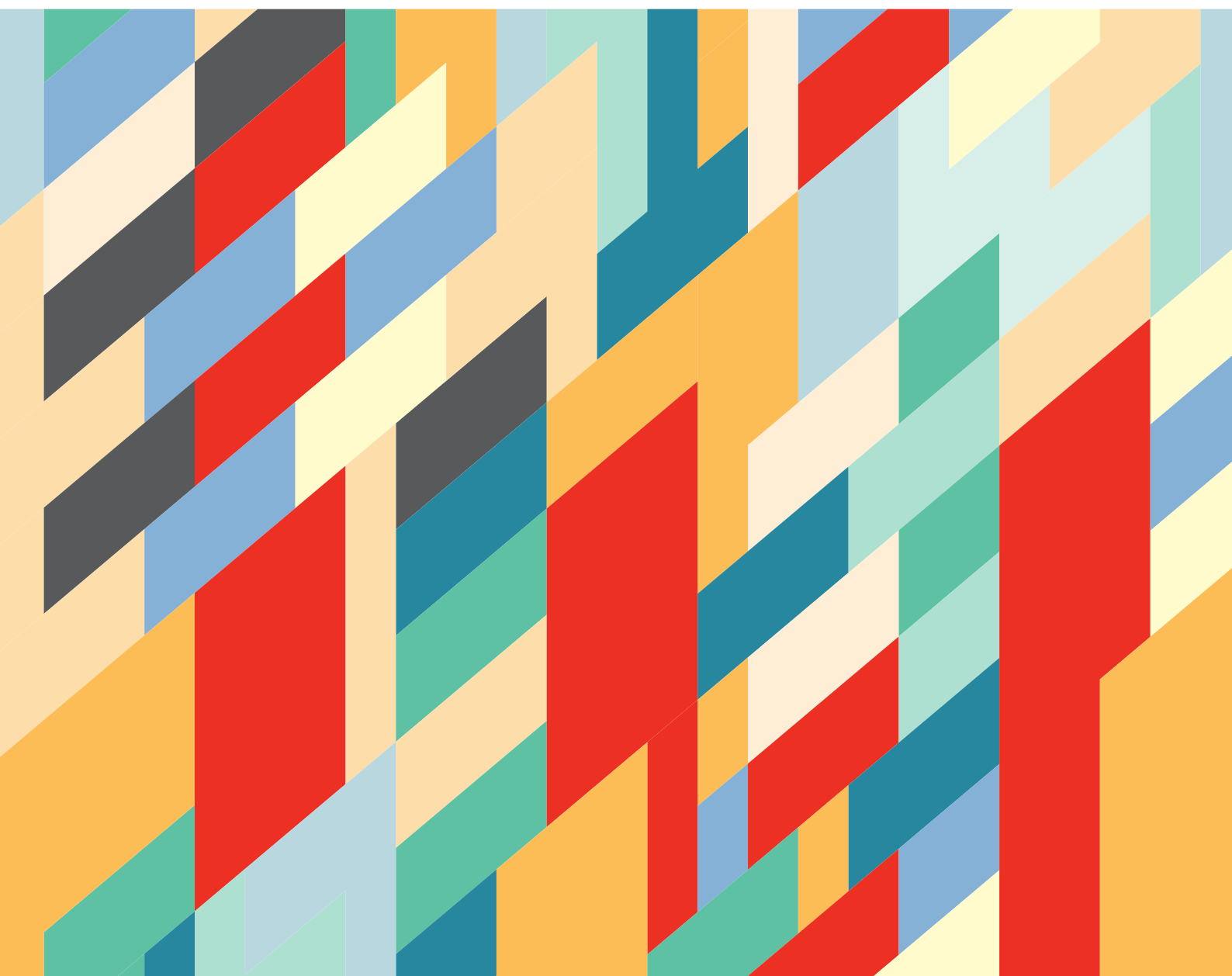# RACGP

Clinical risk management in general practice

A quality and safety improvement guide and educational resource for individual- or group-based learning

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Clinical risk management in general practice: A quality and safety improvement guide and educational resource for individual- or group-based learning

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If you experience a lapse in patient safety in your practice you are advised to contact your medical indemnity insurer/organisation as soon as possible. Non-general practitioner practice team members are advised to speak to the supervising general practitioner (GP), or the practice principal or manager if harm to a patient has occurred.

It is important that all general practice team members are appropriately covered under medical indemnity insurance. GPs should ensure they are appropriately insured if they delegate care to other practice staff members (eg. practice nurses) or if they are involved in supervising or mentoring medical students or other medical practitioners.

Recommended Citation

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A quality and safety improvement guide and educational resource for individual- or group-based learning

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Foreword

Many of us have experienced concern, fear, disappointment, terror or shame when a lapse in service quality almost harmed, or did harm, one of our patients.

We all want to prevent such events from occurring; hence, GPs and their practice teams are increasingly looking for more structured ways to achieve this. In response, the RACGP has developed this resource to promote a systems approach to patient safety.

It can be used as a stand-alone guide or as a QI&CPD education activity for individual or small-group learning.

The generous contributions of the many individuals listed in the acknowledgements will ensure that its content is relevant and useful to GPs and their practice teams trying to master the art and science of continuous quality and safety improvement.

We hope you find it both useful and challenging, and that you will find opportunities to share it with your colleagues.

The RACGP looks forward to receiving any comments you may have, as we continue working together to improve the quality and safety of general practice for our patients, fellow GPs and the members of our practice teams.

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Contents

Introduction

Background

This education module has been developed to help GPs and their practice teams manage clinical risks, errors, near-misses and adverse events.

Its content maps to the RACGP Curriculum Statement on Quality and Safety, which forms part of The RACGP curriculum for Australian general practice and should serve as a starting point for further exploration of this topic.

It starts by outlining different threats to patient safety, then explores human factors that can increase or decrease the risk of patient safety incidents. These include absentmindedness, present-mindedness and error-wise practice.

It then looks at human factors within a clinical context to understand their complex interaction with other factors (such as clinical technologies, infrastructure, systems and processes) and how this can influence the occurrence of patient safety incidents. Some theories of how incidents evolve are presented next.

This sets the scene for the central theme in *Section 5: A 10-step systems approach to patient safety*. This marks a significant turning point in the history of risk and incident management, which previously centred on human error and individual blame. The systems approach to patient safety involves creating a supportive, open and inclusive organisational culture, where clinical risks and incidents can be skilfully discussed, investigated and strategically managed to appropriately address the impacts and prevent recurrences. Following implementation of practice-based solutions and safeguards, it is important to evaluate what did or did not work. This gives practice teams the opportunity to learn from their experiences.

The module closes with a detailed look at the critically important medico-legal implications associated with clinical risks and incidents.

Aim

This resource aims to increase general practice teams' understanding of clinical risks and how they can be managed through a systems approach to patient safety.

This involves:

- creating a just and open organisational culture

- understanding the human and contextual determinants of safety

- supporting skilful identification and investigation of patient safety issues

- implementing safeguards to prevent recurrence

- ongoing patient safety monitoring.

It also gives practice teams the opportunity to develop an understanding of their medico-legal responsibilities and the risks associated with lapses in patient safety.

Reading

- The Royal Australian College of General Practitioners. The RACGP curriculum for Australian general practice 2011. Melbourne: RACGP, 2011.

Quality in healthcare means the best possible health outcomes given the available circumstances and resources, consistent with patient centred care.[1] Safety in healthcare is reducing the risk of unnecessary harm to an acceptable minimum level.[2] Patient safety is the freedom from hazards due to medical care or medical error in the general practice setting.

Although patient safety is only one aspect of quality improvement for general practice, it is a key dimension of *A quality framework for general practice*[3] and is emerging as a core competency for GPs and their multidisciplinary practice teams.

Domains of general practice

The content is intended to achieve learning outcomes across the five domains of general practice (*Table i.1*).

Table i.1 Domains of general practice	
Domain 1	Communication skills and the patient-doctor relationship (eg. patient centredness, communication skills, health promotion, whole-person care)
Domain 2	Applied professional knowledge and skills (eg. physical examination and procedural skills, medical conditions, decision making)
Domain 3	Population health and the context of general practice (eg. epidemiology, public health, prevention, family influence on health, resources)
Domain 4	Professional and ethical role (eg. duty of care, standards, self-appraisal, teacher role, research, self-care, networks)
Domain 5	Organisational and legal dimensions (eg. information technology, records, reporting, confidentiality, practice management)

Learning outcomes

Possible learning outcomes include:

QAST2.3   Apply knowledge of the impact of human factors, such as the role of cognitive overload and resilience, in order to maximise the safety of patients.

QAST1.1   Use effective communication, active listening skills, self-awareness and self-reflection to assess external and internal influences to help reduce hazards to patient safety.

QAST2.2   Understand that changes in the person (eg. change in cognitive state), the patient healthcare context (eg. the emergence of new diseases) and in the nature of clinical care (eg. advances in technology) all create changes that may increase the likelihood of harm to patients.

QAST3.2   Know the epidemiology of harm and error, such as common causes of harm, and how this can focus attention on the most effective interventions for reducing risk of harm to patients.

QAST5.1   Understand that systems-based approaches to health that focus on quality and safety are likely to produce a safer healthcare environment, thus complementing the person-based approach.

QAST5.6   Understand that the development of an open, transparent, supportive and just culture within the general practice setting is regarded as the foundation of safety for patients and members of the healthcare team.

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QAST2.7   Apply knowledge and skills in the identification of the causes of near-misses and adverse events to reduce risk of harm that reflects the Australian general practice setting.

QAST5.9   Assist in the cultivation of meaningful and timely ways of reporting and acting on incident reports.

QAST5.8   Report on incidents including lapses in safety, slips, errors, mistakes, adverse events and near-misses within the practice.

QAST4.6   Undertake quality assurance and quality improvement activities which reduce the likelihood of harm to patients.

QAST5.11   Understand general practice legal obligations (including those relating to medical indemnity insurers), especially in the context of the discussion of adverse events.

See the RACGP Curriculum Statement on Quality and Safety (http://curriculum.racgp.org.au/statements/quality-and-safety) for an expanded list of possible quality and safety learning outcomes across each domain of general practice.

Target audience

This resource is intended for use by the entire general practice team. This includes experienced GPs, registrars, nurses, medical students, allied health professionals, practice managers and administrative staff.

How to use this resource

This resource comprises of six chapters that can be completed in a minimum of 6 hours – excluding the predisposing and reinforcing activities. Each section contains conceptual frameworks (CF), case studies (CS), activities (A) and reading (R) (*Table i.2*).

Table i.2 Active learning components by section			
Chapter	**Active learning component**	**Content**	**Minimum time allocation**
	Predisposing activity	**Questions**	**30 minutes**
1	Threats to patient safety	CF, CS, A, R	30 minutes
2	Human factors	CF, CS, A, R	30 minutes
3	Human factors in context	CF, CS, A, R	30 minutes
4	How incidents evolve	CF, CS, A, R	30 minutes
5	A systems approach to patient safety	CF, CS, A, R	3 hours
6	Medico-legal issues	CF, CS, A, R	1 hour
	Reinforcing activity	**Questions**	**30 minutes**

This resource can be used as a stand-alone guide on clinical risk management in general practice, or as an RACGP QI&CPD activity such as:

- an individual (self-directed) active learning module (ALM)
- online gplearning ALM
- a small-group learning (SGL) activity.

When used as part of an educational activity, learners have the opportunity to gain additional QI&CPD points through completion of:

- individual or group plan, do, study, act (PDSA) cycles, and
- quality improvement reflective activities.

Individual (self-directed) active learning

ALMs are structured educational activities intended to improve GPs' clinical practice by enhancing their clinical knowledge, skills, attitudes and behaviours in a demonstrable way.

To be eligible for 40 Category 1 QI&CPD points, individual learners must:

- identify three to five measurable learning outcomes that can be mapped to the RACGP curriculum and domains of general practice

- ensure that at least one learning outcome addresses a systems-based approach to patient safety

- complete a minimum of 6 hours of structured educational content (excluding predisposing and reinforcing activities)

- ensure that more than two-thirds of this time is interactive or experiential. This can involve:
  - answering the included questions
  - discussing the included conceptual frameworks, questions, activities, case studies, and/or recommended reading
  - role playing.

Individual GP learning ALM

This educational resource can also be completed online as a gplearning activity. More information about this option can be accessed by logging into the gplearning portal via the RACGP website (www.racgp.org.au).

Small, group learning

To be eligible for 40 Category 1 QI&CPD points, for participation in a small-group learning activity, learners must:

- have a minimum of two GP participants and a maximum of 12 participants

- convene a documented planning meeting

- determine three to five measurable learning outcomes that can be mapped to the RACGP curriculum and domains of general practice

- ensure that at least one learning outcome addresses a systems-based approach to patient safety

- plan a series of sessions to achieve the agreed goals

- ensure individual sessions are at least 1 hour in duration

- complete a minimum of 6 hours of educational content

- convene a documented review meeting upon completion of the SGL activity.

PDSA cycles

This is an optional extra activity, worth an additional 40 Category 1 QI&CPD points.

A PDSA cycle refers to a 'trial-based' learning approach in which a quality improvement initiative is tested on a small scale before any changes are made to the wider system.

This is a cyclic process because a desired improvement may not be achieved in one cycle, hence the need to refine the original plan and repeat the process until the desired result is achieved.

Individual PDSA cycles

For individual learners to be eligible for an additional 40 Category 1 QI&CPD points, they must complete a minimum of two rapid PDSA cycles within a 3-month period. This is in addition to meeting all the requirements for the individual (self-directed) ALM listed above.

Group PDSA cycles

For small-group learners to be eligible for an additional 40 Category 1 QI&CPD points, they must complete a minimum of two rapid PDSA cycles within a 3-month period. This process must be led by an appointed facilitator. This is in addition to meeting all the requirements for the small-group learning activity listed above.

More information can be found in the RACGP QI&CPD handbook.

Quality improvement reflection

For the purposes of the QI&CPD Program, GPs must demonstrate they regularly participate in activities that review and evaluate the quality of their work.

Involvement in quality improvement activities is expected at least once every triennium, however, the extent and frequency will depend on the nature of the activity.

The QI&CPD Program recognises that quality improvement activities can take many forms. Inherent quality improvement activities are listed in the RACGP QI&CPD handbook. They include:

- small-group learning activities
- PDSA cycles.

More information about the criteria and point allocation can be found in the RACGP QI&CPD handbook.

Documented evidence

Evidence of successful completion must be recorded and submitted to your state faculty QI&CPD unit in the prescribed application forms for approval of:

- individual (self-directed) learning activities
- small-group learning activities
- PDSA activities
- quality improvement reflection.

The online application forms can be accessed by logging into your account and GP dashboard via the RACGP website (www.racgp.org.au).

For further information, please contact your state faculty QI&CPD team.

Reading and references

Recommended reading is included within each section. All recommended reading material is available from the RACGP John Murtagh Library or can be downloaded free of charge from the internet.

A full list of references is provided at the end of the module.

Predisposing activity: Improving patient safety

Instructions

This activity must be completed before undertaking the remainder of the education module to be eligible for the maximum number of QI&CPD Category 1 points.

This predisposing activity should take approximately 30 minutes to complete. Feedback is not provided for your answers. Many of the same questions will be asked in the reflective activity and you will receive feedback at that stage.

The aim of this predisposing activity is to explore your current understanding of patient safety. There is no need to consult external references to answer questions. Your results are not graded, so please simply record your immediate, personal response to questions.

If you are not in clinical practice when completing this activity, answer the questions by recalling your actions and thoughts when you were last practising or what you believe they would currently be.

Learning outcomes

By the end of this module, participants should be able to:

• define clinical risk, error, near-misses and adverse events

• discuss human and contextual factors that affect patient safety

• describe how patient safety benefits from a just and open practice culture

• describe how to skilfully identify, discuss and investigate patient safety issues

• describe how to skilfully have an open disclosure conversation with a patient and/or their family when an adverse event occurs

• implement patient safety improvement(s) as a result of insight into causal factors

• discuss the associated medico-legal risks and responsibilities.

Your personal learning outcomes

Use the learning outcomes in the RACGP Curriculum Statement on Quality and Safety to identify at least two learning objectives you would most like to achieve by completing this educational resource. Record your answers in the space provided.

Behaviours

Rate how often you do the following actions:

Behaviours	Rarely	Occasionally	Often	Almost always
1. Stop consulting when you are hungry				
2. Stop consulting when you are tired				
3. Demonstrate a willingness to take a thorough and constructive look at problems in patient care				
4. Discuss events that could have caused patient harm with a colleague				
5. Openly and honestly communicate with a patient who has been involved in an adverse event				

Attitudes

Rate the extent to which you agree/disagree with the following statements:

Attitudes	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
6. Medical error is usually the result of multiple factors					
7. Medical errors are common in general practice					
8. A tired health professional is a major threat to patient safety					
9. An angry health professional is a major threat to patient safety					
10. General practice work environments are usually just and open environments in which to address patient safety risks and incidents					
11. An apology – properly worded, expressed and timed – can address the fundamental human needs of a patient to be treated with respect					
12. The quality of the post-incident dialogue between patient and health professional influences whether an adverse event generates medico-legal activity					

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Skills

Rate your confidence in doing the following effectively:

Skills	Very low	Low	Neutral	High	Very high
13. Discussing with a colleague a concern that you have about their practice					
14. Employing communication skills to try to improve a difficult health professional–patient relationship					
15. Preparing for a conversation with a patient in which you disclose that an adverse event has occurred in their healthcare					
16. Documenting an investigation of an adverse event					

Knowledge

Respond true or false to the following statements:

Knowledge	True	False
17. Sincerely acknowledging the patient's and family's suffering as the result of an adverse event opens the door to litigation and should be avoided when disclosing an adverse event to a patient/family		
18. 'Let me tell you how sorry I am that this has happened' is a useful phrase when disclosing an adverse event		
19. Poor communication by the health professional is a common cause of litigation		
20. Copies of patient correspondence regarding an adverse event investigation should be kept in a dedicated incident investigation file separate from health records		

Systems

Do you currently have the following systematic strategies to improve patient safety?:

System	Yes	No
21. An acronym to remind you of the main human factors that threaten patient (and health professional) safety		
22. An ongoing and reliable way of developing an open practice safety culture where practice staff can freely discuss adverse events		

Conclusion

You have finished this clinical risk management predisposing activity.

Activity

Read one of the following references and write down 1–3 points of interest for you in the article. You can choose to share what you found noteworthy with other learners.

- Leonard M, Graham S, Bonacum D. The human factor: the critical importance of effective teamwork and communication in providing safe care. Qual Saf Health Care 2004;13(Suppl 1):i85–90. Available at www.ncbi.nlm.nih.gov/pmc/articles/PMC1765783/pdf/v013p00i85.pdf

- Duclos C, Eichler M, Taylor L, et al. Patient perspectives of patient–provider communication after adverse events. Int J Qual Health Care 2005;17:479–86. Available at http://intqhc.oxfordjournals.org/cgi/content/full/17/6/479?view=long&pmid=16037100

- The Australian Commission on Safety and Quality in Health Care. Open disclosure standard. Canberra: ACSQHC, 2008. Available at www.safetyandquality.gov.au

- Massachusetts Coalition for the Prevention of Medical Errors. When things go wrong: responding to adverse events. A consensus statement of the Harvard Hospitals. Burlington: Massachusetts, 2006. Available at www.macoalition.org

1. *Threats to patient safety*

Giving an incorrect vaccination, failing to follow up a test result or missing a diagnosis are all examples of situations where things just did not go to plan.

Most GPs and their team members can recall the first time in their professional lives when things went wrong, resulting in patient harm. Such unintended consequences can be confronting, even for experienced and skilled GPs and practice teams.

When things go wrong, GPs and their practice teams may question their clinical skills, worry about the medico-legal consequences or feel concerned about how their patient might react.

Often, GPs and their practice teams do not know what to say or do following detection of a clinical risk, error, near-miss or adverse event. However they all want to prevent such events from occurring.

1.1 Risk

Quick points

- Risks can be defined as anything that threatens a practice team's ability to achieve its clinical objectives.

- Risks can arise from a practice's operational, financial, legal or political context.

- Level of risk is determined by the likelihood of an event occurring and the severity of the resulting consequences.

Risk can be defined as anything that threatens a practice team's ability to achieve its clinical objectives or anything that increases the probability of patient harm.

Risk can arise from human (patient or healthcare provider) and contextual factors such as the:

- practice team's operational environment (practice setting, infrastructure, systems and processes, clinical standards, practices, organisational culture, practice management, staff education training, professional development)

- practice's financial arrangements (practice budget, resource allocation, contract management)

- legal factors (medico-legal responsibilities, statutory liabilities, occupational health and safety)

- political climate (changes to health legislation, regulations, funding, education/workforce reform, public health campaigns, or media coverage).[1]

In general, risk is characterised by reference to potential events and expressed in terms of the 'likelihood' and the associated 'consequences' or a combination of these.[4]

Likelihood is the probability of the event occurring and may be described in qualitative terms relating to the frequency of identified or known occurrence (A –E) while consequence is the impact that an event would have on practice objectives, ranging from insignificant to catastrophic (1 – 5).

Likelihood and consequence combined produce the level of risk (Low – Extreme). This can be assessed using a risk matrix such as that shown in *Table 1.1* below.

Table 1.1 A risk matrix					
Consequence					
	1	2	3	4	5
	No patient harm	Minor and brief patient harm	Patient has significant but brief adverse effect	Patient has significant sustained adverse effect	Patient severely affected and may die
A No identified or known incidents	Low	Low	Medium	Medium	High
B Few identified or known incidents	Low	Medium	Medium	High	High
C Some incidents have been identified	Medium	Medium	High	Extreme	Extreme
D Several incidents have been identified	Medium	High	Extreme	Extreme	Extreme
E Multiple incidents have been identified	High	Extreme	Extreme	Extreme	Extreme

Likelihood (row label for A–E)

1.2 Clinical error

Quick points

- Clinical error is an act of omission or commission that contributes to, or could contribute to, an unintended effect.

- Clinical error can occur at any stage in the assessment, treatment or supporting operational/administrative process associated with patient care.

- Unlike risks (which are predictive), clinical errors are not recognised until during or after the event.

Clinical error is defined as an act of omission or commission in the planning or execution of a health service that contributes to, or could contribute to, an unintended effect.[5]

Clinical errors are events in your practice that make you think: 'that was a threat to a patient's wellbeing and should not have happened. I do not want it to happen again'.[6]

Case study – Wendy

Wendy, aged 71 years, is a retired teacher who has seen Dr Suzanne Woo for several years.

Wendy has a 10-year history of arthritis and attends the clinic regularly, usually complaining of flare-ups related to her condition. Her last consultation was 2 months ago.

Wendy sees Dr Woo one Friday morning and has a long list of questions about the management of her arthritis. She also needs an annual influenza vaccination.

Dr Woo addresses Wendy's questions then leaves the consultation room while she retrieves the vaccine from the refrigerator. She prepares for the vaccination in the consultation room. As she is doing so, the telephone rings. It is Jenny, the receptionist, who indicates she has another patient, Mark, on the line with a query about an antibiotic Dr Woo prescribed for him this morning.

Dr Woo talks with Mark for 3 minutes and schedules a review appointment for him at the end of the day. After the call, Dr Woo finishes preparing the vaccination and administers it to Wendy.

As she discards the vial, she realises she has administered a Pneumovax instead of a Fluvax vaccine.

While some clinical errors are recognised immediately, such as Dr Woo administering the wrong vaccine, others – such as missing a diagnosis of breast cancer – may not be apparent for months or years after the error occurs.

Errors can be large or small, clinical or administrative, include actions taken or not taken, and can occur at any stage in the continuum of patient care:

- Prevention
  - Failure to provide prophylactic treatment
  - Inadequate follow-up.

- Diagnosis
  - Use of inappropriate investigations
  - Failure to follow up or act on test results
  - Error or delay in diagnosis.

- Treatment
  - Error in the performance of a procedure
  - Error in administering a treatment
  - Pharmacological complications
  - Avoidable delay in treatment
  - Failure of communication
  - Equipment failure
  - System failure.[7]

Contributing factors include:

- poor recordkeeping
- failure to review a patient's medical history
- illegible prescriptions
- ineffective communication between patients and/or healthcare professionals
- actions of others involved in the patient's care (including the patient)
- assessment-related factors such as errors in judgement, failure to recognise signs and symptoms, and inadequate patient assessment.[7]

The most frequently reported mitigating factors include:

- good fortune (chance factors)
- early intervention by the GP or patient
- the patient's good physical health.[7]

Where they occur, errors have the potential to give rise to near-misses or adverse events. These are explored in *Section 1.3*.

1.3 Near-misses

Quick points

- Near-misses are events that almost (but do not) result in harm.

- Instead of being forgotten, near-misses play on your mind as you look for probable causes.

- Near-misses share similar causes to adverse events and therefore provide a useful way to identify safety issues before patient harm occurs.

A near-miss is an event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention.[8]

Case study – Rob

Dr Smith and Dr Kinsley work in a large practice with three practice nurses and a three-bed treatment area. The patient's name and required treatment is written on a vaccine request form and placed on the desk in the treatment area.

Dr Smith's patient, Rob Jones, presents with large splinter in his foot. As it has been many years since Rob's last tetanus shot, Dr Smith removes the splinter and asks Rob to wait near the treatment area for a tetanus vaccine.

Dr Kinsley's patient, Ron James, presents for his second dose of hepatitis A vaccine prior to an overseas working holiday. He had been given a booster dose of tetanus vaccine and combined hepatitis A and typhoid 1 month earlier.

Susie, an experienced practice nurse, has been asked by Dr Smith to give Rob a tetanus vaccine. She calls the name 'Rob Jones' and Ron James, who is sitting closest to her, indicates that he is the patient and follows her to the treatment room.

As she is about to administer the vaccine, Susie pauses and asks Ron to repeat his name and date of birth. She immediately realises that his name is different to that on the vaccine request form. She asks Ron what vaccine he is meant to be having.

Susie realises that she has just averted a possible adverse event and that this patient safety incident would be considered a near-miss.

After averting a possible adverse event, Susie is concerned about the potential for the incident to occur again. After discussing her concerns with her team leader, it is decided that the incident and potential safeguards will be discussed at the practice team meeting scheduled for the following day.

All team members at the practice team meeting are made aware of the near-miss and are informed of new procedures that will be implemented to reduce the risk of future confusion and patient harm.

A near-miss can be different to other lapses in safety. Instead of being forgotten or dismissed, near-misses continue to play on the mind of those involved while they try to identify what went wrong and how to prevent the incident from occurring again.

> *'It played on my mind. I kept thinking about it after I went home. It could have been disastrous.'*

Because near-misses share similar causes to adverse events (ie. they are indistinguishable from adverse events that cause harm in all but the outcome), they give us the opportunity to learn from mistakes and develop preventive strategies and safeguards.

1.4 Adverse events

Like near-misses, adverse events arise from errors: that is, acts of commission or omission in the planning and execution of a health service. However, in contrast to near-misses (that do not cause harm) adverse events may result in unintended patient harm.

Case study – Michael

Michael attends Beachside Practice late on a Friday afternoon. He has a minor dog bite to his leg, sustained while running on the beach after work.

The practice nurse, aware that the GP is running very late, cleans and dresses the wound. She then asks the GP, Dr Quick, to review the patient prior to him leaving the surgery and to chart the adsorbed diphtheria and tetanus (ADT) immunisation administered.

Dr Quick observes a fit-looking young man. He does not look at the wound but accepts the nurse's clinical opinion that it is a minor wound that has been cleaned and dressed appropriately.

Dr Quick is unfamiliar with the patient but asks him if he has any health problems or is taking any medication, to which the patient replies, 'No'. Dr Quick makes a brief note in the patient's file but does not review the patient's medical history.

Three weeks later, Michael presents to Dr Quick complaining of fevers, sweats and shortness of breath. On reviewing his medical record, Dr Quick realises that Michael has previously been diagnosed with a heart murmur due to rheumatic fever in childhood.

The dog bite wound is severely infected. Michael is admitted to hospital with acute bacterial endocarditis. He requires many weeks of intravenous antibiotics and ultimately a mitral valve replacement.

This serious outcome would have been largely preventable if antibiotics had been prescribed at the time of the injury. Michael failed to mention his health condition because he had felt well for many years. Dr Quick had failed to review the patient history and therefore did not identify the need for prophylactic antibiotics.

While some people use these two terms interchangeably, 'adverse event' and 'adverse outcome' have quite different meanings. An adverse event is an incident in which unintended and unexpected harm resulted to a person receiving healthcare. An adverse outcome is a less than optimal outcome for the patient, which was not preventable and was not the result of a system's failure, nor a consequence of their healthcare'. That is, an adverse outcome is primarily related to the natural course of the patient's illness or underlying condition.[8]

1.5 Frequency of occurrence

Quick points

Available research suggests:

- one error occurs per 1000 Medicare items billed

- there are two errors for every 1000 patients seen

- for every fatal accident, there are 600 minor incidents (requiring only first aid) that can reveal opportunities for safety improvement.[9]

Available research

Research into the frequency of errors, near-misses and adverse events is limited in Australian general practice. Therefore, it is difficult to determine its true rate of occurrence.

Existing studies have used different definitions and methods of data acquisition such as:

- direct observation of patient care

- retrospective review of case notes

- use of data from national reporting systems

- use of indirect measures such as hospital admission rates (as an indicator of the quality and safety of general practice care).

This has led to highly variable conclusions. The largest and most comprehensive study to date has been the Threats to Australian Patient Safety (TAPS) study conducted in 2006. The sample of participating GPs reported one error for every 1000 Medicare items billed, and about two errors for every 1000 individual patients seen.[9]

Reading

- Makeham MAB, Kidd MR, Saltman DC, et al. The Threats to Australian Patient Safety (TAPS) study: incidence of reported errors in general practice. Med J Aust 2006;185:95–8.

The Bird ratio

Because risks, errors, near-misses and adverse events are considered part of the same chain of events, some safety analysts have concluded that the causes of (relatively high-frequency) nonfatal incidents should be investigated to prevent them from recurring and causing more serious harm.

This view hinges on the work of Frank Bird and Herbert Heinrich. In 1969, Bird, who was then the Director of Engineering Services for the Insurance Company of North America, undertook a study of industrial accidents.[10] He was interested in the accident ratio of 1 major injury to 29 minor injuries to 300 no-injury accidents first discussed in the 1931 book, *Industrial accident prevention* by Herbert Heinrich. Since Heinrich estimated this relationship, Bird wanted to determine what the actual reported relationship of accidents was by the entire average population of workers.

Bird analysed more than 1.75 million accidents reported by 297 cooperating companies. These companies represented 21 industrial groups employing 1.75 million employees who worked over 3 billion hours during the exposure period analysed. The study revealed that for every reported fatal accident, there were 10 reported serious accidents (resulting in disability), 30 accidents (involving lost time or medical treatment) and 600 incidents requiring first aid (*Figure 1.1*).[10]
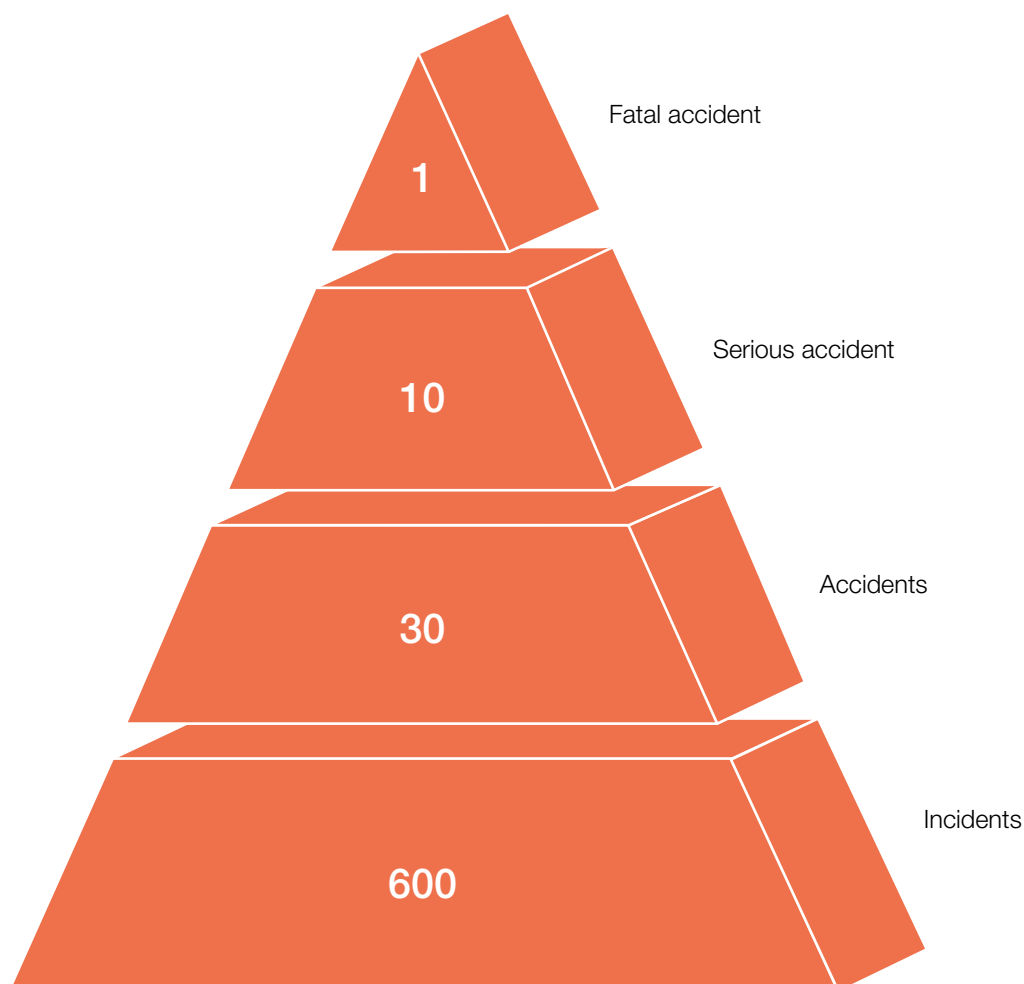
Figure 1.1 The Bird ratio

Source: O'Neill, S., Martinov-Bennie, N, Cheung, A and Wolfe, K. (2013) Issues in the measurement and reporting of work health and safety performance, 'Accounting for WHS Governance' Research Paper 2. Safe Work Australia. Canberra, November.

1.6 The benefits of risk and incident management

Quick points

Risk and incident management:

- improves the quality and safety of patient care
- reduces the risk of adverse events and costly litigation
- improves treatment outcomes and patient experiences
- improves staff morale, job satisfaction and retention.

Risk and incident management is an integral part of good clinical governance. It is an iterative process consisting of steps, which, when undertaken in sequence can:

- improve the quality and safety of patient care
- reduce the risk of adverse events and costly litigation
- improve treatment outcomes and patient experiences.

As will be discussed in later sections, successful implementation of risk and incident management systems involves creating a 'safety culture' that is open, inclusive and supportive of those who want to actively participate in risk and incident management. This results in improved staff morale and job satisfaction, which correlates with greater discretionary effort.[11] Greater discretionary effort can in turn lead to improved patient care and higher levels of both patient and practice team satisfaction. Improved staff morale and job satisfaction has also been correlated with longer staff retention, thus cutting the cost of ongoing performance management and recruitment efforts, which can cost a practice 90% of an average-performing staff member's salary or up to 200% of a high-performing staff member's salary.[12]

The improved patient safety resulting from proactive risk and incident management has a further positive flow-on effect by reducing litigation and impacting favourably on GPs' medical indemnity premiums. Some medical indemnity insurers now offer GPs and general practices reduced premiums if formal risk and incident management systems are in place for quality improvement purposes, as this lowers their risk profile.

Finally, having risk and incident management systems in place helps general practices meet the *RACGP Standards for general practices*[13] for accreditation purposes. A practice's accreditation status determines its eligibility for Medicare Practice Incentive Program payments.

2. Human factors

2.1 What are human factors and why are they important?

Although errors are (more often than not) the result of factors beyond the individual themselves, human factors have an important role to play in patient safety. Therefore, it is important to understand what they are and why they are important.

Quick points

- Human factors are our individual characteristics, capabilities and limitations.
- Human factors can have a positive or negative impact on patient safety.
- Human factors interact with other factors in a situation to produce a positive or negative outcome.

By definition, human factors are our individual characteristics, capabilities and limitations. These are all the personal qualities that individuals bring to their position of employment, such as intelligence, knowledge, skills, experience, sensory capabilities and attitudinal states such as alertness, motivation or fatigue.[14] These qualities influence all that we do, and how we interact with other factors in various environments.

Human factors are also dynamic and can change in any given situation, exerting either a positive or negative influence on the course of events. What often determines whether human factors have a negative or positive effect on a situation is whether the participants are absentminded or present-minded in their actions.

2.2 Absent-mindedness

Quick points

- We are all absent-minded at times (both at home and work).
- Absent-mindedness increases the risk of human error occurring.
- Absent-mindedness can be prevented (or reduced) by being alert to internal and external cues (being present-minded).

'One day in the late 1970s, Professor James Reason was making tea while the cat was clamouring to be fed. He efficiently opened the tin of cat food and put it in his teapot. The two components got mixed up. Both the teapot and the cat's feeding dish afforded the same opportunity – putting "stuff" in.'

Often we do not need to think too deeply about what we are doing if it is a simple task or if it is something we have done before. In fact, it is sometimes better not to over-think some tasks, as this can disrupt the task or potentially take our concentration away from something else we may need to do at the same time.[15]

However, at some stage, we have all unintentionally done or forgotten to do something, just as Professor Reason did when he put the cat food in the teapot.

When unintended consequences arise, we can sometimes think of reasons as to why it has happened – perhaps we were tired, distracted or in a hurry. However, in other instances, we cannot due to absent-mindedness.

Absent-mindedness increases the risk of human error occurring. Consider the case of Francesca.

Case study – Francesca

Francesca presents to the practice late on a Friday afternoon with a laceration on her right forearm. She does not have a scheduled appointment but asks to see her regular GP, Dr Myers, this afternoon. Dr Myers agrees to squeeze her in at the end of the day to suture the cut.

Dr Myers asks the new practice nurse, Claire, to set up for her in the treatment room and have Francesca ready for her procedure.

The nurse takes a suture pack from beside the steriliser where a number of packs have cooled and are ready to be put away. Because the day has been very busy, Claire has not yet had a chance to put them back on their usual shelf.

She is quite preoccupied with all that she needs to do to have everything set up to Dr Myers' liking and does not notice that the pack she picks up is one that has been cleaned and wrapped but has not yet been sterilised

Dr Myers hurries into the treatment room to begin cleaning and suturing the wound and registers that something is not quite right. After a brief reflection she recognises that the tape on the sterile pack has not changed colour as it would have if the pack had been through the steriliser.

Claire acknowledges that she must have picked up an unsterilised pack by mistake.

By recognising the role that absent-mindedness plays in the occurrence of human error, we can identify ways of preventing it, thus mitigating the risks absent-mindedness poses to patient safety.

Common circumstances under which absent-mindedness may occur are when a person is Hungry, Anxious/Angry, Late or Tired (HALT). A useful way to remember these four human factors that can compromise patient safety is to use the HALT acronym.

When you see these human factors in yourself or others, this acronym can help remind you to HALT what you are doing, re-assess the situation, and implement safeguards to support patient safety.

Consider the following example of the anxious patient, Sarah.

Case study – Sarah

Sarah, aged 35 years, has recently moved into the area. She comes in to see you as she is worried about a mole on her arm. She seems quite anxious and says she is in a hurry.

On further questioning, you find the mole has not changed recently and on examination it does not look suspicious. You reassure Sarah and ask her to regularly check the mole and come back to see you if it changes. You explain to Sarah what she needs to look for: the shape, colour and size. She seems to understand what you say.

You then:

- Photograph the mole and keep this image and a written description of the mole in Sarah's notes and record that you have advised her to keep 'watch' for any changes to the mole and return to you if she sees a change.

OR

- Photograph the mole and keep this image and a written description of the mole in Sarah's notes and record your advice (as above) but also provide her with printed information. The handout lists what Sarah needs to watch for and reinforces your verbal advice. You note in her patient record that you have given Sarah this written information.

Potential outcomes

- As a result of Sarah's anxiety and lack of concentration in the consultation, she goes home and misunderstands your advice. Sarah notices changes to the mole but believes that your advice was that she did not need to return unless she notices another mole looking different. Sarah returns to see you two months later for an oral contraceptive pill prescription and you notice the mole now looks suspicious. The mole looks different from the description you wrote in the notes and from the photo you took. You remove the mole and pathology identifies a melanoma in situ and the margins of the excision are clear.

OR

- One month after seeing you, Sarah notices that the mole looks more raised than before. She reads the note that you gave her and follows your advice to return to you. When you see her the next day, you remove the mole. Pathology shows the mole was a melanoma in situ and the margins of the excision are clear.

Both of these pathways result in near-misses. However, one had more potential to result in an adverse event. In the first example, luck (in the patient returning for another condition) was the initiating safeguard against harm. Your subsequent vigilance and detailed notes ensured the mole was managed, but the outcome could easily have been poor.

In the second example, you empowered Sarah to take an active role in her own care by recognising her limited ability to understand and recollect important information during the first consultation. This prompted the use of a safeguard (the written information) and promoted shared responsibility.

Activity

Absent-mindedness at work

Consider a time when you have been absent-minded at work. It may be as simple as putting out your hand to pick up the telephone only to remember that the telephone was moved to the other side of the desk a week ago.

- What do you think caused you to act absent-mindedly?

- What could be done to prevent the same absent-minded action occurring again?

Reading

- Reason J. Absent mindedness risk management. The Health Report, ABC Radio national, 19 December 2005. Available at www.abc.net.au

2.3 Present-mindedness: linking internal and external cues

A useful way to understand what makes great GPs and practice teams is to reflect on their ability to:

- listen to intuition while drawing on knowledge and experience (internal cues)

- respond quickly or pre-emptively to external factors (external cues)

- communicate well with others both in the team and with patients.

Being aware of internal and external cues is integral to clinical excellence because it leads to two fundamentally important risk-mitigating human factors:

- present-mindedness (the opposite of absent-mindedness)

- error-wise practice.

When we correctly locate or do something which we could easily have done incorrectly (due to absent-mindedness) we are acting in a present-minded way. That is, something in our thought pattern intervenes to prevent us acting in an absent-minded way. In these circumstances we are in tune with internal and external cues and are able to interpret and respond to them. This is a positive human factor – that of being aware of, and appreciating, the impact of multiple factors in a situation.

Consider the following example.

Case study – Melanie

Melanie comes in to see Dr Morgan. She brings her 2-year-old daughter with her, as she was not able to find a babysitter. Melanie explains she has noticed a small lump behind her ear which she is worried about.

She is quite distracted by her daughter who, although being held on her lap, is inquisitive and not happy to sit still. As a result, Dr Morgan also finds it more difficult to examine and speak with Melanie.

Dr Morgan discovers Melanie has been unusually tired and has had symptoms consistent with a cold for the past two days. Melanie explains she initially thought it was 'just a cold' but became concerned when she noticed the lump.

As a result of the child's restlessness, it is difficult for Dr Morgan to explain that he believes it is probable the lump is an enlarged lymph node related to her cold. He explains the usual treatment for a cold and advises Melanie to come back if she continues to feel unwell or worse, if the lump changes or does not resolve.

As Melanie is tired, unwell and distracted, Dr Morgan decides to write down the main points of what he has explained so when Melanie gets home, she will be able to re-read it and remember what was discussed.

Dr Morgan also finds writing the information down has helped to clarify his thoughts. Dr Morgan notes in her medical record that written information was given and why.

In this example, Dr Morgan demonstrates awareness of internal cues, such as the child distracting her mother, thus reducing her ability to understand what was discussed – the external cues. Dr Morgan also noticed the child's behaviour was making it more difficult for him to think clearly and convey important information – another example of an internal cue. Dr Morgan's awareness of such internal and external factors, and his ability to see the potential to reduce patient safety, is a positive human factor – that of situational awareness. As a result, Dr Morgan was able to implement safeguards to compensate for negative situational factors and thus improve the treatment process and outcome.

Figure 2.1 is a diagrammatic representation of how Dr Morgan might have consciously weaved backwards and forth between the internal and external realms of information.

External cues	Weaving back and forth	Internal cues
Clinical presentation		Patient distracted by the child – reduced ability to understand
Results of physical examination		Doctor distracted by the child – reduced ability to think
Clinical advice/actions taken		Patient's experience

Integrated understanding and course of action
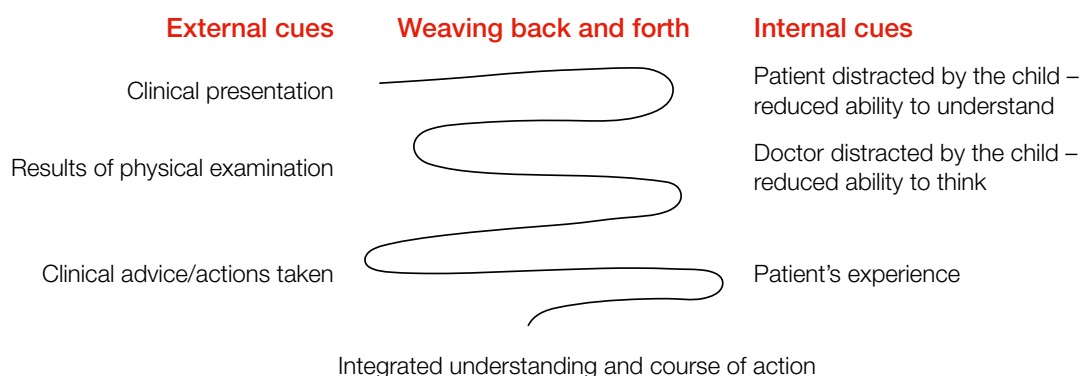
Figure 2.1 Present-mindedness and the patient-centred model of care[16]

Activity

Patient-centred care

Consider a time when your awareness of internal and external cues prompted you to identify or respond to a patient in a way that supported their safety.

- What were other factors involved in the situation?

- How could you use the patient-centred medicine model to represent these factors?

2.4 Error-wise practice

Quick points

- Being aware of the potential for errors is being error-wise.

- Such present-mindedness enables a quick and effective response to errors if and when they occur.

'Being error wise is recognising situations that have a high potential for causing harm.'[17]

No situation can be impermeable to negative human or other situational factors. Negative factors will always prevail to an extent.

Great GPs and practice teams are not necessarily the ones not making errors. They are the ones who:

- recognise error-prone situations

- are aware of the potential for a situation to result in harm

- have contingencies in place

- detect their errors

- compensate for their errors.[17]

This constitutes error-wise practice. Reason describes this as an 'attitude of mind' which involves:

- accepting that errors can and will occur

- looking for potential hazards before embarking upon a task

- having contingencies ready to deal with anticipated problems

- not letting professional courtesy get in the way of checking colleagues' knowledge and experience, particularly when they are strangers

- appreciating that the path to adverse incidents is paved with false assumptions.[18]

Consider the following example.

Case study – John

John, aged 48 years, is married with a teenage son. You have been his GP for the past 5 years. He is known to have asthma. He takes an inhaled corticosteroid and uses a reliever which effectively controls his asthma.

Today John presents to you feeling more short of breath than usual and is using his reliever more often. John has removed the carpet in his home and is sanding the floorboards. These environmental changes may be exacerbating his asthma. However, your instincts tell you there is more to it. On questioning, you find out John also has chest pain on exertion. He tells you he did not want to mention this as, 'It's not important and the pain goes away quickly'.

He says that as the pain occurs, he takes a couple of paracetamol tablets, sits down for a rest and the pain eases. John believes his shortness of breath is 'just his asthma playing up'. On further questioning, John tells you his father died following a myocardial infarction at 51 years of age and he is fearful of having the same heart disease.

Your instincts in this case led you to further discuss and investigate the symptoms with John. It also led to John describing his cardiac symptoms, which you were able to investigate and address. Your instincts also allowed you to open up a channel of communication with John. This gave him the opportunity to discuss his fears and emotions in response to his father's death.

The positive outcome you achieved is a result of listening to your instincts (internal cues) – a human factor that can promote patient safety.

Activity

Error-wise practice

Consider how you can implement error-wise practices in your practice.

- If you have already implemented some of these practices, how did you achieve this?
- What went well? What would you do differently next time?

Reading

- Lertzman R. From absentminded to error-wise: a conversation with James Reason. Safer Healthcare, 3 January 2006. Available at www.saferhealthcare.org.uk

2.5 Error-wise practice: using reminder systems

Quick points

- Effective reminder systems can support error-wise practice.
- There are five universal elements to an effective reminder: conspicuity, contiguity, content, context and countable.

Reminder systems can be used to manage risk or the potential for error. Reminders can promote positive human factors such as being alert to potential hazards. James Reason identifies the five universal elements of a good reminder as:

- conspicuity – being able to catch a targeted person's attention at the critical time
- contiguity – being positioned as close as possible in time and space to the location of the necessary action
- content – providing enough information about what needs to be done
- context – providing information about the 'when' and 'where' of the item to be remembered
- countability - allowing the targeted person to count off the number of discrete actions or tasks to be done.

Understanding how a reminder can be made effective enables us to design and integrate reminders in our work environment that can be used effectively by all team members.

Activity– Using reminder systems

Information technology can facilitate electronic appointment scheduling, provide clinical decision support and clinical protocols and help maintain disease registers linked to patient recall and reminder systems. These can enable patient safety.

- What do you think the biggest challenges are in routinely using electronic recall and reminder systems?
- What can be done to overcome these challenges?

Reading

- Reason J. Combating omission errors through task analysis and good reminders, Qual Saf Health Care 2002;11:40–4.
- Makeham MA, Saltman DC, Kidd MR. Lessons from the TAPS study: recall and reminder systems. Aust Fam Physician 2008;37(11):923–24.

2.6 Avoiding error traps

Quick points

- Error traps are circumstances that cause the same errors to occur irrespective of who is involved.

- Awareness of the potential for error traps (through situational awareness) can help us implement safeguards to prevent an error from recurring.

'There are circumstances which lead people to make exactly the same kind of error. We're not talking about error prone people, we're talking about error prone situations.'[17]

Error traps are circumstances that can cause the same error to occur repeatedly irrespective of the person involved. Often the person who falls in the trap appears to be to blame.

Being aware of this possibility is an important first step to safeguarding patient safety. To become aware, we need to link our internal and external cues in a situation so we can understand the potential threat.

Once we know a threat exists, we can do something to prevent it causing harm – that is, implement a safeguard. Consider the historical case study of Organon, maker of the contraceptive implant Implanon. Implanon was first introduced in Australia in May 2001. Factors such as convenience, low cost to patients and the apparent low failure rate made it attractive to many Australian women, resulting in rapid uptake. Yet in the 18 months following its introduction, Implanon was associated with an unprecedented number of adverse incident reports to medical indemnity insurers, including almost 100 unintended pregnancies.[19]

Case study – Error traps (Implanon)

Implanon is a progestogen-only implant that acts as a long-term (3-year) contraceptive. In clinical trials it demonstrated a lower failure rate than existing forms of contraception, such as the oral contraceptive pill and barrier methods.

Training sessions for GPs appear to have focused on teaching them how to insert the implant, practising on a manikin, but did not fully explore the problems that could arise when the implant was used in clinical practice. The sessions had a high attendance rate by GPs, who were keen to learn the insertion technique, but many still reported problems with clinical use.

The implant is supplied with an applicator that looks similar to a syringe, with a cannula and obturator ('plunger'). However, the technique of insertion is opposite to that for a syringe, as the obturator remains fixed while the cannula is withdrawn. Many health professionals who attended training sessions reported that this counterintuitive action was not easily mastered.

In addition, the implant and obturator used in the training sessions contrasted in colour (blue and white, respectively), while those supplied in the commercial product were both white. This was extremely confusing for some health professionals when they first used the implant clinically. Further, there was little emphasis in the training sessions on the disclosure of risk and the need to adequately document the process and procedure.

The implant could be difficult to palpate if inserted deeper than the subdermal layer or if the area was swollen. Consequently, some patients remained fertile when they assumed they had adequate contraception.

A proportion of unintended consequences (including almost 100 in the first 18 months of release) resulted from the use of Implanon.

The reasons behind the unintended consequences were not always clear; possibilities include failure to insert the implant, timing of insertion, implant failure, migration away from the site of insertion, difficulty finding and removing the implant due to it not being radio-opaque and interaction with other medications.[19]

How might a GP and their practice team have avoided this error-trap? *Figure 2.2* shows internal and external cues that could have been used to identify and mitigate the risks to patient safety.

External cues	Weaving back and forth	Internal cues
The practice is very busy today		I feel tired and hungry as I worked through lunch
The applicator is the same colour as the implant		It did not seem like the implant inserted properly
I am unable to palpate the implant after insertion		I have heard of others experiencing problems with insertion due to product design
I am unable to see if the implant is still in the applicator		

Awareness to support patient safety

↓

Implement safeguards

Figure 2.2 Implanon example: awareness of internal and external cues[16]

In view of the internal and external cues, the treating GP could have implemented the following strategy to avoid the existing error traps:

- Schedule an initial appointment to:
  - disclose the risks and benefits
  - check for contraindications
  - explain the procedure
  - plan the appropriate date of insertion having regard to the patient's menstrual cycle
  - provide information about the cost of the procedure.

- Allow adequate time during the insertion appointment to:
  - verify the patient's consent/form
  - check the device before insertion
  - palpate the implant after insertion
  - advise the patient of recommended follow-up.

- Subsequently document insertion and removal of the implant according to the RACGP's checklist and record this in the patient's medical record.[20]

3. Human factors in context

3.1 Human factors in context

Quick points

- Human factors are one element in a cluster of factors that influence outcomes and can increase or reduce the likelihood of error.

- To understand the role of human factors, we need to appreciate that they interact with other factors in a situation.

Human factors do not exist in isolation – they exist within a dynamic environment where other factors co-exist and exert an influence. This includes human, task and contextual factors such as:

- patient characteristics (age, gender, ethnicity, lifestyle)

- healthcare provider characteristics (knowledge, skills, experience)

- nature of the work (tasks/procedures, complexity of treatment, caseload)

- physical environment (lighting, noise, temperature, distractions, layout)

- social environment (organisational culture, group norms, staff morale, communication)

- management (staffing, organisational structure, rostering, commitment to quality and safety).[14]

In 2005, Rosser studied the rate at which such factors contribute to general practice errors in Australia, England, the Netherlands, New Zealand and the United States. It was found that errors were due to:

- process factors, eg office administration, filing, charts (80%)

- environmental factors (60%)

- service provider factors (60%)

- patient factors (nearly 39%).[21]

The example of Dr Walters illustrates the interaction of human and contextual factors and the resulting potential for error.

Case study – Dr Walters

Sunny Dale Practice usually stores the lignocaine with adrenaline and the plain lignocaine next to each other in the cupboard in the treatment room. The boxes containing the ampoules, and the ampoules themselves, are the same size.

A recent near-miss occurred when Dr Walters almost used the lignocaine with adrenaline for a ring block of a finger. She noticed that she had picked up the wrong ampoule when she went through her mental checklist (drug, dose, route) before she gave the anaesthetic. As a result, the practice staff team had a meeting where they discussed the near-miss. It was agreed that the boxes of anaesthetic would be placed apart from each other, in different areas of the medication cupboard. In addition, red coloured stickers would be attached to the box of lignocaine with adrenaline. This would help distinguish it from the plain lignocaine.

Tony, a practice nurse, was not at the practice staff meeting where the incident and proposed solution were discussed and there was no note on the cupboard advising of the changes. Tony did not understand why the boxes had been moved. He put the boxes back to their original position where he thought they belonged. Soon after, Dr Morgan went to use the plain adrenaline but absentmindedly picked up the lignocaine with adrenaline (which was placed back near the plain adrenaline). Dr Morgan noticed the error when he checked the ampoule and realised it contained adrenaline.

The practice decided to start a communications book to ensure all team members are alerted to important information. A note was also placed on the cupboard to remind all team members of the change.

Human factors

The positive human factors in this case study include Dr Walter's awareness of the potential for incorrect medication administration and her mental checklist, and Dr Morgan's visual check of the ampoule.

The negative human factors include the failure to communicate important information and the failure of Tony, the practice nurse, to ask another team member about the external cues: the boxes being in a different place and the red label attached to the lignocaine with adrenaline box.

Resource factors

The resource factors include the different coloured labels that were available to colour code the lignocaine (a positive factor and safeguard) and the failure to put a reminder note on the cupboard advising of the changes (a negative factor and failure to safeguard).

System factors

The compromising system factors include the lack of a communication system to support the verbal communication at the practice staff meeting. This would have ensured that staff who were not present at the meeting were nonetheless notified of the changes.

Environmental factors

The environmental factors include the busy practice in which the doctors and other practice staff work.

3.2 The three bucket theory

> ### Quick points
>
> - The three buckets are tools for measuring the overall mix of positive and negative factors for assessing patient safety.
>
> - The three buckets are self, context and task.
>
> - The 'sum' of the positive and negative factors in each bucket provides a clue to the tendency of a situation to be positive or negative for patient safety.
>
> - This assessment can be used to identify deficits and indicate where possible safeguards could be implemented.
>
> - A situation cannot be made free of all potentially negative factors, therefore the aim is to reduce these as much as possible while increasing and supporting positive factors.

A useful way to think about the mix of positive and negative factors in a situation is provided by Reason, who describes a 'three bucket model of error likelihood'.[18] In this model there are three areas or 'buckets' that influence error likelihood (*Figure 3.1*).

Self   Context   Task

Figure 3.1 The three bucket model

Within each of these 'buckets' there is a mix of positive and negative factors and influences (eg. tiredness increases the negative factors in the 'self' bucket but there may be increased positive factors in the 'task' bucket, such as the task being straightforward). The overall mix of positive and negative factors across the buckets may result in a net positive balance for patient safety. In any given situation, the probability of unsafe acts being committed is a function of the amount of 'bad stuff' in all three buckets.[18] Reason notes that full buckets (with respect to the bad stuff) do not guarantee the occurrence of an unsafe act, nor do almost empty ones ensure safety (they are never wholly empty). We are dealing with probabilities rather than certainties.[18]

This way of thinking about a situation and the propensity for error is simple and quick. Consider the following example of David.

Case study – David

On Monday, a senior receptionist calls in sick. Belinda, one of the practice nurses, helps out Trudy, the junior receptionist who is on duty.

While Belinda is seeing a patient, David, a new patient, calls the practice. He assertively asks to see one of the GPs that day. Trudy attempts to advise David that he needs a long appointment (as the practice policy is for new patients to have a long appointment) but that there are none left for the day. David downplays how long he needs to see the GP and explains that he is in quite a bit of pain. Trudy 'gives in' and fits David into a short consultation with Dr Morgan.

When David, aged 67, arrives, Belinda is busy speaking to a patient on the telephone. Dr Morgan calls David in before Belinda is able to complete a new 'patient check' or advise Dr Morgan that she has not had the chance to do this.

When completing a new patient check, nurses make a note on the computer record if the patient has an allergy, or if none, 'nil known' is recorded. The software automatically defaults to 'nil' if no information is entered.

Dr Morgan does not realise David has not been seen by the nurse, and misunderstands the 'nil' under allergies to indicate the patient has been asked about allergies.

As David is leaving, he asks Dr Morgan what he should do for the pain in his back until tomorrow when he is scheduled for a longer appointment. Dr Morgan hands David a sample packet of an analgesic medication and advises him to use a heat pack.

As he is about to take his first dose of the analgesic, David notices that it contains codeine, which he is allergic to. He decides not to take the medication and mentions it to Dr Morgan the next day.

In this example of a near-miss, we can see the three buckets of self, context and task, each having positive and negative facts in them (*Tables 3.1a–c*).

Table 3.1a Self	
Potentially negative	**Potentially positive**
Trudy is not assertive with David over the telephone	Trudy is aware of practice policy for long appointments
Dr Morgan is very busy and probably tired	Dr Morgan checks the allergy information on the patient record
Belinda does not communicate that the new patient check had not been done	David is aware of his allergies and checks the medication before taking it
Dr Morgan does not appreciate the potential for confusion as a result of the software default setting to 'nil'	
David does not tell Dr Morgan about his allergy	

Table 3.1b Context	
Potentially negative	**Potentially positive**
It is a busy day at the practice	Reception duties continue with Belinda's help
The senior receptionist is away	Dr Morgan arranges for David to return for a longer appointment the next day to complete a thorough assessment
As a result of Belinda helping on reception, she has reduced ability to undertake her usual duties	
A short consultation reduces Dr Morgan's ability to assess David properly. Other patients are booked, so he is unable to extend the appointment	

Table 3.1c Task	
Potentially negative	**Potentially positive**
A new patient check is not completed, which reduces the information available for Dr Morgan	Dr Morgan checks David's allergies on the electronic record
There is insufficient time for a thorough assessment, which is compounded by the lack of new patient check information	Dr Morgan advises David of the need to return the next day for a longer appointment
Dr Morgan does not confirm allergies with David	

Overall we can see there were more potentially negative factors involved and this is consistent with the outcome – a near-miss (the patient nearly took medication which he is allergic to). Therefore it would be important to counter these negative factors by increasing the positive factors (including the human factors which are included in the 'self' bucket).

Activity

Applying the three bucket model

Think about a situation where you could see potentially negative factors in one of these buckets (self, context or task) and where a positive factor(s) in another compensated to ensure patient safety.

- Consider what factors were involved, which bucket they fit into, and how they influenced the outcome.
- Also think about what the positive factor was and how you could promote this in other situations.

4. How incidents evolve

Quick points

- Risk, errors, near-misses and adverse events share similar causes.

- Reason uses the Swiss Cheese Model to illustrate how errors can lead to near-misses or adverse events.

- Dovey's Toxic Cascade Theory likens risks, errors, near-misses and adverse events to a stream that begins as a trickle and ends as a torrent.

In the previous sections, we reflected on some human and contextual factors that can positively or negatively influence patient safety. Here we will look at how these factors can contribute to or prevent a near-miss and/or adverse event over time using:

- Reason's Swiss Cheese Model [22]

- Susan Dovey's Toxic Cascade Theory.[23]

In closing we will look at how these theories help us to learn from space shuttle disasters.

4.1 The Swiss Cheese Model

Reason, an English academic, has spent much of his life looking at why errors and accidents occur in the aviation industry and in healthcare. Reason proposed what is referred to as the Swiss Cheese Model of system failure. According to this model, every step in the patient treatment process is likened to a slice of Swiss cheese as:

- the holes in each slice represent opportunities for clinical error

- the cheese represents a defensive barrier.

In an ideal system, an active or latent error that passes through a hole in one layer is intercepted by the cheese in a subsequent layer, thus averting disaster (*Figure 4.1*). The more cheese and the fewer (or smaller) holes in each layer, the lower the risk of an adverse event occurring. Consider the below application of the Swiss Cheese Model to the prevention of an adverse reaction to codeine.

4. Intercepted by effective GP-patient communication

3. Further undetected due to incomplete medical record

2. Allergy undetected due to administration error

1. New patient with undisclosed allergy to codeine

5. Adverse reaction to codeine averted
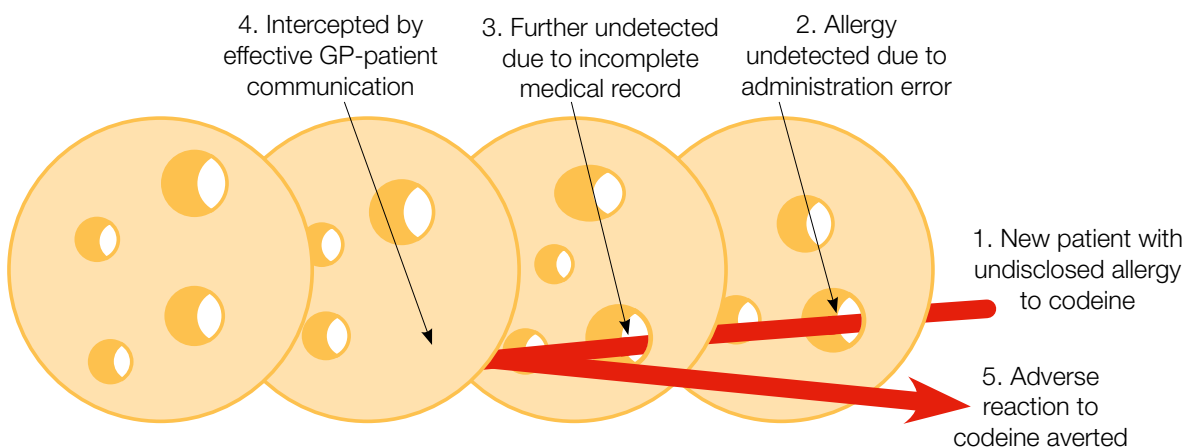
Figure 4.1 An ideal system[22]

For an adverse event to occur, all the holes need to be aligned, allowing an error made at the beginning of the treatment process to be carried through from start to finish – thus compromising patient safety. This is an inherently flawed system (*Figure 4.2*).
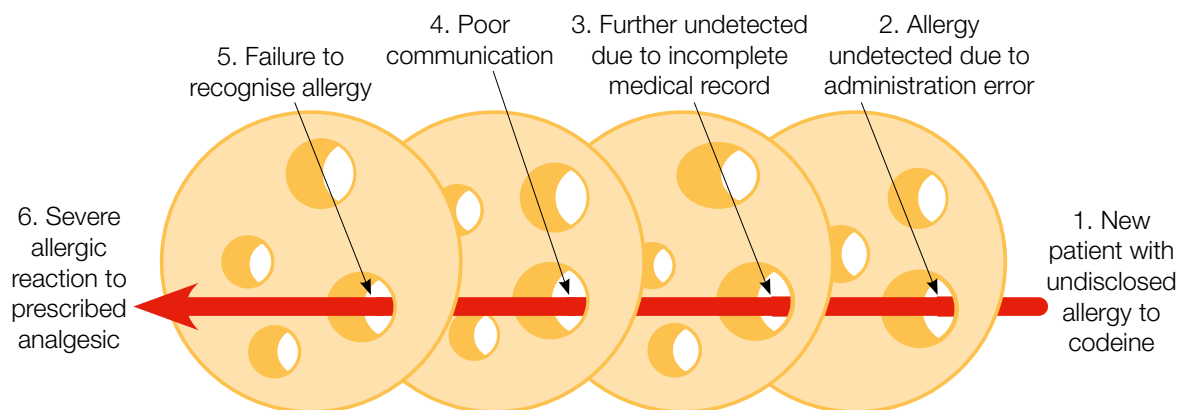
Figure 4.2 A flawed system[22]

In summary, Reason's model is based on the premise that humans are fallible, and errors are to be expected and should be seen as consequences rather than causes, with their origins in amenable 'upstream' systemic factors.[24]

> ### Reading
>
> - Reason J. Human error: models and management. BMJ 2000;320:768–70

4.2 Toxic cascades

Risks, errors, near-misses and adverse events can also be considered part of a 'toxic cascade', where the cascade begins with the potential for harm and moves through to extreme harm. The Toxic Cascade Model presents an approach to patient safety that locates upstream sources and downstream consequences of errors.[23]

The Toxic Cascade Model presents four levels of potential threats to patients' safety (trickles, creeks, rivers, torrents), which can progress in a similar fashion to rapids in a river: as the river narrows, the water goes faster and the flow becomes more powerful.[23]

Trickles

Trickles make virtually no noise and are largely unseen. In healthcare they are analogous with relatively minor errors much as a misfiled patient record that is noticed and corrected without any impact on quality or safety of patient care. The upstream causes are rarely explored and their downstream consequences remain unknown.

Creeks

Creeks are louder and more visible than trickles. In healthcare they are easily recognised as risks to patient safety. Healthcare examples include prescribing drugs to patients who have contraindications. Such clinical errors worry general practice teams due to the seriousness of the potential patient harm. Their occurrence is immediately addressed. Their upstream sources are seldom explored and their downstream consequences often remain unknown.

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Rivers

Rivers are too large to be ignored. Their existence re-defines the surrounding landscape. Healthcare examples include undiagnosed fractures that result in patient harm. When such events occur patients, other clinicians and courts seek to assign personal responsibility, fault and blame.

Torrents

Torrents are powerful. Stopping them seems impossible. The healthcare analogy includes clinical errors that result in patient mortality.

Reading

- Dovey S, Fryer G, Green L, Phillips R. Toxic cascades: a comprehensive way to think about medical errors. Am Fam Physician 2001;63:847.

4.3 Learning from space shuttle disasters

Quick points

- The notion of personal blame and incompetence is no longer considered accurate, appropriate or an effective response to error.
- Organisational culture and a broad array of other situational factors must be addressed as part of risk and incident management.

Insights from other high-achieving industries can be useful in medicine. The aerospace industry has undertaken considerable work in risk and incident management. The human–human and human–technology interfaces provide similar challenges and potential for error.

Aerospace industry efforts to understand how adverse events evolve have led to the conclusion that errors are most appropriately understood from a systems perspective, where a number of factors play a role in the outcome of a situation.[25] The notion of personal blame and incompetence is no longer considered an accurate, effective or appropriate response to errors, near-misses or adverse events.

Case studies drawn from two high-level US reports published in response to the space shuttle disasters help illustrate the system view of error causation.

Case study – The *Challenger* accident

The decision to launch the space shuttle *Challenger* was flawed. Those who made the decision to launch on 28 January 1986:

- were not aware of the recent history of problems concerning the O-rings and their joints

- were not aware of the initial written recommendation of the contractor advising against the launch at temperatures below 53°F

- were not aware of the continuing opposition of the engineers at Thiokol after management reversed its position

- did not have a clear understanding of Rockwell's concern that it was not safe to launch because of ice on the pad.

If the decision makers had known all of the facts, it is highly unlikely that they would have decided to launch the shuttle.[26]

Seventeen years after the *Challenger* disaster, the space shuttle *Columbia* shared a similar fate resulting from similar causes.

Case study – The *Columbia* accident

The Columbia Accident Investigation Board recognised early on that the accident was probably not an anomalous, random event, but likely rooted to some degree in NASA's history and the human space flight program's culture.

Historical factors included:

- political considerations

- lack of an agreed national vision for human space flight

- mischaracterisation of the shuttle as operational rather than developmental

- changing priorities over the life of the Space Shuttle Program

- reliance on past success as a substitute for sound engineering practices (such as testing to understand why systems were not performing in accordance with requirements).

Cultural factors included:

- organisational barriers that prevented effective communication of critical safety information and stifled professional differences of opinion

- lack of integrated management across program elements

- the evolution of an informal chain of command and decision-making processes that operated outside the organisation's rules.

Operational factors included:

- resource constraints

- time-schedule pressures

- lack of planning for possible risk

- lack of response to known risks.[27]

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The Columbia Accident Investigation Board's conviction regarding the importance of these factors strengthened as the investigation progressed. In its final findings, conclusions and recommendations, the Board placed as much weight on the historical, cultural and operational causal factors as on the more easily understood, and corrected, physical cause of the accident.

This historical example can serve to remind similarly high-achieving individuals, like healthcare professionals, working in a complex and technology-dependent environment, that:

- we need to be mindful, when we discuss errors, that we do not allow historical and cultural perceptions of error, or the notion that medical professionals are infallible, to cloud the investigation and related discussions

- even the most high-achieving individuals in their field can experience errors – the causes of which extend beyond the individual

- even the smallest elements in the safety chain can be critical in preventing harm

- simple errors can involve multiple contributing factors

- the elements that culminate in a near-miss are worth investigating as they provide us with an early warning system for more serious incidents.

Activity

Learning from shuttle disasters

- Has reading these excerpts changed your opinion of the causes of adverse events?

- What is your response to these report findings?

5. A systems approach to patient safety

5.1 The historical response: a culture of blame

> ### Quick points
>
> - Naming, blaming and shaming is a historical but unhelpful and inappropriate response to error.
> - A mindset of perfectionism, which is common in medicine, hinders effective risk and incident management and sets an unrealistic benchmark.

As the space shuttle disaster investigations revealed, adverse events can rarely be fully explained by reference to human fallibility alone, yet historically this assumption has prevailed in the medical profession.

> *'A large and ever present cultural barrier is the deeply embedded belief that quality of care, and error free clinical performance, are the result of being well trained and trying hard.'*

In this paradigm, inevitable mistakes are viewed as episodes of personal failure, with the predictable result that these events are minimised and not openly discussed.

The RACGP review, *A conspiracy of silence*, found that the culture of medicine is perpetuated by the type of people who choose a career in medicine. They are typically inclined towards a benchmark of perfection that does not allow for, or recognise, normal human frailty.[27]

> *'Medical practice is widely recognised as an occupation with high workplace expectations and responsibilities. Patient demands are also commonly high.'*[28]

Virtually every doctor knows the sickening feeling of making a bad mistake.

> *'You feel singled out and exposed – seized by the instinct to see if anyone has noticed. You agonise about what to do/whether to tell anyone, what to say. Later, the event replays itself in your mind. You question your competence but fear being discovered. You know you should confess, but dread the prospect of potential punishment and of the patient's anger.'*[29]

The well-known phrase 'naming, blaming and shaming' illustrates the traditional process for responding to an error 'yet it is arguable that shame is the universal 'dark side' of improvement.'[24]

Medical malpractice laws have supported this approach, as successful prosecution, and the extraction of compensation, rely on the concepts of personal responsibility, fault and blame.

This has had an impact on the capacity and willingness of health professionals to identify and openly discuss risks, errors, near-misses and adverse events. Health professionals often fear the consequences of telling someone about a 'slip-up' or a lapse in clinical quality.

> *'I wanted to say something, but I did not know how people would react.'*

This diminishes the opportunity to learn from mistakes and address patient safety issues.[30]

Activity

Medical culture

Reflect on your practice and think of a time when you felt perfection was an expectation.

- How did this make you feel?

- Do you ever place unrealistic expectations on yourself?

- Have others placed unrealistic expectations on you?

- How do you think these expectations affect your ability to consider and discuss incidents with your colleagues?

5.2 A 10-step systems approach to patient safety

The next few sections explain the shift away from a culture of individual blame towards a relatively new systems approach to patient safety, for which we have outlined 10 steps.

Step 1. Creating a just and open culture

Quick points

- Creating a just and open culture supports effective risk and incident management.

- A just and open culture is not a blame-free culture – it is one where there is clarity in accountability, and leadership is honest, effective and consistent.

Culture can be defined as the organisation's pattern of response to challenges, whether challenges are explicit (a crisis) or implicit (a latent problem or opportunity).[30]

Practices that foster a just and open culture, centred on patient safety, openness and honesty, demonstrate an increased capacity for continuous quality and safety improvement.[31, 32]

Fostering a just and open culture is not analogous to a blame-free culture. It simply identifies the need to move away from blaming individuals towards a culture with a balance of accountability and responsibility. It does so by making practice staff feel they are able to discuss risks, near-misses and adverse events with their colleagues and the practice team without fear of personal or professional sanctions.

> *'Recognising and dealing with mistakes in a supportive environment is an essential precursor to dealing with mistakes systematically and holistically.'[33]*

Case study – Jeff

Dr White, a practice principal, sees a new patient, Jeff, aged 57, for the first time late one afternoon. Jeff's appointment has been fitted in to a busy schedule at his request, as he says he is 'pressed for time'.

He and Dr White discuss the reason he has made the appointment: urinary frequency and dysuria for the past 24 hours.

Dr White quickly assesses Jeff, performs urinalysis and settles on a provisional diagnosis of a urinary tract infection. They agree that Jeff will return the following afternoon for a longer consultation, when a detailed history can be taken and the presenting problem will be fully explored. As he is leaving, Jeff asks if there is any treatment that he can take until the results are back as he is finding the symptoms quite distressing.

Dr White gives him a sample of an antibiotic as a short-term measure. As both she and Jeff are in a hurry, Dr White does not enter it into her clinical software, as she normally would with prescription drugs.

The sample contains trimethoprim and sulphmethoxazole. Jeff is highly allergic to sulphur. At home Jeff reads the label and decides not to take the medication as he is concerned about the 'sulphur' component. He returns the next morning and discusses the issue with Dr White.

Dr White is disturbed by how easily Jeff could have been harmed. The sequence of events preoccupies her throughout the day.

Dr White wants a practice where she can feel confident to discuss the incident, ask for help and be supported by her fellow GPs and practice staff.

A just and open safety culture is one where there is:

- a shared perception of the importance of safety
- confidence in the efficacy of safeguards or barriers
- organisational learning
- committed leadership
- a supportive approach to risk/incident review and investigation
- communication based on mutual trust, respect and honesty.[34]

The capacity of practices to develop a safety culture is thought to be dependent on three primary factors:

- the quality of communication between the practice team
- an agreement at all levels of the practice that safety is a priority
- confidence that safety measures or safeguards developed by the practice team are adequate and suitable for their purpose.

Ten steps towards creating a supportive environment are:

1. Developing the ability to recognise 'taken for granted' assumptions and mental models, and how they affect people's behaviour and performance.

2. Entertaining doubt, developing a questioning attitude and respecting the legitimacy of others' viewpoints.

3. Modelling assertive communication.

4. Reminding people that their contribution to the work of the practice is valuable.

5. Finding time to celebrate milestones, both professional and personal.

6. Remembering to use people's names, especially when seeking their attention or assistance (eg. 'Helen, could you please help with this?').

7. Finding ways to deal with conflict and stress.

8. Making a public commitment to quality improvement and following through in your actions.

9. Creating a sense of urgency to solve shared problems collectively.

10. Demonstrating your willingness to take a hard look at problems and to do so in a sensitive yet structured manner. A punitive or controlling response can inhibit the flow of information and reinforce barriers to discussion that may otherwise unmask the underlying causes of errors, near-misses or adverse events.

Activity

A just and open culture

- How does the atmosphere at your practice affect your ability to raise patient safety issues?

- What helps you discuss patient safety issues with colleagues?

- What stops you from discussing patient safety issues with colleagues?

- What could you do to make it easier to raise patient safety issues, both for you and your colleagues?

Step 2. Identifying patient safety issues

Quick points

- Accurately identifying different patient safety issues is critical as each type of event carries very different medico-legal implications.

- Clinical risks or patient safety incidents can be identified by clinical or nonclinical staff, patients, students, visitors or other sources.

Identifying clinical risks, errors, near-misses or adverse events is not always straightforward. An Australian study of older people considered at high risk of medication misadventure found that 19% had experienced an adverse drug reaction which had not been detected in routine clinical care, even though most were using multiple medicines, had comorbidities and were aged over 65 years.[35] Hence, it is important to be alert for weaknesses in the system and maintain a level of vigilance and awareness.

While it is clinical staff who are more likely to come across (or be involved in) a clinical incidents, it may be non-clinical staff, the patient, their carers or others who can help identify that something has not gone to plan. Clinical risks or incidents may be identified by:

- a staff member at the time of the incident (GP, registrar, practice nurse, practice manager, receptionist)

- staff – retrospectively when an unexpected outcome is detected

- a patient or carer who expresses concern or dissatisfaction with the patient's healthcare, either at the time of the incident or retrospectively

- other sources, such as other patients, visitors, students or other practice staff.[36]

Activity

Identifying patient safety issues

List the people who you think might identify clinical risks or incidents in your practice.

- Does your list contain mostly clinical staff, or have you considered patients, their carers and others?

Step 3. Having crucial conversations

Quick points

- Discussing identified risks, error, near-misses and adverse events can be difficult.
- There are strategies and approaches you can use to make discussing risks or lapses in patient safety easier.
- One approach to make risks, near-misses and adverse events easier to discuss is to use 'crucial conversation' skills.

It can be difficult to tell someone else about an identified clinical risk, error, near-miss or adverse event.

> *'I wouldn't mention something like this. I'd just try to be more vigilant myself. But, I do not want it to happen again. I can not just ignore it.'*

Once a risk, error, near-miss or adverse event has been identified, it is important to discuss it with someone. This enables you to share your feelings and begin exploring the causes and possible improvements. Unless a GP, or another member of the practice team, can tell someone else about a risk, error, near-miss or adverse event, it is difficult to make the systemic improvements that will prevent future errors from occurring.

Consider the following information about critical conversation skills in conjunction with the relevant medico-legal content explored in *Section 6*.

Crucial conversation skills

Research suggests that only 5–15% of healthcare workers (depending on the issue) are able to confidently discuss risks, errors, near-misses and adverse events within their practice.

Crucial conversation skills can help us approach difficult discussions about patient safety issues and can also help us implement change. There are four key steps to effective, crucial conversations:

1. Master your story.
2. Create safety.
3. Share the facts.
4. Invite dialogue.

These will be explored in relation to the example of the GP who runs late:

> *The facts are that the GP has been late three times in the past month. As a result, his morning patients have waited for about 30 minutes beyond their appointment and are now irritated. To keep patient appointments flowing and reduce the tension in the waiting room, you and another GP see the late GP's first two patients on his list.*

Master your story

First, you need to be clear as to what the conversation needs to be about. At this stage, the facts of the issue need to be separated from your emotions. It's important you realise that your emotions are something you produce.

Next, think about how you have interpreted the facts and what story you may be telling yourself. It is easy for us to be swept up in the 'story' we tell ourselves to 'explain' the facts. These stories can lead to an unhelpful emotional response. We can fall into the trap of starting the conversation with our assumptions and emotions rather than with the facts.

There are three basic stories that we tell ourselves to explain facts. They are:

• Victim stories – 'It's not my fault.'

• Villain stories – 'It's all your fault.'

• Helpless stories – 'There's nothing else I can do.'

These often arise from victim stories.[36]

The story you tell yourself in the case of the GP who runs late may be that the GP is selfish and rude, and you have to 'prop' up him – and the practice – by seeing his patients. Analyse this and work back to what the facts are, and try to understand what the issue really is. Also consider whether a reasonable, rational or decent person could have made the same mistake or behaved in the same way as the person you are concerned about.[36] Remember that expectations that are unrealistic can influence how you interpret a situation.

Finally, also consider what your role may be in the issue – sometimes we filter out what we may have done to contribute to a situation or issue.

Create safety

This second stage is critical. If you do not allow the other person to feel safe and not personally threatened, they may become defensive. This can close down any chance of a successful conversation.

When people feel unsafe in a conversation they commonly respond with either 'silence' or 'violence'.[36] If you are in a conversation and the other person appears to be responding with silence or violence, step out of the discussion and re-establish safety. Once safety is re-established, you can re-enter the discussion about the issue.

A silent response can include avoiding, withdrawing or masking (such as using sarcasm). A violent response can include verbal attempts to coerce, control or convince the other person (ie. name calling).[36]

Ensuring 'mutual respect' and 'mutual purpose' can create safety.[37] Mutual purpose is about ensuring that the other person is confident that you care about their goals and that they trust your motives for having the conversation. This links to respect – the other person needs to be confident that you respect them and are not pursuing the conversation for the wrong reasons (ie. personal attack).

People do not become defensive because of what you are saying to them; they become defensive because of why they think you are saying it. The problem is not the feedback. The problem is the lack of safety.[37]

For example, you may say, 'I know I am not a partner in the practice but I noticed something the other day that I think you might want to know about. Can I tell you about it?'. Wait for the person to give you the okay to go ahead before continuing, otherwise it will look like you do not respect them and not interested in their goals. They may then disengage from the discussion. Follow up by demonstrating your intentions and respect. You may want to say something like:

> *'I'm sure at times I do things that bother others, and I hope you would let me know if you ever noticed this happening. By the same token I'd hope that my colleagues would be receptive to my observations. I have noticed that … '*

Share the facts

Many people make mistakes in giving feedback by mixing their judgements or conclusions with facts. They may, without even realising it, have mixed motives. Strip away that motive entirely and focus on the facts.[36]

It is important to only mention the objective facts at this stage. Facts are the least insulting. If you do want to share your story, do not start with it. Your story could easily surprise and insult others.[37]

As established in *Master your story*, the facts are that the GP has been late three times in the past month. As a result, his morning patients have waited for about 30 minutes beyond their appointment and are now irritated. To keep patient appointments flowing and reduce the tension in the waiting room, you and another GP see the late GP's first two patients on his list.

You may say: 'Yesterday morning you arrived 30 minutes late for work. I noticed you have been late three times in the past month.' Keep your emotions and your 'story' out of this stage of the conversation. If this filters into the discussion, you risk losing the sense of 'safety' initially created thus undermining the participants trust.

Invite dialogue

The next step is to ask the other person what they think of the issue. Use an open-ended question which demonstrates you are interested in what they think and that you respect them. This also shows you have not jumped to any conclusions. End with a question that encourages open dialogue.[38] For example, you may follow up from the last step by asking, 'Can we chat about this?'

What if the problem keeps happening?

If you find yourself having the same conversation twice, you are having the wrong conversation.[32]

Let's say the problem keeps happening after you spoke to the GP about it and felt that you had both reached an agreement that he would arrive to work on time.

The conversation that you need to have in this example is different now – the discussion is now about a pattern of behaviour (the GP continues to arrive late despite asking him to arrive on time) rather than the content (that they are late).

It is important that you present only the facts and not an emotional 'story' to explain the situation. After you have shared the facts (that this is a pattern of behaviour and how it affects you) invite dialogue from the other person.

You may want to say something like:

> *'Twice in the past month, I have attempted to let you know how important it is that you arrive on time in the morning. I have noticed over the past two months you have been late at least twice a week. This is a pattern and it is putting me in a difficult position. Either I continue to take extra patients to cover for you and increase my workload and stress, or I leave the practice. How do you see it?'*

During a structured discussion it is more likely that an incident's causes will be detected. This can help a practice team identify the most appropriate course of remedial action. A structured discussion might be a precursor to a discussion at a practice team meeting.

Activity

Practise a crucial conversation

Using the following example, discuss how this crucial conversation could be approached using the four steps: master your story, create safety, share the facts and invite dialogue.

You have returned from four weeks' leave, during which time another doctor has seen your patients. Over the next few weeks you notice that a couple of these patients return for review of liver function tests you had ordered. These tests showed mild abnormalities. On questioning the patients, they reassure you that the 'nice young doctor' told them their test results were fine. You are concerned about the GP's skills in interpreting the significance of abnormalities in liver function test results.

Involving the practice team

'Having shared our fears and feelings with a trusted colleague, we are better able to discuss issues in a larger group.'[24]

Involving the practice team in a discussion about a risk to, or lapse in, patient safety, can enhance and make patient safety improvements more effective.

There are often elements of a clinical risk or patient safety incident that are influenced by other team members, or where other team members have (or potentially have) experienced the same near-miss.

As discussed in the previous section, having a just and fair culture within the practice will help to provide an environment that facilitates effective discussion.

Many practices hold regular practice meetings where issues that affect the quality and safety of patient care are discussed. These practice meetings could provide a useful venue to analyse clinical risks or patient safety incidents. Practice meetings are likely to be more effective than other forms of communication because information about clinical improvements and safeguards can be shared simultaneously by the entire practice team.

It can help if:

- the group is representative of the entire practice team

- people are happy about participating

- the core membership remains constant

- participants know each other and each others' roles

- the group consists of 8–10 people (generally, small groups function better than large groups).

Teams that are familiar with meeting regularly and reviewing patient care seem to find facilitated case discussions more rewarding than teams that do not because the initial process of identifying areas of concern seems to be less threatening.

A team that is unaccustomed to meeting regularly may want to start with a broader discussion about quality improvement before it proceeds to case discussion.

Barriers may exist both interprofessionally (eg. between GPs and general practice nurses) and intraprofessionally (eg. between longstanding and newer doctors).

Some degree of tension always exists within an established team. This tension can be used constructively in a safe environment to stimulate critical thinking.

Participants who are 'innovators' in the team may meet resistance from others who prefer a slower rate of change. This might produce conflict. Longstanding personality clashes may also surface.

A comfortable, quiet place is essential. Holding the discussions during the day makes it easier for all staff to attend, but it is difficult to avoid routine interruptions. Make sure those 'holding the fort' know not to interrupt unless essential.

Generally 20–45 minutes will be needed for each case. Cases generating emotional topics may need up to an hour. Make sure that you:

- establish basic ground rules

- structure the discussion

- keep to time

- encourage contributions from all participants

- clarify and summarise frequently

- encourage participants to speak for themselves (using 'I' not 'we')

- maintain confidentiality

- encourage participants to accept responsibility for initiating change

- recognise emotion within the discussion, acknowledge it and allow appropriate expression within the group

- decide what will be documented (especially improvements), and by whom

- rotate the record-keeping role.

Before the discussion, choose a case/incident of particular concern or interest. Circulate sufficient information for people to come prepared to discuss this case.

Reading

- Maxfield D, Grenny J, McMillan R, et al. Silence kills: the seven crucial conversations for health care. VitalSmarts, 2005.

- Maxfield D, Grenny J, Patterson K, et al. Dialogue heals: the seven crucial conversations for healthcare professionals. VitalSmarts, 2005.

- Patterson K, Grenny J, McMillan R, et al. Crucial confrontations. New York: McGraw-Hill, 2004.

- Patterson K, Grenny J, McMillan, R et al. Crucial conversations: tools for talking when stakes are high. New York: McGraw-Hill, 2002.

Step 4. Prioritising issues

Quick points

- Patient safety risks and incidents of varying frequency and consequence occur often.
- Prioritising them allows us to analyse and respond in an appropriate and timely way.
- Using risk matrices and incident logs can help us prioritise them.

There will be some clinical risks or lapses in patient safety that will require more immediate attention than others. Some will also be more readily amendable to analysis and safeguard implementation than others.

The level of control a GP or practice team has over the causes can influence the priority that may be placed on a patient safety risk or incident. Before embarking on an investigation and analysis of the causes, it is important to prioritise and select the appropriate lapses in patient safety – particularly where there are multiple lapses in patient safety.

How might you set priorities for analysing lapses in patient safety? Here is a quick way to determine which lapses should be the subject of structured analysis:

- Start with a flexible approach based on any request by GPs or practice staff to analyse an incident. As part of this process address the barriers to raising risks or incidents, as these will decrease the number likely to be reported.

- Encourage people to use their instinct about what to report and analyse. General practices that have begun to analyse risks or lapses in patient safety raised by their GPs and practice staff have found it easy to agree on which ones to pursue.

- Develop a short list of events that the staff agree should never happen and need systematic exploration if they do (eg. a warfarin-related misadventure). The public hospital system has a list of 'sentinel events'.

- Use a risk matrix and incident log to rank and record what is reported according to the likelihood of recurrence and the severity of the potential consequences.

Using a risk matrix

The likelihood of an incident's occurrence, combined with the severity of the potential consequences, produce a 'level of risk' according to which that incident can be ranked relative to others.

Case study – Jeff, continued

When Dr White discusses the incident involving Jeff with her fellow GPs, they all agree it is essential that any patient safety risks or incidents raised by members of the practice team be discussed. The GPs decide they will start with an informal process of developing a consensus about whether a detailed analysis needs to occur.

Dr White and her colleagues risk rate the incident to decide if it warrants detailed analysis. Referring to a risk matrix (eg. *Table 1.3*), Dr White and her colleagues think about the incident's:

- likelihood of recurrence (almost certain, likely, possible, unlikely, rare)

- consequence (catastrophic, major, moderate, minor, insignificant).

Dr White and her colleagues decide that the likelihood of occurrence is 'possible' given that:

- the practice is often busy in the afternoon

- an audit has shown the rate of recording of known allergies for new patients was 80%

- the practice has a history of using free samples to introduce patients to new medicines.

With regard to 'consequence', Dr White and her colleagues agree that the associated consequences could be 'catastrophic' – as a patient could die from a severe allergy.

Their analysis yields an 'extreme' risk rating. The practice decides this 'extreme' risk rating warrants structured exploration of the causes and a strategy to reduce the likelihood of recurrence.

Refer to *Chapter 1* for more information about how to determine 'likelihood' and 'consequences' using a risk matrix.

Using risk/incident logs

Some practices use an incident log to record risks, errors, near-misses and adverse events. The log can assist in prompting discussion and response through regular review processes. It typically contains a list of identified risks or incidents, their risk ranking and (following incident investigation and analysis) information about the root causes and potential responses.

A log can be considered an internal quality control and improvement tool by enabling a practice to monitor its level of, and responsiveness to, safety concerns. An incident log can also help GPs and their practice teams monitor and support a coordinated response to risks or lapses in patient safety, if used appropriately and effectively.

However, there are potential medico-legal implications so it is useful to check with your medical indemnity insurer before using a log. Care needs to be taken regarding the information included in the log, who has access to it and how the information is used.

It is important to respond to risks or lapses in safety identified in the log (such as through implementing improvements) as there may be medico legal concerns if a potential problem is identified but not responded to.

Principles of risk/incident log use

While risk and incident logs can help promote discussion of near-misses and adverse events, caution needs to be taken to ensure that only pertinent information about the event is noted. This ensures patient privacy is maintained and the medico-legal implications are addressed.

Logs must be kept secure (either physically or electronically) and access must be controlled. It is also important that safety concerns and incidents are responded to in an appropriate period of time. If an example is used from the log for discussion outside the practice, it should be reconstructed as a fictitious example.

Refer to *Section 6* for further information about related medico-legal considerations.

Activity

Risk matrix and incident log use

Jot down a short list of events that are serious enough for you to want to ensure they would never happen in your practice (eg. medication misadventure, pathology results from a breast lump not being acted on).

- What do you think people in your practice would think of the list? Would they agree? Would they have additions or deletions?

- How would you use a risk matrix to help prioritise these?

- How would the incident log look and how could it be used to prompt and facilitate patient safety discussion?

Step 5. Investigating patient safety issues

Quick points

- Understanding why a clinical risk exists, or why an incident has occurred, allows us to identify appropriate preventive measures.

- There are three methods for analysing near-misses and adverse events: a chain of events timeline, a cause and effect diagram, and a framework of contributory factors.

When a lapse in patient safety occurs, an investigation may be critical to finding out what happened. Occasionally, you will be armed with sufficient information to get to the bottom of a matter yourself. Sometimes further investigations are required to better understand how and why the lapse in patient safety occurred.

Reviewing near-misses and adverse events is an opportunity to reflect on what the incident reveals about gaps in the practice systems. In a sense, the near-miss and adverse event and its subsequent investigation act as a 'window' on the systems in the practice.[39]

Do not start looking for causes unless you are prepared to make changes. The search for a cause without subsequent improvements can be demoralising, and from a legal perspective it may highlight that you understood the problem's cause but did nothing to rectify it.

An investigation aims to answer three key questions:

- What happened?

- How/why did the event occur?

- What can be done to prevent it happening again?

If these can be answered, you are well placed to follow up with the patient and openly discuss the practical steps your practice has taken to prevent a similar event from happening again.

Successful models of risk/incident investigation and analysis have a number of common characteristics (*Table 5.1*).

Table 5.1 Typical characteristics of successful models of risk/incident investigation	
Just and fair	The culture of the practice is open and just, but not blame free
	Creating a culture of justice is an essential first step to creating a culture that values safety
Supportive	The practice supports members who discuss risks or lapses in patient safety
Safe	Those involved are confident that their trust will not be betrayed and that they can discuss lapses in patient safety without risk of repercussion
Clearly defined	There is a single, inclusive definition of the clinical risk, error, near-miss or adverse event
Quick and easy	The way in which risks or lapses in patient safety are reported fits easily into the other ways that the practice safeguards patient safety
Private	Discussions are confidential and data is de-identified
Systems focused	Significant reductions in the likelihood of error are achieved by the redesign of systems
	Focusing on the individuals' contribution to error can isolate their unsafe acts while ignoring the unsafe system context
Timely and effective	Rapid meaningful feedback is provided to all interested parties within the practice
Spontaneous	People can respond when a lapse in patient safety occurs
	The analysis might be delayed, but people know when it will occur
Retrospective	Although reporting is spontaneous and rapid, it is useful to be able to look at the context in which the event took place, despite the risk of hindsight bias
	People can sometimes see other events or causes that were not apparent immediately
Useful and worthwhile	Results can be demonstrated, used at a local level and they do not end up in an administrative 'black hole'
Well led	There is sustained support from the practice leaders for the identification of patient safety incidents, analysis of causes and system improvements.

Who should be involved in the investigation?

There is value in bringing together a diverse team, as each member will reflect on a near-miss or adverse event from their own point of view, as influenced by their position in the workplace: a practice nurse and GP may approach the adverse event differently, each bringing valuable contribution to the investigation.

On occasion you may need to ask staff or practice colleagues direct questions or have them ask those questions. In some cases, to properly investigate the true cause(s) of an incident, you may feel that questions need to be asked of people or institutions outside the practice (eg. consultants, private or public hospitals).

Note: Where investigations involve sharing information which identifies a patient, the capacity to undertake them lawfully will be affected by privacy laws.

What techniques should be applied?

Refer to *Chapter 6* for information about related medico-legal considerations.

There are many investigative and analytical techniques that can assist you to determine possible causes and identify possible safeguards:

- The chain of events timeline.
- The cause and effect ('fishbone') diagram.
- Framework of contributory factors.

We will now work through each of these methods in turn, using the case of Dr Kenny and his patient Albert as an example.

Case study – Albert

Patient background

Albert, aged 67 years, is a retired landscape gardener who has attended Dr Kenny's clinic for over 20 years. He has a history of hypertension, osteoarthritis in his right knee and the occasional migraine, but is otherwise a healthy man. Albert's last consultation at the practice was 3 months ago when he received a Fluvax. Dr Kenny reviewed his blood pressure, which was normal.

Presentation

Albert presents to Dr Kenny on a Wednesday morning complaining of a pigmented lesion on his forehead but is otherwise well. He became aware of this approximately 2 months ago when he had a haircut. Albert tells Dr Kenny he has noticed the lesion has changed colour and size over the last 2 months and is now slightly tender.

Dr Kenny examines the lesion and recommends an excision biopsy. He and Albert have a short conversation about the reason for the biopsy. Dr Kenny does not seem concerned, so Albert presumes there is no cause for alarm.

Dr Kenny walks with Albert to the front reception, where he asks Carolyn, the head receptionist, to schedule Albert a long appointment for a biopsy the following day. She provides Albert with a written appointment card.

Excision biopsy

The following afternoon, Albert attends the consultation and Dr Kenny proceeds with the biopsy. Dr Kenny advises Albert that the stitches will need to be removed in a week. Albert will be out of town, visiting his daughter at this time, so he will arrange for his daughter's GP to remove the stitches.

Dr Kenny also indicates to Albert the results should be back 'some time next week'. There is no formal discussion about 'who is contacting whom' regarding follow-up of the test results.

Results

Albert's biopsy results return early the next week. As per practice protocol, Dr Kenny reviews the pathology and enters the results into the patient's electronic file.

The results reveal a melanoma with a Breslow thickness of 3.5 mm with one edge extending to the excision margin. Dr Kenny realises this is quite concerning and will require a wide excision of 1–2 cm and consideration of sentinel lymph node biopsy.[2]

Contacting Albert

Dr Kenny asks Carolyn to ring and schedule an appointment for Albert as soon as possible, preferably that day or the next. However, when she rings, she finds that Albert's telephone number is disconnected.

On checking his address details on the system, Carolyn sees they were last updated in 1999. She sends Dr Kenny an email to inform him of this.

Case study – Albert (*continued*)

Dr Kenny

Later that afternoon Dr Kenny reads Carolyn's note. He enters the attempt to follow up Albert into his patient record.

The medical record software used by the practice has a standard follow-up letter. Dr Kenny prints the letter, which triggers the pathology result as having been actioned.

A distraction

While the letter is printing, Dr Kenny's telephone rings. Carolyn says it is Mrs Sharp, who sounds very unwell and wants to speak to him. The conversation lasts 10 minutes as he is concerned about her. By the time he finishes, his attention has focused on the care he needs to arrange for Mrs Sharp before leaving for the day.

With this distraction, the letter to Albert gets mislaid on his desk and is never sent.

Three months later

Three months later, at the end of a busy Monday morning, Dr Kenny reviews his afternoon list and sees Albert's name. He recalls the name but can not recollect why. He opens Albert's electronic file to read the last entry.

The entry indicates the biopsy result was received from pathology and that it was 'actioned' but he sees no documentation to support this. However, there is an entry stating an attempt was made to contact Albert by telephone, but his number was disconnected.

Dr Kenny sees Albert's pathology was clinically significant and is conscious there has been a lapse in the quality of care his practice normally provides.

Next, we discuss several mechanisms for identifying factors that may have led to such error.

Chain of events timeline

Most near-misses and adverse events do not result from a single act but from a chain of events (*Chapter 3*). Drawing up a timeline of events involves recording key contributing actions/events that preceded the adverse event over time (eg. administering the wrong vaccination may be counted as a single error). However, the incident may be the result of multiple contributing errors (a cascade) that led causally to another.[40]

The intention of a chain of events timeline is to identify what actually happened and consider potential safeguards or barriers that could be put in place to prevent a similar event occurring again (*Figure 5.1*).

There are three steps to developing a chain of events:

1. Chart the timeline of events from the near-miss or adverse event, backwards in time. Ask the question: 'What actually happened?'

2. Consider: 'What should have happened?' or 'What would I like to have happened in the situation?'

3. Consider what safeguards or barriers could be put in place to prevent the adverse event happening again.

| **What actually happened (factors that led to the adverse event)** | Patient does not communicate change of contact details to the practice | No formal conversation between the GP and patient regarding practice protocol for follow-up

No documentation in patient's record stating system of recall has been explained to the patient | The practice is unable to follow up test results by phone due to an incorrect phone number on file | The follow-up letter is misplaced on the GP's desk and is not mailed

There are no mechanisms to ensure test results are followed up | GP does not document efforts to follow up in the patient's record | Three months after initial biopsy, the patient attends the practice and staff are informed of the delay in following up test results |

| **What should have happened to prevent the adverse event?** | Patient alerts practice staff of change of contact details | GP explains to patient the process for follow up of test results

This conversation is recorded | The practice is able to contact the patient and schedule a timely appointment | The practice activates its recall system and sends a letter to the patient's home address | GP documents the attempts at follow-up in the patient's record | Clinically significant test result is acted on in a timely manner |

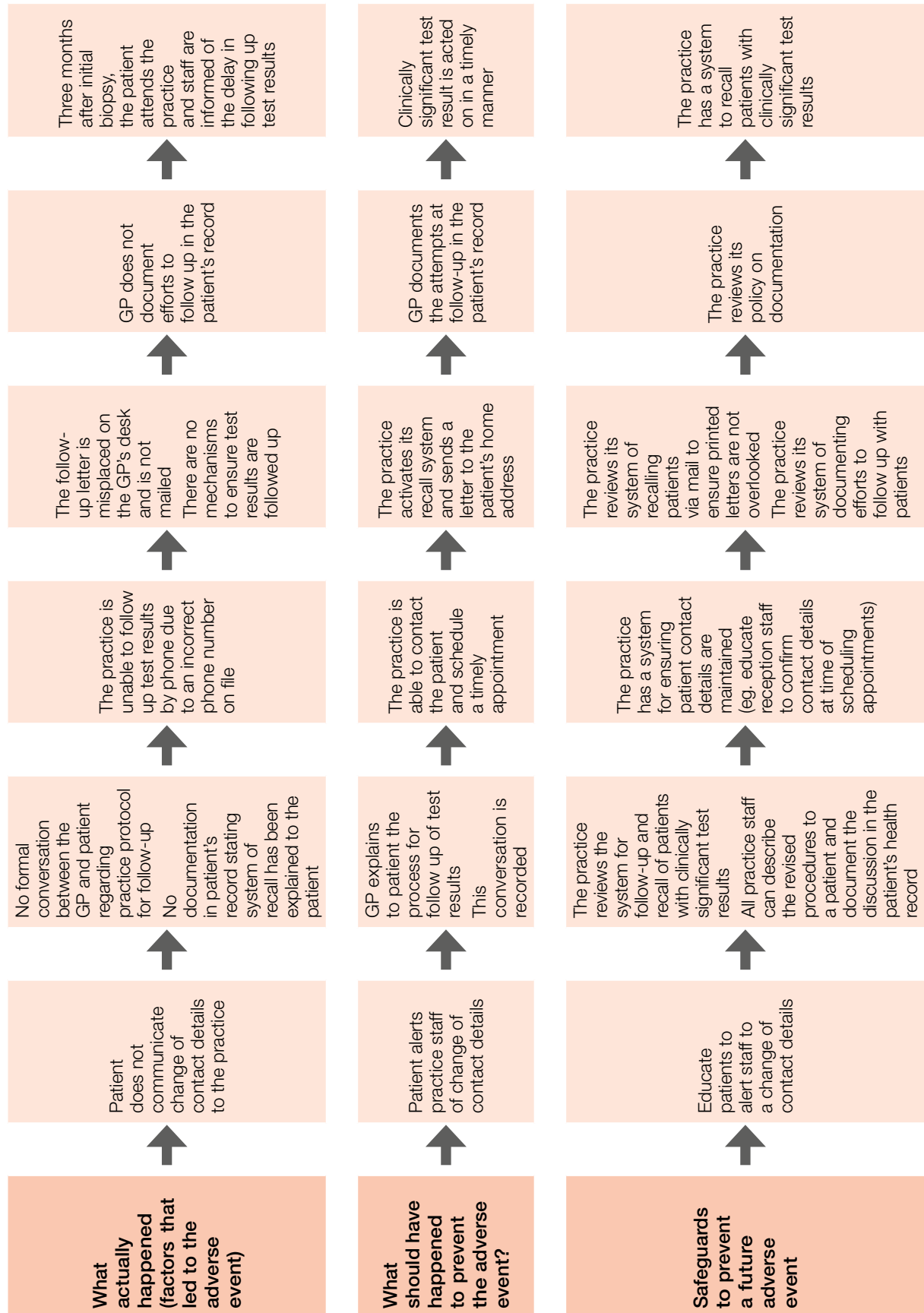| **Safeguards to prevent a future adverse event** | Educate patients to alert staff to a change of contact details | The practice reviews the system for follow-up and recall of patients with clinically significant test results

All practice staff can describe the revised procedures to a patient and document the discussion in the patient's health record | The practice has a system for ensuring patient contact details are maintained (eg. educate reception staff to confirm contact details at time of scheduling appointments) | The practice reviews its system of recalling patients via mail to ensure printed letters are not overlooked

The practice reviews its system of documenting efforts to follow up with patients | The practice reviews its policy on documentation | The practice has a system to recall patients with clinically significant test results |

Figure 5.1 Chain of events

Cause and effect diagram

The cause and effect diagram looks at identifiable causes of events and then examines the underlying causes to develop 'solutions'. It was invented by Professor Kaoru Ishikawa of Tokyo University, an expert in quality management who first used it in 1943 to help explain to a group of engineers how a complex set of factors could be related to help understand a problem. The diagram has since become a standard analysis and problem-solving tool. It is often called an Ishikawa diagram, after the inventor, or fishbone diagram, after its shape.

Issue 1

Issue 2

Issue 3

Issue 4
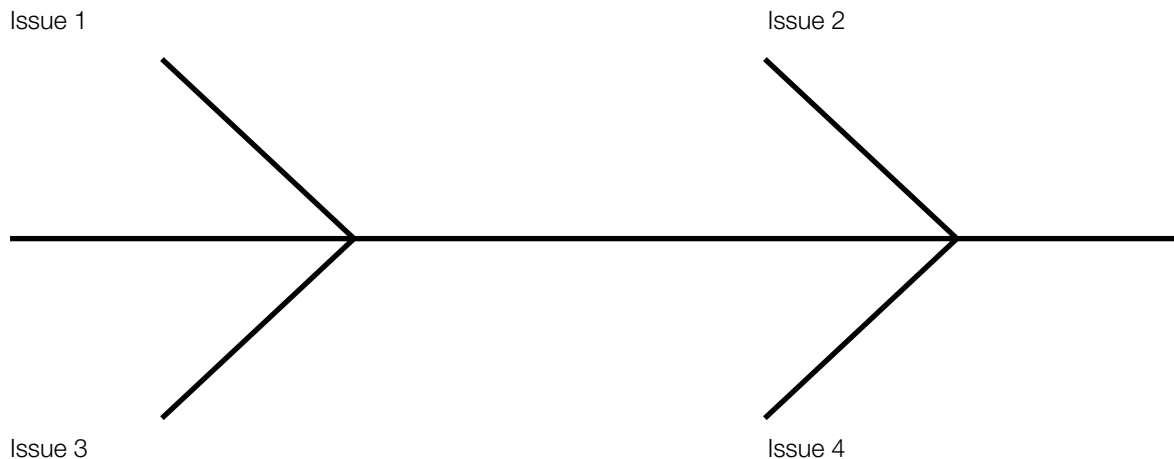
Figure 5.2 Cause and effect diagram

The primary purpose is to generate a comprehensive list of possible causes. When thinking about underlying causes it is useful to consider the systems that 'allowed' the adverse event to occur. This process can lead to immediate identification of major causes and point to the potential safeguards or, failing this, it may indicate the best potential areas for further exploration and analysis (visit www.hci.com.au/cause-and-effect-diagrams).

At a minimum, preparing a cause and effect diagram will lead to greater understanding of the problem. The advantage of this diagram is its scope and depth. The disadvantage is that it can take a little longer to do. It may be easier to group problems together under broad categories such as:

- patient/GP/practice team factors
- policy or procedural factors
- task or technology factors (ie. equipment)
- environment factors (*Figure 5.3 and Figure 5.4*).
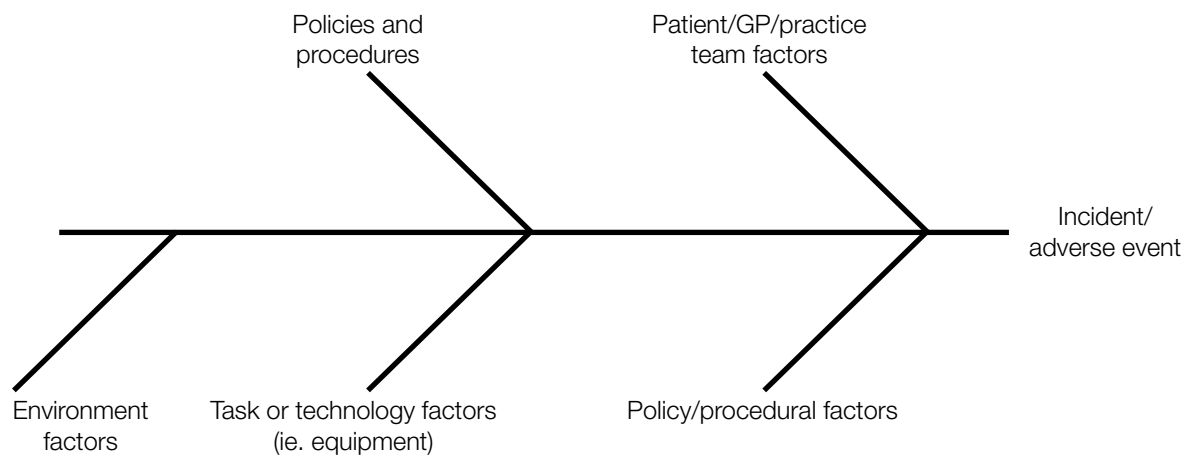
Figure 5.3 Incident/adverse event cause and effect diagram
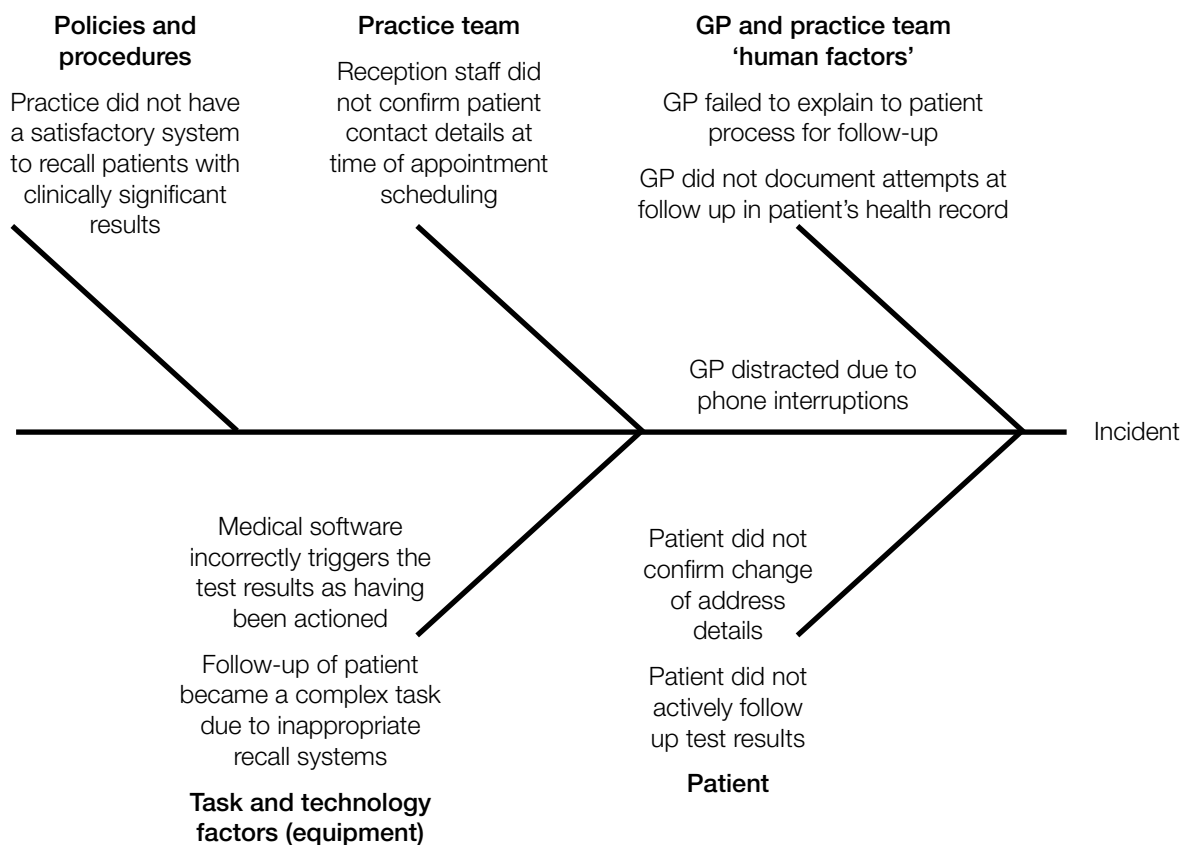
Figure 5.4 Incident/adverse event cause and effect diagram: worked example

Framework of contributory factors

Charles Vincent, Director of the Clinical Safety Research Unit, Imperial College London, extended a model developed by James Reason and adapted it for use in healthcare.[41]

The model classifies the error producing contributory or influencing factors that affect clinical practice.[41] The framework provides the conceptual basis for reviewing near-misses and adverse events, allowing a range of possible influencing factors to be considered as the underlying contributors to a near-miss or adverse event (*Table 5.2*). Once potential influencing factors are identified, it is possible to develop appropriate safeguards or mitigating actions.

Table 5.2 Framework of contributory factors	
Factor type	**Influencing factor**
Patient factors	Presenting conditions (eg. complexity of the patient, comorbidities)
	Language and communication skills or barriers
	Personality
	Psychological factors
Task and technology factors	Complex or simple task
	Availability of decision-making support systems
	Availability and accuracy of test results
	Availability and use of practice protocols
GP factors	Knowledge, skills and attitudes toward safety
	Clinical knowledge and skills
	Competence
	Mental and physical health (this includes tiredness and stress)
Practice team	Knowledge, skills and attitudes towards safety
	Clinical knowledge and skills
	Competence
	Mental and physical health
	Verbal communication
	Written communication
	Team leadership
	Supervision and seeking help
Environment	Staffing levels and skills mix
	Workload 'business' of the practice (eg. 'hectic' day, multiple phone interruptions)
	Safety culture
	Design, availability and maintenance of equipment
	Physical environment
Organisation and management factors	Administrative and practice management support
	Financial resources and constraints
	Practice structure
	Practice policies and standards
	Safety culture and priorities
	Links with external organisations (eg. pathology companies, hospitals, divisions of general practice, allied health professionals)

Reading

- Vincent C. Framework for analysing risk and safety in clinical medicine. BMJ 1998;316:1154–57.

Step 6. Identifying safeguards

Quick points

- After determining why a patient safety incident has occurred, potential safeguards, to prevent it recurring, can be identified.

- In doing so, it is important to consider the effectiveness and difficulty of implementing the safeguard.

- An ease/impact analysis can assist in prioritising safeguards.

'It wasn't enough to know the cause; I wanted to prevent a recurrence. That's the point, after all.'

Understanding why a near-miss or adverse event occurred is important. However, being able to take this knowledge and use it to identify safeguards against the near-miss or adverse event occurring again is a powerful and important step.

The factors that cause, or interact with other factors to cause, a near-miss or adverse event are important to consider in terms of how they can be removed or mitigated. Similarly, any positive factors, such as situational awareness, that may have been involved need to be strengthened and encouraged.

The five ways to identifying potential safeguards to determine the common causes, examine what prevented harm, define best practice, brainstorm solutions and identify what is feasible. These provide a structured way to work. The approach moves from identifying the causes of a near-miss or adverse event (undertaken in *Step 5*) to identifying a solution to promote good practice and address the factors identified in your analysis. Most GPs and general practice staff are very familiar with looking for innovative solutions to problems, and to making improvements to the care they provide.

The suggested approach to identifying potential safeguards is as follows:

- Determine the common causes – The models of analysis outlined earlier will assist in providing you with a list of causes. Look for common causes (eg. which words are used repeatedly in a cause and effect diagram?).

- Examine what prevented harm – With a near-miss, something prevented the harm from occurring. It might have been a checking mechanism, a vigilant staff member or a knowledgeable patient. Identify what the barrier was. Defences like this might easily be strengthened to prevent other errors. This is a quick but valuable step.

- Define best practice – Develop a clear description of what is good practice in this area, especially what you expect to do in your practice. Because this approach is like an audit cycle, it is important to have a clear description of what you want to occur.

- Brainstorm solutions – Record as many possible options for improvements, safeguards, or solutions, without deciding which ones are better or worse. It is very helpful to let the discussion be as creative as possible as useful insights can arise. There can be particular value in the differing viewpoints that arise from broad involvement of the practice team.

- Identify what is feasible and practical – This can also highlight differences of approach that can give rise to misunderstandings.

Activity

Using the example of Albert, work through the table of contributing factors (*Table 5.3*). Brainstorm as many safeguards and mitigating actions as possible for each contributory factor.

Table 5.3 Contributing factors: the case of Albert		
Factor	**Contributing factors**	**Mitigating actions/safeguards**
Patient	Patient did not communicate change of contact details to practice staff	Educate patients to alert staff to a change of contact details
	Patient was unfamiliar to the GP, with no history of complex comorbidities	Maintain vigilance, particularly with long-term, familiar patients
	Patient did not follow up test results with the practice	Educate patients to discuss with GP the process for follow-up of test results
Task and technology	Medical software used by the practice triggers the test results as having been actioned when a follow-up letter is printed	Review medical software and build software limitations into the practice system for recall of patients with clinically significant test results
	Follow-up of patient became a complex task due to the lack of systems to recall patients with clinically significant results	Ensure all practice staff are aware of the system for follow-up and recall of patients
GP	The GP overlooked explaining to the patient the process for follow-up of test results	Ensure all practice staff can describe the practice system of follow-up and recall of patients with clinically significant test results
	The GP did not document the attempt at follow up in the patient's health record	Review system of how patients are alerted to the practice system of recall
	The GP was distracted from his primary task by a telephone call and subsequently failed to mail the letter	Review practice policy of documenting attempts at follow up in the patient's health record
		Review system for managing telephone calls (to minimise interruptions)
		Review systems to ensure follow-up via mail is streamlined across the practice
Practice team	The patient's contact details were not confirmed at the time of appointment scheduling	Review practice system for ensuring patient contact details are maintained (eg. reception staff confirm contact details at time of scheduling appointments)
Environment	There was no strong culture of safety and communication within the practice or between patients and practice staff	Ensure mechanisms are in place for effective communication
		Ensure practice team, including GPs, meet to discuss what happened, contribute quality improvement ideas and review the system of recall and follow-up
Organisation and management	There was no standard process for inducting new staff into the practice, including the practice protocol for follow-up and recall of test results	Establish a stable staff structure within the practice
		Require all new staff to familiarise themselves with the practice system for follow-up and recall of test results

Adapted with permission from Vincent C. Patient safety. London: Churchill Livingstone Elsevier, 2006:108.

Prioritising safeguards

Once you have finished the investigation, you will likely be left with a range of possible solutions and safeguards; it is important to prioritise these. Be mindful that it is not always feasible or desirable to implement all of them.

One way to establish priorities is to use an ease/impact analysis (*Box 5.1*).

EASY to do Has LITTLE IMPACT	EASY to do Has HIGH IMPACT
HARD to do Has LITTLE IMPACT	HARD to do Has HIGH IMPACT

Box 5.1 Ease/impact analysis

Start with the potential solutions/safeguards that are easy to implement and have a high impact. These solutions are sometimes called the 'low hanging fruit'. Next, attend to those that are hard to do, but have a high impact.

This approach can be shown in a simple matrix, where each potential solution is slotted into one of four quadrants (*Box 5.2*).

EASY to do Has LITTLE IMPACT Put notice in waiting room reminding patients to report change of address/contact details	EASY to do Has HIGH IMPACT Establish a practice policy where reception staff confirm contact details for all patients at time of appointment scheduling
HARD to do Has LITTLE IMPACT Identify limitations in clinical software systems and lobby the appropriate companies to modify the software	HARD to do Has HIGH IMPACT Practice nurse explains to all new patients the practice system for follow-up of test results

Box 5.2 Worked example ease/impact analysis

In making priorities, ask: 'What does it really take to implement the safeguards to improve your systems?'

Also think about the way people in the practice may react to the proposed changes:

• Does someone have a lot invested in the way things work at the moment?

• Does someone have a strong opinion about the potential changes?

Think about the benefits for each person and answer the questions:

• What's in it for me?

• Who needs to take action to make the change a reality?

• Who needs to be aware of the change?

• How can you make them aware of it? (ie. do you have regular staff meetings where this information is conveyed?)

- Does the change need to be reflected in the practice's policy and procedures manual?

- Who is responsible for making sure this happens?

- How and when will you 'iron out' any wrinkles if the change does not work the way you intended or does not achieve what you want?

Step 7. Implementing safeguards

Quick points

- Change management is sometimes necessary to implement safeguards and improvements.

- There are some common elements for effective change management that can be implemented.

Case study – Sunny Dale Practice

Leading an organisation through change, even where the change is simple, can be challenging. However, change that involves the whole general practice team is often necessary for effective implementation of quality and safety improvement.

Sunny Dale Practice does not have a good team communication system. Messages are written on notes that sometimes get lost among other pieces of paper on desks and often do not get passed on. This can be a problem, particularly when a message is urgent or important. Although the practice staff are all vigilant in ensuring messages are passed on (a positive human factor), this poses a potential problem for patient safety.

Dr Morgan is concerned and decides to talk to the practice team about creating a communications system that everyone will be able to use to address the problem. The communications system will create a safeguard for patient safety and support the staff.

Before talking to the team, Dr Morgan thinks about what change management techniques he can use to ensure the change is effective. He begins by having a crucial conversation with the team so that everyone understands why the current system is a problem. The team agree there are problems, but do not know what else they can do – they are all busy and can not use a system that will take too much time.

The team members brainstorm ideas and agree to use the practice's software system to send internal emails at the time they receive information. This way, an electronic trail can be left to keep track of messages. Messages can be flagged as important or urgent, and regular system backups ensure messages do not get lost.

All the staff and GPs in the team agree that any urgent issues that are emailed are also printed off and brought to the person's attention as soon as possible so they are not accidentally overlooked.

There are common barriers and pitfalls in change management, but there are also common ways to improve the effectiveness of managing the change. Change management will be successful if certain key elements are present. The common key elements of successful change are:

- The people involved can see the point of the change, agree with it and have the skills to do it.

- Surrounding structures are consistent with, and support, the change (eg. reward systems).

- Those involved can see people they respect in the team modelling the change.[42]

The National Health Service (NHS) in the United Kingdom has put together a checklist for good change management:

- Have you personalised the change?

- Have you sorted out the nuts and bolts of the issues?

- Is the change integrated?

- Is the environment supportive?

- Have you created new behaviours?

- Do you 'reward' the right behaviours?[43]

Activity

Reflect on experiences where you have been involved in effective change management.

- What approaches do you think could be used in general practice to assist in effectively managing change?

- What was effective/not effective?

Reading

- Lawson E, Price C. The psychology of change management. McKinsey Quarterly 2003:31–41.

Step 8. Evaluating performance

When a change has been implemented, it is important to review:

- what worked, and why

- what did not work, and why

- whether the change is sustainable.

A PDSA cycle (*Figure 5.5*) is an effective means of achieving this. Deming cycles, or PDSA cycles, are a continuous quality improvement tool consisting of a logical sequence of repetitive steps for continuous quality improvement. A PDSA cycle can be used to measure progress and determine if the implemented safeguard has resulted in an improvement (*Figure 5.6*).

Plan

- Plan the test or observation.

- State the objective/hypothesis of the test.

- Make predictions about what will happen and why.

- Develop a plan to test the change (Who? What? When? Where? What data needs to be collected?).

Do

- Try out the test on a small scale.
- Document problems and unexpected observations.
- Begin analysis of the data.

Study

- Set aside time to analyse the data and study the results.
- Complete the analysis of the data.
- Compare the data to your predictions.

The 'study' part of the cycle is the key to learning what changes lead to improvement.

Act

- Refine the change based on what was learned from the test.
- Summarise and reflect on what was learned, describing the actions you will take as a result of these findings for your next cycle of the PDSA.

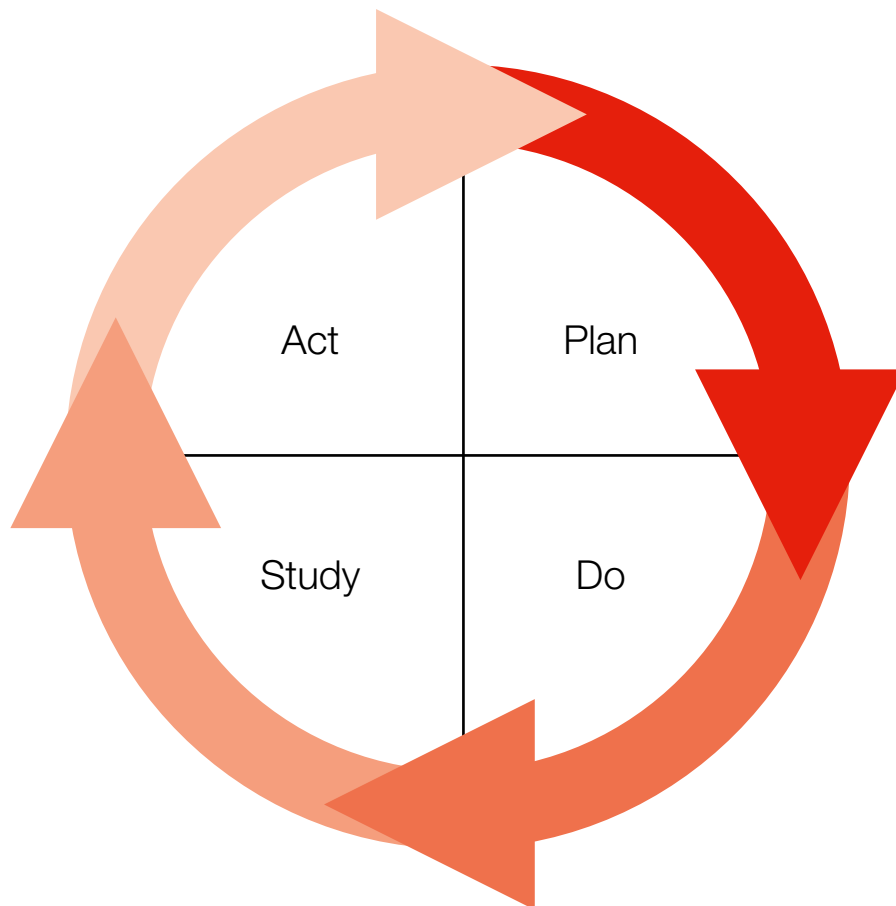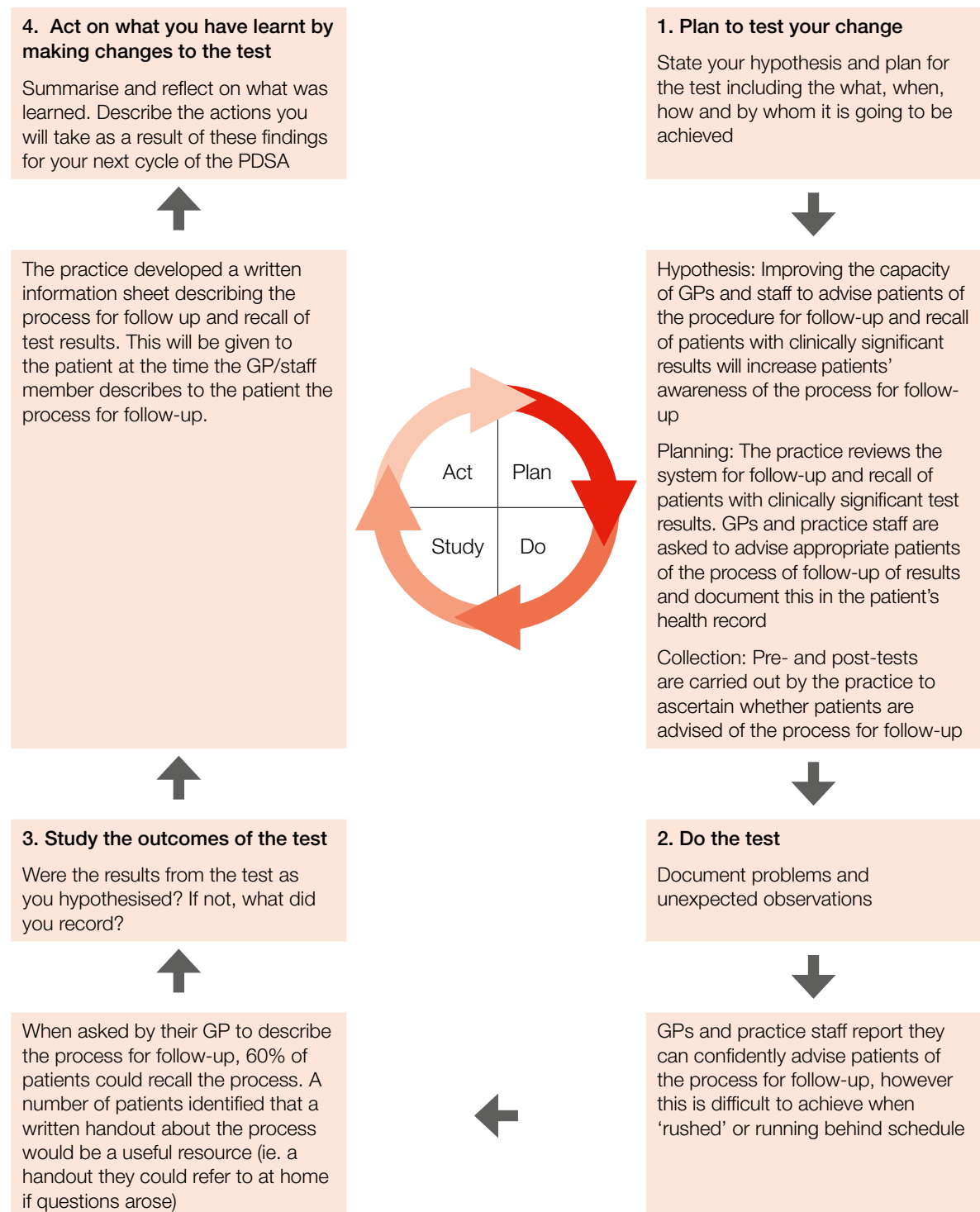Prepare a plan for the next test, if necessary.

Figure 5.5 The PDSA cycle

Source: Courtesy of The W. Edwards Deming Institute®

It is useful to familiarise yourself with PDSA cycles. They are short and quick to complete, and provide rapid feedback.

4. Act on what you have learnt by making changes to the test

Summarise and reflect on what was learned. Describe the actions you will take as a result of these findings for your next cycle of the PDSA

The practice developed a written information sheet describing the process for follow up and recall of test results. This will be given to the patient at the time the GP/staff member describes to the patient the process for follow-up.

1. Plan to test your change

State your hypothesis and plan for the test including the what, when, how and by whom it is going to be achieved

Hypothesis: Improving the capacity of GPs and staff to advise patients of the procedure for follow-up and recall of patients with clinically significant results will increase patients' awareness of the process for follow-up

Planning: The practice reviews the system for follow-up and recall of patients with clinically significant test results. GPs and practice staff are asked to advise appropriate patients of the process of follow-up of results and document this in the patient's health record

Collection: Pre- and post-tests are carried out by the practice to ascertain whether patients are advised of the process for follow-up

3. Study the outcomes of the test

Were the results from the test as you hypothesised? If not, what did you record?

When asked by their GP to describe the process for follow-up, 60% of patients could recall the process. A number of patients identified that a written handout about the process would be a useful resource (ie. a handout they could refer to at home if questions arose)

2. Do the test

Document problems and unexpected observations

GPs and practice staff report they can confidently advise patients of the process for follow-up, however this is difficult to achieve when 'rushed' or running behind schedule

Figure 5.6 PDSA cycle: worked example

Activity

Completing a PDSA cycle

When returning to your practice, try to apply the knowledge and skills you have acquired thus far through the implementation of a PDSA cycle. Start small and at a level at which you feel comfortable. Observe your practice, its system and processes. Take note of the human and contextual factors that arise, and the effect they have on the quality of patient care and treatment outcomes.

- Choose an example of a clinical risk, error or near-miss where patient harm could have occurred but did not, either due to chance or timely intervention. Try to identify the causal factors (human and contextual) and consider what could be done to prevent them adversely impacting patient safety in the future.

- Implement the patient safety improvements you have identified with assistance from others in the general practice team as appropriate.

- Determine how you will evaluate your intervention's degree of success at achieving the intended benefit(s).

- Conduct and evaluate post-implementation and share the lessons learnt with your practice team.

At each stage of the PDSA cycle, carefully consider the associated medico-legal implications and consult your medical indemnity insurer where any uncertainty exists.

For further information about the completion of PDSA cycles refer to the RACGP QI&CPD handbook.

Reading

- Carroll JS, Rudolph JW, Hatakenaka S. Lessons learned from non-medical industries: root cause analysis as culture change at a chemical plant. Qual Saf Health Care, 2002;11:266–9.

Step 9. Sharing insights and improvements

> *'After the workshop, I realised what great ideas they had in other practices. We'll definitely adopt some of them.'*

Risks, errors, near-misses and adverse events occur in other general practices. The benefits from your lessons, improvements and insights can be multiplied if other people also adopt them.

Innovations that you create may be very valuable for your colleagues. It may also have extra legitimacy because it comes from fellow GPs and practice team members. Things you can do to share insights and improvements include:

- sharing a de-identified example of a risk, error, near-miss or adverse event as part of a small group learning activity (this is likely to attract QI&CPD points)

- giving a presentation at a practice meeting

- writing a letter to the editor of a journal such as *Australian Family Physician* (*AFP*) or submit the safety tips you have developed for possible inclusion in *AFP*

- publishing your initiatives in medical indemnity insurer's newsletters

- advising manufacturers and the RACGP about safety hazards or design faults you have identified

- celebrating within your practice that you have worked together to successfully improve the quality of your care for your patients.

Refer to *Chapter 6* for further information about the related medico-legal considerations.

Step 10. Maintaining vigilance

Quick points

- It is important to remain aware of the potential for lapses in patient safety to ensure effective and timely responses can occur. A supportive environment helps to achieve this.

- Sharing cautionary tales with others (eg. a medical defence organisation or medical indemnity insurer bulletin) can help others to learn from your experience. Exercise care to ensure patient privacy is protected.

- Potential medico-legal implications need to be considered when sharing cautionary tales – using near-misses is generally a good place to begin.

'We tend to let our guard down over time. What can we do about that?'

It is important to maintain a focus on what is going on around individuals and to look for weaknesses in the system. This is not an attempt to focus on everything; rather, it is identifying, appraising and grasping the significance of critical elements within a practice setting.

GPs and their practice teams involved in the development of this publication searched for mechanisms that help them remain vigilant without creating an overwhelming burden. Maintaining safety in your practice requires a mindset of intelligent wariness – being able to clearly see what systems, structures and factors are at play that create or reduce patient safety. This is an ongoing process and requires involvement from all general practice team members. Tips and tools that can be used to help maintain vigilance are discussed in this section.

An open and just culture is important to enable everyone in the team to feel supported to maintain vigilance.

Ways to maintain vigilance include:

- communication techniques

- communication structures

- personal vigilance, self-monitoring and monitoring others.

Using crucial conversation skills (*Step 3*) helps if you need to speak to an individual about concerns you have about patient safety.

Communication techniques

Speak clearly and assertively

Get the individual's attention (using their name is the best way); indicate your concern, worry, unease, lack of comfort; specifically outline the problem and suggest a way to address it. Agree on what to do.

> *'Helen, this month's audit shows that only 60% of new patients recorded their allergy status. We'll need to remind the receptionists to check the forms when they are handed back. Will you do that today, please? Great, thanks.'*

Verify verbal communication

This involves asking for clarification, reading back key communication (like medication dose, phone contact details, patient name) and acknowledging that the information has been read back correctly.

> *'Now let me check I've got that right. You called the ambulance before ringing here so it's on its way and your husband has taken his Anginine. Is that correct?'*

When witnessing an event, say something about it and make a statement about what will fix it

Assertive staff learn, often by modelling, to say something to alert those who need to know, and then work with those involved to fix the problem before harm occurs.

> *'I put my can of drink in the vaccine fridge yesterday: I know I shouldn't have and this morning it's frozen solid. That could be a problem for the vaccines, couldn't it?'*

Refer to *Chapter 6* for further information about related medico-legal considerations.

Communication structures

Briefings and clinical handover

These need not be long. They encourage people to gain or maintain their familiarity with processes and procedures that might be used (eg. a short briefing for everyone involved before an invasive procedure). They allow people the opportunity to volunteer information that might be critical and to advise of any safety concerns and risks. This can allow for problems to be anticipated and for solutions to be volunteered. Briefings and handover can also allow people to inform other team members about personal issues that could impact on performance (eg. make a person easily distracted) or require the redistribution of work.

Debriefings and self critique

Debriefings can be short and focus on the activity, rather than generating solutions for the future. They allow team members the opportunity to reflect on what was effective and ineffective and the way the team worked. They provide the opportunity to learn from successes and errors. Debriefings can be used routinely (eg. after procedures) or following something unexpected.

Monitoring techniques

It is important not to ignore personal cues and thoughts. The following cues are important:

- confusion or 'gut feeling'

- no one watching or looking for hazards

- use of improper procedures

- departure from guidelines

- fixation or preoccupation (eg. not responding to two or more comments or being overwhelmingly focused)

- unresolved discrepancies.[44,45]

It helps to seek feedback and to be open to the possibility that a slip, lapse or mistake has occurred.

Refer to *Chapter 6* for further information about related medico-legal considerations.

Activity

Monitoring techniques

Consider how you can maintain vigilance in your personal practice and also in the broader general practice environment.

- What tools may be used to help members of the team be vigilant?

- Do any themes emerge? For example, does communication present as an important issue?

- How can the ideas be applied in practice?

6. *Medico-legal issues*

Earlier, we explored the features of a just and open culture. However, that culture can sometimes appear to clash with a legal system which analyses adverse events entirely from a fault- or blame-based perspective. Additionally, the conventional thinking in the medical community (and elsewhere) is that 'anything said or done by you will be used against you'.

This section explores some key medico-legal issues that should inform your approach to, and understanding of, adverse event management, open disclosure and related matters.

6.1 Different events and patients bring different repercussions

The literature indicates that patients take legal action not so much because of poor clinical outcomes (though those outcomes can certainly cause litigation), but because of poor communication – either before or after those outcomes become known.

It also suggests that health practitioners feel much better when they are given the freedom to speak openly with their patients. While wishing to do this, the GP and practice staff may still fear that participating in an open disclosure conversation will only make a bad medico-legal situation worse, potentially fuelling medico-legal activity.

It is very important to understand that not all adverse events are equal. Medico-legally speaking:

* medico-legal fallout can range from nonexistent to extremely significant
* different adverse events (and associated communication processes) generate different types of medico-legal problems; some generate none
* the quality of the post-incident dialogue between patient and health professional is critical and may influence whether an adverse event generates medico-legal activity.

Often, the medico-legal repercussions of an adverse event will depend on a combination of the:

* attitude of the patient
* severity, or perceived severity, of any resulting injury
* capacity of the patient or their lawyer to establish a legal basis for the claim.

The attitude of the patient is largely determined by the quality of the relationship (ie. the communication) both before and after the patient safety incident occurred.

6.1.1 Law reform and the courts

Largely as a result of so-called tort law reform, it is increasingly difficult for patients to take legal action for injuries allegedly suffered at the hands of a health professional. While laws differ between jurisdictions, the general effect for patients is that it is harder to start legal proceedings; once started, it is harder to win; if they win, they recover less compensation than previously.

6.1.2 Medical negligence litigation

This is where the patient wants to be compensated because they feel they have been the victim of medical negligence. Their lawyers start proceedings via the court system (eg. Supreme, County or District Court).

It is important to understand that even if an adverse event cannot generate medical negligence proceedings (eg. because the patient is unable to establish the four key elements for a successful negligence action), there may be other legal consequences.

6.1.3 Disciplinary processes

This is a process where the patient does not seek (or cannot get) compensation but is seeking accountability. They want someone to investigate the practitioner's conduct or performance – for example, whether they might be guilty of unprofessional conduct or professional misconduct.

In this situation, the Australian Health Practitioner Regulation Agency (AHPRA) will get involved. AHPRA is an agency which supports 14 national health profession boards (including boards for medical practitioners and nurses).

In these settings, the presence or absence of negligence (or even the presence or absence of injury) is often immaterial. Instead, the relevant tribunal scrutinises a range of different issues related to the practitioner's (and their practice's) general professionalism and standards of professional conduct. Occasionally, they will also look at a professional's systems and quality of practice.

6.1.4 Coronial investigation/inquest

Where the adverse event causes (or may have caused) death, the quality of medical management is likely to be investigated by the coroner, and there may be a formal inquest.

Sometimes an adverse event can generate one or more of these medico-legal repercussions. When this happens, they tend to be the inevitable consequence of the adverse event, and have nothing to do with the content or quality of post-event communication. On the other hand, sometimes the content and quality of the post-event communication can have the effect of dissuading the patient from taking the matter any further.

The possibility that the adverse event may generate one or more of these medico-legal processes does not mean you should refrain from entering into the open disclosure process. It simply means that you need to include those contingencies when undertaking a preliminary medico-legal 'triage' of the adverse event.

6.2 What's the chance of medico-legal action?

Many adverse events do not generate any medico-legal activity. This can be because the patient has no interest in pursuing the matter (possibly because they perceive the injury or incident to be trivial or at least not worth taking further), or the various legal prerequisites for taking action cannot be met.

The probability of medico-legal action is increased if:

- the adverse event is substantial (eg. a disabling injury or condition or the delayed diagnosis of a significant illness)

- the patient forms the impression, rightly or wrongly, that the health professionals involved are being less than forthright in discussing the issues with them

- the circumstances by law automatically trigger a legal process (eg. certain deaths must be investigated by the coroner).

If these situations occurred, it would be no surprise to be confronted with a medico-legal problem, no matter what the quality or content of post-event discussions may have been. Even where some medico-legal process is inevitable, it is still important to keep the lines of communication open. That may help to take the 'heat' out of the dialogue. It also probably means health professionals need to use greater than usual care holding the discussions, which may in turn warrant earlier than usual liaison with, and guidance from, insurers.

In most other situations, the medico-legal future of an adverse event is less certain. Early, open, accurate and honest communication may therefore not only maintain healthy therapeutic dialogue but might also nip a future medico-legal complaint in the bud. However, bear in mind that these discussions are not designed or intended to act as an anti-litigation tactic, even though they may have that impact incidentally.

In any event, and whatever the potential medico-legal repercussions, you have a responsibility to be open and honest with your patients – see for example the Medical Board of Australia's *Good medical practice: a code of conduct for doctors in Australia*.

Activity

List the types of adverse events that you consider:

- least likely to generate medico-legal activity

- most likely to generate medical legal activity.

Feedback: Medico-legal consequences are unlikely in situations where:

- there is no injury or the injury is relatively trivial and the patient is satisfied with the communications, discussions and explanations

- the injuries, although not trivial, fail to reach the thresholds required to start legal proceedings in your jurisdiction

- the adverse event is in no way caused by your or your staff's negligence (as that term is understood by lawyers), suboptimal or less than professional care.

6.3 What if the adverse event relates to someone else?

When you first find out about an adverse event, it may relate to a health professional other than you, such as:

- a staff member

- another health professional

- another health professional in your practice who is not your employee (eg. contracted or self-employed allied health professionals/nurses or fellow GPs) or health professionals in other practices or healthcare settings (eg. hospitals).

Each scenario is discussed below.

6.3.1 An adverse event involving a staff member

Under the principle of vicarious liability, an employer is automatically legally liable for the negligent acts and omissions of employees that take place within the course and scope of the employee's job. This principle does not apply to nonemployees.

However, just because an adverse event involves your employees (and vicarious liability therefore operates), you should not assume that:

- your employees' interests necessarily coincide with yours

- they can, and should, look to your insurer for medico-legal protection.

You need to consider the following:

- Is the employee covered for negligence claims under your policy, the practice policy or another policy? If so, which policy?

- If employees are covered for negligence/compensation claims, they may not be covered for instances such as disciplinary complaints to their own professional registration body or coroner's inquests.

- If employees are covered for any or all of these matters, they have independent rights, including the right to seek independent advice.

- If employees are covered for all/any of these contingencies, their views and recollections of events may differ from those of others in the practice team, including yours.

- If/when this happens, it can put you and them in a situation of conflict. They may need independent advice and protection, and may also be reluctant to cooperate with your investigations or share information with you.

- Sometimes (rarely), the employee may decline to cooperate because they perceive (rightly or wrongly) that they could confront disciplinary sanction from you, or external authorities, or that their employment may be terminated.

Let us look a little more closely at how your interests may not coincide with your employees' interests and their rights.

Employees have the right:

- to seek appropriate legal advice and disclose information to legal advisers in a manner that attracts legal professional privilege

- to be treated fairly by the employer institution and receive natural justice and procedural fairness

- not to be defamed

- on some occasions, to seek appropriate advice and guidance from their own insurers, if they have any contractual obligations to those insurers.

Although employees may not cooperate or choose to exercise their rights, in most situations, they cooperate with legitimate inquiries into an adverse event.

The impact of the privacy law will be discussed later.

6.3.2 An adverse event involving another health professional

Sometimes you may be the first to learn about an adverse event, although it relates to acts and/or omissions of another doctor. This can occur when the patient is uncomfortable speaking to the doctor 'responsible' or you are the first to discover it (and hindsight reveals it has involved one or more practitioners in the past).

In some situations, the other practitioners may be friends, colleagues or your competitors, who may or may not know about the event.

Whatever the situation, you need to act professionally in your dealings with the other practitioner(s) and the patient, while also recognising your relevant legal obligations – one of which is the obligation concerning 'mandatory notification' to AHPRA (discussed in *Section 6.4.1*).

In speaking to the patient:

- encourage them to approach the other practitioner to discuss their concerns. If they do not want to do this, you may seek their permission to approach the other practitioner on their behalf. You do not have to do this, but it may well be in the interests of all concerned to do so

- avoid criticising the other practitioner – often you will not possess sufficient information or background to make such a criticism

- if appropriate, explain that the concerns about the other practitioner are baseless (but not unless you are confident you are right).

If you are uncertain of what to say, or who to speak with, consider approaching a respected colleague or contact your liability insurer.

6.3.3 An adverse event involving non-employees and health professionals in other clinical settings

As explored earlier, adverse events are often brought about through a series of errors (or missed opportunities for improvement), rather than an isolated lapse on the part of one health professional.

This can be the case where, superficially, it looks like only one doctor was 'responsible' for the adverse event, but harm was suffered while the patient was under another doctor's watch.

Further investigation may also suggest that multiple health professionals were in fact potentially involved. For example, in the case of a late diagnosis over a long period where there were opportunities for others to make the diagnosis earlier and start required treatment.

Again, the health professionals involved may or may not be related to your practice. If they are not part of your practice, communication with them can be a difficult and sensitive process.

Do not assume you are entitled to communicate with them in order to undertake necessary investigations as:

- you need to ensure that any 'external' discussions comply with privacy law

- it is possible that they do not wish to cooperate fully or their insurers may not want them to.

6.4 Adverse events arising from unlawful activity or an impaired health professional

On rare occasions, you may suspect an adverse event is linked to unlawful or criminal activity, an improper act, or omission by a health professional. For example:

- a boundary violation (eg. improper sexual conduct)

- treatment or diagnosis by a health professional while under the influence of drugs or alcohol (regardless of whether it causes an adverse event).

If you suspect this to be the case, the usual approach to the open disclosure process as outlined in this module is probably not appropriate.

Additionally, if you have more than a mere suspicion – but in fact have 'reasonable belief', then you may be required by law to notify the authorities (see discussion in *Section 6.4.1* about potential 'mandatory notification' responsibilities).

Seek advice from your liability insurer, not because of personal exposure, but because they employ experienced medico-legal experts who can help guide you through this tricky situation in a manner that is fair to all parties.

In particular, they will need to guide you through what can be a legal minefield of defamation law (eg. if you tell a patient or colleague of your suspicions and they turn out to be unfounded, that practitioner may be entitled to sue you for defamation).

6.4.1 Mandatory notification responsibilities

By law, health professionals are required to notify AHPRA or a national board of 'notifiable conduct' by:

- another practitioner (in any health profession, not just medical or general practice)

- a student who is undertaking clinical training, with an impairment that may place the public at substantial risk of harm.

Notifiable conduct by registered health practitioners is defined as:

- practising while intoxicated by alcohol or drugs

- sexual misconduct in the practice of the profession

- placing the public at risk of substantial harm because of an impairment (health issue)

- placing the public at risk because of a significant departure from accepted professional standards.

The requirement to notify starts once the health professional has a 'reasonable belief' (that is, a belief based on reasonable grounds), rather than simply a mere suspicion.

Where that reasonable belief exists, then the practitioner must notify the authorities and a failure to do so may itself attract disciplinary proceedings and additional consequences if they are the employer of the person who should have been notified about.

Practitioners who notify in 'good faith' will be protected from any defamation complaint from the person notified about. But be aware that protection relates only to the communications from the practitioner to AHPRA/the relevant board, rather than communications from the practitioner to anyone (and everyone) else.

The obligation to notify the authorities will not exist where:

- the practitioner acquired the belief in the course of obtaining information during certain medico-legal proceedings or quality assurance activities

- the practitioner believes/reasonably believes that the authorities have already been notified by someone else

- in Western Australia, the practitioner is the treating practitioner of the practitioner (or student) who is believed to have engaged in the notifiable conduct.

These mandatory notification responsibilities can sometimes be challenging and sensitive. AHPRA has developed several resources to help practitioners understand and work their way through the issues. It would also sometimes be appropriate to consult your insurers to better understand your rights and obligations.

6.5 Telling patients about an adverse event

6.5.1 Preparing for an open disclosure conversation

What to say and do following an adverse event is a common concern for GPs and practice staff. If communication appears rehearsed, defensive or concealing, it can often do more harm than good. Therefore, it is important for the GP to provide an environment where the patient receives the information they need so they can understand what has happened. Both the patient and the practice team need to feel supported when things go wrong.

When some people think about adverse events, their first and only thought is of a major catastrophe, or at least an incident in which patients suffer significant harm. But not all adverse events are of equal significance or effect, or trigger the same level of response. Sometimes, and for less significant adverse events, an effective and meaningful open disclosure process can take place quickly and with minimal time, effort or use of resources.

6.5.2 Timing of an open disclosure conversation

Some adverse events are not discovered for weeks or months and, once discovered, allow an opportunity to plan an open disclosure conversation. However, many minor events are managed in the immediate practice environment, leaving no time to plan. This is why GPs and all practice staff need to feel confident fulfilling the minimum requirement of:

- acknowledging that an adverse event has occurred

- listening to the patient

- offering an empathetic expression of regret for what has happened – including saying sorry.

The logistics of the conversation should also be considered. For example:

- When and where will it take place?

- Who should lead the open disclosure process? (This is usually the person directly involved in the adverse event – the GP or practice nurse – who may be supported by the practice manager)

- Who should or should not be there? (It may not always be appropriate for the GP to be involved. A highly agitated and stressed GP may exacerbate the situation)

- What are you going to say? What words will you use?

- What are the likely reactions of the patient and their family?

Another way of looking at the open disclosure process is to break it down into a series of phases or components. When preparing for the discussion you should:

- review the facts

- identify and involve appropriate participants

- use an appropriate setting.

In starting the discussion you should:

- determine patient's and family's readiness to participate

- assess the patient's and the family's medical literacy and ability to understand.

Remember: patient and family 'participation' means just that. The process involves a dialogue/conversation and not just a speech, and it is important that they are given the opportunity to communicate their experience, impressions and concerns.

When presenting the facts, describe:

- what happened – simply

- what is known of the outcome at this point

- the next steps.

Also:

- sincerely acknowledge the patient's and the family's suffering

- say sorry (unless there is a compelling reason not to – see later discussions).

In concluding the discussion:

- summarise the key points

- repeat the questions raised (and the answers)

- establish if the patient needs a follow-up appointment to discuss the incident and arrange an appointment as per practice protocol

- document the event and the discussion.

The dos and do nots of documentation are explored in *Section 6.9*.

> ### Activity
>
> - Refer to the example of Albert in *Section 5*. Albert is due for his appointment after lunch. Imagine you are Dr Kenny. Think about how you would manage the consultation with Albert. What words would you use to tell him there has been a lapse in quality of care?
>
> - Role play the conversation between Albert and Dr Kenny in pairs, as part of a workshop or small group learning activity.

6.5.3 The right words: preparation is the key

The open disclosure conversation does not need to be a tightly scripted, well-prepared speech. For some minor adverse events, a simple apology and explanation is all that is needed. However, when the adverse event is serious, or perceived to be serious by the patient, more is needed to heal the potential rift in the relationship.

It is important to practise the words you will use so you feel comfortable and natural with the language when the need arises, without appearing to be rehearsed, defensive or concealing.[46]

The following text (adapted from readings listed below) provides examples of useful words and phrases to use with the patient and their family in an open disclosure conversation.

- 'Let me tell you what happened. There has been a significant lapse in quality and we failed to follow up with you and tell you about your diagnosis of malignant melanoma.'

- 'Let me tell how sorry I am that this has happened.'

- 'I want to discuss with you what the diagnosis means for you, but first I'd like to apologise.'

- 'I want to discuss with you what this means for your health.'

- 'I'm sorry; this shouldn't have happened. Right now, I do not know exactly what happened, but I promise you we're going to find out and do everything we can to make sure it does not happen again.'

- 'I will get back to you as soon as we know what happened and we can talk about the steps our practice will take to prevent it happening again.'

- 'Our practice takes this very seriously and we will look into it to find out exactly what happened and what we can do to prevent it happening again.'

- 'Do you have all the information you need? I'm here if you have any other questions.'

- 'Here is my telephone number. You can contact me if you have any questions or concerns. If you telephone and I'm busy with a patient, I promise to call you back the same day.'

- 'I know it's hard to take it all in so I'm happy to go over this again another time.'

- 'Would you like me to contact you to set up another meeting to talk about what has happened and answer any questions you may have?'

> ### Reading
>
> - Massachusetts Coalition for the Prevention of Medical Errors. When things go wrong: responding to adverse events. A consensus statement of the Harvard Hospitals. Burlington: Massachusetts, 2006.
> - The Australian Commission on Safety and Quality in Health Care. The Australian Open Disclosure Framework. Health care professionals handbook. Commonwealth of Australia, 2003.

6.5.4 The wrong words

It is easy to get an apology wrong, either because it was:

- intended but not actually delivered
- delivered but not accepted
- delivered and accepted but the quality of disclosure was deficient or misleading, and as a result makes matters worse.

It is also easy to inadvertently use words that carry a different legal meaning from those intended. You can do several things before and after the open disclosure discussion to avoid that risk:

- Prepare yourself and team members involved in the discussion.
- Document the discussion. This is particularly important as parties to a discussion (about adverse events and other issues) often have very different (but honestly held) recollections of what was discussed.

Documentation is further discussed in *Section 6.9*.

While ultimately the success of an apology rests on the dynamic between the parties involved, rather than any set of words, there are particular expressions best left alone.

Do not:

- state that you are 'liable' or 'responsible' for the harm caused to the patient
- state that another healthcare practitioner is liable for the harm caused to the patient
- say the event should not have happened or could have been avoided
- say that you caused something when in fact you did not
- give so-called apologies which worsen the situation because they are either:
  - too vague (eg. 'I apologise for whatever it is that happened to you')
  - passive (eg. 'Mistakes have been made'), although sometimes a passive expression is the right choice, for example when you do not know who made the mistake, or the identity of that person is irrelevant to the point you are seeking to make
  - conditional (eg. 'If I did anything wrong, I am sorry').

6.5.5 You be the judge

What is your reaction to the following conversation between Dr Kenny and Albert? What are its strengths and weaknesses?

GP: 'Good afternoon, Albert. I'm glad you arranged an appointment to come in. Let's talk about why you are here today. I want to talk to you about the biopsy we took from your forehead about 3 months ago.'

Albert: 'Oh, I'd forgotten about that. I assumed there was no problem because I did not hear back from you. Everything was fine, wasn't it?'

GP: 'Well, Albert, I'm very sorry to tell you that the pathology actually revealed you have a nodular melanoma on your forehead. It's an invasive form of melanoma and tends to grow more rapidly in depth than other melanomas. I am very sorry that we did not contact you earlier to tell you this.'

Albert: 'Are you serious? What does it mean? Why did not you tell me this 3 months ago?'

GP: 'Right now, I do not know exactly why or how this happened but I promise you we're going to find out. I'll do everything I can to help you through this.'

Albert: 'The biopsy was only 3 months ago, so it can not be that bad?'

GP: 'I know this is really hard to take in, but the melanoma you have is a particularly aggressive type of cancer which grows quickly.'

Albert: 'So what you are telling me is that the time lost is critical, and now I am in a bad situation.'

GP: 'We're not sure yet whether the lost time has affected the growth of your melanoma. We'll need to send you to a dermatologist. I will personally arrange the referral to an excellent dermatologist for you. Once again, I'm very sorry about the delay. We can spend as much time as you need today talking through your questions, but I would also like you to come back and see me tomorrow so we can talk about this further. You are welcome to bring your wife or another relative or friend with you.'

Albert: 'I do not know what to say. You are telling me I have a potentially life-threatening spot on my forehead and to make it worse you forgot to tell me about it! That's completely unacceptable. But I will take up your offer and come back tomorrow with my wife. She'll probably have questions of her own.'

GP: 'I want you to know our practice takes this very seriously and we will look into finding out exactly what happened and what we can do to prevent it happening again.'

6.5.6 Improving your communication during an open disclosure conversation

'The literature indicates that patients sue not so much because of poor clinical outcomes (although they certainly do sue for that), but because of poor communication either before or after those outcomes became known. It also suggests that health professionals feel better when they are given the freedom to speak openly with their patients.

A helpful way of improving an open disclosure conversation is seeing it from the patient's perspective. Think:

- If I were in this position, what would I want done?

- How would I like my doctor to respond?

Patients' reactions to adverse events are influenced by a range of factors:

- Value system – considering an adverse event from the patient's cultural and/or religious point of view may make it easier to respond to adverse events in a way that meets the patient's particular needs, and is a useful technique when grappling with the practical questions of what to say and do after the event.

- Expectations – these include the patient's view of how the GP/practice team should respond.

- Previous experience – what previous experience has the patient had with the healthcare system? This can influence their reaction.

- Pre-existing relationship with the GP – do they have a 'regular' GP and did the adverse event occur with the regular GP?

- Quality of relationship with the GP – patients are less likely to sue if the existing rapport with their health professional has been good.

Upon hearing bad news, the most common reactions are anger, denial and crying:

- Anger – this represents a cluster of emotions such as shock, hurt, annoyance and fear in an aggressive defensive response: 'Why me?' It may help if you verbally confirm how frustrating and upsetting the situation must be and acknowledge that anger is an understandable response.[47]

- Denial – some patients take longer than others to accept bad news. This is often just a temporary reaction, frequently followed by anger. It is important that the patient and family understand, at a minimum, the basics of the adverse event.[48]

- Crying – for many people, watching someone cry is uncomfortable, however, in an open disclosure situation, acknowledging the appropriateness of crying can convey sensitivity to an otherwise difficult conversation.[49]

Be mindful of your communication with specific populations.

Activity

Think about what you could do to improve your own communication with a patient during an open disclosure conversation.

After doing so, read the list below. There may be some types of improvements that you did not list.

- Sit next to the patient rather than across from them. Having a desk between you and the patient can seem distant and separate.

- Be mindful of your body language – assume an open body posture, keeping your hands open and arms resting by your side. Research has shown than only 35% of a message received is based upon the words used. The remaining 65% of the message is interpreted through nonverbal communications.

- Give the patient some control. Allowing patients and/or family members to make choices creates a more even power balance.

- Resist the urge to make excuses and avoid deflecting an apology.

- Give the patient the opportunity to have someone else in the room such as a family member.

- Do not use medical jargon. Although patients are often familiar with medical terms, their understanding may be incomplete or incorrect.

- Consider language barriers and use an interpreter as necessary (only use a family member or friend if absolutely necessary).

- Speak slowly and clearly. When stressed, people are unable to process rapid amounts of information. Allow the patient time to understand the potential implications of your words.

- Do not overwhelm the patient with information or oversimplify things.

- Managing a patient's and their family's emotions are an important part of the process.

6.5.7 When the patient does not know

What if you know about an adverse event but the patient does not yet know?

While you may not have told a patient about an adverse event, do not assume they do not know! Often, they know without you telling them; indeed, they can be the first to raise it.

Sometimes the patient is the last to know, which can happen when that patient:

- was affected by anaesthesia or sedation at the time

- is a child

- is intellectually or cognitively impaired

- has undergone investigations which reveal unexpected bad news.

It can also happen where the healthcare practitioners (not the patient) recognise that things could and should have gone better. Examples include diagnosis which could and arguably should (but for the adverse event) have been made earlier, or where the case could and should (but for the adverse event) have been managed better.

While it will often be obvious that the patient should be told, sometimes it will not be so obvious. As a general rule, you should reflect upon the risk that silence in these situations could do more harm than good to your patient. It could generate fear, destroy or further erode trust and confirm suspicions they may already be developing. It might also expose you to a further complaint of 'cover-up', with disciplinary repercussions.

6.5.8 What if disclosure could harm the patient?

It was emphasised earlier that not all adverse events are created equal, some can be very minor. In the case of minor events, sometimes you may feel it would do the patient more harm than good to generate an open disclosure process. Even if an adverse event is significant, in some cases, you may feel it would be in the interests of the patient to either downplay or ignore it.

Rather than seeking to analyse the situation by asking: 'Why should I tell?', we recommend that you should instead consider: 'Why shouldn't I tell?' Only very rarely would you be legally or ethically justified in not having the discussion. If you are concerned that disclosure may harm or complicate the patient's recovery due to their emotional and psychological state, you may decide to defer the disclosure discussion. However, do not use this to justify postponing disclosure indefinitely.

If you are uncertain if disclosure may do more harm than good, one option is to obtain a second opinion from a respected colleague or from your insurer. If you do decide against disclosure, you must ensure you are ready, willing and able to justify that position to a court or a tribunal, or, for that matter, to the media.

There may well be occasions where such justification is valid, but do not assume that silence is likely to be looked upon kindly by the courts, your peers or the community.

6.5.9 More guidance: the Australian Open Disclosure Framework and Related Resources

The *Australian Open Disclosure Framework* provides an excellent overview on managing patients with particular needs. The Australian Commission on Safety and Quality in Health Care (ACSQHC) maintains the framework and has developed many excellent resources to help with its implementation, including the reading recommended here.

> ### Reading
>
> - The Australian Commission on Safety and Quality in Healthcare. The Australian Open Disclosure Framework. Implementing the Australian open disclosure framework in small practices. Commonwealth of Australia, 2014.

6.6 The role of an apology in the open disclosure conversation

An apology, properly worded, expressed and timed, can address the fundamental human need of a patient to be treated with respect. That need exists both for situations where there has been a serious adverse event and for those that may seem 'trivial'.

Apologies are not designed to admit fault, but they do acknowledge that something has gone wrong and that the patient is unhappy (eg. keeping patients waiting for a long time in reception, while no-one's fault, tends to get them hot under the collar). A simple and brief apology can defuse that anger and simultaneously show that you know and care about the issue.

For these reasons, an apology should be regarded as an indispensable communication tool in the doctor-patient relationship (and one that can be used in a range of situations – not just after adverse events).

As a leading advocate for apology following adverse events stated:

> *'Open, honest communication is essential to maintaining and restoring trust, and to providing appropriate ongoing care. It is not difficult to preserve trust when times are good – where there have been no problems in the delivery of care. The real test is preserving the relationship when something has happened that may strain it. How the communication process is handled profoundly influences the reactions of patients and their families.'[50]*

> ### Reading
>
> - Lazare A. Apology in medical practice: an emerging clinical skill. JAMA 2006;296:1401–4.

6.6.1 Apologies and expressions of regret: a medico-legal perspective

As mentioned in the introduction to *Section 5,* traditional approaches to handling error focus on identifying the person responsible and assigning blame or punishment in some way.[24]

Fears around medico-legal consequences are built on the concepts of personal responsibility and fault. Apologising to a patient goes against this natural tendency to distance oneself from error. Fear of litigation is one of the most common reasons for not openly discussing adverse events and apologising. Concerns have been expressed that an apology, while beneficial to the patient, may not be in the best interests of the doctor.

The concerns are two-fold as some doctors fear an apology may:

• be used as an 'admission' against their interests, either as an admission of liability or admission of some other factual matter which it is not in their strategic interest to make

• compromise their entitlement to coverage from their insurer.

Insurance issues are addressed in *Section 6.7*.

> ### Reading
>
> • The Australian Commission on Safety and Quality in Health Care. The Australian Open Disclosure Framework. Saying sorry: a guide to apologising and expressing regret. Commonwealth of Australia, 2013.

6.6.2 What the law says about apologies

In its resource, *Saying sorry: a guide to apologising and expressing regret*, the ACSQHC describes the varied picture of apology law throughout Australia.

Each jurisdiction has differing 'apology laws'. On balance, the various jurisdictional apology laws neither protect nor hinder the practice of open disclosure. The laws share common features across jurisdictions but variations exist. Five Australian apology statutes (Western Australia, Victoria, Northern Territory, Tasmania, South Australia) expressly exclude statements containing acknowledgment of fault or liability in the definition of the apology, although the wording of these acts can be interpreted in various ways.

In New South Wales, an 'apology' means an expression of sympathy or regret, or of a general sense of benevolence or compassion, whether or not the apology admits or implies an admission of fault. An apology is not considered to be an admission of fault or liability and is not taken into account in determining fault or liability.

There is also variation in the types of legal proceedings to which these laws apply. These variations are summarised next.

6.6.3 What about making an apology in my state or territory?

All jurisdictions have laws that protect (and therefore encourage) the making of apologies and other forms of benevolent gesture. Those laws were not specifically introduced to help open disclosure, but obviously can be used for that purpose as well.

Each jurisdiction has slightly different laws and exceptions. In some jurisdictions, the protection only applies to comments made before legal proceedings commence. In others, it is not available in connection with allegations of sexual misconduct (ie. alleged 'boundary violations') by a health practitioner.

These laws are designed to encourage open communication and early resolution of a complaint by removing concerns that an apology could be used in court against the person who apologised. Arguably, in many respects, these laws do not change the old legal situation but certainly make them more explicit.

In most jurisdictions, apology laws do not protect admissions of liability or fault, as opposed to apologies or benevolent gestures. However, in New South Wales and the Australian Capital Territory, even the admission of fault is legally protected.

To complicate matters, it is not always easy to be specific on which words will and will not constitute an admission of fault. For these reasons, it is important you understand what to say so you do not make an unintended admission of fault.

However, sometimes an adverse event has arisen because health professionals, members of their practice staff or practice systems were truly at fault; in any view, the patient has been the victim of negligence and that negligence has harmed them. In these situations, it may be that a prompt and candid admission of fault is not only justifiable but also desirable and appropriate. This is particularly so where the failure to confront

the situation early could affect the GP both emotionally and legally.

However, before any such admissions of liability/responsibility are made, it is strongly recommended you first speak with your liability insurer.

Table 6.1 Apology laws in Australia				
State/territory	What is protected	How the protection works	What is not protected	Source
Australian Capital Territory	Apology: an oral or written expression of sympathy or regret, or of a general sense of benevolence or compassion, in relation to an incident, whether or not the expression admits or implies fault or liability in relation to the incident	The apology is: • not an express or implied admission of fault • not relevant to deciding fault or liability in relation to the incident • inadmissible as evidence of fault or liability		*Civil Law (Wrongs) Act 2002*
Northern Territory	Expression of regret: an oral or written statement by a person who expresses regret for an incident that is alleged to have caused a personal injury, and that does not contain an acknowledgement of fault by that person	Expression of regret cannot be used in a proceeding as an admission of liability or negligence, and is inadmissible as evidence in a proceeding	Acknowledgement of fault Expressions of regret made after commencement of a proceeding	*Personal Injuries (Liability and Damages) Act 2003*
New South Wales	Apology: an expression of sympathy or regret, or of a general sense of benevolence or compassion, in connection with any matter whether or not the apology admits or implies an admission of fault in connection with the matter	In considering civil liability of any kind, the gesture does not constitute an express or implied admission of fault or liability, and is not relevant to the determination of fault or liability, and is not admissible in any civil proceedings as evidence of fault or liability	Civil liability in respect of an intentional act done by the person with intent to cause injury or death, or that is sexual assault or other sexual misconduct	*Civil Liability Act 2002*

Table 6.1 Apology laws in Australia				
State/ territory	What is protected	How the protection works	What is not protected	Source
Queensland	Apology: an expression of sympathy or regret, or of a general sense of benevolence or compassion, in connection with any matter, whether or not it admits or implies an admission of fault in relation to the matter.	• does not constitute an express or implied admission of fault or liability by the person in relation to the matter • is not relevant to the determination of fault or liability in relation to matter • is not admissible in any civil proceeding as evidence of the fault or liability of the person in relation to the matter	Apologies relevant to civil liability of a person for an unlawful sexual assault or other unlawful sexual misconduct committed by the person	*Civil Liability Act 2003*
South Australia	Expressions of regret: where the defendant or a person for whose tort the defendant is liable, expressed regret for the incident out of which the cause arose	No admission of liability or fault will be inferred from the making of the expression of regret		*Civil Liability Act 1936 (formerly the Wrongs Act 1936)*
Tasmania	Apology: an expression of sympathy or regret, or of a general sense of benevolence or compassion, in connection with any matter which does not contain an admission of fault in connection with the matter	Apology made by or on behalf of a person in connection with any matter alleged to have been caused by the fault of the person: • does not constitute an express or implied admission of fault or liability • is not relevant to the determination of fault or liability • is not admissible in any civil proceedings as evidence of fault or liability	Acknowledgement of fault Where the apology is relevant to civil liability in respect of an intentional act that is done with intent to cause injury or death or that is sexual assault or other sexual misconduct	*Civil Liability Act 2002*
Victoria	Apology: written or oral expression of sorrow, regret or sympathy but does not include a clear acknowledgement of fault Fee waiver or reduction, written or oral	In any civil proceeding (which includes tribunal inquiries and disciplinary matters) where death or injury is the issue, the gesture cannot be used as an admission of liability or unprofessional conduct or unsatisfactory professional performance	Clear acknowledgement of fault	*Wrongs Act 1958*

Table 6.1 Apology laws in Australia				
State/ territory	What is protected	How the protection works	What is not protected	Source
Western Australia	Apology: an expression of sorrow, regret or sympathy by a person that does not contain an acknowledgement of fault by that person	An apology made by or on behalf of a person in connection with any incident giving rise to a damages claim • does not constitute an express or implied admission of fault or liability • is not relevant to the determination of fault or liability • is not admissible as evidence in any civil proceeding as evidence of fault or liability	Acknowledgment of fault	*Civil Liability Act 2002*

6.6.4 Do these apology laws force me to apologise?

These apology laws protect GPs and practice team members who apologise but do not require them to make the apology.

However, failure to apologise (and for that matter, to effectively communicate) could, in certain circumstances, generate legal and ethical issues.

6.6.5 If I use these new apology laws, will that stop me from being sued?

The giving of the apology does not in itself create a legal bar or impediment to any future complaint. Sometimes, even a comprehensive and sincere apology may not stop the patient from taking the matter further.

As stated earlier, a properly given apology can go a long way towards healing the disruption in the doctor–patient relationship and may also discourage the patient from wanting to explore legal avenues. This is because litigation often arises not so much from the adverse event but from the lack of effective communication between patient and professional, both before and after that event occurred.

Anything that improves or restores communication can help to reduce litigation. Statistics show that health professionals who have a good relationship with the patient both before and during an adverse event are less likely to be sued.

Never assume that an apology is only useful if it stops litigation; even if an apology fails to do it, that does not mean it should not be given.

6.6.6 What about concessions that a health professional caused the injury? Will that put them in trouble even under the apology laws or with their insurers?

In the often highly charged setting of a serious adverse event, treating doctors can be tempted to make certain assumptions about the cause of the event. Often, on proper reflection and analysis, the most superficially obvious 'cause' is either not relevant, one of several factors, or the most obvious manifestation of one or more root causes. Making a wrong concession about cause and effect can cause difficulty with your insurers. This is because a negligence claim (which is what the liability insurance policy protects against) consists of several components. The most obvious one is 'liability' – the duty of care owed to the patient was breached.

To successfully recover compensation via negligence law, the patient needs to establish not only that the breach occurred but all the elements of a negligence action. These elements are that the:

- duty of care existed between doctor and patient

- doctor failed to discharge his or her duty of care to act reasonably

- patient has an injury

- injury was caused by the breach of duty of care.

6.6.7 The law and apologies: admissions of fault or responsibility

Under the law of negligence, a patient and their lawyers need to do more than establish that the doctor failed to exercise reasonable care. To successfully sue a doctor, one of the other necessary components is 'causation' – the link or connection between the alleged breach of duty and the injury for which the patient sues.

If there is a breach of duty but no injury, or if the injury is unrelated to the breach but occurred independently, then the negligence claim fails. This is because the patient has failed to establish the

required relationship of 'causality' between the breach and the injury.

As causality is such an important ingredient in any negligence claim, some insurers may not only be concerned about the risk that doctors admit fault, but also whether they improperly admit causation: 'I am sorry I did this to you' states nothing about fault or accepting responsibility, but does assert that the doctor caused the injury. Insurers may not look kindly upon wrong or inappropriate admissions of causality.

The apology laws have not been tested; despite the fact that they are meant to encourage risk-free communication, limits exist. As the apology laws in states and territories (*Table 6.1*) show, those limits vary throughout Australia and some versions do not protect admissions of fault, while others do.

What has not yet been tested is whether an admission of causality, being a necessary component of a negligence claim, is therefore also an admission of fault so that it is not protected in those jurisdictions that do not protect admissions.

Does this mean the doctor should not only avoid admissions of fault/responsibility but also admissions of causality? The short answer is 'no'. A factually accurate statement of causality is appropriate and sometimes necessary. What needs to be avoided are admissions made in error, where on calmer or better analysis, the issue of causality is not as clear as perhaps initially assumed.

The key message is this: do not tell the patient you caused something unless you are absolutely certain that you have.

In all other cases, consider using words such as:

- 'I am very sorry this happened to you.'

- 'I am very sorry about this, and we are now going to look into why it happened.'

- 'I am very sorry about this. I am not yet sure why or how it happened and I will need to look into that further.'

6.6.8 Why should I apologise if the patient is just wrong?

Sometimes the patient has in any view 'got it wrong'. If anything, this reinforces the need to spend time with the patient to explore their understanding and explain the situation, and through this process explain why their dissatisfaction is without foundation. Even in these situations, an expression of regret is still appropriate; the regret relates to your concern that the patient is dissatisfied.

If the patient is unhappy with an outcome, take the opportunity to explore their concerns with them. If it seems they have formed a mistaken view about an alleged adverse event, it does not necessarily mean that you must undertake a comprehensive open disclosure process. Rather, it reinforces the need to communicate early, clearly and often, including occasionally an expression of regret over the concern.

Remember:

- The patient may have 'got it wrong' or formed a wrong conclusion because they did not receive enough (or the right) information in the first place.

- The patient may have formed a view or had an expectation that ultimately proved to be unfounded.

Sometimes, those expectations arise because of inadequate preliminary discussion with patients about the proposed treatment. In these circumstances, it is not only unsurprising that they are upset with the final result, but it also reflects a possible deficiency in the earlier communication process (in relation to 'informed consent').

6.7 Contacting your medical indemnity insurer

6.7.1 When should I first contact my medical indemnity insurer?

Where a patient has suffered harm requiring prompt attention, your immediate and prime concern should be for their care and support. The initial action should be the immediate clinical requirements of the situation.

Your insurer will want to know as soon as possible about incidents that could give rise to a claim under the policy. Indeed, under their contract of insurance with you, they have a right to be notified, and failing to notify could constitute a breach of that contact.

6.7.2 Can I apologise before I contact the insurer?

Generally, no insurer will take issue with the doctor communicating facts accurately to a patient and apologising appropriately. However, you must be confident that your facts are right. Often, this is not easy to do shortly after an adverse event happens.

Your liability insurance cover is a contract. Under that contract, you may have several responsibilities, which potentially affect the timing and content of your communication with patients.

Your contractual obligation is to:

• make no admissions, at least without the insurer's approval

• promptly notify the insurer of a claim or a circumstance that may give rise to one

• do nothing that will prejudice the defence of a claim against you.

So generally, you do not need to speak with your insurer before having these basic discussions with your patient. This is even more so where the adverse event is relatively minor, with low potential of generating medico-legal problems.

However, any insurer would be unhappy where the practitioner:

• admitted fault or used ambiguous words that suggested such an admission (eg. where the words used to apologise were interpreted by the patient, rightly or wrongly, to constitute not just an apology but an admission of fault where no such admission was in fact intended)

• mismanaged the discussion by either failing to prepare for it or not having the required skills to engage in it effectively and productively

• gave the patient information which was wrong or which unfairly and inappropriately compromised the professional's capacity to defend his or her position in court or before a tribunal

• told the patient their injuries were caused by the acts or omission of the doctor or of his/her staff when that in fact was not the case.

While in principle many insurers have no objection to their members making an apology or doing so without first notifying them, they may nevertheless wish to be made aware as soon as possible. This can assist them to know about, and have some control over, the process and also, when needed, help guide the member through a range of potentially difficult issues.

Difficult issues not only include working out what should/should not be said in discussions with the patient, but also the extent to which further investigations should attract some form of legal protection, particularly where the adverse event is likely to generate litigation or associated medico-legal activity.

For these reasons, it is often good to contact your insurers early – sometimes even before you start speaking with the patient.

Early contact is desirable in the following situations:

• Where you feel you need support: often the health professional is the 'second victim' of an adverse event; they might feel isolated, ashamed or guilty. Many practitioners have not been trained to communicate effectively with patients and their family members following an adverse event and may need help doing so.

• Where you are not sure where you stand: where you become aware of an adverse event before the patient does, the insurer and their medico-legal adviser can help guide you through your obligations and then help you to communicate and investigate appropriately.

• When the discussions are likely to be difficult: this can be either because of the personalities involved, the medical/factual issues or because future legal action is a real possibility.

- When you are not sure about the proper rules of engagement: there may be uncertainty about having the discussion and, in particular, about avoiding admissions or making unsubstantiated/unproven comments or drawing unsubstantiated/unproven conclusions. Your insurers can help and you can also get a lot of useful information via the resources created by the ACSQHC (cited in readings throughout this document).

- When you are not sure if it warrants formal discussion: there may be times when the health professional wonders whether to contact the insurer at all, because the matter seems trivial.

As well as familiarising yourself with your contractual obligations, you should also review any materials the insurers have produced on open disclosure. These should clarify what they are happy for you to do/not do without first speaking to them.

6.8 Confidentiality and privacy

6.8.1 Comply with both the spirit and the letter of privacy laws

The privacy laws make it clear that you should always adopt practices that are most respectful to your patients' right to privacy and your relevant legal obligations in relation to privacy. These obligations relate to the way you collect, use (internally) or disclose (externally) information about them for the purposes of any open disclosure exercise.

The open disclosure process will sometimes require you and your staff to use available information about the patient to work out what went wrong and to learn lessons from that. Sometimes, you might need to get extra information – from the patient or from others (outside your practice) involved in caring for the patient.

A common feature of the privacy laws is the need to obtain the patient's consent — unless the laws specifically identify situations when that consent is not needed.

As your open disclosure process should involve an early acknowledgement to the patient that there has been an adverse event, that would provide the most obvious time to explain to the patient how you propose to go about investigating the adverse event and what sort of information you need to obtain and from whom.

If at that point the patient expresses concerns about your proposed information-gathering practices, you need to have a further discussion to clarify and explore their concerns. If it is clear they are not giving their consent, you should respect their wishes but explain to them the consequences of doing so. In most situations, the patient is likely to give their consent. That consent does not need to be in writing; it can be verbal. It can be express/explicit but also implied (eg. by their failing to object to the information-gathering process you have proposed to them).

6.8.2 Confidentiality/privacy laws: discussion with the practice team

The privacy law does not stand in the way of discussions and investigations with the practice team provided they are conducted in a manner consistent with law and least intrusive of the patient's privacy rights and interests. For example, in the case of Albert (*Section 5*), Dr Kenny wanted to share lessons learned with other members of his practice.

This sharing forms a critical part of the open disclosure process. A group discussion may not require or justify the identification of the patient and it can be done without mentioning the patient's name.

6.8.3 The impact of privacy laws and confidentiality on an investigation

In this section, we explore the impact of privacy laws on the open disclosure process, specifically the investigation process. In particular, we focus on the *Privacy Act 1988* (the Act), which applies to all GPs throughout Australia.

During an investigation, you will often need to speak to a range of people other than the patient, for example:

- the patient's close relatives or support person, or, where the patient lacks decision-making capacity (eg. due to cognitive impairment or being a child), their authorised representative

- health professionals within your practice

- occasionally health professionals outside your practice (consultants, hospitals, laboratories)

- your medical indemnity insurer.

In each instance, you may need to disclose certain information about the patient and about the incident. That is, you need to share identifying information. You may also want to get information about the patient from them.

Your capacity to do so is constrained by longstanding confidentiality obligations as well as by more recent privacy laws. The main privacy legislation relevant to you (in some jurisdictions there is additional, state-based legislation) is the *Privacy Act 1988*.

Since March 2014, the Act articulates a number of Australian Privacy Principles which you and your practice must comply with. The Australian Privacy Principles replace the National Privacy Principles.

These privacy laws are triggered whenever you deal with information in which the patient is identified or where they could be identified from the information shared. In other words, the laws do not apply to your handling of de-identified information. It is sometimes not easy, though, to establish when data has been truly and effectively de-identified.

Reading

- The Office of the Australian Information Commissioner. Privacy Business Resource 4: De-identification of Data and Information. Australian Government, 2014.

While privacy laws can sometimes be confusing, there are three key principles to bear in mind that should help ensure your information-sharing practices are lawful:

(a) Comply with the RACGP *Standards for general practices – Criterion 4.2.1 Confidentiality and privacy of health information*

Criterion 4.2.1 Confidentiality and privacy of health information sets out the requirements for a systematic approach to managing the confidentiality and privacy of patient health information in your practice. It is important to note that legislation overrides this standard and general practices need to comply with the relevant privacy laws.

This standard for the purposes of accreditation is intended to provide practices with a framework on how to go about documenting and protecting patient information through policies and processes. Ensuring that patients and health professionals have a shared understanding about how, when and why patient health information is used and shared is critical to your capacity to lawfully investigate an adverse event. However, it is sometimes not enough, especially when in the course of an investigation you want or need to 'collect' (as named in the privacy laws) information about the patient from outside the practice.

Reading

- The Royal Australian College of General Practitioners. Standards for general practices, 4th edition. Melbourne: RACGP, 2010. Available at www.racgp.org.au/your-practice/standards/standards4thedition/practice-management/4-2/confidentiality-and-privacy-of-health-information

(b) Obtain the patient's consent when seeking information from outside the practice

Unlike situations when you want to share information within the practice (called 'use' under the privacy law) or give information about the patient to people outside the practice (called 'disclosure'), there are special and different legal requirements when you want to 'collect' information about the patient from outside of the practice. When it comes to such 'collection', you should first obtain your patient's express consent.

Patient consent does not need to be in writing, but it does need to be a meaningful and informed consent. To do that, it is prudent to canvass the following matters with your patient:

• Indicate you want to do further investigations.

• Explain broadly that these investigations may require them to disclose information about the patient. Tell them who you want to share information with and why. When you want to collect information about the patient from people outside the practice, be more specific (and if you think you know exactly who you need to speak to, and what type of information you need to collect, tell them).

• Indicate that in exchanging information with others, you will disclose only the information relevant to the investigation (as opposed to other health information about the patient which is irrelevant to the investigation).

• Most importantly, explain why it is necessary to do this and what the consequences are in relation to completing the investigation. If it jeopardises your capacity to investigate the matter, you should tell them so, and what that means.

If, after that discussion, the patient still refuses, you must abide by their wishes (unless you are required by law to notify the matter to another person).

(c) The optimal road to privacy compliance: ongoing liaison with the patient

Even if you can establish that consent is not strictly required (eg. because your open disclosure process falls within the 'directly related secondary use reasonably expected by the patient'), it is always a good idea to communicate with the patient. This is particularly so in the case of open disclosure, which, as the name suggests, requires communication and openness.

Often the quickest, easiest and most 'privacy respectful' way for you to deal with any and all privacy/confidentiality concerns is to seek your patient's consent. Once they understand what you want to do and why and provide their consent, privacy/confidentiality concerns are no longer an impediment to the investigation.

6.8.4 When do you not need consent?

De-identified information

You do not need the patient's consent when you are sharing or collecting de-identified information, or information that does not relate specifically to a given patient. For example, an investigation may be undertaken with no mention of a patient's name or any personal details that would identify them to the other person.

Usually, de-identifying patient information is not practical in an open disclosure process as it requires the use, disclosure and collection of information that identifies the patient.

However, some discrete issues may not require the patient to be identified (eg. enquiries of other institutions or laboratories concerning their usual systems, quality control processes).

Directly related secondary purpose that the patient would expect

You also do not require the patient's consent where the proposed collection, use or disclosure of (identifying) personal information about them falls under any of the recognised exceptions under the privacy legislation. The most potentially relevant exception that might (but not always) excuse you from obtaining consent is where the open disclosure process (and the exercises and information-gathering steps relevant to it) are what the law would regard as a directly related secondary purpose that is the sort of thing your patient would reasonably expect.

The use disclosure falls within the 'primary purpose' for which you initially collected the information

You also do not need consent from the patient where your proposed use and disclosure of information about them is for the primary purpose for which it was collected. Usually, the primary purpose for which patient information is collected is to treat the patient's presenting condition or illness. Sometimes (but not always), investigations following an adverse event could be construed as being undertaken for that primary purpose – to find out what happened so as to better treat the patient. In that case, there is an arguable case that no further consent from the patient is required.

6.8.5 Discussions with your insurer

Doctors routinely correspond with their liability insurer after a serious adverse event or other incident that might generate a claim under the policy. This is routinely done without seeking patient consent. This practice is justifiable under the privacy law.

6.9 Documentation

In this section, we deal with the documentation of the initial open disclosure discussion, then look at the documentation of the subsequent investigations/discussions.

6.9.1 Documenting the early discussion

Documentation is critically important clinically (communicating information to other members of the treating team) and legally (recording what was done).

Documentation of the open disclosure process broadly relates to two, often distinct, phases:

- initial discussion

- subsequent investigation(s) and related discussion(s).

The ACSQHC identifies the following key considerations for documentation in relation to the patient record:

- The patient record must be up to date before the first meeting, including a comprehensive account of the adverse event as it is initially understood.

- The patient record should document the:
    - time, date and place of the disclosure discussion and the names and relationships of those present

    - plan for providing further information to the patient, their family and carers

    - offers of support and the responses received

    - questions posed by the patient, their family and carers and the answers given

    - plans for follow-up as discussed with the patient, their family and carers

    - progress notes relating to the clinical situation and accurate summaries of all points explained to the patient, their family and carers.

6.9.2 Documenting the investigation of the adverse event

Investigating an adverse event can create a lot of paperwork, whether undertaken internally (within the practice) or externally (contacting health professionals outside of the practice). The investigation can be undertaken orally, in writing or both.

The result of the investigation may generate a change in practices, systems or protocols. When that happens, those changes may also be documented.

Practitioners need to be aware of, and sensitive to, the risks that might accompany the creation of documents recording the adverse event investigation. At the same time, practitioners should not overstate or overreact to those risks. Overstating the concerns about legal risk can create a barrier to meaningful involvement in the quality improvement initiatives that form an integral part of an open disclosure process.

6.9.3 Can my patient (and their lawyers) see what I wrote?

Be aware that unless you have obtained specific legal protection, all documentation about an adverse event involving a patient could be accessible by that patient, their lawyers, courts and tribunals.

Access could happen in one of several ways:

- Where the documentation identifies the patient, the patient has a statutory right of access under the *Privacy Act 1988* (and in some jurisdictions may have other statutory access rights under state statutes such as the Victorian *Health Records Act 2001)*.

- Whether or not the patient is identified in the records, the patient and their lawyers may also obtain the records through a range of court processes such as subpoena, warrant or discovery of documents.

- Courts and inquisitorial bodies (eg. disciplinary authorities/coroners court) generally have wide investigative powers which often enable them, particularly with patient consent, to obtain paperwork.

6.9.4 Where should the paperwork be stored?

It is prudent to keep all investigation-related documentation separate from the patient health record, even if it relates to one single patient (as opposed to a 'systemic' issue).

Investigation-related documentation can be stored in a dedicated incident investigation logbook. To ensure confidentiality and security, the logbook may be kept where the confidential human resources and business materials are stored (ie. in a secure location away from the patient health records). For more information, see the RACGP *Standards for general practices*.

6.9.5 Types of legal protection of documentation

A patient (or their lawyer with the patient's authority) can request to see the paperwork generated in the course of investigating an adverse event. The only usual exception is where the documentation is protected by legal privilege.

In practice, invoking legal privilege arises in one of two ways:

1. After you have contacted your insurer and you/they feel the matter requires legal privilege to be invoked – the insurer would generally do this if it felt that the adverse event is likely to give rise to legal proceedings and that it is in the interests of the potential defendant (you) to protect the paperwork. If, as a result of those early discussions, the insurer feels that the paperwork (including that recording the investigation of the adverse event) needs to be legally protected, they will appoint lawyers to coordinate the matter. Investigations and documentation created at the request of or with the supervision of lawyers is legally protected.

2. Contacting your own lawyer rather than the insurer's lawyer – hospitals, particularly public hospitals, have more options for legal protection than you do (eg. some hospitals rely upon statutory protection available for certain hospital committees or in respect of certain hospital activities – the protection varies between jurisdictions – which look into adverse events). This statutory protection has come to be known as 'qualified privilege' protection.

Unfortunately, no such statutory protections are currently available to GPs or general practices. This means the only legal protection available to them is through legal privilege.

In the absence of such privilege, paperwork could be obtained through the various processes previously outlined.

6.9.6 When to consider seeking legal privilege regarding documentation

While it is often not easy to predict which adverse events will and will not generate legal claims, sometimes it is quite obvious that legal consequences are almost inevitable (eg. an angry patient with a serious injury which they believe, rightly or wrongly, is your fault). In these situations, it is strongly recommended that you seek advice from your liability insurer before creating any documentation. That advice may lead to:

• the protection of the documentation under legal privilege

• a modified form of nonprotected documentation.

The fact that documentation could become accessible to the patient, their lawyers, a court or a tribunal does not necessarily mean you should not create it. The documents may simply constitute an accurate record of appropriate, risk management-based investigations which in no way further implicate you or your practice.

6.9.7 When paperwork bites

Sometimes paperwork can come back to 'bite' you and the practice because either it:

• does not fairly or accurately record what really happened and thereby can be used against you

• accurately represents what happened but this reflects poorly on you or the practice and potentially supports a legal complaint

• reveals chinks in your armour, in that the (unavoidably) retrospective review of events shows opportunities that were available, with hindsight, to avoid the incident.

6.9.8 How to lessen the bite

In many respects, the main aims of the investigation are to get information and learn lessons in order to improve the quality and safety of general practice. The extent to which those lessons are documented is in many ways of secondary importance.

Practices could justify a range of documentation techniques, some of which are more detailed than others. In some cases, the practice may decide to keep documentation at a minimum and instead focus on verbal communication, both between staff, and between staff and the patient. At other times, the practice may seek to retain a more extensive document trail.

The Australian Open Disclosure Framework suggests that: 'documents should be restricted to clinical facts that have been verified, as far as possible, and should not:

• attribute blame to any health professional or health service organisations

• record opinions about staff, patients, their family and carers or other people, unless those are expert opinions with supporting evidence for the opinion recorded

• contain statements about another person which are, or are likely to be, defamatory.'

6.9.9 Documents: help or hindrance?

Documentation is a critical means of communicating important information between health professionals and members of the treating team. It can work for and against you, as it constitutes evidence of steps taken to respond to an adverse event. This evidence can be critical in the legal setting to demonstrate that the practice did respond appropriately to the event, in the sense that:

• it was identified and responded to

• a sensible analysis was undertaken, with the right questions asked of the right people

• when more information was gained, meaningful analysis was undertaken.

> ### Reading
>
> • The Australian Commission on Safety and Quality in Health Care. The Australian Open Disclosure Framework. Implementing the Australian open disclosure framework in small practices. Commonwealth of Australia, 2014.

Only communicate and document what is known to be correct and ensure anything recorded is fair, accurate and correct, and not inflammatory, emotive, angry or defamatory. This approach should help rather than damage a defence, particularly where there is a delay between any adverse event and a legal proceeding.

If, despite these efforts, you encounter a situation where the documentation is wrong, confusing or misleading, all is not lost, as the paperwork constitutes only one form of evidence, which can possibly be rebutted through other evidence. For example, if the patient's lawyers seek to exploit an error in your records, your representatives can still lead verbal evidence from you or from others to reveal the true position.

True and accurate documentation is harmful when it accurately reveals that the patient truly came to harm because of negligence. This is not necessarily a bad thing as doctors and their insurers are not in the cover-up business. Patients harmed as a result of mismanagement deserve and are entitled to be compensated. That is why liability insurance exists.

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Reinforcing activity: Improving patient safety

Introduction

This reflective reinforcing activity is the final component of the clinical risk management ALM. It should take approximately 30 minutes to complete. Your responses are not graded so please simply record your immediate, personal response to each question for your own benefit.

If you are not in clinical practice at the time of completing this activity, answer questions by considering what your actions and thoughts would currently be.

Your learning outcomes

What is the most important learning outcome(s) that you have gained from this module?

You may choose to share your thoughts with fellow learners.

Behaviours

What is something you will do differently as a result of considering the human factors that affect patient safety?

Your may choose to share your thoughts with fellow learners.

Rate how often you do the following:

Behaviours	Rarely	Occasionally	Often	Almost always
1. Stop consulting when you are hungry				
2. Stop consulting when you are tired				
3. Demonstrate a willingness to take a thorough and constructive look at problems in patient care				
4. Discuss events that could have caused patient harm with a colleague				
5. Openly and honestly communicate with a patient who has been involved in an adverse event				

Attitudes

Rate the extent to which you agree/disagree with the following:

Attitudes	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
6. Medical error is usually the result of multiple factors					
7. Medical errors are common in general practice					
8. A tired health professional is a major threat to patient safety					

Attitudes	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
9. An angry health professional is a major threat to patient safety					
10. General practice work environments are usually fair and open environments in which to address potential risks to patient safety					
11. An apology – properly worded, expressed and timed – can address the fundamental human needs of a patient to be treated with respect					
12. The quality of the post-incident dialogue between patient and health professional influences whether an adverse event generates medico-legal activity					
13. Senior GPs talking about their past mistakes with less experienced practice team members is a useful strategy to help practice staff cope with adverse events if they occur					

Skills

Rate your confidence in doing the following effectively:

Skills	Very low	Low	Neutral	High	Very high
14. Discussing with a colleague a concern that you have about their practice					
15. Employing communication skills to try to improve a difficult health professional–patient relationship					
16. Preparing for a conversation with a patient in which you disclose that an adverse event has occurred in their healthcare					
17. Documenting an investigation of an adverse event					

Knowledge (1)

Respond 'true' or 'false' to the following statements:

Knowledge	True	False
18. Naming, blaming and shaming is an appropriate response to medical error		
19. A mindset of perfection promotes effective risk management		
20. The three areas that influence the chance of error in the three bucket framework of factors that affect patient safety are self, colleagues and task		

Feedback

'Naming, blaming and shaming' is a historical but unhelpful and inappropriate response to error. It contributes to mindset of perfectionism, which hinders effective risk management and sets an unrealistic benchmark.

The three buckets represent the three areas that influence the chance of error in the three bucket model of error likelihood. The buckets are self, context (not colleagues) and task.

Knowledge (2)

Respond 'true' or 'false' to the following statements:

Knowledge	True	False
21. The open disclosure conversation should not be a tightly scripted speech		
22. Poor communication by the clinician is a common cause of litigation		
23. An employer is automatically legally liable for an employee's negligence if it occurs within the scope of the employee's job		

Feedback

The open disclosure process should not be a tightly scripted, well prepared speech. For some minor adverse events, a simple apology and explanation is all that is needed; however, when the adverse event is serious, or perceived to be serious by the patient, more is needed to heal the potential rift in the relationship. It is important to practise the words you will use so you feel comfortable and natural with the language when the need arises. Without it, it is true that poor communication by the clinician is a common cause of litigation.

Under the principle of vicarious liability, an employer is automatically legally liable for the negligent acts and omissions of employees that take place within the course and scope of the employee's job. This principle does not apply to nonemployees.

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Knowledge (3)

Respond 'true' or 'false' to the following statements:

Knowledge	True	False
24. Sincerely acknowledging the patient's and family's suffering as the result of an adverse event opens the door to litigation and should be avoided when disclosing an adverse event to a patient/family		
25. 'Let me tell how sorry I am that this has happened' is a useful phrase when disclosing an adverse event		
26. Copies of patient correspondence regarding an adverse event investigation should be kept in a dedicated incident investigation file separate from health records		
27. Failure to apologise can generate legal issues		
28. It is legally unclear whether patients must be informed of adverse healthcare events when trivial harm has occurred		
29. You must be 100% certain that you caused an error before telling a patient that you did		

Feedback

Sincerely acknowledging a patient's/family's suffering due to an adverse event is a core element of the open disclosure process. 'Let me tell you how sorry I am that this has happened' is a useful phrase when discussing an adverse event.

Copies of patient correspondence regarding an adverse event investigation should not be kept in the patient's personal health records. All investigation related documentation should be kept in a dedicated incident investigation file, separate from health records.

Failure to apologise (and to effectively communicate) can, in certain circumstances, generate legal and ethical issues. It is uncertain whether failure to mention an adverse event constitutes a breach of duty of care under the law of negligence in cases of no or trivial harm resulting from the near-miss/adverse event. Never tell a patient that you caused something unless you are absolutely certain that you have.

Systems

Do you currently have the following systematic strategies to improve patient safety?

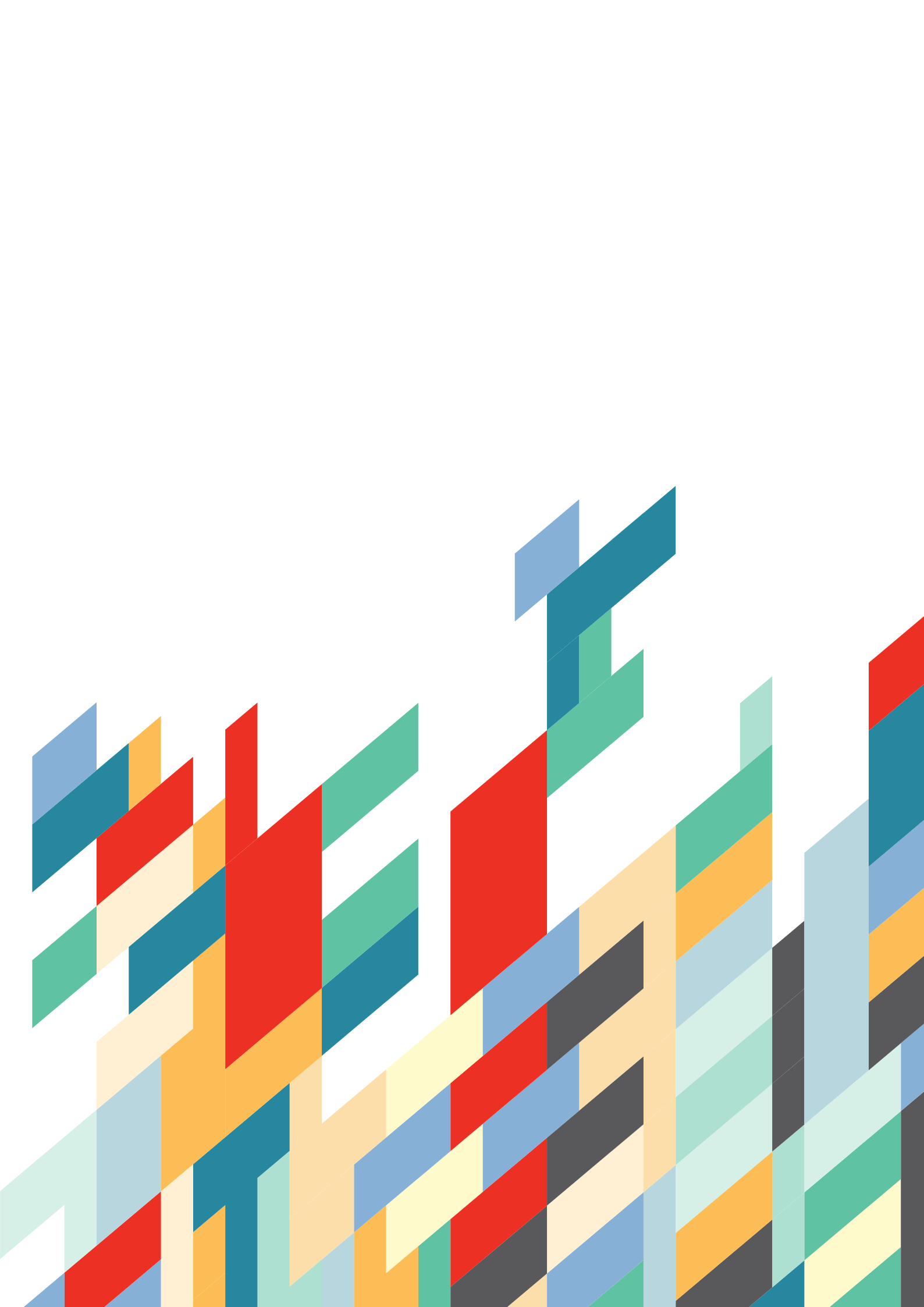| System	Yes	No
30. An acronym to remind you of the main human factors that threaten patient (and clinician) safety		
31. An ongoing and reliable way of developing an open practice safety culture where practice staff can freely discuss adverse events		

Feedback

The HALT acronym (hungry, anxious/angry, late, tired) is a simple and useful way to identify four primary human factors that can negatively affect patient safety. The benefit of this acronym is that it also indicates a course of action to take when you identify one of these human factors in yourself or others (ie. to halt what you are doing, reassess the situation, and address the factor(s) or implement additional safeguards to support patient safety).
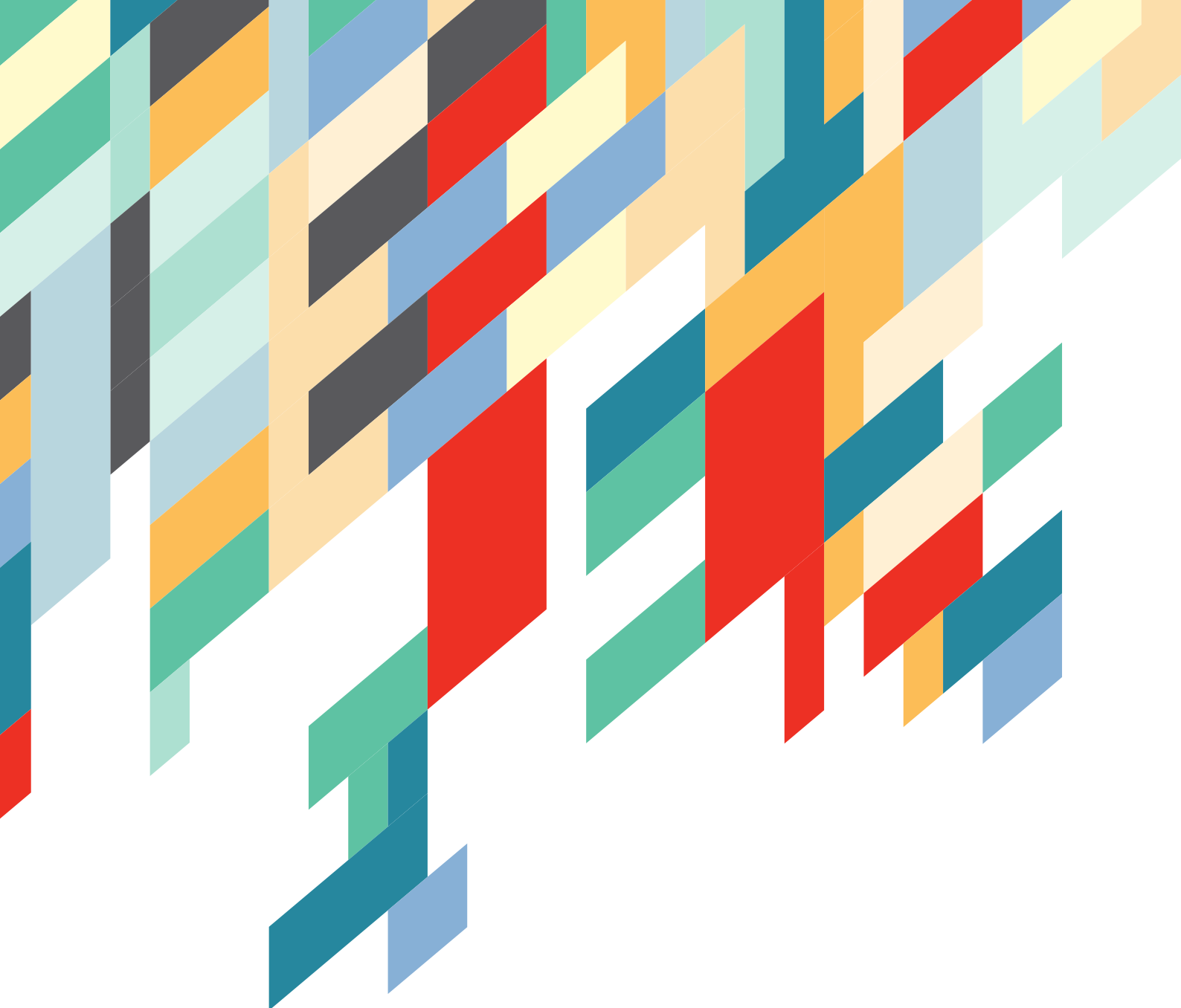
Incorporate formal quality review processes into regular practice processes. Include discussing risks, errors, near-misses and adverse events at every team meeting and discuss them informally whenever possible. Invite senior healthcare professionals to share their stories and what they learned from them. Implement systematic changes to practice protocols to reduce the chance of error occurring. Develop an agreed practice policy on open disclosure and create clear guidelines on how to manage adverse events. Involve all team members in the process.

Conclusion

You have now finished the risk management in general practice reinforcing activity.

Refer to the instructions in 'Individual (self-directed) ALM', at the start of this resource, for guidance on how to apply for QI&CPD points following successful completion of all relevant requirements.