

Australian Open Disclosure Framework

Better communication,
a better way to care



AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE



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Glossary

Accreditation	A status that is conferred on a health service organisation or individual when they are assessed as having met particular standards relating to quality of care and patient safety.
Admission of liability	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 another.
Adverse event	An incident in which harm resulted to a person receiving health care. Note: This term is used interchangeably with 'harmful incident'. <i>See Harm</i>
Adverse outcome	An outcome of an illness or its treatment that has not met the clinician's or the patient's expectation for improvement or cure.
Apology	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. <i>See also Admission of liability, Expression of regret</i>
Carer	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. ¹ 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. ²
Clinical risk	The combination of the probability of occurrence of harm and the severity of that harm.
Clinical risk management	<i>See Risk management</i>
Clinical workforce	The nursing, medical and allied health professionals who provide patient care, and students who provide patient care under supervision. This may also include laboratory scientists.
Clinician	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.
Commission	Australian Commission on Safety and Quality in Health Care
Complication	A detrimental patient condition that arises during the process of providing health care. ³
Consumer	Patients and potential patients, carers and organisations representing consumers' interests. ⁴



Glossary

Corporate risk	Potential liabilities, exposures and dangers faced by an organisation or corporation. These can be financial or reputational.
Corporate risk management	See <i>Risk management</i>
Disability	Any type of impairment of body structure or function, activity limitation or restriction of participation in society.
Error	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. ³
Ex gratia	'Out of good will', usually referring to financial reimbursement or recovery payments. By definition, ex gratia payments are not an admission of liability.
Expression of regret	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>
Harm	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. ³
Harmful incident	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'.
Health care	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.
Healthcare record	See <i>Patient record</i>
Health service organisation	A separately constituted health service that is responsible for the clinical governance, administration and financial management of a service unit providing health care. A service unit involves a group of clinicians and others working in a systematic way to deliver health care to patients. This can be in any location or setting, including pharmacies, clinics, outpatient facilities, hospitals, patients' homes, community settings, practices and clinicians' rooms. Unless specified the term <i>health service organisation</i> includes all of these and other settings in which health care is provided.
Health service contact	A nominated employee of the health service organisation who acts as an ongoing point of contact and provides information and support to the patient throughout the open disclosure process.

Higher-level response	<p>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.</p> <p>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.</p> <p>See also <i>Lower-level response</i></p>
Incident	See <i>Adverse event</i>
Liability	The legal responsibility for an action.
Lower-level response	<p>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.</p> <p>See also <i>Higher-level response</i></p>
Medical record	See <i>Patient record</i>
Multidisciplinary team	A healthcare team comprising individuals from various professions (nursing, medical, allied health, administrative, management) and disciplines within these professions.
National Safety and Quality Health Service (NSQHS) Standards	<p>A set of 10 standards which provide a clear statement about the level of care consumers can expect from health service organisations. They also play an essential part in accreditation arrangements which commenced in January 2013.</p> <p>See also <i>Accreditation</i></p>
Near miss	An incident that did not cause harm but had the potential to do so. ⁵
Next of kin	<p>Synonymous with family member and may include:</p> <ul style="list-style-type: none"> • spouse or domestic partner • son or daughter who has attained the age of 18 • parent • brother or sister, who has attained the age of 18.
No-harm incident	An error or system failure that reaches the patient but does not result in patient harm.
Nominated contact person	Any individual who is formally identified by the patient as a nominated recipient of information regarding their care in accordance with local processes and legal requirements.



Glossary

Non-clinical workforce	The workforce in a health service organisation who do not provide direct clinical care but support the business of health service delivery through administration, corporate record management, management support or volunteering.
Open disclosure	<p>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.</p> <p>Open disclosure is a discussion and an exchange of information that may take place over several meetings.</p>
Outcome	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).
Patient	<p>A person receiving health care. Synonyms for patient include 'consumer' and 'client'.</p> <p>In this document, patients can also refer to support persons such as family members and carers.</p> <p>See also <i>Support person</i></p>
Patient harm	See <i>Harm</i>
Patient record	Consists of, but is not limited to, a record of the patient's medical history, treatment notes, observations, correspondence, investigations, test results, photographs, prescription records and medication charts for an episode of care.
Patient safety	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. ³
Qualified privilege legislation	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.
Quality (health care)	The degree to which health services increase the likelihood of desired outcomes and are consistent with current professional knowledge.
Quality improvement	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.
Reimbursement	The act of paying for somebody's expenses without an admission of liability.

Risk	The chance of something happening that will have a negative effect. It is measured by consequences and likelihood.
Risk management	<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>Clinical risk management</p> <p>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>Corporate risk management</p> <p>Activities of an organisation or corporation to identify and reduce potential financial or reputational liabilities, exposures and dangers.</p>
Service recovery	The process used to ‘recover’ dissatisfied individuals or patients by identifying and fixing the problem, or making amends for the failure in customer or clinical services.
Staff	Anyone working within a health service organisation, including self-employed professionals such as visiting medical officers.
Statute	A written law passed by a legislature at the state or federal level.
Support person	<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"> • family members / next of kin • carers • friends, a partner or other person who cares for the patient • guardians or substitute decision-makers • social workers or religious representatives • where available, trained patient advocates. <p>References to support person should be read with the words, ‘where appropriate’.</p>
System failure	A fault, breakdown or dysfunction within operational methods, processes or infrastructure.
Systems improvement	The changes made to dysfunctional operational methods, processes and infrastructure to ensure improved quality and safety.
Treatment	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.



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Preface

The *Australian Open Disclosure Framework* (the Framework) is designed to enable health service organisations and clinicians to communicate openly with patients when health care does not go to plan.

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 institutional 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 health service organisations and important part of healthcare quality improvement.

The Framework provides a nationally consistent basis for communication following unexpected healthcare outcomes and harm. It is designed so that patients are treated respectfully after adverse events.

The Framework is intended for use by Australian health service organisations across all settings and sectors and describes open disclosure practice and considerations that may affect local implementation. It can be used to inform new open disclosure policies and modify existing ones.

The Framework is divided into two parts. Part A describes organisational requirements for open disclosure. It includes the rationale and scope of the Framework, as well as key considerations. Part B describes open disclosure practice.

Endorsement of the Framework

In December 2013, the Framework was formally endorsed by Australian Health Ministers.

The Framework has been officially endorsed by the following professional organisations:

- Australian College of Nursing
- Australian and New Zealand College of Anaesthetists
- Royal Australian and New Zealand Colleges of Obstetricians and Gynaecologists
- Royal Australasian College of Physicians
- Royal Australasian College of Surgeons
- Society of Hospital Pharmacists of Australia

The Framework is supported by the:

- Australasian College of Emergency Medicine
- Royal College of Pathologists of Australia

A document to support the use of the Framework, *Implementing the Open Disclosure Framework in Small Practices*, has been officially recognised as an Accepted Clinical Resource by The Royal Australian College of General Practitioners. This resource, and other supporting materials, can be accessed at www.safetyandquality.gov.au/opendisclosure.

The National Safety and Quality Health Service Standards

The *National Safety and Quality Health Service (NSQHS) Standards* were endorsed by Australian Health Ministers in 2011 and provide a clear statement about the level of care consumers can expect from health service organisations.

Open Disclosure is mandated in the *NSQHS Standards (Standard 1, Criterion 1.16)*⁴ and is subject to accreditation.

Background

The Framework replaces the *Open Disclosure Standard* (the Standard). The Standard was endorsed by Australian Health Ministers in 2003 and was the first national open disclosure policy. Since 2003, there has been considerable research activity in open disclosure. Much of the research evidence has been generated in Australia.

The Australian Commission on Safety and Quality in Health Care reviewed the Standard in 2011–2012 to:

- consider the Standard in the context of current research and evidence of, and experience with, open disclosure
- identify where the Standard does and does not reflect current evidence
- recommend changes to the Standard.

The review found that the Standard remained mostly relevant but could benefit from further refinement. Recommended changes to the Standard were intended to:⁶

- encourage health professional preparation for open disclosure through awareness and training
- increase patient, family and carer involvement in open disclosure.

There were four main review findings:⁶

1. Open disclosure is often conducted as a process of information provision from the service to the patient, but patients prefer it as an open dialogue.
2. Health professionals support disclosure but barriers remain to its practice, including:
 - a. perceived medico-legal consequences of disclosure
 - b. concerns about preparedness for involvement in open disclosure
 - c. tensions between the principles of openness and timely acknowledgement, and the requirement for providers to take early advice from their insurers following a harmful incident.
3. Overseas evidence and Australian experience suggest that disclosure is more effective as an ethical practice that prioritises organisational and individual learning from error, rather than solely as an organisational risk management strategy.
4. Open disclosure has been found to create larger benefits for the health system and patients by fostering cultures of openness and trust.

The *Open Disclosure Standard Review Report*⁶ contains information and references that can be of use in developing local open disclosure policy and practice.

Terminology

National consultation on the Framework identified concerns regarding the term 'open disclosure' which is seen, by some, to harbour negative connotations and carry legalistic overtones. However, the term 'open disclosure' is used and embedded in Australia and internationally and remains recognised at this point.

While no consistent alternative was agreed, the concern is noted and the Framework emphasises that open disclosure:

- is a dialogue between two parties
- is not a legal process
- does not imply that an individual or service has blameworthy facts to disclose.

PART A: Organisational preparedness

1 Introduction

Every day many thousands of healthcare interventions occur across Australia. These interventions are often complex, delivered in high-pressure environments and involve multiple practitioners working in teams and across organisations. Excellent outcomes are most often the result, but modern health care also carries significant risks and, at times, things do not go to plan. Adverse events and patient harm can and do occur.

Open disclosure describes the way clinicians communicate with and support patients, and their family and carers,^a who have experienced harm during health care. Open disclosure is a patient right, is anchored in professional ethics, considered good clinical practice, and is part of the care continuum.

Over the past two decades, open disclosure has been recognised as a practice that can benefit patients and clinicians involved in adverse events. Open disclosure is inherently complex, and is challenging and difficult for all participants. However, its systematic practice can assist health service organisations to manage adverse events compassionately and provide broader benefits through improved clinical communication and systems improvement.

^a The expression *patient, their family and carers* is used in this document to emphasise that support persons should, where appropriate, be included in open disclosure discussions. Support persons can also include partners, friends, guardians or social workers, or, where available, trained patient advocates.

1.1 Definition of open disclosure

Open disclosure is the open discussion of adverse events that result in harm to a patient while receiving health care with the patient, their family and carers. 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, their family and carers 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.

It is important to note that open disclosure is not a one-way provision of information. Open disclosure is a discussion between two parties and an exchange of information that may take place in several meetings over a period of time.

1.2 The purpose of this document

The Australian Open Disclosure Framework (the Framework) is a national initiative of the Australian, and state and territory governments, in conjunction with private health services, through the Australian Commission on Safety and Quality in Health Care (the Commission). It is intended to contribute to improving the safety and quality of health care.

Open disclosure is an inherently complex and difficult process. This document provides a flexible framework designed to be used by health service organisations in all settings and sectors when developing or amending policies and procedures for open disclosure.

Organisations should develop open disclosure policies and procedures that are tailored to local needs and resources, and the relevant legal, regulatory, institutional and cultural context.

In particular, policies and procedures should include the following.

- Appropriate training and education for relevant staff to ensure a consistent and informed approach to open disclosure.
- Mechanisms for involving consumers and clinicians in developing policies and procedures.^b
- Insurer requirements of health service organisations and professionals, and procedures for involving them in policy development at an early stage.

The *Open Disclosure Standard Review Report* contains information and references that can be of use in developing local open disclosure policy and practice.⁶

Box 1: Adapting the Framework to your setting

The Framework describes complete, higher-level open disclosure. In its entirety it is therefore most directly applicable to high-risk, acute healthcare settings.

Health service organisations and healthcare providers in rural areas, the sub-acute sector, primary and community-based care, mental health, and small practices including sole practitioners are encouraged to adapt the Framework to suit their particular context. The eight principles described in Section 1.3 provide a useful starting point for such adaptation.

In this document, and unless otherwise specified, *health service organisation* includes all settings including pharmacies, clinics, outpatient facilities, hospitals, patients' homes, community settings, practices and clinicians' rooms.

Resources and materials to support open disclosure implementation in various settings are available through the Commission web site www.safetyandquality.gov.au/opensdisclosure

^b This is an accreditation requirement under *Standard 2 of the National Safety and Quality Health Service Standards: Partnering with Consumers*. For more detail see Section 6.2 and www.safetyandquality.gov.au



1 Introduction

1.3 Open disclosure principles and process

1.3.1 Principles

The Framework is designed to be applicable within the complex and dynamic processes of modern health care. It attempts to address and balance the interests of patients, clinicians, managers, health service organisations and other key stakeholder groups such as healthcare consumers, medical indemnity insurers and professional organisations.

The Framework's eight guiding principles are:



Open and timely communication

If things go wrong, the patient, their family and carers 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.



Acknowledgement

All adverse events should be acknowledged to the patient, their family and carers as soon as practicable. Health service organisations should acknowledge when an adverse event has occurred and initiate open disclosure.



Apology or expression of regret

As early as possible, the patient, their family and carers 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 (see Section 1.5).



Supporting, and meeting the needs and expectations of patients, their family and carers

The patient, their family and carers 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.



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

Health service organisations should create an environment in which all staff are:

- 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.



Integrated clinical risk management and systems improvement

Thorough clinical review and investigation of adverse events and adverse outcomes should be conducted through processes that focus on the management of clinical risk and quality improvement. Findings of these reviews should focus on improving systems of care and be reviewed for their effectiveness. The information obtained about incidents from the open disclosure process should be incorporated into quality improvement activity.



Good governance

Open disclosure requires good governance frameworks, and clinical risk and quality improvement processes. Through these systems, adverse events should be investigated and analysed to prevent them recurring. Good governance involves a system of accountability through a health service organisation's senior management, executive or governing body to ensure that appropriate changes are implemented and their effectiveness is reviewed. Good governance should include internal performance monitoring and reporting.



Confidentiality

Policies and procedures should be developed by health service organisations with full consideration for patient and clinician privacy and confidentiality, in compliance with relevant law (including Commonwealth, state and territory privacy and health records legislation). However, this principle needs to be considered in the context of *Principle 1: Open and timely communication*.



1 Introduction

1.3.2 The open disclosure process

This section summarises the open disclosure process in table and diagram format. The elements of open disclosure are presented in **Table 1**. Flow charts for the higher and lower-level open disclosure response are presented in **Figure 1** and **Figure 2**.

More detail can be found in the relevant sections of Part B of the Framework.

Table 1: Key considerations and actions during the open disclosure process

<p>1. Detecting and assessing incidents Section 7</p>	<ul style="list-style-type: none"> • Detect adverse event through a variety of mechanisms • Provide prompt clinical care to the patient to prevent further harm • Assess the incident for severity of harm and level of response • Provide support for staff • Initiate a response, ranging from lower to higher levels • Notify relevant personnel and authorities • Ensure privacy and confidentiality of patients and clinicians are observed
<p>2. Signalling the need for open disclosure Section 8</p>	<ul style="list-style-type: none"> • Acknowledge the adverse event to the patient, their family and carers including an apology or expression of regret • A lower-level response can conclude at this stage • Signal the need for open disclosure • Negotiate with the patient, their family and carers or nominated contact person <ul style="list-style-type: none"> – the formality of open disclosure required – the time and place for open disclosure – who should be there during open disclosure • Provide written confirmation • Provide a health service contact for the patient, their family and carers • Avoid speculation and blame • Maintain good verbal and written communication throughout the open disclosure process
<p>3. Preparing for open disclosure Section 9</p>	<ul style="list-style-type: none"> • Hold a multidisciplinary team discussion to prepare for open disclosure • Consider who will participate in open disclosure • Appoint an individual to lead the open disclosure based on previous discussion with the patient, their family and carers • Gather all the necessary information • Identify the health service contact for the patient, their family and carers (if this is not done already)

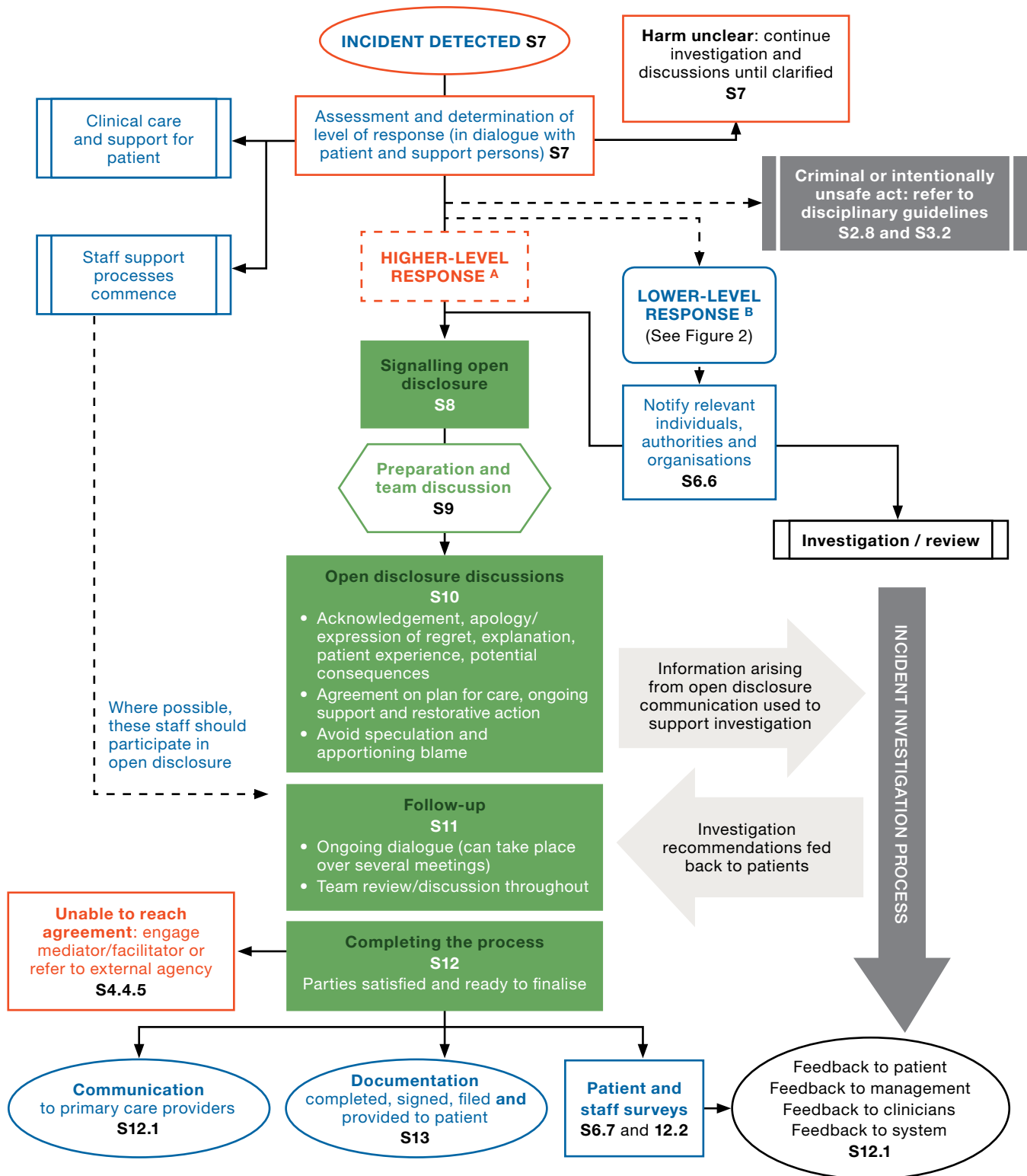
PART A: Organisational preparedness

<p>4. Engaging in open disclosure discussions Section 10</p>	<ul style="list-style-type: none"> • Provide the patient, their family and carers with the names and roles of all attendees • Provide a sincere and unprompted apology or expression of regret including the words 'I am sorry' or 'we are sorry' • Clearly explain the incident • Give the patient, their family and carers the opportunity to tell their story, exchange views and observations about the incident and ask questions • Encourage the patient, their family and carers to describe the personal effects of the adverse event • Agree on, record and sign an open disclosure plan • Assure the patient, their family and carers that they will be informed of further investigation findings and recommendations for system improvement • Offer practical and emotional support to the patient, their family and carers • Support staff members throughout the process • If the adverse event took place in another health service organisation, include relevant staff if possible. • If necessary, hold several meetings or discussions to achieve these aims
<p>5. Providing follow-up Section 11</p>	<ul style="list-style-type: none"> • Ensure follow-up by senior clinicians or management, where appropriate • Agree on future care • Share the findings of investigations and the resulting practice changes • Offer the patient, their family and carers the opportunity to discuss the process with another clinician (e.g. a general practitioner)
<p>6. Completing the process Section 12</p>	<ul style="list-style-type: none"> • Reach an agreement between the patient, their family and carers and the clinician, or provide an alternative course of action • Provide the patient, their family and carers with final written and verbal communication, including investigation findings • Communicate the details of the adverse event, and outcomes of the open disclosure process, to other relevant clinicians • Complete the evaluation surveys
<p>7. Maintaining documentation Section 13</p>	<ul style="list-style-type: none"> • Keep the patient record up to date • Maintain a record of the open disclosure process • File documents relating to the open disclosure process in the patient record • Provide the patient with documentation throughout the process



1 Introduction

Figure 1 Flow chart outlining the key steps of open disclosure (Note: S = Section)



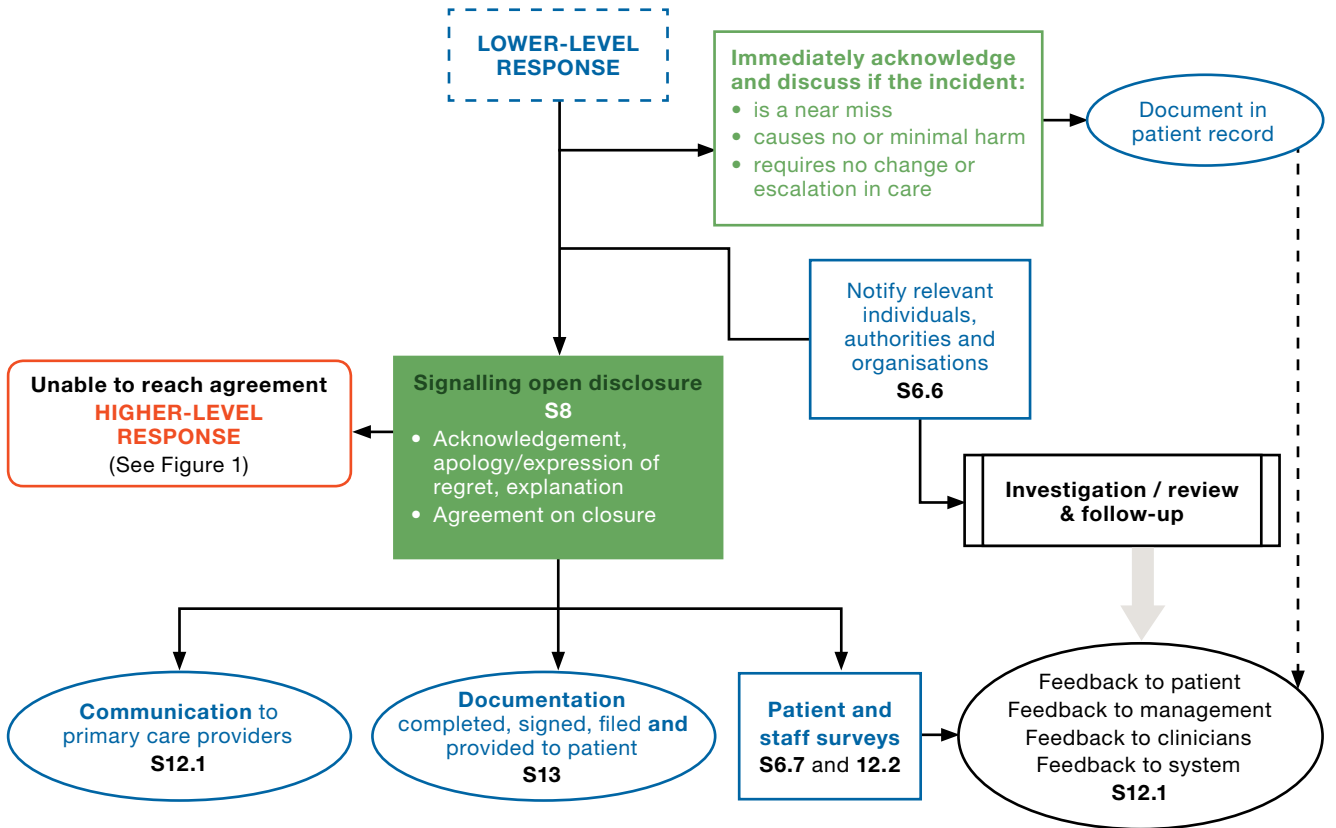
A General indications – higher-level response:

1. Death or major permanent loss of function
 2. Permanent or considerable lessening of body function
 3. Significant escalation of care / change in clinical management
 4. Major psychological or emotional distress
 5. At the request of the patient
- S7.3**

B General indications – lower-level response:

1. Near miss / no-harm incident
 2. No permanent injury
 3. No increased level of care required
 4. No, or minor, psychological or emotional distress
- S7.3**

Figure 2 Lower-level response





1 Introduction

1.4 Culture and communication

Every health service organisation is unique, be it a tertiary hospital, a rural clinic or small practice. In order to implement open disclosure in accordance with the above principles, and continually improve the quality and safety of services, two underlying factors must be addressed in all settings: developing a safe and just culture, and fostering effective communication.

1.4.1 Developing a safe and just culture

In creating an environment that minimises patient harm, there is a need to ensure systems learning while at the same time maintaining professional accountability. Health service organisations need to foster a culture where people feel supported and are encouraged to identify and report adverse events so that opportunities for system improvements can be identified and acted on. This should include the following.

- Providing an environment where patients, their family and carers:
 - receive the information they need to understand what happened
 - can contribute information about the adverse event and, where possible and appropriate, participate in the incident review.
- Creating a culture where patients, their family and carers, clinicians and managers all feel supported.
- Integrating open disclosure with investigative processes to identify why adverse events occur.
- Implementing the necessary changes in systems of clinical care based on the lessons learned.

While implementing open disclosure, a health service organisation will operate:

- within its own policies, procedures and processes
- within existing or upgraded integrated risk management frameworks and quality improvement processes
- in accordance with applicable Commonwealth, state and territory laws and regulatory requirements
- within the requirements of insurance and employment contracts.

1.4.2 Communication

Effective communication with patients commences from the beginning of an episode of care and continues throughout their care. There is an ethical responsibility for clinicians to maintain honest and open communication with patients, their family and carers, especially if care doesn't go to plan.

Ensuring that communication after adverse events is open, honest and timely is important to improving patient safety. Open disclosure is already occurring in many areas of the health system, and the Framework forms a basis for more consistent and effective communication following adverse events. This includes communication between clinicians and:

- patients, family and carers
- their colleagues and peers
- the non-clinical workforce.

1.5 Saying sorry

Apology and/or expressions of regret are key components of open disclosure, but also the most sensitive. 'Saying sorry' requires great care.

The exact wording and phrasing of an apology (or expression of regret) will vary in each case. The following points should be considered.

- The words 'I am sorry' or 'we are sorry' should be included.
- It is preferred that, wherever possible, people directly involved in the adverse event also provide the apology or expression of regret.
- Sincerity is the key element for success. The effectiveness of an apology or expression of regret hinges on the way it is delivered, including the tone of voice, as well as non-verbal communication such as body language, gestures and facial expressions. These skills are often not innate, and may need to be practised. Training and education in open disclosure should address this (see Section 6.5).
- 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, their family and carers cope with the effects of a traumatic event. It also assists clinicians in their recovery from adverse events in which they are involved.

It is important to note that apology or expression of regret alone is insufficient, and must be backed up by further information and action to ensure effective open disclosure. See Section 10.2 for further guidance.

1.5.1 Factual explanations and speculative statements

One of the principal aims of open disclosure is to restore patient trust in clinicians and the healthcare system. For patients, this requires early acknowledgement of harm and an apology or expression of regret. However, over-promising or making statements that are subsequently retracted can undermine trust.

The distinction between an apology or expression of regret and a factual explanation of the adverse event must be understood because both can occur during the same conversation. An apology or expression of regret can be given once harm has been recognised. A factual explanation requires the facts to be established.

It is important that clinicians avoid making speculative statements during an initial disclosure. The following should be considered when signalling open disclosure and preparing for a formal open disclosure process.

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

1.5.2 Apology and admission of liability

Appendix 1 details legal aspects of open disclosure, including apology and admission of liability.

2 In-scope considerations

This section discusses the matters to consider when open disclosure is being introduced and practised by health service organisations. These include:

- defining patient harm and adverse events in health care
- preventability of adverse events and patient harm
- managing:
 - near-misses and no-harm incidents
 - adverse events related to the physical environment of care
 - adverse events occurring elsewhere
- establishing patient-clinician relationships through good communication
- nominating a patient contact person
- criminal and intentionally unsafe acts.

2.1 Adverse events in health care

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. 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.’³ This is the definition of harm used in the Framework.

In the Framework, ‘adverse event’ means an incident in which a person receiving health care was harmed. In addition, it will be 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.

This broader meaning is important because the patient’s view on whether harm has been suffered may differ from the clinician’s or health service organisation’s view.

2.2 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, family and carers 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 little risk.

2.3 Near misses and no-harm incidents

An adapted open disclosure for near misses and no-harm incidents, where appropriate, and using a lower-level response (see Section 7.3), should be incorporated into health service organisation policies.

2.3.1 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.

2.3.2 No-harm incidents

For no-harm incidents, 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, their family and carers, 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, their family and carers who may otherwise have felt let down by the service.

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, family and carer trust in the service?



2 In-scope considerations

2.4 Adverse events related to the physical environment of care

If harm is caused by the environment of care (e.g. an equipment malfunction), the process of harm assessment and open disclosure preparation and response described in the Framework should be followed (see also Section 7.5).

2.5 Adverse events occurring elsewhere

An adverse event may have occurred in a practice or an organisation other than that in which it is identified. With an increasing proportion of care provided in the community setting, the mechanisms for responding to adverse events that occurred elsewhere are important.

The individual who first identifies the possibility of an earlier adverse event should notify the personnel responsible for clinical risk in their organisation.^c The clinical risk personnel should 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.

If the open disclosure process has not already commenced in the other organisation, the process should be initiated after consultation, and in collaboration with the other practice or organisation.

The thorough clinical review of the adverse event and the disclosure process should occur, where possible, in the health service organisation where the adverse event took place.

While it is acknowledged that these circumstances can be complex, it is important that patients' right to know is respected. The eight principles of the Framework should be used as a basis for managing these situations.

2.5.1 Delayed notification of adverse events

There will be times when an adverse event is not immediately recognised. The suggested process for managing these situations is described in Part B of the Framework (Section 7.4).

2.6 Communicating early

While not part of the open disclosure process, all care (including how well the patient–clinician relationship is established) can influence the outcome of open disclosure. This may include the following.

- Ensuring that the consent process is thorough and the patient understands all aspects of the procedure or treatment (see Section 3.1).
- Formally nominating support persons (see below).
- Engendering trust through open communication and other behaviours.
- Providing information on the roles and responsibilities of patients in clinical decision-making (while at the same time respecting any decision to defer this to the healthcare team).
- Providing information on open disclosure in the event that things go wrong.
- Documenting all relevant information in the patient record.

^c In smaller health service organisations (e.g. community pharmacies), the individual who identifies the possibility of an earlier adverse event can fulfil this role.

2.7 Nominated contact person(s)

An important part of early communication is for the patient to nominate a contact person. A nominated contact person is any individual who is formally identified by the patient as the formal recipient of information regarding their care through local legal process and requirements. It is essential that this individual is nominated as early as practicable, and their details are noted on the patient's admission form and documentation.

Information about an adverse event will be given to a patient's nominated contact person in appropriate circumstances, taking account of the patient's wishes, confidentiality and privacy requirements, and the organisation's internal policies. The nominated contact person should be involved in the open disclosure process from the outset so they can give appropriate support to the patient.

In cases of a dispute, such as between family and partners or friends about who should receive information, the patient's wishes as expressed on the admission form should have precedence. In addition, some people have a legal relationship with the patient that entitles them to receive information (for example, a parent, legal guardian or executor).

In situations where it is not possible for a patient to formally identify a nominated contact person (such as an emergency), clinicians and administrators should use their discretion in relation to any persons accompanying the patient (and who do not have a pre-existing legal relationship with the patient).

Health service organisations, practices and practitioners are encouraged to develop guidelines and policies on this matter, in accordance with local laws and regulations (see also Box 2 in Part B, and Appendix 1).

2.8 Criminal or intentionally unsafe acts

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 individual responsible for clinical risk and the chief executive officer should be notified immediately. Management should follow their local complaints and disciplinary process, or refer the matter to the appropriate authority. Disciplinary processes are outside the scope of the Framework (see Section 3.2).

In these situations, open disclosure will be modified to accommodate the context and particular circumstances. The individual who is the subject of the process should not be involved in the open disclosure dialogue. The health service organisation should try to keep the patient, their family and carers informed of progress with the criminal, or other, investigations, which will require liaison with the relevant authority.

3 Out-of-scope considerations

This section discusses matters that are outside the scope of the Framework and which include:

- the informed consent process
- disciplinary proceedings
- large-scale disclosure
- health service organisation human resources management
- clinician training in educational institutions
- incident investigation and quality improvement.

It is important to note that while these matters are outside of the scope of this document, they complement and contribute to effective open disclosure practice. For instance, the outcomes of open disclosure discussions may be influenced by the informed consent process that took place at the beginning of the episode of care. In some cases, the need to engage in open disclosure may depend on how well the informed consent process was carried out.

Effective open disclosure is supported by robust clinical governance and incident investigation systems.

3.1 Informed consent

The consent process is outside the scope of the Framework, but it is important in establishing the patient–clinician relationship (see Section 2.6). Obtaining informed consent from a patient before starting treatment is a legal requirement, and law imposes a duty on clinicians to:

- warn of material risks, complications, side effects and other potential outcomes
- discuss alternative options
- discuss the consequences of not proceeding with the intervention.

It is also important that:

- all information is provided in a way that patients can understand
- patients are informed of fees, charges as well as any additional costs that may be incurred as a result of treatment and diagnostic tests.

The consent process affects the management of a subsequent incident and the open disclosure process by:

- establishing trust and communication between the patient, their family and carers, and clinicians
- influencing whether and how harm is perceived by the patient.

The National Health and Medical Research Council's *General Guidelines for Medical Practitioners on Providing Information to Patients* provide information on informed consent.^d

More specific detail on informed consent should be sought from local consumer representative groups, state and territory health departments, peak bodies and associations.

3.2 Disciplinary processes

Information and guidance on disciplinary processes are outside the scope of the Framework. However, it is important to ensure that open disclosure continues when a referral is made to a disciplinary process. The patient, their family and carers expect, need and benefit from prompt acknowledgement and further information as it becomes available and useful information for system improvement may emerge.

Care should be taken to avoid potential conflict between disciplinary processes, open disclosure and incident investigations. This includes ensuring that the rights of the person subject to the disciplinary process are recognised and respected, including having an opportunity to respond to findings by the incident investigation, and the right to legal, union or other representation.

All states and territories have enacted national law dealing with the registration of clinicians in most health professions. More information regarding the mandatory reporting of clinicians under this scheme can be obtained from the Australian Health Practitioner Regulation Agency (www.ahpra.gov.au).

The following should be considered.

- Health service organisations and practitioners should have policies and procedures available about how and when to make a referral to a disciplinary process based on the relevant statute.^e
- Reporting requirements under the relevant statutes and policies should not be an impediment to open disclosure practice in accordance with the principles set out in Section 1.3.

3.3 Large-scale disclosure

Disclosing multiple adverse events or large-scale harm (or potential harm) to multiple individuals or the general public is out of scope of the Framework.

Relevant health service organisations are advised to have procedures in place to expedite decision-making in the event of multiple or large-scale incidents, and assess each situation promptly with legal counsel and public relations departments.

^d See www.nhmrc.gov.au/guidelines/publications/a-z-list

^e It should be noted that registration and reporting of some healthcare professions falls outside the scope of AHPRA. Health service organisations should ensure that these professions are covered under these policies and procedures.



3 Out-of-scope considerations

3.4 Human resources

Managing adverse events, including open disclosure, is a complex process. The Framework describes the necessary steps and strategies to support staff effectively during open disclosure. These strategies will intersect with local human resources policies, the nature, structure and function of which are outside the scope of this Framework.

3.5 Educational institutions

Open disclosure is recommended as an integral part of modern health care. Institutions that train and educate clinicians are encouraged to reflect the principles and content of the Framework in curricula.

3.6 Open disclosure, incident investigation and quality improvement

Open disclosure is not intended to replace thorough review and investigation of adverse events. Effective open disclosure relies on, and complements, clinical incident investigation and quality improvement in health care. Open disclosure dialogue with harmed patients, their family and carers should provide insights and information about the causative factors of an incident, the incident cascade, the overall patient experience and the quality of care. This information can add value to risk management and quality improvement.

The *National Safety and Quality Health Service Standards* require health service organisations to have formal clinical governance frameworks, with systems and policies for incident management and investigations. These should include 'reporting, investigating and analysing incidents (including near misses), which all result in corrective actions' and improvement to quality and patient safety (see also Section 6.2).⁴

The Framework assumes that health service organisations have incident management systems and policies in place.

3.6.1 Feedback to patients, families and carers

Recommendations from incident investigations should not only be disseminated and implemented to prevent recurrence. In addition, patients, their family and carers should be kept informed of progress of investigations during the open disclosure process. They should be made aware of outcomes from investigations including:

- the system causes of the harm they experienced
- the role of individual clinicians (without apportioning blame)
- findings and recommendations
- changes to systems as a result of the investigation (see Section 11).

3.6.2 Involving harmed patients in the investigation

Information provided by patients, their family and carers about an adverse event should, where possible, be used to help determine the causes of the adverse event and improve the quality of care. Health service organisations may offer harmed patients, families and carers involvement in the investigation process.

The consent and permission of all stakeholders must be obtained, and health service organisations are encouraged to develop policies on patient involvement in incident investigation (or incorporate it into existing incident management policies).

3.6.3 Legal considerations in sharing information from incident investigations

Legal considerations for certain types of clinical incident investigations are discussed in Section 6.9 and Appendix 1. These considerations vary according to jurisdiction so it is important to obtain legal advice in each case, as well as during the formulation of relevant policies and procedures.

4 Patient considerations

After experiencing harm, patients expect prompt acknowledgement and open communication. It is important that patients, their family and carers are shown empathy, openness and honesty, and are given reassurance and support. Patients, their family and carers should also be encouraged to ask questions.

Key patient considerations are:

- communication (verbal and written)
- advocacy and support
- reimbursement of out-of-pocket expenses
- avoidance of repeat harm to another
- other individual circumstances.



4 Patient considerations

4.1 Communication

Communication is essential to ensure good clinical outcomes and that patient expectations are met. Health service organisations need to create an environment that facilitates open and effective communication.

Some people may require a different style of communication to help them understand what has happened or is happening to them. It is the health service organisation's responsibility to work with the patient's family, carers and other support persons (or people who understand the patient's communication needs) to determine the best way to communicate with the patient.

Local policies and practices should be in place for the following outcomes.

- Ensure early identification of the patient's needs by documenting at the time of admission:
 - the name of the patient's nominated contact person (see Section 2.7); this person may not be the same as the patient's next of kin or other support people
 - whether the patient may require an interpreter service (see Section 4.1.1).
- Encourage patients to be actively involved in their care, and to notify the clinical team of any issues or conditions that may affect their care.
- Provide assurance that an ongoing care plan will be developed in consultation with the patient, their family and carers and that the plan will be followed through (see Sections 8–10).
- Provide information about open disclosure at the beginning of the episode of care.
- Include the patient's family and carers (and other relevant persons) in discussions about an adverse event, where the patient agrees.
- Provide information about the adverse event to the patient, their family and carers and their support persons.
- Provide information about the open disclosure process to patients, families and carers, verbally and in writing, and in a language or communication style that they understand throughout the process.
- Ensure that, if a patient chooses to refrain from active engagement in their care and defer decision making to the clinical team, the patient remains informed of the care process at all times.

4.1.1 Ensuring appropriate communication with culturally and linguistically diverse patients

Ensuring appropriate and effective communication is an important consideration particularly when patients, their family and carers come from linguistically or culturally different backgrounds to the clinician. For example, the patient may have difficulty understanding medical terms, even if they are otherwise proficient in English. Similarly, English may be the second language of the patient, their family and carers and or the clinician.

Cultural differences can also impede effective communication. For example, patients from backgrounds in which authority figures are perceived negatively, or in which the gender of the treating clinician is an issue, will require culturally appropriate considerations.

The need for interpreter services should be identified as soon as the patient makes contact with the health service. The admission process should identify the first language of all patients and also their preferred language of communication. Care should be taken with those for whom English is not a primary language. If an adverse event occurs, the physical effects of the illness and the emotional effect of the event may affect the patient's ability to communicate in English.

When a patient has difficulty communicating in English, or at the patient's request, a professional interpreter or a clinician who can speak the patient's language should be used. The use of family (or other support persons) to interpret should be only with the express consent of the patient, and when a professional interpreter is not available.

Clinicians should only be requested to interpret in the event that professional interpreters are absent or unavailable.

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, their family and carers' needs and with their agreement) are included in discussions regarding adverse events and their investigation and management.

If available, an Indigenous liaison officer should be involved from the outset to ensure the process occurs in a culturally appropriate manner.

4.1.2 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 a larger font.

4.2 Advocacy and support

Patients will often need help and support after experiencing an adverse event. Support may be provided by family members, carers, support persons, social workers, religious representatives and trained patient advocates.

Where more detailed long-term emotional support is required, the health service organisation must ensure the patient, their family and carers are advised about how to access appropriate counselling or support services.

Health service organisations should provide patients, their family and carers with the following.

- Information (including contact details) about services provided by social workers, religious representatives and trained patient advocates who can provide emotional support and help patients, their family and carers identify issues of concern, provide information about appropriate community services and support patients meeting with these services.

- Contact details of a staff member (the health service contact) who will maintain an ongoing relationship with the patient, their family and carers. Where possible, restrict telephone use to arranging meetings or conveying specific information. More detailed discussion or explanation should be conducted in face-to-face meetings.
- Information about how to make a complaint, including contact details for the relevant state or territory health complaints agency, and the patient's (and their nominated contact person's) right to access their medical record.

4.2.1 Substitute patient support

Patients often present unaccompanied for treatment or health care. If an unaccompanied patient who has not identified a nominated contact person is harmed, the clinician or health service organisation should take reasonable steps to identify the patient's family, carers or other persons who may be able to:

- a. provide support to the patient during open disclosure, whilst ensuring, where possible, that the patient's privacy and wishes are respected
- b. be the point of contact for the health service organisation and participate in the open disclosure process in the event of a patient death.

The person/persons can have a role in communicating to their extended family and other relevant individuals (see Box 2 in Part B, and Appendix 1).

If the patient does not have access to a support person the health service organisation should ask the patient if they wish someone to be appointed to fulfil this role.

It may be difficult to appoint somebody within the health service organisation who is sufficiently removed from the adverse event. A person external to the health service organisation may be identified to fulfil the role.

Larger health service organisations should have an officially appointed patient advocate to fulfil this role.



4 Patient considerations

4.3 Reimbursement of out-of-pocket expenses and ongoing care

Open disclosure is most effective if it is coupled with restorative action. This includes a pledge of practical support for patients, families and carers to cope with the effects of harm. Those who have been harmed often indicate that bearing the cost of care and out-of-pocket expenses can be determining factors in initiating litigation. Out of pocket expenses may include, but not be limited to, transport, child care, accommodation and meals.

An open disclosure process can break down because of delays in practical support following harm. A prompt offer of reimbursement for out-of-pocket expenses incurred as a direct result of the adverse event sends a strong signal of sincerity.

It is generally accepted that practical support made on an ex gratia basis does not imply responsibility or liability. The context for financial reimbursement will vary between sectors and jurisdictions. Health service organisations and clinicians should liaise with legal counsel, insurers and other stakeholders to develop guidelines for providing assistance to harmed patients, their family and carers when preliminary investigation indicates that this would be appropriate.

It is recommended that reimbursement of out-of-pocket expenses only be undertaken on written legal advice and after consultation with the insurer (particularly if the insurer is to meet the cost).

4.3.1 Ongoing care: cost and other considerations

Patients who have been harmed will often require ongoing treatment or care, which may be provided at the same health service organisation or at another. Agreeing on matters of ongoing treatment, such as billing and other costs (e.g. transport in rural areas), is important given the potential for disagreement to undermine open disclosure.

Ongoing treatment costs need to be discussed openly and in a timely fashion, based on individual needs and circumstances. The circumstances will depend on factors including the incident resulting in harm, or specific regulations such as those governing Medicare billing.

Health service organisations should engage in these discussions with the patient, their family and carers as soon as practicable after harm is identified.

Health service organisations and individual clinicians should clarify any relevant restrictions and requirements around ongoing care with their indemnity insurer(s) prior to engaging in these discussions (particularly if the insurer is to meet the cost).

4.4 Particular patient circumstances

The approach to open disclosure can vary depending on the patient's personal circumstances.

4.4.1 When a patient dies

Where an adverse event has resulted in a patient's death, it is crucial that communication with people who were close to the patient is sensitive, empathic and open. Establishing open channels of communication may allow support persons to indicate if counselling or other assistance is needed. The health service organisation's policies and practices should ensure that support persons receive information, care and support.

Cases of untimely, unexpected or unexplained death must be reported to the coroner. In this situation, families need to know about the information they can expect to receive, and time frames for the coronial process. It is important that the deceased patient's family, carers and other persons are kept up to date with what is happening, and that personal contact is maintained by the health service organisation throughout the coronial process. This may be subject to requirements of the coroner and legislation.

Health service organisations should ensure that all staff are aware of coronial legislation and requirements relevant to their jurisdiction and sector. More information on this is provided in Appendix 1.

4.4.2 Children

When an adverse event involves a child, the clinical team will, together with the parents, need to make informed but complex assessments of what the child should be told. In the case of young people who may have legal competency, the involvement of parents in the process will be comparable to that of consent for treatment involving the child, and the team will need to weigh up the young person's maturity.

The clinical team should assess the involvement of young people in the open disclosure process on a case-by-case basis, taking account of whether the child is mature enough to receive the information and having regard to the wishes of the young person and the parents, where appropriate.

4.4.3 Patients with mental health conditions

There are several factors to consider in open disclosure to patients with mental health conditions, irrespective of whether the patient is subject to mental health legislation. Disclosure of information relating to treatment, including open disclosure of adverse events, applies equally to people with a mental health condition.

Patients are entitled to all relevant details concerning their treatment, including instances where an adverse event occurs, with the timing of the disclosure subject to the clinical team's assessment of how this will affect the patient's health and their ability to understand what is said (see Section 9.2).

4.4.4 Patients with cognitive impairment

Patients with a cognitive impairment should be involved directly in communications about what has happened to them. It is the organisation's responsibility to work with relevant support or other persons to determine the most accessible type and format of communication for the individual involved. A third party who understands the communication needs of the patient may be required to assist.

The patient may have a legal guardian, or an attorney appointed under an enduring power of attorney. It should not be assumed that the person named in an order or power of attorney has the legal right to act in all circumstances on behalf of the patient. It will be necessary to determine the legal effect of any such relationships, which vary according to the terms of each guardianship order or power of attorney. Only some jurisdictions give the attorney the right to consent to treatment on behalf of the patient. These issues must be carefully considered in assessing whether disclosure of an adverse event and the decisions to be taken can be made to (or by) a third party in the absence of the patient's informed consent to do so.

4.4.5 Breakdown in post-incident communication and patient-clinician relationship

Sometimes, despite the best efforts, the relationship between the patient, their family and carers and the health service organisation and individual staff can break down. The patient, their family and carers may not accept the information provided or may not wish to participate in the open disclosure process.

In situations where there has been a breakdown in the relationship between the patient, their family and carers, and the health service organisation, it is important to rebuild patient trust. The following strategies may assist.

- Deal with the problem earlier rather than later.
- With the patient's agreement, ensure that their family, carers and other relevant persons are involved in discussions from the beginning.
- Ensure the patient, their family and carers have access to support services as described in Section 4.2.
- Ensure the appropriate staff member (e.g. a senior clinician) is aware of a potential relationship breakdown by communicating early warning signs (e.g. patient communicating concern to other members of the team, lodging a *Freedom of Information* application).
- Offer the patient, their family and carers another health service contact with whom they may feel more comfortable. This could be another member of the treating team or personnel responsible for clinical risk.
- Use a mediation or conflict resolution service to help identify the issues between the health service organisation and the patient, their family and carers and to look for a mutually agreeable solution (see Section 5.2.4).
- Involve the services of the local health complaints office if the patient, their family and carers wants to lodge a formal complaint.
- Assess whether sufficient weight has been given to the patient's version of events and whether reasonable efforts have been made to seek information from all key witnesses, including witnesses identified by the patient, their family and carers.

5 Staff considerations

Clinicians (and the non-clinical workforce) may be affected by being involved in an adverse event, and may require emotional support and advice in the aftermath of the incident. It should be noted that clinicians and staff who were involved in an adverse event can benefit from participating in open disclosure, including a sincere apology or expression of regret where appropriate.

The staff involved in the open disclosure process should be provided with access to assistance and support and with the information they need to fulfil the role required of them. To support staff, health service organisations should endeavour to ensure the following.

- Provide advice and training on the management of adverse events, communication skills, and the need for practical, social and psychological support.
- Promote an environment that fosters peer support and discourages the attribution of blame.
- Make certain that clinicians are not discriminated against because of their involvement in an adverse event or open disclosure.
- Ensure that patients, their family and carers are aware that personal information about clinicians that is not related to the adverse event or the open disclosure will not be disclosed.
- Have formal support processes and provide facilities for formal or informal debriefing for those involved in an adverse event, where appropriate, as part of the support system; this should be separate from the requirement to provide statements for the purposes of investigation.
- Provide information on the support systems that are currently available for clinicians who are distressed by an adverse event (e.g. Doctors' Health Advisory Service, medical defence organisations, professional and collegiate associations and trade unions, health service counsellors, employee assistance scheme, referral to specialised mental health care where appropriate) and encourage timely consultation with these organisations and advisers.
- Provide information to clinicians on incident investigation and its outcomes.
- Develop specific and locally tailored support mechanisms and systems in their own institutions or in collaboration with neighbouring facilities.

5.1 Staff rights and responsibilities

Health service organisations should ensure that policies, protocols and practices regarding open disclosure focus on restoration, service recovery and improving quality and patient safety, not on attributing blame. If appropriate, issues relating to individuals should be left to disciplinary processes.^f

Criticism and adverse findings against individuals should be avoided. If adverse findings must be made, the individual should be treated fairly and afforded natural justice, including giving the person the opportunity to comment on any adverse findings and taking those comments into account. This will also help to avoid defamatory statements (both written and verbal). Each individual's involvement in adverse events should be considered in the context of factors such as staffing, skill mix and work load.

Health service organisations have an obligation to recognise the right of individuals to seek appropriate advice and guidance from their indemnifiers and other relevant advisers, and to act in accordance with such advice.

Staff (especially the clinical workforce) have the following responsibilities.

- Acknowledging their role in adverse events and conveying an apology or expression of regret.
- Participating in open disclosure training and education as required.
- Participating in open disclosure processes as required.
- Supporting their colleagues following an adverse event, and refraining from blaming and potentially defamatory actions. This needs to be balanced with ethical behaviour and principles of transparency and openness.

5.1.1 Legal and disciplinary considerations for clinicians

The interests and circumstances of staff may not be the same as the health service organisation, particularly if it appears that the incident may lead to disciplinary proceedings or give rise to legal liability. See Section 3.2 for more detail on disciplinary proceeding and Appendix 1 for more detail on legal considerations.

5.2 Involvement in open disclosure

Where appropriate, open disclosure should be an interprofessional process, and the participants from the health service organisation will vary depending on circumstances.

5.2.1 Clinicians involved in the incident

It is recommended that clinicians involved in adverse events be given the option to participate in the disclosure. The stage at which this occurs will depend on a range of factors including the circumstances surrounding the adverse event,^g the experience of the clinician, and their confidence and preparedness for open disclosure. Clinicians should be provided with the appropriate support and preparation to participate in open disclosure. However, there will be circumstances where staff may identify that they do not feel prepared to participate, and these should be acknowledged and respected.

Health service organisations have a duty to recognise and protect staff from potential situations that may cause additional conflict and harm.

f Patients and support persons are entitled to learn (and advise) of individual actions and system failures relating to the adverse event. This is not in the context of apportioning blame, but rather in terms of understanding the entire incident. See Part B: Open disclosure practice.

g Policies and procedures should be developed in relevant settings where VMOs, non-salaried or contracted clinicians are required to lead or participate in open disclosure.



5 Staff considerations

5.2.2 Use of a substitute clinician to lead open disclosure

When it is not possible for the most senior clinician responsible for the clinical care of the patient to be present, an appropriately senior person who is trained in open disclosure processes should lead the disclosure. This will assist effective communication with the patient, their family and carers without jeopardising the rights of clinicians or their relationship with the patient.

5.2.3 Assistance with initial disclosure discussion

The person leading the disclosure should be able to nominate someone to assist them with the disclosure interview. It is recommended that, where possible, this is someone with experience or training in disclosure.

5.2.4 Facilitators

In situations where there is difficulty conducting open disclosure or finding an agreeable outcome, an independent facilitator may be arranged to help the discussions (see Section 4.4.5).

5.2.5 Legal counsel

Open disclosure is not a legal process. While legal advice may be sought throughout an open disclosure process, generally legal counsel should not directly participate in open disclosure discussions.

5.2.6 Junior clinicians

Junior clinicians, or those in training, may benefit from observing and participating in open disclosure. These individuals should not carry out the disclosure except where:

- the incident is minor
- the senior clinician responsible for care of the patient is present for support
- the patient, their family and carers agrees
- the junior clinician has received adequate training to undertake the disclosure
- the junior clinician is willing to participate in the process.

6 Organisational considerations

Institutional arrangements within the health service organisation will strongly influence open disclosure practice. Organisational considerations will include:

- governance and risk management
- health service accreditation
- education and training of staff
- leadership and engagement by senior management
- notification of relevant authorities
- insurance and legal considerations.

Ensuring appropriate institutional arrangements will encourage and support clinicians (and all staff) to engage in open communication with patients, their family and carers.



6 Organisational considerations

6.1 Governance and risk management

Every health service organisation, from small practices to tertiary hospitals, should foster and demonstrate the capacity and willingness to learn from adverse events, and to disseminate learning for the wider good of the community.

Good governance, risk management and quality improvement require that health service organisations learn from, and improve, their performance through continuous monitoring, and by reviewing healthcare systems and processes. Health service organisations need to ensure appropriate direction and internal control through a system of clinical and corporate governance.

To achieve this, health service organisations should:

- acknowledge that health care involves inherent risk and that there is a need to reduce this risk wherever possible
- generate a culture that encourages:
 - notification of, and open and honest communication about, adverse events
 - open discussion of incidents, and framing these as learning opportunities
- eliminate unnecessary punitive action against those involved in an adverse event, while ensuring appropriate professional accountability
- foster community awareness of the occurrence of adverse events.

6.2 NSQHS Standards and accreditation

The Framework assumes that relevant health service organisations will have integrated clinical governance, risk management, and incident notification and investigation systems and processes, as required under the *NSQHS Standards*.

The 10 *NSQHS Standards* set out clear standards for relevant organisations. *Standards 1 and 2* are concerned with governance, risk management and consumer involvement.

Standard 1: Governance for safety and quality in health service organisations requires that health service organisations “implement governance systems to set, monitor and improve the performance of the organisation and communicate the importance of the patient experience and quality management to all members of the workforce”.⁴

Standard 1 (Criterion 1.16) requires the implementation of an open disclosure process. Actions for health service organisations includes, that an open disclosure process is in place and consistent with national open disclosure standard and the clinical workforce is trained in open disclosure processes.

For more information on the evaluation requirements and criteria for open disclosure under the *NSQHS Standards* accreditation scheme visit www.safetyandquality.gov.au

6.3 Organisational responsibilities

Where possible and applicable, health service organisations should ensure the following.

- Prioritise the implementation and resources to support open disclosure practice in accordance with the *Australian Open Disclosure Framework*.
- Integrate open disclosure programs and policies with local governance, risk management and quality improvement processes.
- Provide training and support to clinicians in communication skills, investigation and grading of adverse events, risk management and management of legal issues (see Section 6.5).
- Actively promote and disseminate information about open disclosure policy and procedures to all staff.
- Actively inform patients about open disclosure, preferably at the time of admission (including what type of information can and cannot be provided following an incident).
- Actively inform patients about available complaint processes.
- Designate key staff members to participate in, and have responsibility for, open disclosure practice and implementation (as part of broader clinical governance and risk management).

- Ensure that a timely response to adverse events can be initiated out of hours and at weekends if necessary.
- Have established systems to identify adverse events through a variety of mechanisms (see Section 7.1).
- Have processes for identifying and implementing change to improve healthcare safety.
- Implement appropriate monitoring and review mechanisms for the open disclosure process, including routine collection of measures of open disclosure performance (see Section 6.7).
- Advise clinicians of their obligation to notify their insurer(s) about an incident and planned response.

6.4 Responsibilities of leadership and senior management

A health service organisation's leadership and executive will have ultimate responsibility for ensuring that appropriate policies, processes and practices are in place and that, if necessary, changes occur to improve patient safety. They should also ensure that those with operational responsibility for a health service organisation have the means to implement recommended changes.

To enable implementation and uptake of open disclosure, organisational leaders should:

- explicitly support open disclosure as a:
 - patient right
 - organisational requirement
 - integral part of healthcare provision
 - opportunity to learn from adverse events and from patients
- request regular reports on open disclosure practice, including performance measures and data (see Section 6.7)
- participate in open disclosure training and open disclosure (when required and appropriate).

6.5 Open disclosure education and training

Health service organisations should provide open disclosure education and training as part of professional development programs. Where possible, training and development should be made available where appropriate to non-clinical workforce such as administrative staff, legal counsel and insurers.

Education and training should prepare clinicians for the experience of adverse events, and equip them with the communication skills to participate confidently in open disclosure.

Current evidence and practice suggests a modulated approach consisting of:

- general introductory and refresher training for all clinicians
- specialised coaching of a smaller group of 'experts' who support others following an adverse event and during open disclosure. If possible, this training should include simulation and role-playing, including real-time feedback
- 'just in time' training to prepare the clinical and, where appropriate, non-clinical workforce immediately before an open disclosure dialogue begins.

Open disclosure education and training should:

- promote a team approach
- reflect consumer-centred values, principles and rights
- cover the legal aspects of open disclosure (see Section 6.9 and Appendix 1)
- describe the benefits for patients and clinicians
- develop communication skills, especially active listening skills
- describe the evidence on patient needs, preferences and expectations
- incorporate real-life patient stories.

It is recognised that resource constraints can act as considerable barriers to achieving this approach in some settings (e.g. rural areas, small practices). Practitioners and management in these settings may wish to explore the possibility of collaborating with other practices, or joining nearby larger health service organisations' education and training networks.



6 Organisational considerations

Another important aspect of open disclosure education in this regard is fostering awareness among early career clinicians that:

- they will be involved in adverse events during their career
- managing these situations actively, openly and transparently is of critical importance to a positive outcome.

6.6 Notifying relevant individuals, authorities and organisations

A range of individuals, organisations and authorities may need to be notified about adverse events and open disclosure processes. Although this will vary depending on the setting and context, health service organisations should ensure that notification requirements for adverse events align with local open disclosure policy and practice.

6.6.1 Clinical risk personnel

Where appropriate, clinical risk management staff should always be informed of an adverse event. Senior management should be notified in smaller health service organisations without a clinical risk manager.

6.6.2 Insurers

Insurers of health service organisations and insurers of individual practitioners will need to be notified in accordance with timely notification requirements. These requirements will differ between jurisdictions, settings and between the public and private sector. Health service organisations and clinicians should liaise with their insurers to determine exact requirements.

This requirement should not interfere with prompt communication with patients, their family and carers (see Section 6.8).

6.6.3 Management

Management will usually be notified of adverse events by clinical risk personnel. However, when a major incident occurs that may attract media attention, or where a criminal act is suspected, senior management should be notified immediately and in accordance with the health service organisation's incident management policy (see Section 2.8).

6.6.4 Other clinicians

Other organisations and individuals, such as the referring general practitioner, residential care facility or other community-based clinician, should be contacted at an early stage so that they are informed and can offer their support and continuing care to the patient. This should be with the patient's agreement.

6.6.5 Coroner

Cases of untimely or unexplained death and suspected unnatural deaths must be reported to the coroner as required by local legislation. Health service organisations and their management should ensure that all staff are aware of coronial legislation and requirements relevant to their jurisdiction and sector. For more detail see Appendix 1.

6.6.6 Notification to relevant statutory and other appropriate authorities

When there are adverse outcomes, health service organisations may need to respond to a variety of external requirements, reviews or queries, including requirements of Commonwealth, state, territory and regulatory bodies. The health service organisation's policy on incident management and open disclosure should clearly state these requirements to ensure that legal and insurance obligations are met.

6.7 Measurement, evaluation and internal reporting

Measurement is a key component of clinical governance, risk management and quality improvement. Internal measurement and evaluation fosters and contributes to accountability and a performance culture. Health service organisations should evaluate open disclosure performance and integrate outcomes into quality improvement, clinical governance and performance monitoring.

Patients, their family and carers and participating staff members should be surveyed so that their open disclosure experience can inform quality improvement. Caution is required when obtaining feedback (see Section 12).

Suggested open disclosure measures are provided in Appendix 3. These are intended for internal, quality improvement and will not be requested for accreditation purposes, but health service organisations may choose to use these or similar measures as evidence in the accreditation process (see Section 6.2). Health service organisations, practices and practitioners are encouraged to adapt them to suit local settings and contexts.

Suggested patient and staff survey templates can be found with other open disclosure supporting materials on the Commission web site www.safetyandquality.gov.au/opendisclosure

6.8 Insurance considerations

Indemnity insurance providers can play an important role in the successful uptake of open disclosure by influencing clinician and health service behaviour in their advice following patient harm. It is recommended that insurers promote open disclosure to clients as an appropriate strategy in the context of incident management.

Indemnity insurance can be provided by independent insurance companies, by employers, or both.

6.8.1 Employer indemnity arrangements

Employers who also provide indemnity have additional responsibilities to their employees. While responsible for professional indemnity, they have the usual industrial relations, human resource and privacy responsibilities incumbent on employers. Employers need to balance these roles while promoting the benefits of open disclosure.

Employer indemnity providers can promote open disclosure uptake by:

- collaborating with professional bodies and associations
- providing clear, evidence-based direction on managing adverse events
- incorporating insurance requirements into open disclosure education and training.

6.8.2 Independent indemnity providers

Independent insurers can promote uptake of good open disclosure practice through:

- providing clear, evidence-based direction on managing adverse events
- incorporating open disclosure into information, training and education provided to clinicians and healthcare services.

Information provided by insurers to clinicians should be placed in the context of jurisdictional requirements.

6.8.3 Insurance considerations in the open disclosure process

An adverse event may involve more than one insurer. Clinicians and staff involved in the adverse event or its management should be fully aware of their responsibilities in relation to their insurance.

Medical defence and health professional indemnity organisations and institutional 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 person or organisation 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 the health service organisation or 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).

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

Health service organisations should ensure that:

- insurers are consulted when developing local open disclosure policies and procedures to discuss notification requirements before implementing an open disclosure policy
- staff responsible for clinical risk and open disclosure are aware of which events are notifiable to comply with insurance requirements
- clinicians understand their professional indemnity requirements in relation to adverse events and open disclosure.



6 Organisational considerations

6.9 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. Clarification is therefore needed to facilitate open disclosure. Legal and insurance considerations are presented in more detail in Appendix 1.

6.9.1 Jurisdictional and local context

The legal context for open disclosure will vary between jurisdictions and types of health service organisations (e.g. public and private). Organisations need to clarify how the legislation that applies to them affects the practice of open disclosure, and how it intersects with qualified privilege, apology law and coronial legislation.

In healthcare settings, a number of clinicians are likely to be involved in an adverse event. They will be responsible to the patient and the health service organisation, although the specific legal basis of the relationship with the organisation will vary depending on whether the clinician is regarded under the law as an employee or as an independent contractor.

These legal issues need to be considered prior to, and during, open disclosure.

PART B: Open disclosure practice

This section outlines the steps, elements and activities involved in conducting open disclosure according to current successful practice.

It is not intended that all of the steps and actions will be completed, in exact order, in every situation. Open disclosure is a very complex and sensitive undertaking, and can be a difficult process. As such, there is not one standardised way to conduct open disclosure. Flexibility is required to meet specific circumstances and the needs of patients and clinicians, and in the context of different health service organisations and sectors. Open disclosure policies and procedures will need to adapt to ensure appropriateness.

Part B should be read as a guiding framework for open disclosure. Its contents are summarised in Section 1.3, which also includes an open disclosure flow chart.

Box 2 Privacy and confidentiality

All discussions should have regard to the ethical and legal requirements relating to confidentiality and privacy of patients and clinicians (see Appendix 1).

Nominated contact person(s) are by default entitled to receive information and participate in open disclosure *unless otherwise instructed by the patient*. Support persons should, where possible and with the patient's consent, be included in open disclosure discussions. However, there are two potential concerns that will require caution and consideration:

1. In cases where a patient is incapacitated, there can be a tension between timely open disclosure with support persons and protecting the patient's privacy and confidentiality. This will most often be addressed by the patient identifying a nominated contact person in advance (see Section 2.7). However, there will be instances where the patient may, in retrospect, have wished to cease the nomination because of the private nature of the issues that may be brought to light as a result of an adverse event but was unable to do so.

In the absence of a nominated contact person, clinicians may be perceived as giving unsatisfactory general comments to support persons without risking patient complaints. In turn, this may risk complaints from the support persons.

2. It is acknowledged that open disclosure discussions cannot generally be managed effectively with a large number of people. Where necessary, a smaller cohort of support persons should be identified for participation. These individuals can then, if appropriate, pass on the information to other support persons.

7 Detecting and assessing incidents

Key considerations and actions

- Detect incidents through a variety of mechanisms
- Provide prompt clinical care to the patient to prevent further harm
- Assess the incident for severity of harm and level of response
- Provide support for staff
- Initiate a response, ranging from lower to higher levels
- Notify relevant personnel and authorities
- Ensure privacy and confidentiality of patients and clinicians are observed

Open disclosure formally begins with the recognition that the patient has suffered harm during treatment or care. Health service organisations should have appropriate mechanisms to identify adverse events.

7.1 Identifying an adverse event

An adverse event might be identified:

- by a clinician or staff member at the time of the incident
- by clinicians retrospectively when an unexpected outcome is detected
- by a patient, their family and carers at the time of the incident or retrospectively
- through established complaint mechanisms
- through incident detection systems, such as incident reporting or patient record review
- from other sources, such as detection by other patients, visitors, students or other staff.

It is important that all incidents are considered, regardless of the mechanism through which they were detected.

7.1.1 Supporting patient and clinician as a priority

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. Responsible management personnel should be advised and should gather any evidence that will assist in investigating the event. Where appropriate this should occur in consultation with the clinical risk team and executive.

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

7.2 Initial assessment to determine the level of response

The individual who detected the incident should make an initial assessment of the incident, usually in consultation with a senior clinician. This process will consider the severity of harm and the level of response required. The level of response required will be determined by the effect, severity or consequence of the incident (the process is outlined in the next section).



7 Detecting and assessing incidents

7.3 Lower and higher-level responses

The incident response will be determined by the effect, severity or consequence of the incident. Examples of incident types and suggested responses are described in **Table 1**.

Table 1: Potential responses to various situations and incidents

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

Table 2 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, their families and carers 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.

Table 2: Criteria for determining the appropriate level of response

Incident type	Criteria
Lower-level response	<ol style="list-style-type: none"> 1. Near misses and no-harm incidents 2. No permanent injury 3. No increased level of care (e.g. transfer to operating theatre or intensive care unit) required 4. No, or minor, psychological or emotional distress
Higher-level response	<ol style="list-style-type: none"> 1. Death or major permanent loss of function 2. Permanent or considerable lessening of body function 3. 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) 4. Major psychological or emotional distress 5. At the request of the patient

7.3.1 Adverse drug events

Medicines are the most common therapeutic intervention in Australia. While most medicines are delivered safely, their use and delivery carries inherent risks, and it has been estimated that over 1.5 million Australians suffer an adverse drug event (ADE) each year.⁷

Where ADEs are the result of omission or the administration of the wrong dose, the criteria set out in Section 7.3 should guide the appropriate level of response. More detail on medication errors and open disclosure, in particular adverse drug reactions (ADRs), is provided in Appendix 2.

7.4 Delayed detection of harm

In some cases patient harm may not be detected for some time. These adverse events may have occurred elsewhere (see Section 2.5). It is important to consider the principles of open disclosure in these situations (see Section 1.3).

In this situation health service organisations in all settings and sectors should:

- notify the patient, their family or carers of what has occurred
- inform other healthcare providers, such as the patient's general practitioner or residential care facility or community care provider of the incident

- notify the clinicians who were involved in the incident
- commence an investigation of the incident and establish the facts.

Based on the particular circumstances, open disclosure should then proceed as outlined in the Framework. Where possible the clinicians who were involved in the incident should participate in the open disclosure process.

The process will need to be adapted in these situations to cater for the needs of the patient, their family and carers, as well as the clinicians. For instance, open disclosure meetings may need to take place in a suitable location or by videoconference.

7.5 Device safety

Technological advances are introducing increasingly complex instruments, implants and devices in health care. Incident detection systems and mechanisms should be continually updated to ensure harm caused by a failure and malfunction of medical devices (as opposed to their incorrect usage or application) are captured, triggering open disclosure and notifying the responsible organisation(s).

8 Signalling the need for open disclosure

Key considerations and actions

- Acknowledge the adverse event to the patient, their family and carers including an apology or expression of regret
- **A lower-level response can conclude at this stage**
- Signal the need for open disclosure
- Negotiate with the patient, their family and carers or nominated contact person
 - the formality of open disclosure required
 - the time and place for open disclosure
 - who should be there during open disclosure
- Provide written confirmation
- Provide a health service contact for the patient, their family and carers
- Avoid speculation and blame
- Maintain good verbal and written communication throughout the open disclosure process

8.1 The initial discussion

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

- the adverse event is acknowledged to the patient, their family and carers
- an apology or expression of regret is given (see Sections 1.5 and 10.2)
- the effect of the incident, including all known facts and the consequences, are described.

If a lower-level response is indicated, it is likely that the disclosure process will be completed after the initial discussion.ⁱ

An example of appropriate wording for a lower-level response initial discussion is:

'I am/we are sincerely 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 keep an eye on you for the next 24 hours and will ask you to let us know if you feel anything unusual. We do not expect that you will need to stay here any longer than originally planned.'

The person conducting the initial discussion may be one of a number of health professionals and clinicians.^j This should be determined by the circumstances and the health service organisation's policy.^k

Unless there are specific indications, or the patient, their family and carers requests it, the open disclosure process will occur at the local service delivery level with participation of those directly involved in the incident.

Where relevant, reporting to management will occur through standard mechanisms consistent with local clinical governance, risk management and quality improvement policy and practice. These reports should be analysed to detect high-frequency events.

Lower-level responses should be evaluated as described in Sections 6.7 and 12.2.

If a higher-level response is indicated, the initial discussion will have an additional two actions.

1. Signal the need for open disclosure.
2. Negotiate (where possible) with the patient, their family and carers about:
 - a. the format required for discussions and meetings
 - b. the logistical details of the open disclosure.

An example of appropriate wording for a higher-level response initial discussion is:

'I am/we are sincerely sorry that this has occurred. It is clear that something went wrong and we are investigating it right now. We will give you information as it comes to hand. 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.'

8.2 Avoiding speculation and blame

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

8.3 Maintaining good internal communication throughout the process

Good internal communication is critical throughout the period the open disclosure process takes place. Absence of good communication can result in patients, their family and carers receiving conflicting information and mixed messages.

^h Flexibility in this regard will be required in some settings. A full explanation should be given to the patient, family and carers in such situations.

ⁱ In some states and territories this is referred to as 'clinician disclosure'.

^j If there is any uncertainty, a senior clinician should be engaged. For a higher-level response, this will always be the senior clinician responsible for the patient.

^k Where relevant, the organisation's policy should also specify when to notify and involve the CEO and other management.

9 Preparing for open disclosure

Key considerations and actions

- Hold a multidisciplinary team discussion to prepare for open disclosure
- Consider who will participate in discussions
- Appoint an individual to lead the open disclosure based on previous discussion with the patient, their family and carers
- Gather all the necessary information
- Identify the health service contact for the patient, their family and carers (if this is not done already)

The remainder of Part B describes the next steps for higher-level responses. Higher-level responses will vary depending on circumstances and harm severity. The two main types of higher-level response 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.

9.1 Team discussion

Where appropriate and relevant, the multidisciplinary team and all other clinicians involved in the adverse event, including the most senior clinician, will communicate as soon as possible after the event to achieve the following.

- Establish the basic facts (clinical and other facts).
- Assess the event to determine the appropriate response.
- Identify who will take responsibility for discussion with the patient, their family and carers (see below).
- Consider the appropriateness of engaging patient support at this early stage, including the use of a facilitator or a patient advocate (see Section 4.2).
- Identify immediate support needs for everyone involved.
- Ensure that all team members maintain a consistent approach in any discussions with the patient, their family and carers.
- Consider legal and insurance issues, both for the organisation and the clinicians, and notify the relevant people (see Sections 6.6, 6.8 and 6.9).
- Consider how to address issues regarding ongoing care such as billing and other costs, which should be addressed at the earliest opportunity.

The composition and conduct of the team discussion will depend on the size and structure of the health service organisation, and may not be indicated in a small practice environment.

The patient record must be up to date before the team discussion takes place.

9.1.1 Choosing the individual to lead the disclosure

The individual leading the disclosure should, where possible, be the most senior clinician who is responsible for the care of the patient. Ideally, the lead person should:

- be known to the patient, their family and carers
- be familiar with the facts of the adverse event and the care of the patient
- be of appropriate seniority to ensure credibility
- have received training in open disclosure
- have good interpersonal skills
- be able to communicate clearly in everyday language
- be able and willing to offer reassurance and feedback to the patient, their family and carers
- where possible and appropriate, be willing to maintain a medium to long-term relationship with the patient, their family and carers.

The decision about who will make the disclosure should, where possible, be made in consultation with the patient, their family and carers, clinical risk personnel and (if appropriate) senior management (in relevant health service organisations). If for any reason the senior clinician is unable to lead the open disclosure, a substitute will need to be selected but, ideally, the senior clinician should still be present at the discussion.

The person leading the open disclosure may require the support of a senior staff member with appropriate skills.

Section 5.2 contains further detail on staff involvement in open disclosure.



9 Preparing for open disclosure

9.2 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, their family and carers 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
- where possible, the decision should be independently verified by a practitioner or colleague who was not involved in the adverse event. This verification must also be documented in the patient record.¹

If open disclosure is deferred with the patient but is held with the patient's family, carers or other relevant persons, the process should recommence with the patient at a later date.

9.3 Arranging the first meeting

9.3.1 Timing, location and attendees

The timing and location of the first face-to-face open disclosure meeting should be decided in consultation with the patient, their family and carers. It may not be appropriate to conduct the open disclosure where the harm occurred. In these cases, other arrangements should be considered. Videoconferencing may also be appropriate.

The patient, their family and carers should be consulted about which clinician and health service staff will participate in the open disclosure meeting.

Factors to consider include the:

- patient's clinical condition
- availability of key staff
- availability of the patient's family and carers and other relevant support persons
- availability of support for staff
- patient's preferences (and those of their family and carers)
- patient's privacy and comfort
- patient's physical and mental health.

The patient, their family and carers may need time to consider these matters.

If for any reason it becomes apparent that the patient, their family and carers would prefer to speak to a different clinician(s) than those designated to lead the open disclosure, the patient's wishes should be respected and, if possible, an acceptable substitute provided (see Sections 4.4.5, 5.2.2 and 5.2.4).

9.3.2 Health service contact

The patient, their family and carers should be provided with the name and details of a health service contact person who should provide information and support to the patient and relevant persons throughout the open disclosure process, and manage the open disclosure to its completion. It is preferable that a single person fulfil this role throughout the process, and it is recommended that they should not have been directly involved in the incident.

The patient should identify their nominated contact person if they have not already done so (see Section 2.7).

9.3.3 Written information

The patient, their family and carers should be given written information on open disclosure in a language or communication style they understand, if this has not already been done at the time of admission. The information should be provided in an appropriate format.

¹ It is recognised that this may not be possible in some contexts such as smaller health service organisations and in rural settings.

10 Engaging in open disclosure discussions

Key considerations and actions

- Provide the patient, their family and carers with the names and roles of all attendees
- Provide a sincere and unprompted apology or expression of regret including the words *I am* or *we are sorry*
- Clearly explain the incident
- Give the patient, their family and carers the opportunity to tell their story, exchange views and observations about the incident and ask questions
- Encourage the patient, their family and carers to describe the personal effects of the adverse event
- Agree on, record and sign an open disclosure plan
- Assure the patient, their family and carers that they will be informed of further investigation findings and recommendations for system improvement
- Offer practical and emotional support to the patient, their family and carers Support staff members throughout the process
- Support staff members through the process
- If the adverse event took place in another health service organisation, include relevant staff if possible.
- If necessary, hold several meetings or discussions to achieve these aims

Open disclosure will usually occur over the course of several discussions. The first open disclosure meeting may be the first part of an ongoing dialogue and communication process.



10 Engaging in open disclosure discussions

10.1 Key components of open disclosure discussions

The key components of open disclosure discussions are listed below.

1. The patient, their family and carers are told the name and role of everyone attending the meeting, and this information is also provided in writing.
 2. A sincere and unprompted apology or expression of regret is given on behalf of the health service organisation and clinicians, including the words 'I am' or 'we are sorry' (see Sections 1.5 and 10.2). Examples of suitable and unsuitable phrasing of an apology are provided in Box 3 in Section 10.2.
 3. 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, their family and carers understand the information, and considers any relevant information related earlier by the patient, family and carers. Speculation should be avoided.
 4. The patient, family and carers have the opportunity to tell the clinicians 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, their family and carers that their views and concerns are listened to, understood and considered.
 5. The patient, family and carers are encouraged to talk about the personal effect of the adverse event on their life.
 6. An open disclosure plan is agreed and recorded in which the patient, their family and carers outline 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 (see Section 13) and a copy provided to the patient, their family and carers.
 7. The patient, their family and carers are assured that they will be informed of any further reviews to determine why the adverse event occurred, the nature of the proposed process and the expected time frame. The patient, their family and carers are given information about how feedback will be provided on the investigation findings, by whom and in what timeframe, including any changes made to prevent recurrence.
 8. An offer of support to the patient, their family and carers should include:
 - a. ongoing support including reimbursement of out-of-pocket expenses incurred as a result of the adverse event (see Section 4.3)
 - b. assurance that any necessary follow-up care or investigation will be provided promptly and efficiently (see Section 4.3.1)
 - c. in relevant settings, clarity on who will be responsible for providing ongoing care resulting from the adverse event
 - d. contact details for services they may need to access
 - e. information about how to take the matter further, including any complaint processes available to them.
 9. The patient, their family and carers engage in open disclosure with staff. Staff are supported by their colleagues, managers and health service organisation, both personally (emotionally) and professionally (including through appropriate training, preparation and debrief; see Sections 6.5 and 9).
 10. In cases where the adverse event spans more than one location or service, health service staff will ensure that, where possible, all relevant individuals from these additional institutions are involved in the open disclosure process (see Section 2.5).
- It is not necessary to cover every component in the first disclosure meeting. For instance, a full explanation of why an adverse event occurred may not be possible until the causative factors are known.
- A written account of the open disclosure meeting should be provided to the patient, their family and carers.

10.2 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 prevent the adverse event from happening again.
- Agree to provide feedback information from this when available.

Box 3: Examples of appropriate phrases during an apology

- *'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

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

11 Providing follow-up

Key considerations and actions

- Ensure follow-up by senior clinicians or management, where appropriate
- Agree on future care
- Share the outcomes of investigations and the resulting practice changes
- Offer the patient, their family and carers the opportunity to discuss the process with another clinician (e.g. a general practitioner)

Follow-up with the patient, their family and carers is an important step in higher-level responses to open disclosure. Lower-level responses may require no or minimal follow-up.

11.1 Key components of follow-up

The senior clinician involved in the adverse event (or senior management, if appropriate) should be involved in the follow-up discussion, which should occur at the earliest practical opportunity. The patient, their family and carers 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).

They should also be kept informed of the progress and results of any investigation, including whether the results are delayed, pending or uncertain. The health service organisation should notify the patient, their family and carers of any changes to practice that are intended as a result of the investigation, and the changes that have been made to prevent recurrence of the adverse event.

The patient, their family and carers should be offered an opportunity to discuss the situation with another relevant professional, where appropriate. This may include involving the general practitioner, residential care facility or community care provider in the discussion, with the patient's permission.

The patient, their family and carers should be provided with details of a person to contact if further issues arise.

11.2 Completing the process at this stage

If the process of open disclosure is complete at this point, the patient, their family and carers should be asked if they agree that the process is complete, and a note of this should be made in the patient record (see Section 13). Written information about the adverse event and its management should be provided to the patient, their family and carers.

The patient, their family and carers should be offered an evaluation survey or, where it is considered more appropriate, a face to face interview, or both (see Section 12.2).

12 Completing the process

Key considerations and actions

- Reach an agreement between the patient, their family and carers and the clinician, or provide an alternative course of action
- Provide the patient, their family and carers with final written and verbal communication, including investigation findings
- Communicate the details of the adverse event, and outcomes of the open disclosure process, to other relevant clinicians
- Complete the evaluation surveys

The open disclosure process concludes with shared agreement between the patient, their family and carers and the healthcare team. In the majority of cases, this will occur after the adverse event incident review or investigation is completed.

If a satisfactory conclusion cannot be negotiated, the patient, their family and carers should be offered alternative courses of action (see Section 4.4.5).

12.1 Key components for completing the process

12.1.1 Communication

When the relevant review or investigation is complete, the patient, family and carers should be provided with feedback through face-to-face interview or equivalent (e.g. videoconference) and in writing. The interview and document should include the following.

- Details of the incident, including the clinical facts and other relevant facts.
- The patient's concerns or complaints.
- An apology or expression of regret (including the word 'sorry') for the harm suffered.
- A summary of the factors contributing to the adverse event.
- Information about what has been and will be done to avoid recurrence of the adverse event, and how these improvements will be monitored.

If further issues are identified after the process is completed, the patient, their family and carers can re-contact the health service organisation for a response to their questions.

12.1.2 Disclosure of review and investigation findings

In most cases there will be complete disclosure of the findings of relevant review or investigations. A formal, written report should be provided in a language and communication style that the patient, their family and carers will understand.

In some exceptional circumstances it may be considered that disclosure of information will adversely affect the patient, their family and carers' health. In these cases:

- the rationale must be clearly documented in the patient record
- where possible, the decision should be independently verified by a practitioner or colleague who was not involved in the adverse event. If possible, this verification must also be documented in the patient record.^m

In addition, in some cases and jurisdictions, information may be withheld or restricted. This may occur, for example, where:

- investigations are awaiting conclusion of coronial processes (see Appendix 1)
- contractual arrangements with insurers preclude disclosure of specific information
- information is protected from disclosure (see Section 4.4.1 and Appendix 1).

In these cases, the patient, their family and carers will be informed of the reasons for restricting information. This will be documented in the appropriate place (see Section 13).

12.1.3 Continuity of care

When a patient has been harmed during treatment and requires further therapeutic management or rehabilitation, the patient, their family and carers should be clearly informed of their proposed ongoing clinical management. Discharge planning should ensure that ongoing care is provided where it is required as a consequence of the adverse event (see Section 4.3.1).

12.1.4 Communication with the general practitioner, residential facility and other clinicians

When the patient is leaving the care of an acute health service organisation, they should be asked if they agree to a discharge letter being forwarded to their general practitioner, residential facility or community care provider. Where possible these providers should also be telephoned. The discharge letter should contain summary details of:

- the nature of the adverse event and the patient's continuing care and treatment
- the patient's current condition
- any clinical investigations and their results
- any relevant discharge information.

^m It is recognised that this may not be possible in some contexts such as smaller health service organisations and in rural settings.



12 Completing the process

12.1.5 Monitoring improvements

Any changes implemented as a result of a review or investigation should be monitored for their effectiveness. Personnel responsible for clinical risk management should develop a plan for monitoring the implementation and effectiveness of changes.

Where appropriate and possible, this information should be given to the patient, their family and carers.

12.1.6 Communication and continued support for clinicians and staff

Effective communication with staff is a vital step in ensuring that recommended changes are fully implemented and monitored. It will also increase awareness of patient safety and the value of open disclosure.

Clinicians who were involved in the incident must continue to be supported by the health service organisation to minimise any residual emotional and professional harm. Continued support, including debrief, should be active but approached with sensitivity.

12.2 Evaluation of the open disclosure process

Patients, family, carers and other support persons should be given the opportunity to provide feedback on the open disclosure process. The option of a face-to-face interview, where appropriate, and/or a standardised open disclosure evaluation survey should be provided. Sensitivity around how this is conducted will be required.

Staff involved in open disclosure should also provide feedback through a standardised survey where possible. Ideally patient and staff feedback should be completed within four weeks of the end of the open disclosure process. However, sensitivity is required depending on the circumstances.

Suggested evaluation surveys are provided with the supporting materials. To access these visit www.safetyandquality.gov.au/opendisclosure

Survey results should be reported to the organisation's management (see Section 6.7) at regular intervals, along with other internal open disclosure measures (see Appendix 3).

12.3 Communication of lessons learned throughout the health service organisation and the broader healthcare system

Health service organisations should have mechanisms in place to communicate lessons learned and to implement changes to practice as a result of patient harm. This includes improvements to open disclosure practice based on ongoing evaluation.

Organisations should also endeavour to communicate these lessons throughout the broader healthcare system using existing mechanisms and relevant authorities.

13 Maintaining documentation

Key considerations and actions

- Keep the patient record up to date
- Maintain a record of the open disclosure process
- File documents relating to the open disclosure process in the patient record
- Provide the patient with documentation throughout the process

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. Documentation includes patient records, incident reports and records of the thorough review of the adverse event.



13 Maintaining documentation

13.1 Documenting the open disclosure process

Health service organisations should have an open disclosure documentation management process in place.

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

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

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

13.2 Key considerations for documentation

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. In the case of death due to an incident, a copy of the patient record will remain accessible to all those who will be involved in the open disclosure process.

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
- copies of letters sent to the patient, their family and carers and their general practitioner.

Without breaching legal and privacy requirements, documentation should be made available to the patient, their family and carers (see also Appendix 1). A contact point at the health service organisation should be available to answer staff questions regarding documentation and sharing of information.

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Appendix 1

1 Apology, expression of regret and open disclosure

Apology and/or expressions of regret are central to open disclosure (see Section 1.5). 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.

Health service organisations must consider the legislation in force in the state or territory in which they work when developing open disclosure policies and procedures and training staff.

At the time of the publication of this document, these statutory provisions are relatively new and there is little case law that guides their operation and effect.

The *Open Disclosure Standard Review Report* contains more information in this regard.⁶

The report can be accessed at www.safetyandquality.gov.au/opendisclosure

1a Admission of liability

Health service organisation staff need to be aware of the risk of making an admission of liability during open disclosure. In any discussion with the patient, their family and carers during the open disclosure process, the clinician should take care not to speculate on the causes of an incident or pre-empt the results of any investigations. They must not apportion blame, or state or agree that they, other clinicians or the health service 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.

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>

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 or, for public health service organisations, in response to a freedom of information application.

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. Communications in and findings of quality assurance committees and reports to root cause analysis committees are generally not able to be used in evidence in subsequent proceedings. These latter protections are often referred to as 'qualified privilege', although that term is not strictly accurate as a descriptor of the law. The provisions in legislation governing these protections need to be detailed in the organisation's open disclosure policy or guidelines.

Legal professional privilege and 'qualified privilege' are outlined briefly below.

2a Legal professional privilege/client legal privilege

The health service organisation 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 organisation 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 health service organisation or their insurer or the department of health or the health minister that is obtaining the legal advice. Health service organisation staff, both employees and contractors, may have sought their own legal advice and then claimed legal professional privilege for communications between them and their lawyers.

In some instances, the client (the health service organisation or their insurer, the department of health or the health minister) 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.

2b 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 will not trigger a quality assurance activity under the legislation (assuming that the legislation applies in a particular case). Therefore, in many adverse events these protections will not apply.



Appendix 1 Legal aspects of open disclosure

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>

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, health service organisations and clinicians need to be aware that their ability to disclose information to a patient, their family and carers 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.

In developing open disclosure policy, health service organisations need to consider specific conditions on the release of information covered by this legislation.

A health service organisation that has this legislation available to it should describe in its internal open disclosure policy the circumstances in which a quality assurance activity may arise.

3 Freedom of information legislation

Public health service organisations are subject to freedom of information (FOI) legislation, which varies across jurisdictions. The Commonwealth, states and territories have all enacted FOI legislation. These are listed in **Table A3**.

Generally, FOI legislation creates a right to access information contained on records held by government agencies (subject to some exceptions and exemptions) and a right to amend records that contain personal information that is incomplete, out of date or misleading. When health professionals create documents as part of the open disclosure process, they should be aware that the document may become available to the patient, their family and carers. Every effort should be made to ensure that the documents are accurate and are written in appropriate language.

In particular, 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 organisation;
- 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.

Table A3: Freedom of information acts

ACT	<i>Freedom of Information Act 1989</i>
Commonwealth	<i>Freedom of Information Act 1982</i>
New South Wales	<i>Government Information (Public Access) Act 2009</i>
Northern Territory	<i>Information Act 2003</i>
Queensland	<i>Right to Information Act 2009</i>
South Australia	<i>Freedom of Information Act 1991</i>
Tasmania	<i>Right to Information Act 2009</i>
Victoria	<i>Freedom of Information Act 1982</i>
Western Australia	<i>Freedom of Information Act 1992</i>

4 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.ⁿ

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.

Health service organisations and 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, their family and carers 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.

Health service organisations should develop guidelines to ensure that the relevant privacy principles and other obligations of confidentiality are adhered to during the open disclosure process. It is important to note that this legislation also provides patients with the right to access information about their care, such as their patient record.

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, health service organisations 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.

5 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 a health service organisation or health professional. For example, this could occur by a health professional 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, health service organisations should ensure that health professionals are informed, in their open disclosure training, that they must be careful recording information and what is said to and about others during the open disclosure process.

ⁿ *Privacy Act 1988* (Commonwealth) For information on relevant state and territory privacy laws see www.privacy.gov.au/privacy_rights/laws



6 Coronial investigations

Each state and territory has legislation governing the coronial process. These are listed in **Table A4**. The specific duties and responsibilities of coroners vary by jurisdiction but, in general, coroners perform the following functions.

- Establishing the manner and causes of all reportable deaths. These include untimely, unexpected or unexplained death during health care.
- Investigating the circumstances surrounding all reportable deaths.
- Coroners do not determine any criminal or civil liability (however, the coronial investigation can provide valuable insight into causes of the adverse event).
- Coroners 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, including private clinical records and hospital 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 A4**.

Health service organisations in all settings should be familiar with requirements set out under relevant acts and develop local policies and procedures accordingly.

Table A4: 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

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 criteria set out in Section 7.3 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:

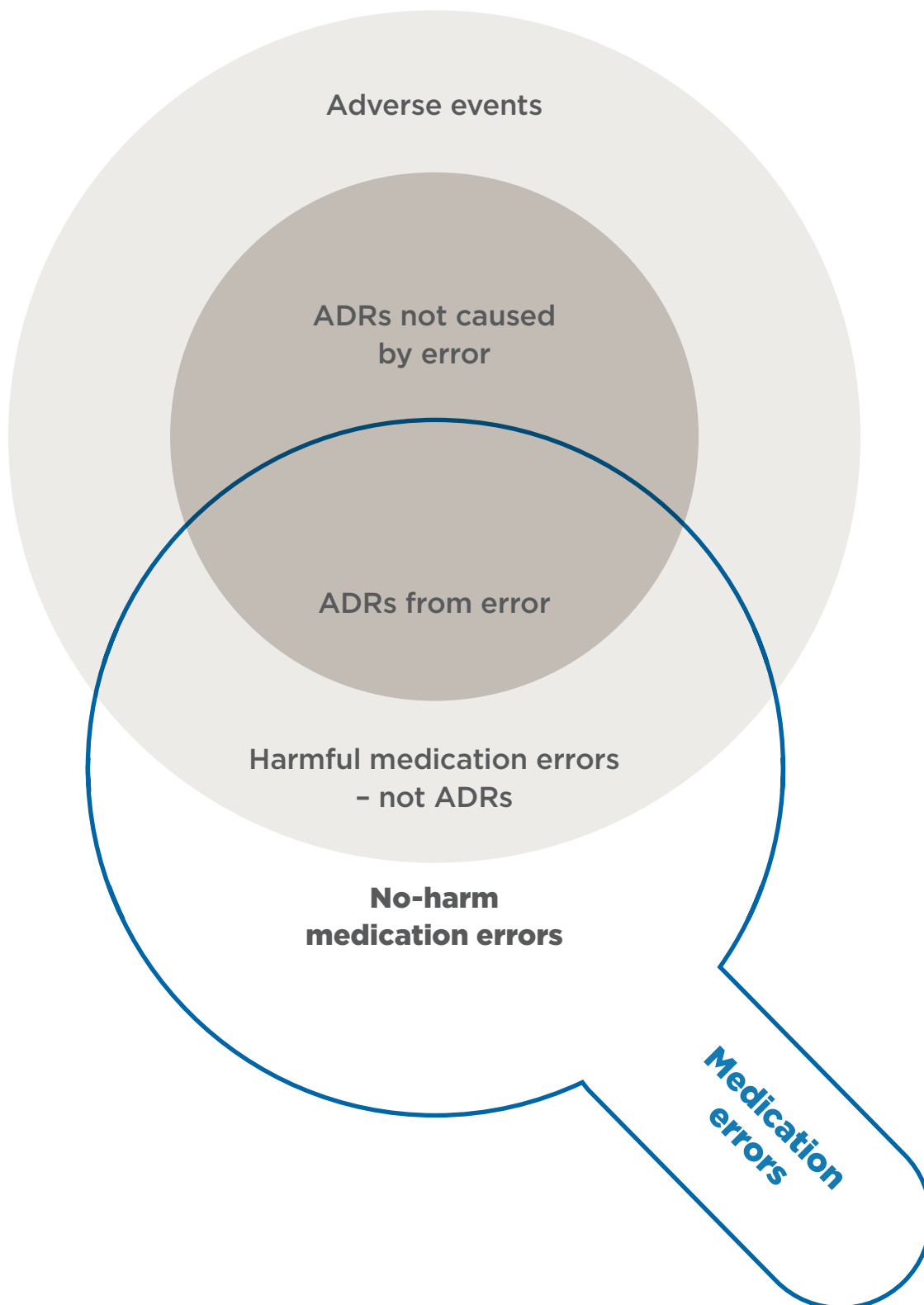
- degree of patient harm
- whether there was prior knowledge of the allergy (i.e. the ADR was preventable)
- whether the patient, their family or carers were not advised of the possibility of the ADR occurring.



Appendix 2 Medication errors, adverse drug events and open disclosure

Figure A2

Diagram showing the relation between adverse events, adverse drug reactions (ADRs) 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 3 Measuring open disclosure for internal quality improvement

Appendix 3

The measures suggested here are intended for internal use to facilitate quality improvement, monitoring and reporting to management. These measures should be integrated with other clinical governance reporting systems and mechanisms.

Information on evaluation requirements and criteria for open disclosure under the *NSQHS Standards* can be accessed at www.safetyandquality.gov.au and follow the links to *Health Service Standards and Accreditation*.

The measures should be adapted to suit local settings and context.

Number of open disclosure processes commenced in a reporting period
Number of open disclosure processes concluded in a reporting period
Number and percentage of open disclosure processes referred to mediation
Number and percentage of open disclosure triggered by: <ul style="list-style-type: none"> • complaints • clinical incident notification • case note review • general observation • patient request
Percentage of sentinel events ^o formally disclosed
Percentage of open disclosure vs. open disclosure requests through: <ul style="list-style-type: none"> • patient initiations • complaints
Results of patient surveys
Results of staff surveys
Percentage of clinicians trained in open disclosure
Results of feedback to training
Results of feedback to open disclosure

^o Sentinel events are adverse events that result in the death of, or serious harm to, a patient. Australian health ministers have agreed on a national core set of sentinel events for which all public hospitals are required to provide data. States and territories define sentinel events differently. ⁸ For the purpose of internal measurement proposed here internal consistency of terminology is the main requirement.



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