as reaching out to Pharmacists' Support Service (PSS) as an accessible service for pharmacists 365 days of the year.

Reporting incidents

Incident reporting is an important element of risk management.

As pharmacists, it is important to recognise that risks in everyday practice can never be fully eliminated, only minimised. An incident that is poorly managed — e.g. involving behaviours such as defensiveness, denying responsibility or avoiding blame rather than acknowledging and addressing the issue — can escalate into a regulatory notification and add to a pharmacist's stress.

Incident reporting is a critical tool in improving patient safety and serves as a foundation for Continuous Quality Improvement (CQI) efforts. The data provided from incident reports can assist individuals and organisations to assess and manage past and future risk by analysing patterns of incidents or near misses. This process can reveal systemic problems that can then be rectified. In this way, practitioners and organisations can proactively address potential issues before they lead to patient harm. Many regulatory bodies require healthcare organisations and professionals to report incidents to ensure compliance with regulatory standards and accreditation requirements.

Incident reports, as with all forms of documentation, should be contemporaneous, robust and retrievable.

It is just as important to report near miss events. Organisational protocols have multiple checking points to prevent adverse outcomes to patients. If a medication incident is overlooked at one checking point and is picked up by another, it is easy to think the system has done its job, but if these incidents continue to slip through, eventually the final checking point will be under additional pressure, increasing the risk that the medication reaches the patient. Reporting near miss events assists in preventing incidents and adverse outcomes for patients.

PDL recommends the following steps for pharmacists who have been involved in an incident that has escalated into a regulatory notification:[29]

- **Seek support early** from both professional organisations and personal networks. Professional organisations such as your professional indemnity provider or PSS can provide guidance to assist with managing the incident and supporting the wellbeing of both the patient and pharmacist.
- **Reflect** on the incident and formulate a plan for improvement and **prevention**.
- Keep clear and thorough **documentation**.
- Practice transparent **communication**.

If a practitioner is concerned about reporting a medication incident, it is valuable to speak with a superior or department head to confirm the correct protocols are followed in reporting an incident. PDL members can also reach out to the PDL Professional Officers to discuss incidents and reporting concerns.

REVISITED CASE STUDY: When an incident turns into a regulatory notification

Post-incident, you are understandably a little rattled and seek some support from Pharmacists' Support Service (PSS). They listen to your concerns and direct you to the **PDL Returning to Practice: A 7-step toolkit for pharmacists**, which helps to validate some of your emotions and redirect them towards acceptance and moving forward.

You then reflect on contributing factors to the incident and work on developing some proactive steps to prevent such a thing from occurring again. The PDL Reflective Practice Activity is useful to walk you through the steps of reflective practice and provides guidance for you to devise an Action Plan. Your Action Plan includes:

- Inventory management: Increase the frequency of stock checks throughout the year. Discuss with the manager which staff member(s) can help and when are good times to undertake this measure.
- New Standard Operating Procedures: Develop a new SOP which emphasises the importance of stock rotation and requirement to return any stock received from the wholesaler that was within 6 months of expiry. All existing products on the shelf within 6 months of expiry are to be marked with a neon sticker. In addition, all pharmacists are to incorporate an extra step in their checking process to ensure expiry dates are verified.
- Support staff: Allocate some responsibilities to dispensary support staff to begin checking expiry dates during the dispensing process, at script out and the till.
- Education and training of existing and new staff: Share learnings from incident and encourage growth and improvement. Take ownership and demonstrate a good reporting culture.
- Audits: Introduce random audits. The manager conducts a random audit, selecting 5 items from the shelf to ensure the newly introduced processes are being followed — and more importantly, that expired items are not dispensed to patients.
- Report to regulator: Detail these actions in response letter.

The regulator was satisfied that the pharmacist was taking purposeful activity to mitigate the risk of this incident from occurring again, and the matter was closed with no further action.

KEY TAKEAWAYS

- An apology that acknowledges distress, even without accepting fault, can de-escalate a difficult situation and can have psychological benefits to the complainant.
- Declining a particular medication or service is sometimes necessary, and it is important to effectively communicate this and assert boundaries.
- It is essential to look after your own physical and psychological wellbeing and feel safe in the workplace.
- Distressing events can be turned into positive learning experiences by having a positive risk culture among the team.
- Embed reflection and prevention strategies as part of your practice. Making mistakes is normal and the learning experience can be invaluable to professional growth.

Activity

Using reflective practice

You are the pharmacist-in-charge and were preparing clonidine 0.01% oral liquid for a child. It is a busy day, and there are many distractions and interruptions to your work. During the lunch rush, you mix up the calculations by resulting in a milligram dose instead of micrograms. The patient is inadvertently overdosed and admitted to hospital.

You report the incident to PDL and seek professional advice on next steps.

Using the PDL Reflective Practice Activity (access appendix, pg. 87), develop an action plan to address the situation described. Focus on self-growth and risk minimisation for future practice.

RECOMMENDED READING

PDL Guides & Resources:

Returning to Practice: A 7-step toolkit for pharmacists

Guide to Incident Management

Incident Reporting 101

Regulatory Notification Factsheet

CLASHED Action Plan

PDL Reflective Practice Activity

PDL Practice Alerts:

I've just received an Ahpra notification, what now?

Have you received an Ahpra notification?

PDL advice on reporting culture

PDL AJP CPD:

The importance and skill of saying no

Dealing with aggression in pharmacy

PDL Reflective Practice Activity

Module 4:

Managing high-risk areas

Putting the Guide into practice

australian pharmacy council ACCREDITED CPD

1.5 CPD credits Group One

Accreditation Number: A2507PDL4

This activity has been accredited for 1.5 hours of Group 1 CPD (or 1.5 CPD credits) suitable for inclusion in an individual pharmacist's CPD plan.

Pharmacist Competencies: 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 2.3, 2.4, 3.1, 4.2, 4.3, 4.4, 4.7

Accreditation expires: 30/6/2027

OBJECTIVE 1

IDENTIFY

Pinpoint areas within your practice where potential risks or harm may occur.

To proactively assess potential risks during all professional activities

To demonstrate leadership and accountability as part of your role in good clinical governance

OBJECTIVE 2

ASSESS

Evaluate the severity and urgency of required actions, using the tools outlined in the Guide.

To contribute toward a culture of continuous learning (selecting relevant CPD activities)

To leverage incidents and near misses as opportunities for practice improvement

To consider appropriate ways to mitigate and control risk in practice

OBJECTIVE 3

MANAGE

Implement and maintain effective systems and processes within your practice.

To work independently and collaboratively to maintain governance systems to prevent and address incidents

To confidently engage in handling and resolving incidents

OBJECTIVE 4

REVIEW

Reflect upon and evaluate outcomes from implemented changes.

To develop reflective practice and self-directed learning to minimise risk of incidents and repeat incidents

To review and adjust your own practices, following near misses or incidents

This module brings together all four learning objectives, illustrating how each stage of the Risk Management Cycle can be applied in practice. It targets five key risk areas commonly associated with incidents. Readers will be encouraged to recognise how the risk principles in this document can also be applied to emerging areas in pharmacy.

Through case studies and practical examples, the PDL Risk Assessment Tool (RAT) will be applied to demonstrate how to anticipate potential risks and implement strategies to minimise the impact of potential risks in identified areas.

After completing this module, pharmacists should be able to:

- Identify and discuss the high-risk areas encountered in general pharmacy practice today.
- Develop your own risk questions in these high-risk areas and an action plan to address concerns using the PDL RAT.
- Recognise emergent risks in the profession and how to apply risk principles in the PDL Risk Management Guide for Pharmacists to minimise the impact.

Overview

PDL continually analyse incident reports and member enquiries to understand the types and frequency of incidents, significance of impact on patients and pharmacists and the frequency of regulatory complaints and actions. While PDL Professional Officers receive calls and incident reports regarding newer services and activities, the majority of reports relate to typical activities with key incident themes remaining the same as in past years.

Ranked in order of greatest significance and impact, the following describe the top five reported areas (Dose Administration Aids, high-risk medicines, dispensing incidents, compounding and medicines by injection). By identifying how these areas might appear in daily practice, pharmacists can strengthen their risk awareness and put in controls to mitigate common errors occurring in practice.

Reflective practice is a systematic learning process where experiences, actions and feelings are acknowledged and new approaches and behaviours can emerge from a situation (e.g. a near miss or incident). Pharmacists are encouraged to adopt reflective practice techniques as they work through this module and make adjustments to their own processes where potential risks are identified.

Cases studies are included for each high-risk area, giving an example of how incidents can arise, to stimulate further thought. NB: Each individual will fill the PDL RAT out differently, depending on their perceptions of risk and their approaches to addressing the issue. Each case study approaches the RAT slightly differently. There is no right or wrong way to use it, as long as the focus is on practice improvement.

1. Dose Administration Aids (DAAs)

The preparation and supply of Dose Administration Aids (DAAs) is considered by PDL to be a high-risk area of practice. DAA patients often have multiple health conditions, multiple medicines, complex dosing requirements, possible impairments such as cognitive (memory or comprehension) or physical (vision) and are trusting that the medicines provided in the DAA are correct as per the prescribers' instructions.

The DAAs are supplied regularly, and administration may be managed by the patient or carer in a private home or by staff at locations such as aged care facilities (ACF) or group homes.

The complexity that arises from the combination of these factors means that any dose error due to pharmacy or patient lapse or misunderstanding can cause significant consequences. PDL has reports of patients experiencing adverse effects ranging from minor to serious including hospitalisation of patients. Furthermore, the frailty of many of these patients can often lead to concerns or regulatory notifications being raised by relatives or care facilities.

Common areas of DAA incidents reported to PDL include the following:

- Packing error with incorrect medicines or strengths
- Prescribed medicines packed at incorrect times
- Changes to dose regime not communicated to the pharmacy or applied by the pharmacy, e.g. new medicine was not commenced or existing medicine was not ceased
- No regular review of the DAA profile with the prescriber
- DAA provided to the wrong patient; by an assistant, delivery person, ACF staff member

In this service provision, risk can present itself from several different perspectives. These interconnected risk factors are discussed in the following.

Your professional role

Pharmacists must be alert to the risks that come with this patient cohort and the accurate preparation of DAAs. Individual practitioners need to ensure that DAA packing profiles are current and accurate, that dispensing is accurate, packing is aligned to prescriber directions, DAA checking is completed accurately, and supply is timely and correct. PDL recommends that review and confirmation of patients' medication charts/packing profiles are conducted regularly with the prescriber. Records reviewed should include non-packed medicines, non-prescription medicines and supplements to ensure the prescriber is informed of all therapy being provided by the pharmacy.

Responsibility for the actions of pharmacy staff involved in the preparation and supply of DAAs is with the pharmacist as well as the pharmacy owner, so consistent procedures and oversight is vital.

Communication and comprehension, trust, engagement and familiarity between a patient and their families, as well as pharmacy staff, could all contribute towards successful medication management via DAAs.

Your patient

Risk factors that may apply for DAA patients could include patient demographic, health literacy, complexity of health conditions, number of medicines and daily doses, physical health including vision and cognitive status, ability to comprehend advice and direction and trust in pharmacist and pharmacy staff.

If a DAA is being self-administered, then pharmacy staff need to ensure the patient understands how to correctly use the DAA. Patients should be made aware of DAA storage requirements which might include exposure to light, heat and moisture, and be offered advice about disposal of empty packaging as recycling of materials may be available.

Your practice setting and culture

Any pharmacy supplying DAAs needs well considered and consistently applied policies for the preparation and supply of a DAA. It is vital that DAA preparation be undertaken in a safe manner with factors such as a dedicated space, sufficient capacity for staff to complete tasks without distraction or interruption, and supply of the DAA accurately to prevent incorrect patient supply.

PDL incident reports highlight occasions of supply of DAAs to the wrong patient so consistent checking processes must be used. This applies to any labelling of patient details on a DAA, any packing of DAAs into bags for supply or delivery and at times of collection or delivery. Delivery of DAAs to an individual or a facility requires a protocol and documentation to ensure safe and accurate supply. DAAs should never be left unattended or in a location that may allow for loss or exposure.

The PDL RAT can be used to plan for and review DAA supply services. Regular review of DAA policies, any related incident reports, feedback from patients and prescribers can inform Continuous Quality Improvement (CQI) activities for this valuable patient service.

CASE STUDY: Dose Administration Aids

You are the pharmacist in charge and are also responsible for the DAA service of the pharmacy.

Mrs Jones is an elderly patient who is on multiple medications for hypertension which are packed in a dose administration aid. Mrs Jones' carer presented a prescription for aspirin 100mg 1 tablet 3 times a week to be packed in the dose administration aid. You update the patient packing profile immediately. The carer collects 4 weeks' worth of DAAs at a time, so you kindly ask if she returns later today at 3pm to give you time to make them up with the new aspirin regimen.

The day is unexpectedly busy and time gets away. You notice that the carer is due to return in half an hour so you hurriedly rush to the back to make up the 4 packs. The pharmacy stays very busy and you are interrupted regularly to check prescriptions for other waiting patients. Still, you manage to complete all the tasks.

In 3 weeks, the carer returns and asks you if it's "normal" for Mrs Jones to experience so much bruising. It has only started happening since the new aspirin has been added. On reviewing the pack, you notice that the aspirin has been packed daily rather than 3 times a week, as prescribed.

Applying the PDL RAT:

Step 1: Define your risk question

"What went wrong in the DAA process for this incident to have occurred?"

Step 2: Assess risk level by using the 'Indicators for determining risk level' column and
Step 3: Enter identified risk level in the 'Current risk status' column

Regulatory & Compliance – no obvious lapses here. **Risk category = LOW**

Clinical – Mrs Jones has noticed that she has been bruising more easily in the last few weeks. There has been an impact to patient safety. **Risk category = HIGH**

Professional – at some point there has been an unintentional lapse in professional practice and that has impacted one of your patients. **Risk category = HIGH**

Ethical – ethical behaviour/integrity upheld. **Risk category = LOW**

Operational – multiple responsibilities for the pharmacist including dispensary services and DAA management may lead to a lapse in attention when checking the completed DAAs. **Risk category = HIGH**

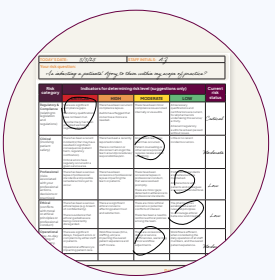
Step 4: Enter date of next review and any observations or planned actions in the 'Actions/notes' section

Actions/notes:	Date of next review:
• Prioritise immediate risk management — ensure patient's wellbeing FIRST. • Reporting — report to professional indemnity insurance provider and internally. • Arrange for uninterrupted DAA checking time regularly, i.e. Thursdays when there is a second pharmacist on duty and Sunday afternoon when it is quiet. If ad hoc changes are needed, allocate one pharmacist to manage the dispensary with support from the dispensary assistant while another pharmacist completes DAA checking. Advise patients accordingly (see next point). • Manage patient expectations with wait times — develop SOP for situations like this. Assess what should be done today and what must wait to ensure accuracy. • Commence a communication book that all DAA staff (pharmacists and dispensary assistant) must read daily BEFORE starting. Changes are summarised and dated. • Team training with all DAA staff — share incident and this action plan, involve everyone in the learning process.	Changes to commence TODAY 7 April 2025 and will be reviewed in 1 month, 7 May 2025. Communication book begins today. Rostering updates to take effect today. SOP development and team training must be completed by next week 14 April 2025. Revisit notes in this PDL RAT on 7 May 2025, anything still need addressing?

Step 5: Regularly review and update

Incidents are an important catalyst for change but we should be ensuring quality improvement processes on a regular basis. Consider doing DAA audit of entire process bi-annually. Discuss with the owner about the best times to schedule these and share resources to support the audit.

Refer to page 48 for how to use the RAT.



2. High-risk medicines

Different jurisdictions use different terminology to categorise medicines such as those in Schedule 8, and other medicines with a potential for dependence, diversion or misuse. These medicines may be referred to as monitored medicines, which are monitored via Real Time Prescription Monitoring (RTPM) systems.

There are also other medicines that are considered high-risk for a range of reasons such as drugs with a narrow therapeutic index, e.g. digoxin, drugs that may have high toxicity such as cytotoxics, drugs that might be used in an off-label manner, e.g. clonidine for children, drugs with many interactions, or unapproved medicines used for unapproved indications such as medical cannabis.

In the following, it will be explored further why PDL view high-risk medicines as worthy of discussion.

Your professional role

PDL receives incident reports where pharmacists may not have applied sufficient consideration to the prescribing and supply of a high-risk medicine. While pharmacists incorporate knowledge, experience and intuition whenever supplying medicines it is important to highlight the extra care and consideration that should be applied when a high-risk medicine is involved. Using a process such as an extra check prior to supply, or review by another pharmacist, can minimise risks to patients. Pharmacists are autonomous registered health practitioners and considered the gatekeepers to medicines. The public and regulatory agencies expect pharmacists to apply clinical and professional judgement to medicine supply. In cases where there are concerns for patient or public safety the pharmacist is expected to take reasonable steps to address those concerns, such as seeking more information from the patient or prescriber, reviewing patient history and information available through systems such as RTPM programs, and reference sources.

Clinical judgement and autonomy come into play here as pharmacists assess risk and risk reduction. A pharmacist should consider deferral, reduction of the quantity supplied or denial of supply if the risk of an adverse consequence can't be appropriately reduced or prevented.

Your patient

Patients may not recognise or understand the higher risks that some medicines may inherently involve or create for patients with certain conditions or other medicines. The pharmacist and pharmacy staff should ensure there are policies that are consistently followed to confirm patient details, patient history and prescriber's intentions. In the case of medicines that have a higher risk of misuse or diversion, the pharmacist needs to understand their legal and professional obligations to ensure the medicine is legitimately prescribed and supplied in a safe manner.

Patients should be informed of a pharmacy's policy to confirm patient identity and validity of prescriptions for certain medicines, and this is done in a manner that is not considered to be discriminatory or judgemental. There may be times when the validity of a prescription can't be immediately confirmed, and the pharmacy should have a policy that all pharmacists can apply to inform the patient of the options available to both the patient and the pharmacist.

Patients may be concerned when a pharmacist takes longer than expected to assess the safety and validity of a prescription or medicine order. Providing patients with an explanation of realistic timeframes and context for any pharmacist actions can help to reassure patients that the supply is occurring in a professional manner. This transparency is also valuable if it's necessary for a pharmacist to defend their actions in the case of a regulatory complaint due to patient dissatisfaction.

Your practice setting and culture

Review of PDL incident reports involving high-risk medicines indicate these situations can occur due to an absence or lack of application of good clinical governance, i.e. the development, application and ongoing review of suitable policies and procedures. Development of processes for pharmacists and pharmacy staff to follow when taking prescriptions or orders for high-risk medicines can reduce the risk for all those involved. Suggested actions could include: confirmation of patient details and identity (e.g. photo identification required for supply of monitored medicines), confirmation of patient weight, age, health conditions and review of patient information (using systems such as dispensing software, My Health Record or RTPM).

CASE STUDY: High-risk medicines

You are a locum pharmacist starting a two-week contract at a community pharmacy today.

A patient approaches you and says they are here to collect their Endone tablets. You confirm their identity by checking their driver's licence and locate a labelled box of 20 Endone tablets in the safe. The patient advises the medicine has been paid for, which you confirm on the point-of-sale system, and hence you then provide them with the box of 20 tablets.

Later in the day, the other pharmacist asks about the remainder of the patient's Endone tablets as they are a staged supply patient and should have only received 4 tablets today. You explain there was no indication anywhere that this medicine was to be supplied in staged amounts and the patient did not mention the extra quantity provided.

How can the PDL RAT help?

The PDL RAT can be used to plan for and review supply of high-risk medicines. The tool may assist the development of policies for staged supply of medicines, supply of opioid replacement therapies, using RTPM systems or reviewing incidents involving this group of medicines. Input from all pharmacy staff when developing or reviewing policies will see the improvement of policies and consistent engagement by staff members.

In this case study, the locum finds a copy of the PDL RAT on the dispensary computer desktop, prints it out and writes his risk question (Step 1) as:

"How can we ensure that all staff, including locums, are familiar with the procedures for Staged Supply service and understand their responsibilities?"

Due to the limited time remaining before he must commence closing responsibilities for the pharmacy, he circles **CRITICAL** for the Regulatory & Compliance Risk category, **HIGH** for Clinical Risk and **HIGH** for Professional Risk category.

In the 'Actions/notes' section, he writes "Suggest store procedures and communication methods be reviewed. I am happy to support this process. FYI - incident report logged and situation remedied" and includes his initials and date.

3. Dispensing incidents

Dispensing incidents involve any incident that occurs from the intake of prescription, or order of medicine, through to clinical assessment of the prescription, prescription input into the dispense software, product selection, scanning, labelling, final check, counselling and supply of the medication. PDL considers a dispensing incident to be any situation where a patient or carer is aware of an error or lapse in the supply of a medicine, even if that discrepancy is rectified before a dose is taken or administered.

In contrast, a near miss event is when a dispensing error is rectified before the patient is involved or aware. Review of PDL incident reports for 2024 shows that more than 45% of all reports were categorised as a dispensing incident. This is one area where incidents can be nearly entirely avoidable.

Your professional role

Dispensing remains a core component of pharmacy practice and incidents in this area are critical in identifying important gaps within the pharmacy's dispensary protocols, workflows, resourcing and capabilities. Good governance systems should be in place and regularly reviewed as part of every pharmacists' set of responsibilities. This is explained in detail in the introductory module.

By reflecting on incidents and actioning change to prevent recurrence of the incident, pharmacists can significantly reduce the risk of future error.

Your patient

The primary role of a pharmacist is to ensure the safe and effective use of medicines, providing expert advice and personalised care to support better health outcomes.

While the profession continues to expand into broader healthcare services, the public still rely on their pharmacies for the core function of dispensing medicines. This responsibility is more than just supplying medication — it involves risk assessment (such as drug-drug interactions, appropriate dosing, contraindications, etc.), educating patients on safe usage, and referral to other healthcare providers as necessary.

Patients often place great trust in pharmacists and may not always question changes in a medicine's name, appearance or dose, or if the received product or service differs from their expectations. Therefore, as trusted healthcare professionals, pharmacists must uphold this trust by ensuring patients receive the right medicine, at the right time, with the right guidance and counselling.

Your practice setting and culture

A significant portion of PDL incident reports cite distractions, high prescription volumes relative to staffing, limited breaks for pharmacists and long work hours as contributing factors.

For this reason, the physical work environment and its culture are crucial in mitigating this high-risk area. Clearly communicated protocols, workflows, well-managed resources and positioning of staff capabilities play a vital role — elements also highlighted in **Your professional role** — as they interact dynamically to ensure the safe and effective delivery of dispensary services.

CASE STUDY: Dispensing incidents

A patient has been dispensed irbesartan 300mg instead of 75mg and accepted the changed appearance of the tablet as being a generic substitute. The patient took the higher dose and experienced significant adverse effects that led to their attendance at hospital. The error was detected, the patient stabilised and the dispensing pharmacy informed. The correct strength was dispensed and the patient has recovered without further consequence.

The PDL RAT can be used to assess the current level of risk in dispensing procedures.

Step 1: Define your risk question

"Is there a risk of this incident occurring again, and how can I prevent that?"

Step 2 and 3: Assess and enter the identified risk level in the appropriate columns

Regulatory & Compliance – MODERATE

Recent audits have identified that the dispensing process is robust and aligned with current regulatory guidelines and the PDL Guide to Good Dispensing.

This recent incident is the first dispensing incident reported for 18 months; however, it was a significant error.

Clinical – CRITICAL

The recent incident had significant impact on the patient's health and hospitalisation was required.

There are no other incidents reported; however, it is critical to understand whether there is risk of this occurring again.

Upon investigation, it appears that the pharmacist did not review patient history to identify that a different strength had been dispensed.

Professional – LOW

Professional standards and behaviours are maintained and all interactions with patients and colleagues are respectful and ethical.

Ethical – LOW

The pharmacy has established a set of rules and principles to encourage ethical behaviour and integrity.

Operational – MODERATE

There are occasional staff shortages which increases the pressure in the dispensary. On the day of the incident, one of the dispensary technicians was unwell and unable to attend work. The pharmacist was dispensing and checking more prescriptions than usual.

Refer to page 48 for how to use the RAT.

Step 4: Enter the date of next review and any observations or planned actions in 'Actions/notes' section

Actions/notes:	Date of next review:
The pharmacist had a higher workload due to the absence of a dispensary technician, challenging their focus on the checking process. The pharmacist did not identify the data entry error and did not review the patient history to determine if the current dispensed medication was safe and appropriate for the patient. When faced with staff shortages, staff will communicate with patients to inform them of a longer than usual wait time. Where possible additional staff will be called in to cover. Meeting with all pharmacists to discuss the incident and the importance of reviewing patient history to confirm the medication being supplied is in line with previous medication supplied. Identifying changes in medication should prompt a check of the prescription and discussion with the patient or prescriber to confirm the change was intended.	Weekly for next 2 months

Step 5: Regularly review and update

Keep the PDL RAT in a dispensary training folder and review all once/year, and train any new staff in new procedures or learnings from previous years.

Refer to page 48 for how to use the RAT.

4. Compounding

Medication compounding occurs when a formulation of a medicine is prescribed but not commercially available. Compounding includes preparing, mixing, assembling, altering, packaging and labelling medicines.

The Australian Pharmaceutical Formulary[30] defines **simple compounding** as "using formulae published in recognised and reputable references (e.g. the APF) or using other formulae for which reliable information is available that confirms their quality, stability, safety, efficacy and rationality". Simple compounding can be performed by any registered pharmacist. By comparison, **complex compounding** involves "special training, competencies, equipment, processes and/or facilities" to manage a higher level of risk.

Compounding carries additional risks as it often incorporates activities such as calculations and considerations around active ingredient compatibilities, appropriate formulae, and determination that the prescribed medicine is safe and appropriate for the patient and the indication.

Compounding errors reported to PDL are relatively low in number and mirror the proportion of compounded medicines supplied compared to overall numbers of prescriptions dispensed in Australia. However, the consequences of a compounding error can be significant as the patient may not have experience of that compounded medicine previously and may not relate side effects to an error. Furthermore, many products are compounded for children, elevating the risk profile for the preparation of the medicine.

Your professional role

Pharmacists supplying compounded medicines are expected to have appropriate training, education and competence in compounding procedures. There are key operational and safety aspects to providing a compounding service, as well as additional requirements regarding appropriate facilities, equipment and working environment. These aspects are particularly important as the complexity of the compounding process and the risk profile of the medicines involved increases.

Appropriate documentation and record-keeping are extremely important for compounding activities as they are vital for preparation, quality assurance and in the case of any adverse event or alleged error.

Documentation in compounding practice can include:

- Risk assessment form
- Master formulae
- Worksheets
- Patient records
- Standard operating procedures
- Staff training records

A good guideline as to whether your documentation is appropriate is to consider whether your records are:

Consistent, reproducible and verifiable

Pharmacy owners have a responsibility to maintain oversight of the operations of all service areas in the pharmacy, including compounding practices.

Your patient

Because compounded medicines do not undergo the TGA verification process for safety, efficacy and quality, they carry an extra component of risk that must be understood and addressed by pharmacists who undertake this service. Pharmacists must exercise vigilance in consideration of the patient profile and ensuring the safety and quality of the tailored medicine.

Patients may be prescribed a compounded medicine for personal, clinical or accessibility reasons. The prescribing of a bespoke product may prevent the patient from identifying an error given the product does not have commercial identification in the form, e.g. marked tablet or capsule, branded packaging or consumer information. Also, patients may be less alert to possible side effects due to expectations the medicine is specifically prepared for their circumstances.

Your practice setting and culture

Consistent application of policies and procedures is vital to ensure compounded medicines are prepared and supplied according to the prescription and the patient's needs. Errors are reported to PDL when lapses occur with preparation of worksheets, assumptions are made regarding accuracy of formulae, shortcuts are taken in preparation or lack of competence for pharmacists overseeing the compounding process.

Compliance with expected standards for the physical premises are exceptionally important not only for patient safety but also for occupational health and safety reasons, such as staff exposure to high-risk substances (e.g. cytotoxics, hormone-based products). It should be part of standard protocols that all pharmacy staff involved in this service are trained on exposure risks and have a good understanding of risk awareness and safety measures when handling substances.

CASE STUDY: Compounding calculation errors — an example in practice

Clonidine suspension is prescribed for children with ADHD and associated behavioural conditions, and is compounded due to lack of a commercially available product. Cases have been reported to PDL of errors where the product has been compounded with 10 times more or less clonidine than prescribed. While 100mcg/mL is a commonly prescribed strength, errors have led to 1mg/mL (1000mcg/mL) or 10mcg/mL being supplied and administered to children. These errors have led to serious consequences, hospitalisations or worsening of behaviours. These errors may be attributed to calculation errors, use of incorrect formulae, poor compounding techniques and lack of consideration for the risk profile of the drug and the patient.

Following an incident, pharmacists may use the PDL Reflective Practice Activity to develop an action plan to address the incident. Working through this activity can help with reflection and acknowledgement of contributing factors — which serve as a guide to devise actionable steps to minimise recurrences in future.

The PDL RAT can also be applied to support pharmacists to identify any behavioural or process changes necessary to manage the risk more effectively. NB: every pharmacist will use the tool differently, and there is no right/wrong answer.

An example of how application of the PDL RAT might look in this case scenario is mapped out as follows:

Step 1: Defining your risk question

Did the pharmacist have sufficient knowledge, experience or competence to compound the clonidine suspension?

Step 2: Assess risk level by using the 'Indicators for determining risk level' column and **Step 3: Enter identified risk level in 'Current risk status' column**

Regulatory & Compliance- LOW

Clinical - HIGH

The calculation error has the potential to cause patient harm and should therefore be given significant weight in the overall risk assessment.

Professional - HIGH

Although a pharmacist may be familiar with compounding procedures and the therapeutic use of clonidine, a lapse — possibly related to compounding technique — suggests that competence may need to be reviewed. Limited clinical consideration at the time may also have influenced how the risk profile of the drug and its potential impact on the patient were assessed.

Ethical - LOW

Operational - HIGH

Individual contributing factors should be reviewed case-by-case, but such errors are often linked to workflow issues — such as frequent distractions or interruptions during compounding or the absence of a second pharmacist to verify calculations. Other factors may also be present and should be addressed accordingly.

Step 4: Set a date for review of planned action

Planned action = Before proceeding with further compounding activities, the pharmacist will seek training and revision from a pharmacist mentor. This collaboration will identify what steps are needed to address any gaps or weak points in service delivery.

Date for review could be within the month. Make sure this is clearly stated in the PDL RAT, e.g. by latest 30 April 2026.

Step 5: Review and update

After undertaking a review of their competence, the pharmacist will continue to monitor their involvement in compounding requests and seek improvement in their practice.

Refer to page 48 for how to use the RAT.

5. Medicines by injection

Pharmacists can now administer a range of medicines by injection nationally. These injectable services include immunisations and other scheduled and unscheduled medicines such as travel vaccines, non-vaccine injectable medicines and vitamins.

There are many considerations that pharmacists and their teams need to incorporate to safely deliver medicines by injection, including:

- An upskilling of pharmacists and staff to professionally manage the range of products that may be administered by a pharmacist.
- Development of policies and procedures to meet the needs of the expanding range of medicines administered in a pharmacy or other approved setting.
- An awareness of potential adverse reactions to these medicines and preparation to manage such events including injuries, allergic or adverse reactions and anaphylaxis.
- Appropriate recording of administration events within the pharmacy and in required systems, e.g. Australian Immunisation Register.
- Ensuring compliance with current legislation in the relevant jurisdiction.

Your professional role

As with all professional services, pharmacists must ensure that they only perform duties within their scope of practice. PDL remind pharmacists to check whether they meet the education, competency, legislative authorisation and accountability requirements before proceeding with administration of any new medicine by injection. The PDL Scope of Practice Checklist (access appendix, pg. 87) offers guidance for pharmacists to understand how to ensure they are working within their scope of practice.

Your patient

Patients are becoming more aware of pharmacists' ability to administer medicines by injection, leading to an increase in requests for this service. While patient autonomy regarding choice of practitioner is good for the consumer, pharmacists need to be alert to patient-related risks that come with this service.

Patient-related considerations that should be addressed prior to administration by injection include patient suitability e.g. have they had a past reaction to a vaccine, injection timing e.g. is the medicine due for administration in relation to previous doses (booster doses of vaccines, regular interval for administration such as denosumab or long-acting buprenorphine) and patient lack of awareness of brand names when these are used in discussion with the patient.

As with dispensing incidents reported to PDL, wrong patient errors may also occur with administration of medicines by pharmacists. Using open-ended questions to confirm the patient expectations regarding the vaccine or medicine is important and can prevent miscommunication leading to an administration error.

There are some important routine measures that can reduce risk to the patient when administering medicines by injection:

- Have a comprehensive pre-screening procedure, e.g. checking the Australian Immunisation Register, confirming expected medicine/vaccine, establishing patient eligibility.
- Allocating sufficient time for patient consultation.
- Keep different vaccines separated and avoid placing multiple vaccines in the same tray, unless they are for same person.
- Ask open-ended questions to ensure patient identity and ensure booking and consent forms are cross-checked to confirm patient identity and expected vaccine.

The PDL Guide to Medicines by Injection (access appendix, pg. 87) more thoroughly explores key routine checks to guide pharmacists in this service area.

Your practice setting and culture

Consistent application of policies and procedures is vital to ensure medicines are administered appropriately and according to patient or prescriber expectations. Errors are reported to PDL when lapses occur with booking services, pre-administration checking and lack of clinical consideration regarding the medicine's indication and timing.

The routine measures discussed in **Your patient** above are applicable in this section as much as in the prior.

Similarly to compounding services, administering medicines by injection requires suitable premises and equipment as set by local regulatory agencies or professional expectations.

CASE STUDY: Medicines by injection

You are a vaccinating pharmacist and have administered many influenza and COVID-19 vaccinations over the last few years. Today you receive a patient request to administer a vitamin B12 injection in the pharmacy. Is this within your scope of practice?

Using the PDL RAT to help with this:

Step 1: Define your risk question

"Is administering vitamin B12 injection within my scope of practice? Should I be doing that?"

Step 2: Assess risk level by using the 'Indicators for determining risk level' column and Step 3: Enter identified risk level in 'Current risk status' column

Regulatory & Compliance- LOW

You have completed all mandated training requirements in your jurisdiction. A recent audit was carried out of the consult room, and it also meets regulatory requirements.

Clinical - HIGH

Vitamin B12 injections have not been administered at the pharmacy before. You have some clinical knowledge regarding vitamin B12 but have not completed any recent education on vitamin B12 deficiency and supplementation. You don't have any clinical records to support the patient's request for the administration of the vitamin injection.

Professional - MODERATE

You are not familiar with how to administer a vitamin B12 injection.

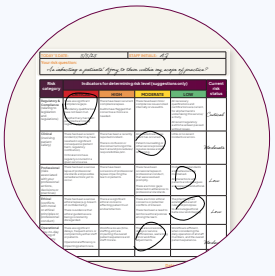
Ethical - LOW

The pharmacy has established a set of rules and principles to encourage ethical behaviour and integrity.

Operational - HIGH

The pharmacy has robust medicines by injection standard operating procedures however this would be an extension of the current service. SOPs would need to be reviewed and adapted to encompass vitamin B12 injections.

Refer to page 48 for how to use the RAT.



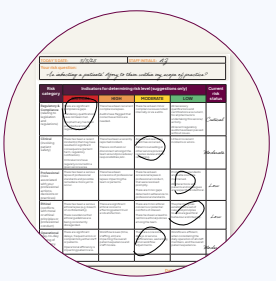
Step 4: Enter the date of next review and any observations or planned actions in the 'Actions/notes' section

Actions/notes:	Date of next review:
• Review resources to ensure competence to administer the injection. • Gather clinical information from the patient or their treating doctor to confirm the administration is indicated and appropriately timed (defer service until these actions are taken). • The MODERATE and HIGH risk ratings for **Professional** and **Clinical risk** categories respectively suggest necessary steps to undertake education on vitamin B12 deficiency and supplementation and review administration technique. • Seek confirmation of clinical need for the vitamin supplementation via review of clinical records such as pathology results and records supporting timing of previous doses. • In collaboration with the pharmacy owner, review the current medicines by injection SOP and expand it to include vitamin B12, particularly how therapeutic need will be established, communication with the prescriber and how this will be documented in a patient's record.	All actions to be fulfilled ASAP and share learnings in team chat.

Step 5: Regularly review and update

This is a good exercise when considering the implementation of a new activity/service that hasn't been done before in the pharmacy. Share this worksheet with the owner and consider sharing with the wider team.

Refer to page 48 for how to use the RAT.



Emerging areas of risk

Overview

As scope of practice continues to expand, so does the range of enquiries received by PDL. As pharmacists contemplate and move into new areas of practice, they need to consider management of risk to the patient, the pharmacist and pharmacy management or owners. Often there is limited information available for the profession. Regulatory agencies and representative organisations may not have information readily available leading to personal interpretation of practice allowances and limits. PDL advises caution and due consideration be applied by pharmacists considering expanding their practice into new areas of service.

Some emerging areas of practice that carry new forms of risk include:

- New forms of technology in the provision of the service
- Medicinal cannabis
- Schedule 3 and 4 nicotine vaping products
- Atypical medicines by injection, e.g. long-acting injectable buprenorphine, monoclonal antibodies
- Pharmacist prescribing activities — either as a pilot or a regulated (business as usual/BAU) service

The principles outlined in these guidelines are adaptable to both current and emerging pharmacy practice, providing pharmacists with a framework to navigate unfamiliar areas of practice. As the profession evolves, these concepts remain universally applicable, ensuring continued relevance over time.

The next two case studies work through some newer service areas in pharmacy and illustrate how risk can present itself when the environment is still relatively unchartered.

Case Study 1 explores some of risks that can present when supplying medicinal cannabis.

CASE STUDY 1: Medicinal cannabis

A new patient has started coming to your pharmacy, and although the patient is familiar with the use of their medicinal cannabis treatment, you are relatively new to supplying cannabis-based therapies.

Upon scanning the electronic prescription token into the dispense software, a number of different selection options are presented on the screen. After selecting and dispensing the item that corresponds to the name and percentage described on the prescription, you advise the patient that you will contact them in 2–3 days after the product arrives from the wholesaler. Upon its arrival, the new cannabis product is entered into the pharmacy's electronic S8 drug register, and you update the item's barcode in the dispensary system to ensure the dispensed item scans successfully. The patient collects their item, and you feel confident in your actions of supplying the medicine.

Five days later, the patient returns to the pharmacy complaining of a lack of sleep, believing you have provided the wrong product. Reviewing the prescription, it is discovered you have supplied the sativa strain in error and the patient's use of product prior to bedtime has resulted in reduced restfulness.

You apologise to the patient and explain that they have received a sativa strain instead of the prescribed indica strain. You immediately call the wholesaler to order the correct product, and they advise you it is out of stock with no fixed date for availability. The prescriber is advised of the error, and they request the patient return to see them. Unfortunately, the patient is upset about the delay in treatment and complains they are experiencing worsening symptoms due to sleep deprivation.

Points to consider:

- What are the dangers of manual brand selection in dispensing software?
- What other medicines should you be wary of, where there is manual selection in the dispensing software?
- How can you upskill your own knowledge between the strains, strengths and nomenclature of medicinal cannabis products?
- This could be new territory for some prescribing GPs also. How can you work collaboratively to ensure optimal use of this medicine?
- What sort of documentation should you do? Think: reporting a near miss, patient consultation/interaction/outcome, prevention of similar errors in future

Useful resources:

- TGA Guidance for the use of medicinal cannabis in Australia
- PDL RAT (access appendix, pg. 87) can support pharmacists to consider what risks may be at play and help to navigate and hence address some of these issues above, before acting

Case Study 2 discusses nicotine vaping products and the importance of having good systems and checks in place (i.e. clinical governance) to minimise the potential risks emerging from the extra complexity with this relatively new service area.

CASE STUDY 2: Nicotine vaping products

You have recently introduced supply of Schedule 3 nicotine vaping products (NVP) in your pharmacy. You note there are some resources and guidelines available to support your practice and you feel relatively confident in offering the service as you are comfortable with providing advice and nicotine replacement therapy products to support patients with smoking cessation.

Sometime after commencing supply of prescription-only NVP you receive a Pharmacy Board notification. The mother of a 16-year-old boy claims the pharmacy has supplied NVP products to her son on more than one occasion. The mother claims her son has never smoked tobacco prior to her discovery of the NVP and is concerned how her son was able to receive these products from the pharmacy.

You remember performing a clinical assessment and have counselled the patient thoroughly, eventually concluding that there was a clinical need for NVP use. You sighted a proof of ID card which appeared to verify that the patient was over 18 years of age. Your practice is to retain a written consent form from the patient, before supplying NVP via the pharmacist (over the counter) pathway. Unfortunately, you did not document this interaction and have misplaced the consent form somewhere.

Points to consider:

- What are the different rules or restrictions around the Schedule 3 and 4 supply pathways?
- Changes to regulation of vapes (and many new service areas) happen frequently. How can you maintain that your knowledge and actions are based on the most up-to-date recommendations/requirements? What resources can you rely on?
- Are the legislation requirements for supply of NVP different across the states/territories? What is the minimum age for which a pharmacist can supply a vape product, and does this change if they have a prescription?
- How are you ensuring due diligence and what measures are you taking towards quality assurance? Think: standard operating procedures, documentation of supply, process for collecting information on near misses or incidents associated with this service provision
- Do all Pharmacy Board notifications against practitioners result in withdrawal of registration? What are some things that you can show or demonstrate that can support your case?

Useful resources:

- PDL Scope of Practice Checklist provides a step-by-step checklist to help pharmacists decide whether they should proceed with a particular service/activity
- PDL Guide to Incident Management can support pharmacists to navigate the steps to take following an incident
- PDL RAT can support pharmacists to consider what risks may be at play and help to navigate and hence address some of these issues above, before acting
- PSA Professional practice guidelines for pharmacists: Nicotine dependence support

KEY TAKEAWAYS

- The principles of risk management covered in these modules are relevant not only to commonly known high-risk areas in pharmacy practice but also to newer services/activities as the profession evolves.
- Be mindful of your role in clinical governance and the importance of having good systems and checks in place.

Activity 1:
Common high-risk areas

Now that you have learned some basic principles of risk and risk management, and considered how they apply in context — it's your turn.

Pick ONE option and complete the activity questions. If you struggle to develop a risk question, you can select a pre-written Case Study from Module 4.

OPTION A

Think about an experience you have had in your workplace that requires attention, involving any of the five high-risk areas discussed or another service area.

e.g. RUM bins — The Return of Unwanted Medicines (RUM) bins are located in the staffroom due to a lack of space in the dispensary. Consider the types of medicines that may be placed in the bin, the risks that may be associated with this practice and how those risks may be reduced.

Develop a risk question.

or

OPTION B

Pick one of the high-risk areas above that resonates with you and develop a risk question in the context of that area.

e.g. Compounding — our pharmacy has experienced an incident where we have sent out the wrong compounded product for a patient twice — once off the original script and once off the repeat. What can I do to make sure this does not happen again?

Develop a risk question.

In Module 2, the Interconnected Risk Factors (Professional role, Patient and Practice setting) were discussed. Describe how each factor can present potential problems, consider their flow-on effect(s) to other areas and how they can each influence the decisions you choose to make.

Your professional role

Your patient

Your practice setting and culture

Now that you have considered the environmental factors, list how each category in the five types of risk in pharmacy practice (Module 1) should be taken into account (write N/A if they are not relevant to your risk question) when assessing and addressing your risk question.

Regulatory & Compliance Risks

Clinical Risks

Professional Risks

Ethical Risks

Operational Risks

Use the PDL RAT (access pg. 45) to come up with a thorough action plan which addresses as many risk factors as possible, to ensure long-term management of your proposed risk. Use the fundamentals of a risk mindset (access pg. 19) to guide your thinking.

If an incident or near miss has occurred, use the PDL Reflective Practice Activity (access appendix, pg. 87) to develop an action plan to address the incident, with a focus on risk minimisation for future practice.

Activity 2: Emerging areas

Your state health department has recently regulated pharmacist prescribing in the management of certain skin conditions.

One day, a mother presents with her 11–month-old son, who has itchy, blister-like sores on his arms and legs. She thinks he "caught something from childcare" and asks if you can help him.

Is this within your scope of practice? Why/why not? Provide an explanation.

What training(s) must you complete in order to be able to offer this service to the community?

What clinical practice guidelines exist to guide you through the management of skin conditions?

How can you differentiate between skin conditions with similar signs or symptoms (e.g. atopic dermatitis, impetigo) and are you authorised to supply appropriate Schedule 4 medicines for these conditions?

What are some counselling points you would provide the mother?
(Consider adverse effects, expectations of the timeline of condition, treatment and expected outcome, when the child should be referred either back to yourself at the pharmacy or to a GP, etc.)

Group 3 CPD activity

The Pharmacy Board of Australia defines Group 3 CPD as where: 'Quality or practice-improvement is facilitated. Activities where an assessment of existing practice (as an individual or within a pharmacy practice), and the needs and barriers to changes in this practice are undertaken prior to the development of a particular activity'. Group 3 activities usually extend over a number of weeks or months. We therefore suggest that where using what you have learned in this Guide results in ALL of the following actions — **identification of a risk in practice, resulting from the review of an incident, near miss, or existing or proposed professional service, using the Risk Assessment Tool to determine the risk level(s) of current practices, actioning steps that lead to improvements in practice to reduce these risks, reviewing outcomes after a suitable amount of time, and ensuring all of this is well-documented** — then this process would be appropriate to record as Group 3 CPD.

RECOMMENDED READING

PDL Guides & Resources:

Guide to Medicines by Injection

Regulatory Notification Factsheet

Scope of Practice Checklist

Guide to Good Dispensing

Supplement to Guide to Good Dispensing: Final Check & Supply of Medicine

PDL Reflective Practice Activity

Access appendix on pg. 87

Glossary

This glossary lists key terms used throughout this document.
Where applicable, definitions align with current guidelines and literature and are included in the References section.

Term	Definition
Clinical Governance	A set of behaviours, policies, procedures, monitoring and improvement mechanisms directed towards ensuring good clinical outcomes.
Risk	An effect that is a deviation from the expected.
Risk Management	A framework of coordinated activities to direct and control an organisation with regard to risk.
The Swiss Cheese Effect	A risk analysis and risk management model depicting a series of system failures that allow for a hazard (e.g. causation of harm) to pass through.
Risk Mindset	The cognitive ability to proactively recognise, assess and manage potential threats in a systematic way. It involves being aware of risks, making informed decisions and thinking ahead to minimise.
Inherent Risk	The risk without considering internal controls or "a raw risk that has no mitigation factors or treatments applied to it".
Controls	A measure that is applied to address risk. Controls include any process, policy, device, practice or other actions that modify risk. Controls may not always exert the intended or assumed modifying effect.
Residual Risk	Risk remaining after risk treatment. Residual risk can contain unidentified risk.
Risk Appetite	The amount of risk an individual is willing to pursue to achieve their objectives.
Risk Tolerance	The level of risk that an individual is comfortable with, based on their personal experiences and preferences.
Perceived Risk	A person's view on a risk, which is reflected by their individual needs, issues, knowledge, beliefs and values.
Actual Risk	The quantifiable aspects of risk, which include aspects such as the likelihood, the impact and the severity of the risk.
Clinical Judgement	The process of sound decision-making and is developed through evidence-based knowledge, practice and experience.
Near Miss	An event where an error is rectified before the patient is involved or aware.
Incident	An event where a patient or carer is aware of an error or lapse in the supply of a medicine, even if that discrepancy is rectified before a dose is taken or administered.
Positive Risk Culture	One where staff at every level appropriately manage risk as an intrinsic part of their day-to-day work.
Regulatory Notification	A formal communication from a regulatory agency and may be due to a complaint being lodged against a practitioner or a compliance issue being flagged.
Reflective Practice	A systematic learning process where experiences, actions and feelings are acknowledged, and new approaches and behaviours can emerge from a situation (e.g. a near miss or incident).

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Appendix

These items can be accessed by PDL members using the QR code.

Risk Assessment Tool (also on pg. 46–47)

Scope of Practice Checklist

Reflective Practice Activity

Guide to Good Dispensing

Supplement to Guide to Good Dispensing: Final Check & Supply of Medicine

Returning to Practice: A 7–step toolkit for pharmacists

CLASHED Action Plan

Guide to Medicines by Injection

Guide to Incident Management

Regulatory Notification Factsheet

Pharmaceutical Defence Limited

Owned by our pharmacist members for over 110 years