

**AUSTRALIAN COMMISSION  
ON SAFETY AND QUALITY IN HEALTH CARE**

**Australian Open Disclosure Framework**

**Supporting materials and resources**

**Implementing the Australian Open  
Disclosure Framework in small  
practices**

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## Table of contents

Preface.....	4
Part A. Background and context.....	5
1 Introduction.....	5
1.1 Definition of open disclosure .....	5
2 Open disclosure principles and practice .....	6
2.1 Summary of open disclosure practice .....	7
3 General considerations.....	10
3.1 Adverse events.....	10
3.2 Communication.....	10
3.3 Ensuring appropriate communication with culturally and linguistically diverse patients .....	11
3.4 Saying sorry.....	11
3.5 Informed consent.....	13
3.6 Practical support and ongoing care for patients .....	13
3.7 Support for clinicians.....	14
3.8 Insurance considerations .....	14
3.9 Legal considerations .....	14
3.10 Criminal or intentionally unsafe acts, and disciplinary processes .....	14
3.11 Codes of practice, standards and guidelines.....	15
Part B. The open disclosure process.....	16
4 Detecting and assessing incidents.....	16
5 Signalling the need for open disclosure .....	20
5.1 Lower-level response.....	20
5.2 Higher-level response .....	20
6 Preparing for open disclosure discussions.....	21
7 Engaging in open disclosure.....	22
8 Completing the process.....	25
9 Documentation .....	26
Appendix 1: Legal aspects of open disclosure.....	27
Appendix 2: RACGP Standards for general practices 4 <sup>th</sup> Edition 2010 .....	31
Appendix 3: Extracts from the <i>Code of Conduct for Registered Health Practitioners</i> .....	32
Appendix 4: Medication errors, adverse drug events and open disclosure .....	33
Appendix 5: Useful phrases for open disclosure discussions.....	35
Appendix 6: Glossary .....	36

## Preface

Open disclosure has been implemented and adopted in various healthcare services both locally and internationally for over two decades. Open disclosure is:

- a patient and consumer right
- a core professional requirement and obligation
- a normal part of an episode of care should the unexpected occur, and a critical element of clinical communications
- an attribute of high-quality healthcare provision and important part of healthcare quality improvement.

The *Australian Open Disclosure Framework* provides a nationally consistent basis for communication when care does not go to plan. It is designed so that patients are treated respectfully after adverse events.

The *Australian Open Disclosure Framework* is intended for use across all Australian healthcare settings and sectors and describes open disclosure practice and considerations that may affect local implementation.

### What is the purpose of this document?

The Australian Commission on Safety and Quality in Health developed this document to assist sole clinicians and those working in small practices implement and practice open disclosure in accordance with the *Australian Open Disclosure Framework*.

A small practice is defined as a practice consisting of one clinician, or a group of clinicians. A clinician is a healthcare provider who is trained as a health professional including registered and non-registered practitioners who spend the majority of their time providing direct clinical care. Clinicians include medical, nursing and dental practitioners, and allied health professionals including radiographers, podiatrists, psychologists, physiotherapists, occupational therapists and alternative therapy practitioners.

It should be read in conjunction with the *Australian Open Disclosure Framework*. In addition, there are other supporting resources which, along with the Framework, can be accessed at [www.safetyandquality.gov.au/opendisclosure](http://www.safetyandquality.gov.au/opendisclosure)

### Endorsement

This document is officially recognised as an Accepted Clinical Resource by The Royal Australian College of General Practitioners (RACGP).

#### General practitioners

The RACGP, in partnership with the Australian Commission on Safety and Quality in Health Care, developed an open disclosure educational module for general practitioners titled *Regaining Trust after an adverse event*.

The resource may also be useful to other healthcare practitioners and is available through the Commission web site at [www.safetyandquality.gov.au/opendisclosure](http://www.safetyandquality.gov.au/opendisclosure)

### Document layout

Like the *Australian Open Disclosure Framework*, this document is divided into two parts. Part A provides the background and context to open disclosure. Part B describes the open disclosure process, tailored to the small practice environment.

## Part A. Background and context

### 1 Introduction

Over the past two decades, open disclosure has been recognised as a practice that can benefit patients and clinicians when care does not go to plan.

Open disclosure can be complex, challenging and difficult for all participants. However, its systematic practice can assist clinicians<sup>A</sup> to manage adverse events compassionately and provide broader benefits through:

- re-establishing trust in patient and clinician relationships
- improving clinical communication
- centering health care on the person
- learning from error by improving care delivery systems and processes.

#### 1.1 Definition of open disclosure

The *Australian Open Disclosure Framework* defines open disclosure as open discussion with the patient, and their family and carer(s)<sup>B</sup> about adverse events that result in harm to the patient while receiving health care.

The elements of open disclosure are:

- an apology or expression of regret, which should include the words 'I am sorry' or 'we are sorry'
- a factual explanation of what happened
- an opportunity for the patient to relate their experience
- a discussion of the potential consequences of the adverse event
- an explanation of the steps being taken to manage the adverse event and prevent recurrence.

Open disclosure is a discussion between two parties. In small practices, open disclosure is more likely to occur as one discussion (or what, in higher-level open disclosure, would be described as the initial discussion). However it can also occur through several discussions and meetings.

While details of the open disclosure process will vary between healthcare settings and sectors, its underpinning principles (see Section 2) are broadly applicable and should be relied upon to guide its implementation and practice.

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<sup>A</sup> Clinician is defined as "a healthcare provider, trained as a health professional. Clinicians include registered and non-registered practitioners or a team of health professionals providing health care who spend the majority of their time providing direct clinical care".

<sup>B</sup> Recognising that it may often be impractical to involve other individuals in the small practice setting, the remainder of this document will refer only to the 'patient'. However, and where appropriate, this should be taken to include other 'support persons' including family, carers, partners or friends.

## 2 Open disclosure principles and practice

Following are the principles of open disclosure as described in the *Australian Open Disclosure Framework* adapted to the small practice context.

### 1. Open and timely communication

If care doesn't go to plan, the patient should be provided with information about what happened in a timely, open and honest manner. The open disclosure process is fluid and will often involve the provision of ongoing information.

### 2. Acknowledgement

All adverse events should be acknowledged to the patient as soon as practicable, and open disclosure initiated. Indemnity insurers should be notified.<sup>C</sup>

### 3. Apology or expression of regret

As early as possible, the patient should receive an apology or expression of regret for any harm that resulted from an adverse event. An apology or expression of regret should include the words 'I am sorry' or 'we are sorry', but must not contain speculative statements, admission of liability or apportioning of blame.

### 4. Supporting, and meeting the needs and expectations of patients

The patient can expect to be:

- fully informed of the facts surrounding an adverse event and its consequences
- treated with empathy, respect and consideration
- supported in a manner appropriate to their needs.

### 5. Supporting, and meeting the needs and expectations of those providing health care

Clinicians and other practitioners should be:

- encouraged and able to recognise and report adverse events
- prepared through training and education to participate in open disclosure
- supported through the open disclosure process.

### 6. Integrated clinical risk management and systems improvement

Small healthcare practices should have a process enabling the review of adverse events to prevent recurrence, enable lessons to be learnt and the quality of care to be improved. The information attained about incidents from open disclosure should be incorporated into these processes.

### 7. Good governance

Small healthcare practices should have appropriate governance and accountability. Good governance includes internal performance monitoring and feedback.

### 8. Confidentiality

Full consideration should be given to patient and clinician privacy and confidentiality in compliance with relevant law (including federal, state and territory privacy and health records legislation). This principle needs to be considered in the context of Principle 1: Open and timely communication.

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<sup>C</sup> Professional indemnity may be voided if open disclosure is not carried out correctly. The advice of the professional indemnity insurer should be obtained before open disclosure is commenced.

## 2.1 Summary of open disclosure practice

The key elements of an open disclosure process in the small practice context are presented in Table 1. A lower-level open disclosure process is illustrated in Figure 1. A similar flow chart of higher-level open disclosure is provided in the *Australian Open Disclosure Framework*.

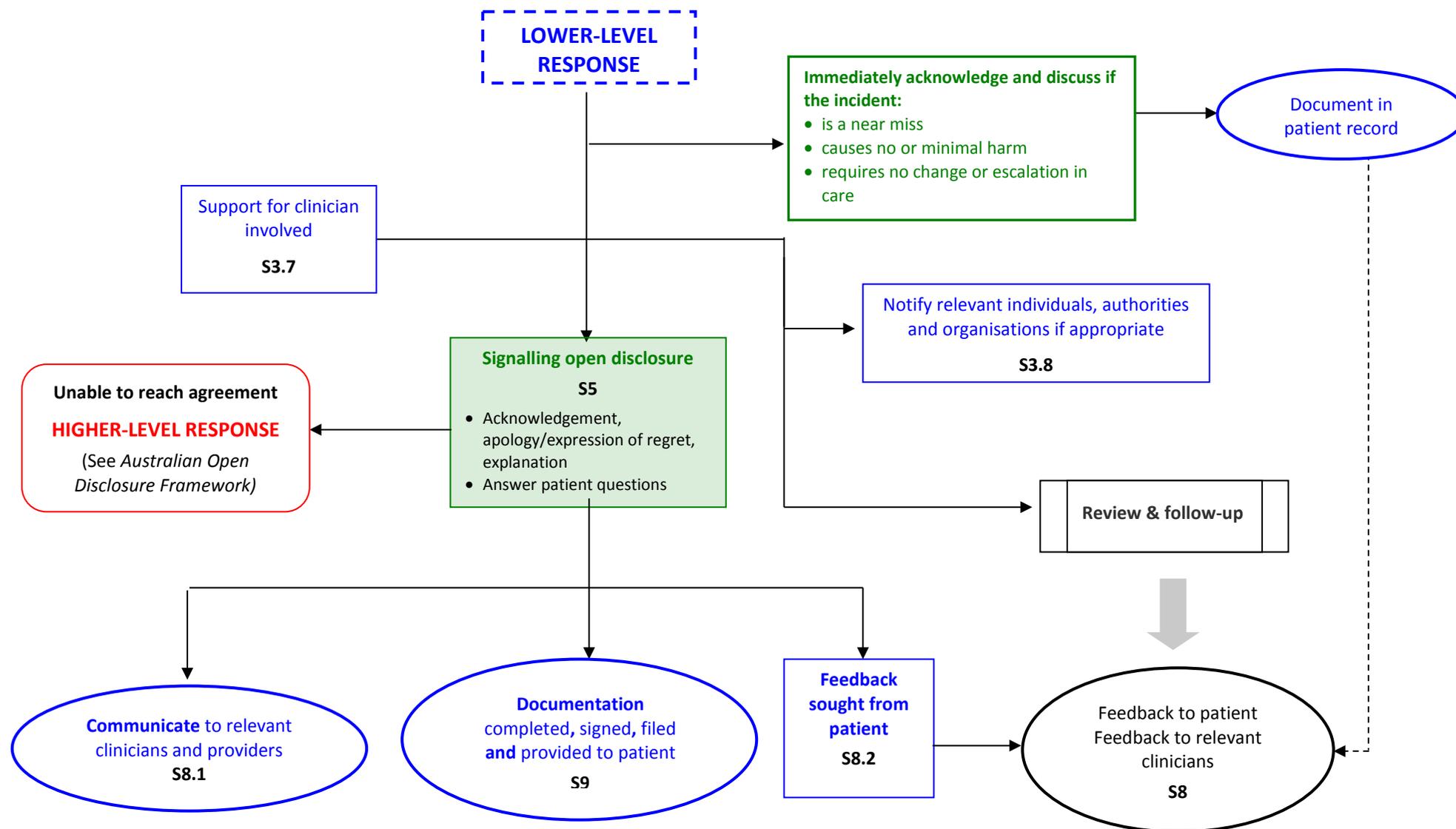
The open disclosure process is described in more detail in Part B of this document.

**Table 1: Key elements of the open disclosure process in small practices (Note: Section references relate to this document)**

<p><b>1. Incident detection</b></p> <p>Section 4</p>	<ul style="list-style-type: none"> <li>• Detect incidents through a variety of mechanisms</li> <li>• Provide prompt clinical care to the patient to prevent further harm</li> <li>• Assess the incident and establish facts on what occurred</li> <li>• Notify relevant individuals, authorities and organisations</li> </ul>
<p><b>2. Signalling the need for open disclosure</b></p> <p>Section 5</p>	<ul style="list-style-type: none"> <li>• Acknowledge the adverse event to the patient including an apology or expression of regret</li> <li>• Note any comments and observations by the patient, and answer any questions the patient may have.</li> <li>• <b>A lower-level response can conclude at this stage</b></li> <li>• Signal the need for open disclosure</li> <li>• Avoid speculation and blame</li> </ul>
<p><b>3. Preparing for open disclosure</b></p> <p>Section 6</p>	<ul style="list-style-type: none"> <li>• Gather all necessary information</li> <li>• Notify, and consult with, professional indemnity insurer</li> <li>• Ensure patient record is up to date</li> <li>• Identify appropriate participants (offer the patient an opportunity to invite a support person if appropriate)</li> <li>• Arrange the first meeting in consultation with the patient</li> <li>• Consider how practical support of the patient for expenses and ongoing care will be addressed</li> <li>• Provide clinician support if appropriate / seek support (if sole practitioner)</li> </ul>
<p><b>4. Engaging in open disclosure</b></p> <p>Section 7</p>	<ul style="list-style-type: none"> <li>• Acknowledge the adverse event</li> <li>• Provide a sincere and unprompted apology or expression of regret including the words <i>I am sorry</i></li> <li>• Clearly explain the incident</li> <li>• Give the patient the opportunity to provide their observations about the incident and ask questions</li> <li>• Encourage the patient to describe the personal effects of the adverse event</li> <li>• If further meetings are required an open disclosure plan is agreed upon, recorded and signed</li> <li>• Assure the patient that they will be informed of further findings</li> </ul>

	<p>of any investigations related to the incident and resulting changes to care delivery</p> <ul style="list-style-type: none"> <li>• Discuss and agree on future care if required</li> <li>• Offer practical and emotional support to the patient</li> <li>• If necessary hold several meetings</li> </ul>
<p><b>5. Completing the process</b></p> <p>Section 8</p>	<ul style="list-style-type: none"> <li>• Assure the patient that further information and follow-up care will be provided</li> <li>• Maintain contact if the investigation is ongoing and share outcomes and practice changes with the patient</li> <li>• Reach agreement with the patient or provide an alternative course of action</li> <li>• Provide a final written and verbal communication to patient</li> <li>• Communicate any relevant information to other healthcare providers</li> </ul>
<p><b>6. Maintaining documentation</b></p> <p>Section 9</p>	<ul style="list-style-type: none"> <li>• Keep the patient record up to date</li> <li>• Maintain a record of the open disclosure process</li> <li>• File documents in the patient record</li> <li>• Provide the patient with documentation throughout the process (verify contents with indemnity insurer)</li> </ul>

Figure 1: Lower-level open disclosure response flow chart (Note S = section of this guide)



## 3 General considerations

This section discusses the matters to consider when open disclosure is being implemented and practised.

### 3.1 Adverse events

There is no universal definition of 'adverse event' because this term depends on the concept of harm, how it is perceived and whose interpretation is used.

'Adverse event' means an incident in which a person receiving health care was harmed. In addition, it is used in this document in the same way that 'harmful incident' is used in the literature to link adverse events specifically to open disclosure and accommodate various interpretations of harm as well as other issues such as preventability, expected complication and error.

The World Health Organization defines harm as '[i]mpairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological.'<sup>D</sup> This broader definition is used here because the patient's view on whether harm has been suffered may differ from the clinician's.

#### 3.1.1 Preventability

The natural progression of a condition or disease process, or predictable therapeutic complications, are not usually preventable and are therefore not classified as adverse events for open disclosure purposes.

However, it is difficult to predict all possible outcomes of healthcare interventions. The cause of an incident can be confounded by a patient's comorbidities, the known complications of a procedure and the natural progression of a disease, either alone or in combination. These can make it difficult to determine whether the incident was preventable or a complication.

Open disclosure may be appropriate even if an incident is deemed unpreventable or is classified as a complication. Open disclosure (especially the apology or expression of regret component) should be modulated in such situations to reflect the circumstances of the incident.

Generally, patients appreciate receiving as much information as possible about unexpected or adverse events, so explaining and disclosing harm resulting from incidents that are difficult to classify has potential benefits, and entails little risk.

### 3.2 Communication

There is an ethical responsibility for clinicians to maintain honest and open communication with patients, especially if care doesn't go to plan.

Ensuring that communication after adverse events is open, honest and timely is important to ensuring patient-centred care and improving patient safety. This includes communication between clinicians and:

- patients and their support persons if appropriate
- their colleagues and peers
- other, non-clinical stakeholders.

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<sup>D</sup> World Health Organization. The International Classification for Patient Safety WHO, 2009

In the small practice environment, there will often be an established therapeutic relationship between the provider and the patient. This provides an advantage for communicating openly if things don't go to plan.

Clinicians can further nurture a positive and enduring relationship with patients by:

- ensuring that the consent process is thorough and the patient understands all aspects of the procedure or treatment (see Section 3.5)
- engendering trust through open communication and other behaviours
- providing information on the roles and responsibilities of patients in shared clinical decision-making (while at the same time respecting any decision to defer this to the provider)
- documenting all relevant information in the patient record.

### 3.3 Ensuring appropriate communication with culturally and linguistically diverse patients

Ensuring appropriate and effective communication is an important consideration particularly when patients come from linguistically or culturally different backgrounds. Cultural differences can also impede effective communication.

The first language of all patients, and also their preferred language of communication, should be established at the beginning of a patient-provider relationship.

While this may be challenging in the small practice environment and for sole practitioners, the need for interpreter services should be identified when the patient makes contact with the practice, and, where possible, an interpreter service arranged. Family (or other support persons) can be used to interpret but only with the express consent of the patient,

#### ***Aboriginal and Torres Strait Islander patients***

Aboriginal and Torres Strait Islander people include a diversity of cultural and linguistic groups. Some Indigenous people experience barriers to communication with clinicians such as language differences, and differences in principles and beliefs regarding health and other matters.

Every effort needs to be made to ensure that the appropriate people (in the context of the patient's needs and with their agreement) are included in discussions regarding adverse events and their investigation and management.

#### **3.3.1 Ensuring appropriate communication with patients with other requirements**

Other communication difficulties may arise and arrangements should be made to facilitate communication. For example, a person who is deaf may require an interpreter or a person with impaired vision may require written material in larger font.

### **3.4 Saying sorry**

In the small practice environment, the patient-clinician relationship can be enduring. In this setting, an apology or expression of regret may therefore take on special significance and be deployed in a variety of circumstances. The RACGP describes apology as “an indispensable communication tool” between clinicians and patients, one that can be used in a variety of situations including after adverse events.<sup>E(p46)</sup>

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<sup>E</sup> RACGP. *Regaining trust after an adverse event. An education module on managing adverse events in general practice.* 2008, Melbourne

Apology and/or expressions of regret are key components of open disclosure, but also the most sensitive.<sup>F</sup> 'Saying sorry' requires great care and the exact phrasing of an apology (or expression of regret) will vary depending on circumstances. The following points should be considered when apologising or expressing regret:

- The words 'I am sorry' or 'we are sorry' should be included.
- Sincerity is the key element for success. The effectiveness of an apology or expression of regret depends on the way it is delivered, including the tone of voice, and non-verbal communication such as body language, gestures and facial expressions. These skills are not often innate, and may need to be practised.
- The apology or expression of regret should make clear what is regretted or being apologised for, and what is being done to address the situation.
- An apology or expression of regret is essential in helping patients cope with the effects of an adverse event.
- It also assists clinicians in their recovery from adverse events in which they are involved.

It is important to note that an apology or expression of regret alone may be insufficient, and may require further information and action to ensure effective open disclosure. For further guidance see Section 7, Box 1 and an additional resource specifically addressing saying sorry as part of open disclosure.<sup>E</sup>

### **3.4.1 Factual explanations and speculative statements**

The *Australian Open Disclosure Framework* stresses the importance of communicating harm and apologising, but that speculative statements and/or apportioning of blame must be avoided. Speculation includes conjecturing on the causes of the harm as well as what will occur as a result of the harm. Making promises or other statements to patients after adverse event that are subsequently retracted can undermine trust.

The following should be considered when communicating early and before all the facts have been established:

- Harm should be acknowledged and an apology or expression of regret provided as appropriate.
- The known facts should be provided.
- There should be no speculation on the causes of an adverse event.
- Blame must not be apportioned to any individual, group or institution.
- The results of reviews and investigations must not be pre-empted.

### **3.4.2 Apology and admission of liability**

The Royal Australian College of General Practitioners' *Regaining trust after an adverse event* explains the medico-legal aspects of apology in the general practice context thus:

*An apology, properly worded, expressed and timed, can address the fundamental human needs of a patient to be treated with respect. That need*

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<sup>F</sup> A resource titled *Saying Sorry: a guide to apologising and expressing of regret in open disclosure* has been developed to accompany the Framework and can be accessed at [www.safetyandquality.gov.au/opendisclosure](http://www.safetyandquality.gov.au/opendisclosure)

exists both for situations where there has been a serious adverse event as well as 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, e.g. 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.*<sup>G(p46)</sup>

Appendix 1 of this document, titled Legal aspects of open disclosure, discusses the legal aspects of apology in open disclosure. See also *Saying sorry: a guide to apologising and expressing regret in open disclosure* available at [www.safetyandquality.gov.au/opensdisclosure](http://www.safetyandquality.gov.au/opensdisclosure)

### 3.5 Informed consent

The consent process is outside the scope of the *Australian Open Disclosure Framework*, but it can often be important in establishing the patient–clinician relationship and expectations of therapeutic interventions.

Obtaining informed consent from a patient before starting treatment is a legal requirement. The National Health and Research Council's *General Guidelines for Medical Practitioners on Providing Information to Patients* provide information on informed consent.<sup>H</sup>

More specific detail on informed consent can be obtained from organisations such as health professional colleges, registration boards and governing bodies and local consumer groups.

### 3.6 Practical support and ongoing care for patients

Higher-level open disclosure after serious adverse events is most effective if it is coupled with restorative action. This may include a pledge of practical support for patients to manage the effects of harm, such as reimbursement for out of pocket expenses which may include, but not be limited to, transport, child care, accommodation and meals.

It is generally accepted that practical support made on an *ex gratia* basis does not imply responsibility or liability. Providers should always liaise with legal counsel and their indemnity insurer (see Sections 3.8 and 3.9) when considering providing assistance to patients who have been harmed, and before any such offers of assistance are made.

While this may be challenging in the small practice environment, it should be noted that open disclosure can break down because of delays in support following harm.

Similarly, patients who have been profoundly harmed will often require ongoing treatment or care, which may be provided by the same clinician(s), at the same practice or at another facility. Agreeing on matters regarding ongoing treatment, such as billing and other costs (e.g. transport in rural areas), is also an important aspect of the open disclosure process.

This needs to be discussed openly and in a timely fashion, based on individual needs and circumstances, which will depend on factors such as the nature of the adverse event, or regulations such as those governing Medicare billing.

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<sup>G</sup> RACGP. *Regaining trust after an adverse event. An education module on managing adverse events in general practice*. 2008, Melbourne

<sup>H</sup> Visit [www.nhmrc.gov.au/guidelines/publications/a-z-list](http://www.nhmrc.gov.au/guidelines/publications/a-z-list)

It is recommended that reimbursement of out-of-pocket expenses and for ongoing treatment be discussed only after consultation with the relevant insurer (particularly if the insurer is to meet the cost).

### **3.7 Support for clinicians**

Clinicians involved in adverse events may suffer negative psychological and emotional effects, and may require support. Support should be sought from colleagues, who also have a responsibility to monitor their fellow clinicians following an adverse event.

Sole practitioners are encouraged to seek support from colleagues external to the practice, or from their professional organisation, association, indemnity insurer and medical defence organisation.

### **3.8 Insurance considerations**

Clinicians and other health professionals should be fully aware of their responsibilities in relation to their professional indemnity insurance. These requirements will differ between settings and indemnity insurance providers.

Insurers may provide medico-legal advisory services to their clients and may wish to discuss and assist in the open disclosure process. Many policies granted by insurers will require the insured clinician to notify and take early advice from the insurer of an adverse event, usually within a certain period of time following the adverse event (known as the notification requirement).

Policies may also set out other conditions that the insurers require of clinicians. These may encompass what the clinician may say before the insurer is notified of the adverse event (if the event is one requiring such notification).

It is important that the advice is sought, and provided, promptly because delays in initiating open disclosure are counterproductive. Equally, the requirement to notify insurers of an incident should not interfere with openness and timely communication with the patient.

### **3.9 Legal considerations**

It is not intended that legal considerations should inhibit implementation and practice of open disclosure. However, uncertainty surrounding the medico-legal aspects of open disclosure is a known barrier to its practice. Legal considerations are presented in more detail in Appendix 1.

### **3.10 Criminal or intentionally unsafe acts, and disciplinary processes**

Patient harm is almost always unintentional. If at any stage following an adverse event it is considered that the harm may be the result of a criminal or intentionally unsafe act, the relevant authorities should be notified immediately. These may include the national boards for the health professions part of the National Registration and Accreditation Scheme, Australian Health Practitioner Regulation Agency (AHPRA), State and Territory health complaint entities other registration bodies, colleges, peak bodies and professional associations, or the police.

Disciplinary processes are outside the scope of the Framework and should be managed separately by the appropriate registration body, such as national boards for the health professions part of the National Registration and Accreditation Scheme in

partnership with AHPRA, state and territory health complaint entities or self-regulated professional organisations.

### **3.11 Codes of practice, standards and guidelines**

Clinicians are encouraged to refer to relevant standards, codes of practice and guidelines of their health professional colleges, registration boards and governing bodies for guidance on specific requirements on open disclosure.

For example, the Royal Australian College of General Practice (RACGP) *Standards for general practices 4<sup>th</sup> Edition* 2010 refer to open disclosure as part of clinical risk management systems (see Appendix 2 for the relevant extract).

Similarly, Section 6.2 of the *A Code of Conduct for Registered Health Practitioners* recognises open disclosure as an important part of patient-clinician communication and risk management (see Appendix 3 for the relevant extracts).

This code of conduct has been adopted by the national boards for the professions part of the National Registration and Accreditation Scheme, in partnership with AHPRA.

## Part B. The open disclosure process

This section describes the open disclosure process based on the steps detailed in the *Australian Open Disclosure Framework* and adapted to the small healthcare practice environment.

It can reasonably be expected that an initial discussion will be sufficient for openly disclosing most incidents experienced in sole clinician and smaller practices. For most, an effective open disclosure can be done quickly and with minimal use of resources.<sup>1</sup> Note that lower-level open disclosure can conclude at Stage 2 *Signalling the need for open disclosure* (see Section 5).

However, more serious incidents will require a formal open disclosure process. It is not intended that all of the actions outlined will be completed, in exact order, in every situation. Open disclosure is a complex and sensitive undertaking that needs to be adapted depending on circumstances.

### 4 Detecting and assessing incidents

Open disclosure formally begins with the recognition that the patient has suffered harm during treatment or care. Patient harm can be detected through various mechanisms. It is important that all incidents are considered, regardless of the mechanism through which they were detected.

It is also important to note that harm is not only physical but can also be psychological (see Section 3.1). For example, the provision of a false positive test result may not cause physical harm but can generate considerable psychological and emotional trauma, warranting an open disclosure response.

As soon as harm is identified, the first priority is prompt and appropriate clinical care and prevention of further harm. Additional treatment should be provided if required and if reasonably practical, after discussion and with the agreement of the patient.

Clinicians (and other staff) involved in the adverse event should be monitored and supported as required (see Sections 3.7 and 6.1).

#### 4.1 Initial assessment to determine the level of response

The individual who detected the incident should make an initial assessment of the incident. This may be in consultation with a colleague. The consideration will include the severity of harm and the level of response required.

In small practices, the causation of most adverse events will be able to be determined immediately, or soon after detection. For some, a review and investigation will need to be conducted before all the facts are known. In the latter scenario the initiation of open disclosure, acknowledgement and open disclosure should not be delayed.

All relevant organisations and authorities, such as indemnity insurance providers, should be notified immediately following detection of an adverse event.

The level of response required will be guided by the effect, severity and consequence of the incident. Table 2 below provides potential responses to incidents in which patients have, or may have been harmed.

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<sup>1</sup> RACGP. *Regaining trust after an adverse event. An education module on managing adverse events in general practice*. 2008, Melbourne

**Table 2: Potential responses to incidents of patient harm or potential patient harm**

<b>Incident type</b>	<b>Response</b>
<b>1. Harm from natural progression of condition or disease process</b> <i>e.g. management of diabetes was unsuccessful</i>	<b>Discuss and explain (lower-level)</b>
<b>2. Complication or natural disease progression</b> a. Anticipated by patient/family via education and consent process b. Not anticipated by patient/family via education and consent process ( <b>go to 3</b> ) <i>e.g. patient not adequately informed of the possibility of side effects from beta blockers and feels that this would have altered their decision to proceed with treatment</i>	<b>a. Discuss and explain (lower-level)</b>  <b>b. Open disclosure (higher or lower-level depending on severity)</b>
<b>3. Patient harm/adverse event</b> <i>e.g. adverse drug event (wrong vaccination given)</i> <i>e.g. patient fall during rehabilitation exercises</i>	<b>Open disclosure (higher or lower-level depending on severity and impact on patient)</b>
<b>4. Clinical ('no harm') incident: reaches patient but no harm</b> <i>e.g. medication error (no/minimal effect on patient)</i>	<b>Generally disclose (lower-level)</b>
<b>5. Clinical ('near miss') incident: does not reach patient</b> <i>e.g. an intercepted failure to follow up test results</i>	<b>Decision based on:</b> <ul style="list-style-type: none"> <li>• context</li> <li>• circumstances</li> <li>• potential ramifications</li> </ul> <b>(lower-level)</b>
<b>6. Patient perception or report of harm</b> <i>e.g. patient perception of delay in diagnosis resulting in poor patient outcome</i>	<b>Discuss and agree on appropriate form of disclosure (higher or lower-level)</b>

Table 3 describes lower-level and higher-level responses linked to criteria for harm that may be used to delineate lower-level and higher-level responses.

It is important to consider that patients can potentially suffer further emotional harm if post-incident communication is managed insensitively. A lower-level response should only be initiated if the risk of further harm (from not conducting higher-level open disclosure) is unlikely. Where uncertainty exists, a higher-level response should be initiated.

#### **4.2 Medication errors and adverse medicines events**

When medication errors resulting in adverse medicines events are the result of omission or the administration of the wrong dose, the same criteria as for other types of patient harm should guide the response.

More detail on medication errors and open disclosure, in particular adverse drug reactions, is provided in Appendix 4.

**Table 3: Criteria for determining the appropriate level of response to an incident**

	<b>Criteria</b>
<b>Lower-level response</b>	<ol style="list-style-type: none"><li>1. Near misses and no-harm incidents</li><li>2. No permanent injury</li><li>3. No increased level of care (e.g. need for domiciliary care) required</li><li>4. No, or minor, psychological or emotional distress</li></ol>
<b>Higher-level response</b>	<ol style="list-style-type: none"><li>1. Death or major permanent loss of function</li><li>2. Permanent or considerable lessening of body function</li><li>3. Significant escalation of care or major change in clinical management (e.g. present to emergency department, surgical intervention, other higher level of care)</li><li>4. Major psychological or emotional distress</li><li>5. At the request of the patient</li></ol>

### **4.3 Adverse events occurring elsewhere**

If it is suspected that a patient has suffered an adverse event at another practice or health service organisation, clinicians should contact that organisation as soon as practicable in order to establish whether:

- the adverse event has already been recognised in the organisation in which it occurred
- the process of open disclosure has already commenced elsewhere
- reviews or investigations are in progress.

This includes situations where the root cause of an adverse event can be attributed to another organisation (e.g. radiology or pathology).

A thorough clinical review of the adverse event and the disclosure process should occur in the organisation where the adverse event took place.

While it is acknowledged that these circumstances can be complex, it is important that the patients' right to know is respected. Depending on the circumstances, it may be appropriate to commence open disclosure with the patient. At a minimum, the fact that an adverse event has, or may have, occurred should be communicated clearly to the patient.

The eight open disclosure principles (see Section 2) should be used as a basis for managing these situations.

### **4.4 Delayed detection of harm**

In some cases, patient harm may not be detected for some time. These adverse events may have occurred elsewhere (see above). In this situation clinicians should:

- notify the patient of what has occurred
- inform other relevant clinicians and healthcare providers of the incident
- notify the clinicians who were involved in the incident
- commence or cooperate with an investigation of the incident and establish the facts.

Based on the particular circumstances, open disclosure should then proceed as outlined in the remainder of this document. The process will need to be adapted in these situations to reflect the needs of the patient as well as the clinician.

#### **4.5 No-harm incidents**

For this type of incident, clinicians must be certain that no harm has actually occurred. The only way to be certain of the absence of harm is to discuss the incident with the patient, which will require acknowledgement that an incident occurred.

It is recommended that this course of action be followed for most no-harm incidents. The risk of doing this is small. In a false negative situation (where harm actually occurred), the disclosure will serve as a way of identifying an adverse event and reassure the patient who may otherwise have felt let down.

In a 'true negative' situation (where no harm occurred), the patient may appreciate the communication and contribute their perspective to the consideration.

It is acknowledged that indiscriminate disclosure of near misses and no-harm incidents is not feasible. The following questions can be used to guide such decisions:

- Will the distress or psychological harm of disclosing the information outweigh the benefit that could feasibly be achieved by disclosure?
- Will disclosure reduce the risk of future incidents?
- Will disclosure maintain patient trust in the clinician?

#### **4.6 Near misses**

In some cases, near misses should instigate open disclosure. Each case should consider the facts, as well as:

- the psychological, physical and clinical consequences of disclosure ('intrusive' near misses)
- the possibility of latent harm
- patient factors such as anxiety and willingness to be involved in clinical decision making (which may be apparent from earlier communication with the patient)
- the patient's personal and clinical history.

#### **4.7 Device safety**

Technological advances are introducing increasingly complex instruments, implants and devices in health care. Clinicians should remain vigilant to ensure harm caused by a failure and malfunction of medical devices (as opposed to their incorrect usage or application) is captured, triggering open disclosure and notifying appropriate organisations.

## 5 Signalling the need for open disclosure

The initial discussion should occur as soon as possible after recognising harm, even if all the facts are not yet known. During the initial discussion:

- the adverse event is acknowledged to the patient and their support
- an apology or expression of regret is given (see Sections 3.4 and 7)
- the effect of the incident, including all known facts and the consequences, are described.

### 5.1 Lower-level response

If harm is minor, it is likely that the open disclosure process will be completed after the initial discussion. The Australian Open Disclosure Framework refers to this as a lower-level response.

An example of appropriate wording for this discussion may be:

*'I am/we are sorry that this has occurred. It is clear that something unexpected has occurred/things didn't go to plan but fortunately it was recognised immediately and we have ensured that you did not suffer any harm from it. However, we will ask you to let us know if you feel anything unusual.'*

### 5.2 Higher-level response

If harm is more serious, and further investigation of the incident is required, the initial discussion will have an additional two actions:

- Signal the need for open disclosure.
- Negotiate (where possible) with the patient and their support persons about the logistical details of the open disclosure.

The Framework refers to this as a higher-level response. An example of appropriate wording for a higher-level response initial discussion may be:

*'I am/we are sincerely sorry that this has occurred. It is clear that something went wrong and we are investigating it right now. It is very important for us to understand your version of what happened. We can go through this now if you like, or we can wait until you are ready to talk about it.'*

It is important to maintain good verbal communication and consistent documentation throughout the open disclosure process

### 5.3 Avoiding speculation and blame

It is important not to speculate, attribute blame to yourself or other individuals, criticise individuals or imply legal liability when holding initial discussions, or during formal open disclosure. All known facts relevant to the adverse event can be made available to the patient subject to any legal restrictions that may apply (see Appendix 1).

## 6 Preparing for open disclosure discussions

The remainder of this section describes the steps for higher-level responses. Higher-level responses will vary depending on circumstances and harm severity. The two main types of higher-level responses are:

1. Initial discussion followed by a formal open disclosure meeting at which all facts are made available and the process is concluded.
2. Initial discussion followed by a formal open disclosure meeting at which all facts are not yet available. Additional formal meetings or discussions will be required before the process concludes.

The key aspects of preparation include:

- ensuring that the patient record is up to date
- establishing the basic facts (clinical and other facts)
- identifying and involving appropriate participants (support persons of the patient as well as the clinician's colleagues)
- identifying immediate support needs for everyone involved
- ensuring a consistent approach in any discussions with the patient
- considering legal and insurance issues and notifying the relevant people and organisations
- considering how to address issues regarding ongoing care such as billing and other costs, which should be addressed at the earliest opportunity in liaison with the relevant organisations.

### 6.1 Clinician support

Clinicians may need support and advice following an adverse event and when preparing for open disclosure (see Section 3.7). Support should be sought from, and provided by, colleagues at the same practice or another practice. Professional organisations, associations and medical defence organisations may also be approached for support and advice prior to commencement of open disclosure.

### 6.1 Deferring open disclosure

Prompt open disclosure may not be indicated in every situation and may need to be deferred in some instances. For example, if the physical or mental health of the patient is not conducive to participating in open disclosure, the process may need to be deferred.

The patient may also request deferral.

In these exceptional cases, a decision not to disclose can be justified as being in the patient's best interest. In these cases the rationale must be clearly documented in the patient record

### 6.2 Arranging the first meeting

The timing and location of the open disclosure meeting may often need to be decided in consultation with the patient. The patient should be given the opportunity to invite support persons to the meeting, and be consulted if other clinicians or colleagues will participate.

Factors to consider include the:

- patient's clinical condition
- availability of key staff
- availability of the patient's support persons
- patient and clinician privacy and confidentiality.

## 7 Engaging in open disclosure

In small practices, open disclosure is more likely to occur as one discussion (or what, in higher-level open disclosure, would be described as the initial discussion). However it can also occur through several discussions and meetings. The important point is that it should commence as soon as possible after recognising harm, even if all the facts are not yet known. At a minimum, the first discussion should:

- acknowledge the adverse event to the patient
- include an apology or expression of regret, as appropriate, including the words 'I am' or 'we are sorry' (see Section 3.4)
- describe the effect of the incident, including all known facts and the consequences
- note any comments and observations by the patient, and respond to questions the patient may have.

For higher-level responses, a review or investigation of the adverse event may commence shortly after the incident. This will inform, and may in some cases run parallel to, open disclosure discussions. In these cases, the discussion should include:

- assuring the patient that any additional information will be communicated
- encouraging the patient to contact the clinician or practice should any latent effects of the adverse event become apparent
- completing required documentation and written communication (see Section 8).

### 7.1 Avoiding speculation and blame

It is important not to speculate, attribute blame to yourself, other individuals or institutions, criticise individuals or imply legal liability during open disclosure. All known facts relevant to the adverse event can be made available to the patient subject to any legal restrictions that may apply (see Appendix 1).

### 7.2 Key components of open disclosure discussions

Open disclosure may occur over the course of several discussions. The key components of open disclosure discussions are:

1. A sincere and unprompted apology or expression of regret is given, including the words 'I am' or 'we are sorry' (see Section 7.2.1).
2. A factual explanation of the adverse event is provided, including the known facts and consequences of the adverse event, in a way that ensures the patient understands the information, and considers any

relevant information related earlier by the patient. Speculation should be avoided.

3. The patient has the opportunity to tell their story about the adverse event to explain their views on what happened, contribute their knowledge and ask questions (the patient's factual explanation of the adverse event). It will be important for the patient that their views and concerns are listened to, understood and considered.
4. The patient is encouraged to talk about the personal effect of the adverse event.
5. If further meetings are required, an open disclosure plan is agreed and recorded in which the patient outlines what they hope to achieve from the process and any questions they would like answered. This should be documented and filed in an appropriate place, and a copy provided to the patient.
6. The patient is assured that they will be informed of any further information on why the adverse event occurred, including any changes made to minimise the risk of recurrence.
7. Where possible and appropriate, an offer of support should be made including:
  - a. ongoing support including reimbursement of out-of-pocket expenses incurred as a result of the adverse event (this should be done following consultation with the indemnity insurer, see Section 3.8)
  - b. assurance that any necessary follow-up care or investigation will be provided promptly and efficiently
  - c. clarity on who will be responsible for providing ongoing care resulting from the adverse event
  - d. contact details for services the patient may need to access
  - e. information about how to take the matter further, including any complaint processes available to the patient.
8. A written account of the open disclosure meeting should be provided to the patient.

### **7.2.1 How to make an apology or expression of regret**

The person(s) apologising or expressing regret during open disclosure should, as relevant and appropriate include the following.

- Acknowledge that an adverse event has occurred or that something didn't go to plan.
- Acknowledge that the patient, their family and carers are unhappy with the outcome.
- Apologise or express regret for what has occurred (including the words 'I am/we are sorry').
- Provide known clinical facts and discuss ongoing care (including any side effects to be aware of).
- Indicate that a review or investigation is being or will be undertaken to determine what happened and to minimise the risk of the adverse event from happening again.
- Agree to provide feedback information from this when available.

## Box 1

### Examples of appropriate phrases during an apology, or expression of regret, and open disclosure

- *'I am/we are sorry for what has occurred'*
- Factual statements explaining how the incident occurred (*'this incident occurred because the wrong label was mistakenly placed on your specimen sample'*)
- Explaining what is being done to ensure it does not happen again (*'we are currently investigating exactly what caused this breakdown in the process and will inform you of the findings, and steps taken to try to prevent recurrence, as soon as we know'*)

### Examples of phrases to avoid during an apology, or expression of regret, and open disclosure

- *'It's all my/our/his/her fault... I am liable'*
- *'I was/we were negligent...'*
- any speculative statements.

See also *Saying Sorry: A guide to apologising and expressing regret in open disclosure* available at [www.safetyandquality.gov.au/opendisclosure](http://www.safetyandquality.gov.au/opendisclosure)

## 7.3 Non-verbal communication and other considerations

Practising the phrasing used to explain the adverse event, and of the apology or expression of regret may pay dividends. Some useful phrases for open disclosure discussions are presented in Appendix 5.

It is also important to consider non-verbal aspects of open disclosure discussions and which includes:

- positioning, such as sitting next to the patient rather than talking across a desk
- body language, such as an open posture
- maintaining eye contact throughout the conversation
- active listening.

The RACGP suggests that clinicians try to see things from the patient's perspective when engaging in open disclosure, and ask the following questions:<sup>J(p42)</sup>

- "If I were in this position what would I want done?"
- "How would I like my doctor to respond?"

Clinicians should also be mindful of using clinical jargon, and take into account the health literacy of the patient.

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<sup>J</sup> RACGP. *Regaining trust after an adverse event. An education module on managing adverse events in general practice.* 2008, Melbourne

## 8 Completing the process

The open disclosure process concludes with shared agreement between the patient and the clinician. If a satisfactory conclusion cannot be negotiated, the patient should be offered alternative courses of action.

Before this occurs, clinicians should endeavour to follow-up with the patient after open disclosure discussions. Where possible and appropriate the patient should be:

- Assured of receiving further information and follow-up care, and should be readily provided with any information they request (without contravening legal constraints).
- Kept informed of the progress and results of any investigation, including whether the results are delayed, pending or uncertain.
- Notified of any changes to practice that are intended as a result of any investigation, and the changes that have been made to minimise the risk of a similar adverse event happening again.
- Offered an opportunity to discuss the situation with another relevant professional, where appropriate.
- Encouraged to contact the practice if further issues arise.

Completion is noted in verbal and final written communication to the patient.

Clinicians are encouraged to discuss the content of this communication with their indemnity insurer.

### 8.1 Communication with other providers

Other clinicians providing care to the patient should be informed of the patient's condition and status following completion of open disclosure.

Similarly when a patient requires further investigation, therapeutic management or rehabilitation, the patient should be clearly informed of their proposed ongoing clinical management.

### 8.2 Evaluation

Where possible, patients should be given the opportunity to provide feedback on the open disclosure process. This will vary depending on factors such as the setting and size of the practice. A simple survey or structured face-to-face interview with the patient can be a useful evaluation tool.<sup>K</sup>

The aim of evaluation is to improve the way open disclosure is practiced.

### 8.3 What if a satisfactory outcome cannot be reached?

Sometimes, despite best efforts, the relationship between the patient and the clinician can break down. The patient may not accept the information provided or may not wish to participate in open disclosure.

In these situations it is important to assess with which aspect of open disclosure the patient is dissatisfied.

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<sup>K</sup> Survey templates for acute settings have been prepared and are available at [www.safetyandquality.gov.au/opendisclosure](http://www.safetyandquality.gov.au/opendisclosure). These can be simplified and adapted to the small practice setting.

It is important that the patient is provided with information on alternative courses of action.

It is inevitable that sometimes an agreed outcome cannot be reached. So long as the appropriate process has been followed and documented, clinicians should not hesitate to advise patients to take the matter to other authorities, such as the relevant health complaints office.

## 9 Documentation

Comprehensive documentation contributes significantly to successful open disclosure. The disclosure of an adverse event and the facts relevant to it must be properly recorded.

Recording commences at the beginning of open disclosure and continues throughout.

It is important that a record is kept of the open disclosure process, including all relevant:

- patient, family and support person contact details
- discussions
- information provided
- logistical details and plans proposed
- agreements and commitments made.

Without breaching legal requirements, all documentation related to open disclosure should be filed in the patient record.

# Appendix 1: Legal aspects of open disclosure

## 1 Apology, expression of regret and open disclosure

Apology and/or expressions of regret are central to open disclosure. All Australian jurisdictions have enacted laws that are designed to protect statements of apology or regret made after 'incidents' from subsequent use in certain legal settings. These laws are listed in Table A1 below.

For example, in NSW, 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.

It should be noted that most of these laws were enacted without open disclosure in mind, and all relate to a wide range of situations and legal contexts.

Clinicians should consider the legislation in the state or territory in which they work when conducting open disclosure.

The *Open Disclosure Standard Review Report* contains more information in this regard.<sup>L</sup>

**Table A1: Apology or expression of regret acts**

ACT	<i>Civil Law (Wrongs) Act 2002</i>
New South Wales	<i>Civil Liability Act 2002</i>
Northern Territory	<i>Personal Injuries (Liabilities and Damages) Act 2003</i>
Queensland	<i>Civil Liability Act 2003</i>
South Australia	<i>Civil Liability Act 1936</i>
Tasmania	<i>Civil Liability Act 2002</i>
Victoria	<i>Wrongs Act 1958</i>
Western Australia	<i>Civil Liability Act 2002</i>

### 1.1 Admission of liability

Clinicians need to be aware of the risk of making an admission of liability during open disclosure. In any discussion with the patient and their support persons during the open disclosure process, the clinician should take care not to:

- speculate on the causes of an incident
- pre-empt the results of any investigations
- apportion blame, or state or agree that they, other clinicians or organisations are liable for the harm caused to the patient.

These restrictions should not impede open disclosure or the benefits that a genuine and sincere apology or expression of regret can provide to both patient and clinician.

<sup>L</sup> Australian Commission on Safety and Quality in Health Care. Open Disclosure Standard Review Report. Sydney. ACSQHC, 2012. [www.safetyandquality.gov.au/opendisclosure](http://www.safetyandquality.gov.au/opendisclosure)

## **2 Protection of communications and documents**

Communications and documents (including emails) prepared following an adverse event may have to be disclosed later in any legal proceedings. It is therefore important that care is taken in all communications and documents to state as fact only what is known to be correct.

In addition, there may be circumstances where it is necessary to conduct the open disclosure process at the same time as other legal or investigative processes. Certain communications with legal advisers may be subject to legal professional privilege or some other kind of legal privilege.

It is possible (but unlikely) that a clinician in a small practice environment will be affected by 'qualified privilege' laws. Nevertheless, legal professional privilege and 'qualified privilege' are outlined briefly below.

### **2.1 Legal professional privilege/client legal privilege**

The clinician or legal adviser may require particular documents to be created (e.g. reports, witness statements) for the purpose of obtaining or giving legal advice on the incident, or for use in legal proceedings, should they eventuate. If so, the clinician should be able to claim that those communications and documents attract legal professional privilege and do not have to be disclosed to a third party (usually the patient in any legal proceedings) or in a freedom of information application.

However, legal professional privilege (also called client legal privilege) applies only in limited circumstances, and a number of important principles need to be considered:

- Legal professional privilege provides that confidential communications, including documents, between a lawyer and client made for the dominant purpose of the client obtaining, or the lawyer giving legal advice or for use in existing or contemplated litigation, are protected from disclosure. A communication can be verbal or in writing.
- Legal professional privilege belongs to the client (not the lawyer) who is receiving the legal advice or legal services. This may be the clinician or their insurer (or the department of health or the health minister) that is obtaining the legal advice.

In some instances, the client (the clinician or their insurer) can waive legal professional privilege so that the protection no longer applies. A waiver can be express or implied. If protection is sought, it is important not to do anything that inadvertently waives the privilege, for example by disclosing the communication or document so that it is no longer confidential.

### **2.2 Legislation to protect quality improvement activities**

The Commonwealth and all states and territories have enacted legislation that protects certain information generated as a result of particular quality improvement activities from disclosure to third parties. These are listed in Table A2.

Commonwealth, state and territory legislation (except for ACT) requires, with limited exceptions, that people who acquire information solely as a result of their membership of, or an association with, a committee or project, must not make a record of, or divulge information to, any person.

There is considerable variation in the legislation and the protection afforded to information generated during this kind of investigation.

Many of the adverse events that trigger an open disclosure process (particularly in the small practice context) will not trigger a quality assurance activity under the legislation. Therefore, in many adverse events these protections will not apply.

When this legislation does apply, information and documentation arising as part of the quality assurance investigation may not be disclosed under the open disclosure process. Accordingly, in these circumstances, clinicians need to be aware that their ability to disclose information to a patient and their support persons who are part of the open disclosure process may be restricted.

It should be noted that in some jurisdictions, it is possible to release some information. Clinicians need to consider specific conditions on the release of information covered by this legislation.

**Table A2: Legislation protecting quality assurance activities**

ACT	<i>Health Act 1993 (Part 4)</i>
Commonwealth	<i>Health Insurance Act 1973 (Part VC)</i>
New South Wales	<i>Health Administration Act 1982 (Part 2 Divisions 6B and 6C)</i>
Northern Territory	<i>Mental Health and Related Services Act 1998</i>
Queensland	<i>Hospital and Health Boards Act 2011 (ss.81-92)</i>
South Australia	<i>Health Care Act 2008 (Part 7)</i>
Tasmania	<i>Health Act 1997 (s.4)</i>
Victoria	<i>Health Services Act 1988 (Part 7 Division 3)</i>
Western Australia	<i>Health Services (Quality Improvement) Act 1994 (Part 2)</i>

### 3 Privacy and confidentiality

In some jurisdictions and in some circumstances, patients have rights under legislation to privacy and confidentiality of personal information, and a right to access their health records.<sup>M</sup>

There is also an implied obligation of confidentiality in common law (because of the nature of the relationship between a clinician and a patient), although legal rights to confidentiality are difficult to enforce, and some breaches of confidence are without legal remedy.

Clinicians are required by legislation to protect the privacy of patients, clinicians and others when conducting investigations, creating reports and making any disclosures during the open disclosure process. Patients should be informed of these requirements. Information obtained as part of the open disclosure investigation should be recorded and stored in accordance with the legislation.

The safest way to ensure there is not a breach of privacy or confidentiality is to obtain the consent of the patient to disclose specified information to nominated persons. This can be done at the time of admission.

From the outset, clinicians should manage patient expectations regarding obtaining personal information about clinicians that is outside the scope of the adverse event in question, its management and the open disclosure process.

<sup>M</sup> *Privacy Act 1988* (Commonwealth) For information on relevant state and territory privacy laws see [www.privacy.gov.au/privacy\\_rights/laws](http://www.privacy.gov.au/privacy_rights/laws)

## 4 Defamation

In the context of open disclosure, it is possible that a clinician or other person could be defamed by a statement (either verbal or written) that is 'published' by another clinician, healthcare professional or organisation. For example, this could occur by a clinician alleging that a colleague is incompetent.

For a defamation action to arise, the communication need only be made to one other person. It is not necessary for a person to be referred to by name in order to be defamed if it can be shown that the person could be readily identified.

Accordingly, clinicians must be careful recording information and what is said to and about others during the open disclosure process.

## 5 Coronial investigations

Each state and territory has legislation governing the coronial process. These are listed in Table A3. The specific duties and responsibilities of coroners vary by jurisdiction but, in general, coroners:

- establish the manner and causes of all reportable deaths. These include untimely, unexpected or unexplained death during health care
- investigate the circumstances surrounding all reportable deaths
- do not determine any criminal or civil liability (however, the coronial investigation can provide valuable insight into causes of the adverse event)
- can make recommendations on public health and safety which can be used to improve systems throughout the health sector.

Coroners can require:

- production of patient records for the purpose of the coronial inquiry
- a post-mortem to be conducted.

The next of kin has a legal right to file an objection to a post-mortem being conducted and the Coroner will take into consideration any such objection. For details regarding the rights of the next of kin in a particular jurisdiction with respect to objecting to an autopsy, please refer to the relevant Act for each state or territory in Table A3.

Clinicians should be familiar with requirements set out under relevant acts and develop local policies and procedures accordingly.

**Table A3: Coroners acts**

ACT	<i>Coroners Act 1997</i>
New South Wales	<i>Coroners Act 2009 No 41</i>
Northern Territory	<i>Coroners Act 2011</i>
Queensland	<i>Coroners Act 2003</i>
South Australia	<i>Coroners Act 2003</i>
Tasmania	<i>Coroners Act 1995</i>
Victoria	<i>Coroners Act 2008 Revised Penalty Provisions</i>
Western Australia	<i>Coroners Act 1996</i>

## Appendix 2: RACGP Standards for general practices 4<sup>th</sup> Edition 2010 <sup>N</sup>

### Criterion 3.1.2 Clinical risk management systems

Our practice has clinical risk management systems to enhance the quality and safety of our patient care.

*Just and open communication is vital*

A systems approach to thinking about adverse events and errors highlights a need to shift away from the immediacy of blaming individual practitioners to cultivating a just, open and supportive culture where individual accountability and integrity is preserved, but mediated by thoughtful and supportive response to error (see the RACGP education module *Regaining trust after an adverse event*).

The practice needs to have a process in place where members of the practice team know who and how to notify when a near miss or mistake occurs, or when there is an unanticipated adverse outcome. All members of the practice team, no matter how junior, should feel empowered to recognise and report near misses and mistakes without fear of recrimination.

A study by Maxfield et al highlights the critical importance of open communication. The study found that people see others make mistakes, violate rules or demonstrate dangerous levels of incompetence repeatedly and over long periods of time in ways that hurt patient safety and employee morale. However, they don't speak up and the critical variable that determines whether they break this chain by speaking up is their confidence in their ability to confront. These findings give practices a powerful reason for focusing on open communication as a vital tool in clinical risk management.

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<sup>N</sup> The full document is available from the Royal Australian College of General Practitioners web site at [www.racgp.org.au/your-practice/standards/standardsforgeneralpractices](http://www.racgp.org.au/your-practice/standards/standardsforgeneralpractices)

## Appendix 3: Extracts from the *Code of Conduct for Registered Health Practitioners*<sup>o</sup>

### 3.10 Adverse events and open disclosure

When adverse events occur, practitioners have a responsibility to be open and honest in communication with a patient or client to review what has occurred and to report appropriately (also see *Open disclosure* at Section 6.2(a)). When something goes wrong, good practice involves:

- a. recognising what has happened
- b. acting immediately to rectify the problem, if possible, including seeking any necessary help and advice
- c. explaining to the patient or client as promptly and fully as possible what has happened and the anticipated short-term and long-term consequences
- d. acknowledging any patient or client distress and providing appropriate support
- e. complying with any relevant policies, procedures and reporting requirements, subject to advice from a professional indemnity insurer
- f. reviewing adverse events and implementing changes to reduce the risk of recurrence (see Section 6 *Minimising risk*)
- g. reporting adverse events to the relevant authority as required (see Section 6 *Minimising risk*), and
- h. ensuring patients or clients have access to information about the processes for making a complaint (for example, through the relevant board or healthcare complaints commission).

### 6.2 Risk management

Good practice in relation to risk management involves:

- a. being aware of the importance of the principles of open disclosure and a non-punitive approach to incident management. a useful reference is the Australian Commission on Safety and Quality in Health Care's *National Open Disclosure Standard* available at [www.safetyandquality.gov.au](http://www.safetyandquality.gov.au)
- b. participating in systems of quality assurance and improvement
- c. Participating in systems for surveillance and monitoring of adverse events and 'near misses', including reporting such events
- d. if a practitioner has management responsibilities, making sure that systems are in place for raising concerns about risks to patients or clients
- e. working in your practice and within systems to reduce error and improve patient safety, and supporting colleagues who raise concerns about the safety of patients or clients, and
- f. taking all reasonable steps to address the issue if you have reason to think that the safety of patients or clients may be compromised.

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<sup>o</sup> See <http://www.ahpra.gov.au/Health-Professions.aspx>

## Appendix 4: Medication errors, adverse drug events and open disclosure

The use of medicines carries inherent risks. Whilst medication incidents rank amongst the most frequently reported incidents in healthcare incident monitoring systems, not all result in an adverse drug event (ADE) and cause patient harm.

ADEs result from (see Figure A2):

- medication errors i.e. a clinician making an error when ordering, dispensing, compounding, administering or monitoring a medicine
- adverse drug reactions (ADRs).

The harm resulting from medication errors is considered preventable and although many medication errors cause minimal or no harm some events can be devastating.

Where ADEs are the result of an error by the health practitioner e.g. omitting to order a drug, administering the wrong drug or dose or giving the drug by the wrong route, the same criteria as for other adverse events should guide the appropriate level of response.

In the case of ADRs, only a small percentage are preventable, and although the incidence of most ADRs (side effects) are known there is often no way of knowing which patients will experience harm.

This is especially relevant where the reaction is idiosyncratic such as severe allergy (anaphylaxis) to penicillin or steroid induced psychosis.

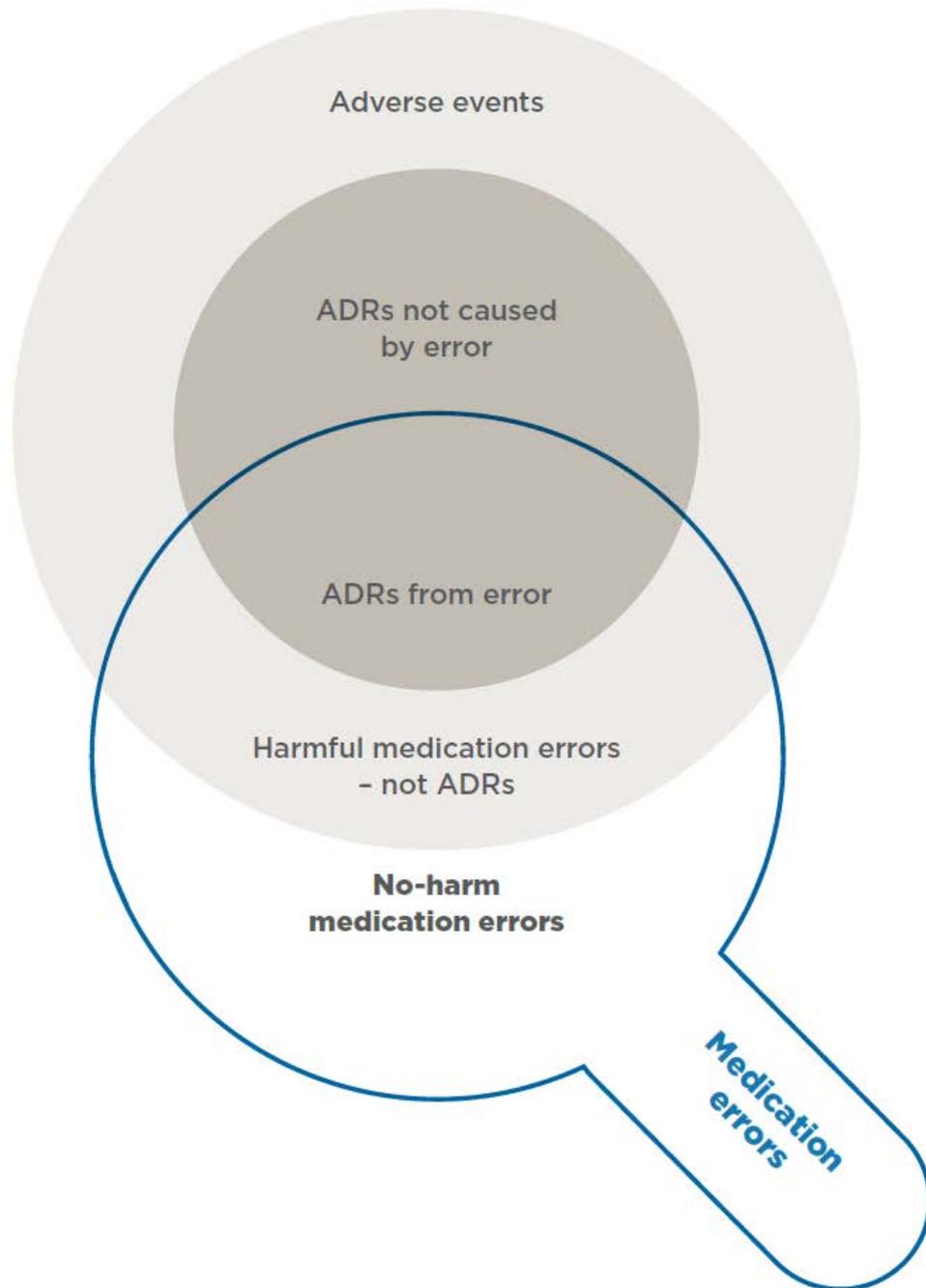
Anticipating the occurrence of ADRs in an individual patient can often be difficult where patients have not (or have not reported to have) been previously administered the drug. In these situations open disclosure is most likely required. This would also be the case where a patient experienced harm from an ADR that could have been prevented (e.g. gentamicin induced ototoxicity resulting from failure to monitor renal function and therapeutic levels and adjust the dose accordingly).

A tailored approach to the different types of ADEs and, in particular, ADRs is required. The level of disclosure will be influenced by:

- a. degree of patient harm
- b. whether there was prior knowledge of the allergy (i.e. the ADR was preventable)
- c. whether the patient, their family or carer(s) were not advised of the possibility of the ADR occurring.

**Figure A1: Diagram showing the relation between adverse events, adverse drug reactions and medication errors.**

Sizes do not reflect the relative frequencies of the incidents illustrated (Adapted with permission from Aronson JK. Medication errors: definitions and classification. *British Journal of Clinical Pharmacology* 2009;67(6):599-604)



## Appendix 5: Useful phrases for open disclosure discussions

The open disclosure process does not need to be a tightly scripted. However, 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,

The following text provides phrases to use with the patient in an open disclosure conversation.<sup>P</sup>

- *‘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 don’t know exactly what happened, but I promise you we’re going to find out and do everything we can to make sure it doesn’t 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?’*

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<sup>P</sup> RACGP. *Regaining trust after an adverse event. An education module on managing adverse events in general practice.* 2008, Melbourne

## Appendix 6: Glossary

<b>Admission of liability</b>	A statement by a person that admits, or tends to admit, a person's or organisation's liability in negligence for harm or damage caused to by another.
<b>Adverse event</b>	An incident in which unintended harm resulted to a person receiving health care. Note: This term is used interchangeably with 'harmful incident'. See <i>Harm</i>
<b>Adverse outcome</b>	An outcome of an illness or its treatment that has not met the clinician's or the patient's expectation for improvement or cure.
<b>Apology</b>	An expression of sorrow, sympathy and (where applicable) remorse by an individual, group or institution for a harm or grievance. It should include the words 'I am sorry' or 'we are sorry'. Apology may also include an acknowledgment of responsibility, which is not an admission of liability. See also <i>Admission of liability</i> , <i>Expression of regret</i>
<b>Carer</b>	A person who provides unpaid care and support to family members and friends who have a disability, mental illness, chronic condition, terminal illness or general frailty. Carers include parents and guardians caring for children. <sup>Q</sup> A person is not a carer if he or she provides this support and assistance under a contract of service or a contract for the provision of services; or in the course of doing voluntary work for a charitable, welfare or community organisation; or as part of the requirements of a course of education or training. <sup>R</sup>
<b>Clinical risk</b>	The combination of the probability of occurrence of harm and the severity of that harm.
<b>Clinical risk management</b>	See <i>Risk management</i>
<b>Clinician</b>	A healthcare provider who is trained as a health professional. Clinicians include registered and non-registered practitioners, or a team of health professionals who spend the majority of their time providing direct clinical care. See also <i>Healthcare practitioner</i>
<b>The Commission</b>	Australian Commission on Safety and Quality in Health Care
<b>Complication</b>	Patients and potential patients, carers and organisations representing consumers' interests.
<b>Consumer</b>	A member of the public who uses, or is a potential user, of healthcare services.
<b>Corporate risk</b>	Potential liabilities, exposures and dangers faced by an organisation or corporation. These can be financial or reputational.
<b>Corporate risk management</b>	See <i>Risk management</i>

<sup>Q</sup> About Carers, Carers Australia [www.carersaustralia.com.au/about-carers](http://www.carersaustralia.com.au/about-carers) (accessed 25 March 2013)

<sup>R</sup> Carer Recognition Act, 2010

<b>Disability</b>	Any type of impairment of body structure or function, activity limitation or restriction of participation in society.
<b>Error</b>	Failure to carry out a planned action as intended or application of an incorrect plan through either doing the wrong thing (commission) or failing to do the right thing (omission) at either the planning or execution phase of healthcare intervention. <sup>S</sup>
<b>Ex gratia</b>	'Out of good will', usually referring to financial reimbursement or recovery payments. By definition, ex gratia payments are not an admission of liability.
<b>Expression of regret</b>	An expression of sorrow for a harm or grievance. It should include the words 'I am sorry' or 'we are sorry'. An expression of regret may be preferred over an apology in special circumstances (e.g. when harm is deemed unpreventable). See also <i>Apology</i>
<b>Harm</b>	Impairment of structure or function of the body and/or any deleterious effect arising therefrom, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological. <sup>R</sup>
<b>Harmful incident</b>	An incident that led to patient harm. Such incidents can either be part of the healthcare process, or occur in the healthcare setting (i.e. while the patient is admitted to, or in the care of, a health service organisation). Note: This term is used interchangeably with 'adverse event'.
<b>Health care</b>	The prevention, treatment and management of illness and the preservation of mental and physical wellbeing through the services offered by the medical and allied health professions.
<b>Healthcare record</b>	See <i>Patient record</i>
<b>Healthcare practitioner</b>	See <i>clinician</i>
<b>Higher level response</b>	A comprehensive open disclosure process usually in response to an incident resulting in death or major permanent loss of function, permanent or considerable lessening of body function, significant escalation of care or major change in clinical management (e.g. admission to hospital, surgical intervention, a higher level of care or transfer to intensive care unit), or major psychological or emotional distress. These criteria should be determined in consultation with patients, their family and carers. A higher level response may also be instigated at the request of the patient even if the outcome of the adverse event is not as severe. See also <i>Lower level response</i>
<b>Incident</b>	See <i>Adverse event</i>
<b>Liability</b>	The legal responsibility for an action
<b>Lower level response</b>	A briefer open disclosure process usually in response to incidents resulting in no permanent injury, requiring no increased level of care (e.g. transfer to operating theatre or intensive care unit), and resulting in no, or minor, psychological or emotional distress (e.g. near misses and no-harm incidents),. These criteria should be determined in consultation with patients, their family and carers. See also <i>Higher level response</i>

<sup>S</sup> World Health Organization. The International Classification for Patient Safety WHO, 2009

<b>Medical record</b>	See <i>Patient record</i>
<b>Near miss</b>	An error or system failure that is intercepted before reaching the patient. It is important to ensure that harm did not occur.
<b>Next of kin</b>	Synonymous with family member and may include: <ul style="list-style-type: none"> <li>• spouse or domestic partner</li> <li>• son or daughter who has attained the age of 18</li> <li>• parent</li> <li>• brother or sister, who has attained the age of 18.</li> </ul>
<b>No-harm incident</b>	An error or system failure that reaches the patient but does not result in patient harm.
<b>Open disclosure</b>	An open discussion with a patient about an incident(s) that resulted in harm to that patient while they were receiving health care. The elements of open disclosure are an apology or expression of regret (including the word sorry), a factual explanation of what happened, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.  Open disclosure is a discussion and an exchange of information that may take place over several meetings.
<b>Outcome</b>	The effect on a patient that is wholly or partially attributable to an incident.  The status of an individual, a group of people or a population that is wholly or partially attributable to an action, agent (i.e. one who/which acts to produce a change) or circumstance (i.e. all factors connected with influencing an event, agent or person).
<b>Patient</b>	A person receiving health care. Synonyms for patient include 'consumer' and 'client'.  In this document, patients can also refer to support persons such as family members and carers.  See also <i>Support Person</i>
<b>Patient harm</b>	See <i>Harm</i>
<b>Patient record</b>	A collection of data and information gathered or generated to record clinical care rendered to an individual. A comprehensive, structured set of clinical, demographic, environmental, social, and financial data and information, documenting the health care given to a single individual.
<b>Patient safety</b>	The reduction of risk of unnecessary harm associated with health care to an acceptable minimum. An acceptable minimum refers to the collective notions of current knowledge, resources available and the context in which care was delivered, weighed against the risk of non-treatment or other treatment. <sup>T</sup>
<b>Qualified privilege legislation</b>	Qualified privilege legislation varies between jurisdictions but generally protects the confidentiality of individually identified information that became known solely as a result of a declared safety and quality activity. Certain conditions apply to the dissemination of information under qualified privilege.
<b>Quality (health care)</b>	The degree to which health services increase the likelihood of desired outcomes and are consistent with current professional knowledge.

<sup>T</sup> World Health Organization. The International Classification for Patient Safety WHO, 2009

<b>Quality improvement</b>	The continuous study and adaptation of a healthcare organisation's functions and processes to increase the probability of achieving desired outcomes and better meet the needs of patients and other users of services.
<b>Reimbursement</b>	The act of paying for somebody's expenses without an admission of liability.
<b>Risk</b>	The chance of something happening that will have a negative effect. It is measured by consequences and likelihood.
<b>Risk management</b>	<p>The design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the institution.</p> <p><b>Clinical risk management</b> Clinical, administrative and manufacturing activities that organisations undertake to identify, evaluate and reduce the risk of injury to patients and visitors, and the risk of loss to the organisation itself.</p> <p><b>Corporate risk management</b> Activities of an organisation or corporation to identify and reduce potential financial or reputational liabilities, exposures and dangers.</p>
<b>Small practice</b>	A practice consisting of one clinician, or a group of clinicians.
<b>Staff</b>	Anyone working within a healthcare practice.
<b>Statute</b>	A written law passed by legislature at the state or federal level.
<b>Suffering</b>	Any subjectively unpleasant experience, including pain, malaise, nausea, vomiting, loss, depression, agitation, anxiety, alarm, fear, grief, humiliation or loss of autonomy.
<b>Support person</b>	<p>An individual who has a relationship with the patient. References to 'support person' in this document can include:</p> <ul style="list-style-type: none"> <li>• family members / next of kin</li> <li>• carers</li> <li>• friends, a partner or other person who cares for the patient</li> <li>• guardians or substitute decision makers</li> <li>• social workers or religious representatives</li> <li>• where available, trained patient advocates.</li> </ul> <p>References to support person should be read with the words, 'where appropriate'.</p>
<b>Treatment</b>	The way an illness or disability is managed by drugs, surgery, physiotherapy or other intervention to affect an improvement in or cure of the patient's condition.