Australian Open Disclosure Framework

Consultation draft

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Suggested citation

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# Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Accreditation</td>
<td>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.</td>
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<tr>
<td>Admission of liability</td>
<td>A statement by a person that admits, or tends to admit, a person’s or organisation’s liability in negligence for harm or damage caused to by another.</td>
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<tr>
<td>Adverse event</td>
<td>An incident in which unintended harm resulted to a person receiving health care.</td>
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<tr>
<td>Adverse outcome</td>
<td>An outcome of an illness or its treatment that has not met the health care professional's or the patient's expectation for improvement or cure</td>
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<tr>
<td>Apology</td>
<td>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.</td>
</tr>
<tr>
<td>Carer</td>
<td>Person who provides personal care, support and assistance to another individual in need of support due to a disability or medical condition, including terminal or chronic illness, mental illness or frailty and age.</td>
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<tr>
<td>Clinical risk</td>
<td>The combination of the probability of occurrence of harm and the severity of that harm.</td>
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<tr>
<td>Clinical risk management</td>
<td>See Risk management</td>
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<tr>
<td>Clinical workforce</td>
<td>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.</td>
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<tr>
<td>Clinician</td>
<td>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.</td>
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<tr>
<td>Commission, the</td>
<td>Australian Commission on Safety and Quality in Health Care</td>
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<tr>
<td>Complication</td>
<td>A detrimental patient condition that arises during the process of providing health care.</td>
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<tr>
<td>Consumer</td>
<td>A patient or potential patient, carer or organisation representing consumers’ interests.</td>
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<tr>
<td>Contact person</td>
<td>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.</td>
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<tr>
<td>Corporate risk</td>
<td>Potential liabilities, exposures and dangers faced by an organisation or corporation. These can be financial or reputational.</td>
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<tr>
<td>Corporate risk management</td>
<td>See Risk management</td>
</tr>
<tr>
<td>Disability</td>
<td>Any type of impairment of body structure or function, activity limitation or restriction of participation in society.</td>
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<tr>
<td><strong>Error</strong></td>
<td>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.(^2)</td>
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<tr>
<td><strong>Ex gratia</strong></td>
<td>‘Out of good will’, usually referring to financial reimbursement or recovery payments. By definition, ex gratia payments are not an admission of liability.</td>
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</table>
| **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* Apology |
| **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.\(^2\) |
| **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** | A collection of data and information gathered or generated to record clinical care rendered to an individual. A comprehensive, structured set of clinical, demographic, environmental, social, and financial data and information, documenting the health care given to a single individual. |
| **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 and can be in any location or setting, including pharmacies, clinics, outpatient facilities, hospitals, patients’ homes, community settings, practices and clinicians’ rooms. |
| **Incident** | See Adverse event |
| **Liability** | The legal responsibility for an action |
| **Multidisciplinary team** | A healthcare team comprising individuals from various professions (nursing, medical, allied health, administrative, management) and disciplines within these professions. |
| **Near miss** | An error or system failure that is intercepted before reaching the patient. It is important to ensure harm did not occur. |
| **No-harm incident** | An error or system failure that reaches the patient but does not result in patient harm. |
| **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** | 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, a factual explanation of what happened and the potential consequences, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence. |
| **Outcome** | The effect on a patient that is wholly or partially attributable to an incident. The status of an individual, a group of people or a population that is wholly or partially attributable to an action, agent (i.e. one who/which acts to produce a change) or circumstance (i.e. all factors connected with influencing an event, agent or person). |
| **Patient** | A person receiving health care. Synonyms for patient include ‘consumer’ and ‘client’. In this document, patients can also refer to family members, nominated support persons, loved ones, partners, carers or guardians. |
| **Patient harm** | See Harm |
| **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. 

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<p>| <strong>Qualified privilege legislation</strong> | 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. |
| <strong>Quality (health care)</strong> | The degree to which health services increase the likelihood of desired outcomes and are consistent with current professional knowledge. |
| <strong>Quality improvement</strong> | 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. |
| <strong>Reimbursement</strong> | The act of paying for somebody’s expenses without an admission of fault. |
| <strong>Risk</strong> | The likelihood that someone or something that is valued will be harmed by a particular hazard. |
| <strong>Risk management</strong> | The design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the institution. <strong>Clinical risk management:</strong> 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. <strong>Corporate risk management:</strong> Activities of an organisation or corporation to identify and reduce potential financial or reputational liabilities, exposures and dangers. |</p>
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<tr>
<th>Definition</th>
<th>Description</th>
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<tr>
<td>Sentinel event</td>
<td>An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase ‘or the risk thereof’ includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called ‘sentinel’ because they signal the need for immediate investigation and response. The terms ‘sentinel event’ and ‘medical error’ are not synonymous; not all sentinel events occur because of an error and not all errors result in sentinel events.</td>
</tr>
<tr>
<td>Service recovery</td>
<td>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.</td>
</tr>
<tr>
<td>Staff</td>
<td>Anyone working within a hospital, including self-employed professionals such as visiting medical officers.</td>
</tr>
<tr>
<td>Statute</td>
<td>A written law passed by legislature at the state or federal level.</td>
</tr>
<tr>
<td>Suffering</td>
<td>Any subjectively unpleasant experience, including pain, malaise, nausea, vomiting, loss, depression, agitation, anxiety, alarm, fear, grief, humiliation or loss of autonomy.</td>
</tr>
</tbody>
</table>
| Support person                                                            | Any individual who is identified by the patient as a nominated recipient of information regarding their care. Support people may include:  
  • a family member, friend, partner or other person who cares for the patient  
  • carers, guardians or substitute decision makers  
  • social workers or religious representatives  
  • where available, trained patient advocates. References to ‘support person’ in this document should be read with the words, ‘where appropriate’. |
| 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 is designed to enable health service organisations and clinicians to communicate openly with patients who have been harmed during health care. It is intended for use by Australian health services 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.

Open disclosure has been implemented and adopted in various healthcare services and countries for two decades or more. Open disclosure is viewed as:

- a patient right
- a clinician responsibility
- a critical element of clinical communications
- an ethical practice
- an attribute of high-quality health service organisations.

The Australian Open Disclosure Framework is a nationally consistent basis for post-harm communication. It is designed so that patients are treated equally and respectfully after adverse events, no matter which health service cares for them.

Background

The Australian Open Disclosure 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 document. Since 2003, there has been considerable research and 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 to:

- consider the Standard in the context of current research and evidence of, and experience with, 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:

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

There were four main review findings:

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. difficulty with communicating openly in the context of risk management.
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.

From January 2013, open disclosure will be an accreditation requirement for health services as described in the *National Safety and Quality Health Service Standards* (Standard 1, Criterion 1.16).\(^4\)

The *Australian Open Disclosure 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.
Part A: Organisational preparedness

1 Introduction

1.1 Background

Every day across Australia, many thousands of healthcare interventions occur. These interventions are often complex, delivered in high-pressure environments and involve multiple practitioners working in teams and across organisations. Excellent clinical outcomes are most often the result, but modern health care also carries significant risks. Unintended incidents can occur and some result in patient harm.

Open disclosure is a response to incidents of patient harm by both the individuals and the healthcare organisation involved. It describes the way clinicians communicate with and support patients who have been harmed during health care. Open disclosure is anchored in professional ethics, is 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 who have experienced adverse events. Its systematic practice can assist health service organisations to manage adverse events humanely and provide broader benefits through improved clinical communication and systems improvement.

Open disclosure includes the open discussion of incidents that result in harm to a patient while receiving health care. The elements of open disclosure are:

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

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

1.1.1 Developing a safe and just culture

In creating an environment that minimises patient harm, there is a need to move away from individual blame to systems learning while at the same time maintaining professional accountability. Health service organisations need to foster an environment 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.

The Framework encourages health service organisations to:

- provide an environment where patients and their support persons
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 investigation

- create an environment where patients, their support persons, clinicians and managers all feel supported if things go wrong
- integrate open disclosure with investigative processes to identify why adverse events occur
- implement 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 Australian Government and state and territory government laws and regulatory requirements
- within the requirements of insurance and employment contracts.

1.1.2 Communication and patient safety

Effective communication with patients commences from the beginning of an episode of care and continues throughout their care. There is an ethical responsibility for health professionals to maintain honest and open communication with patients and their support persons, especially if things go wrong.

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:

- their colleagues and peers
- patients and their support persons
- the non-clinical workforce.

1.2 Principles for open disclosure

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, organisations and other key stakeholder groups. The Framework’s eight guiding principles are:

1. Open and timely communication

If things go wrong, the patient and their support persons should be provided with information about what happened in a timely, open and honest manner. The open disclosure process is fluid and will often involve the provision of ongoing information.
2. **Acknowledgement**

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

3. **Apology or expression of regret**

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

4. **Meeting the needs and expectations of patients and their support persons**

The patient and their support persons may reasonably expect to be:

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

5. **Supporting clinicians**

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.

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

Investigation of adverse events and adverse outcomes should be conducted through processes that focus on the management of clinical risk and quality improvement. Outcomes of investigations should focus on improving systems of care and be reviewed for their effectiveness. The information attained about incidents from the open disclosure process should be incorporated into quality improvement activity.

7. **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.

8. **Confidentiality**

Policies and procedures should be developed by health service organisations with full consideration for patient, support person and clinician privacy and confidentiality, in compliance with relevant law (including federal, 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.

### 1.3 Development of local policies

This document provides a flexible framework designed to be used by health service organisations, professionals and managers 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 need to include:

- appropriate training and education for relevant staff to ensure a consistent and informed approach to open disclosure and to avoid inadvertent admissions of liability
- mechanisms for involving consumers and clinicians in developing policies and procedures
- insurer requirements of health service organisations and professionals, and procedures for involving them in policy development at an early stage.

1.4 Health service accreditation

Incorporating open disclosure into health service policy and practice is an accreditation activity for Australian health services under the Australian Health Service Safety and Quality Accreditation Scheme. A requirement to implement formal open disclosure processes is described in the National Safety and Quality Health Service Standards (Standard 1, Criterion 1.16).

2 In-scope considerations

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

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 therefrom, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological.’ This is the definition upon which the discussion in the report is based.

In this document, ‘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 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 8.3), should be incorporated into health service organisation policies.

2.3.1 Near misses

It is not clear whether near misses should instigate open disclosure. Each case should consider the facts, as well as:

- the psychological, physical and clinical consequences of disclosure
- the possibility of latent harm (providers can feel it is counterproductive to worry patients with information about near misses)
- 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 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, 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 a clinical incident and reassure the patient 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?
2.4 Incidents related to the physical environment of care

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

2.5 Adverse events occurring elsewhere

An adverse event may have occurred in an organisation other than that in which it is identified. The individual who first identifies the possibility of an earlier adverse event should notify the personnel responsible for clinical risk in their organisation. 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
- investigations are in progress.

If the open disclosure process has not already commenced in the other organisation, the process should be initiated. The investigation of the adverse event and the disclosure process should occur, where possible, in the health service organisation where the adverse event took place.

2.6 Admission and pre-incident communication

While not part of the open disclosure process, pre-incident care (including how well the patient–clinician relationship is established) can determine the success of open disclosure. Pre-incident activity may include:

- 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 medical record.

2.6.1 Nominating a support person

An important part of early communication is the formal nomination of a legal support person. It is essential that the support person is nominated as early as practicable and the support person’s details are noted on the patient’s admission form.

Information about an adverse event will be given to a patient’s nominated support person in appropriate circumstances, taking account of the patient’s wishes, confidentiality and privacy requirements, and the organisation’s internal policies. The nominated support 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).

2.6.2 Substitute patient support

Patient support is an important part of open disclosure and quality health care. If the patient does not have access to a support person, the healthcare service should ask the patient if they wish someone to be appointed to fulfil this role.

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

2.7 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.

In these situations, open disclosure will be modified to accommodate the context and particular circumstances. The clinician 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 informed of progress with the criminal investigation, 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.

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

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

- establishing trust and communication between the patient, their support persons and clinicians
- influencing whether and how harm is perceived by the patient.
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 and support persons expect, need and benefit from prompt acknowledgement and further information as it becomes available; and useful information for system improvement may emerge.

Health service organisations should have guidelines about how and when to make a referral to a disciplinary process. Care should be taken to avoid potential conflict between disciplinary processes, and 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.

3.3 Large-scale disclosure

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

Healthcare services 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.

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 the 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 curriculums.

3.6 Incident investigation

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.\(^4\)

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

Effective open disclosure relies on, and complements, clinical incident investigation. Open disclosure dialogue with harmed patients and their support persons can provide insights and information on 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.
Patients should be kept informed of how investigations are progressing during open disclosure. They should also 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.

3.6.1 Legal considerations in sharing information from incident investigations

Legal considerations for certain types of clinical incident investigations are discussed in Section 7 and Appendix 2. These affect the extent of protection provided to documents and communications, as well as if and how information collected or findings can be disclosed to patients. These considerations vary according to jurisdiction, and it is important to obtain legal advice in each case, as well as during the formulation of relevant policies and procedures.

3.6.2 Involving harmed patients in the investigation

Information provided by patients and support persons about an incident should, where possible, be used to help determine the causes of an incident and improve the quality of care. It may be appropriate to involve patients 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).

4 Patient considerations

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

- communication
- advocacy and support
- reimbursement of out-of-pocket expenses
- other individual circumstances.

4.1 Communication

Communication is essential to ensure that patient expectations are met. Health service organisations need to create an environment that facilitates open and effective communication. Policies and practices should be in place to:

- ensure early identification of the patient’s needs by documenting at the time of admission:
  - the names and contact details of individuals who will provide assistance and support to the patient
the name of the individual that the patient has nominated as their official support person (see Section 2.6.1); this person may not be the same as the patient’s next of kin or other people providing assistance

whether the patient may require an interpreter service (see Section 4.1.3)

• 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 and their support persons, and that the plan will be followed through (see Sections 9–11)

• provide information about open disclosure at the beginning of the episode of care

• include the patient’s support persons in discussions about an adverse event, where the patient agrees

• provide information about the adverse event to the patient and their support persons

• provide information about the open disclosure process to patients and their support persons, both verbally and in writing, and in a language or communication style that they understand

• ensure that, if a patient dies as a result of an adverse event, support persons are provided with information, care and support, subject to the requirements of the coroner and legislation; support persons should also be referred to the coroner for more detailed information

• 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 Tailoring communication to the needs of patients

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

4.1.2 Ensuring appropriate communication with Indigenous Australians

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 matters.

Every effort needs to be made to ensure that the appropriate people (in the context of the patient’s needs and with the patient’s 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.

4.1.3 Ensuring appropriate communication with patients with language or cultural diversity considerations

Communication can be difficult if the patient or their support persons 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 clinician.
Cultural differences can impede effective communication. For example, patients from backgrounds in which authority figures are perceived negatively, or in which the gender of the treating health professional is an issue, will require special consideration.

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.

### 4.1.4 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. For someone with a mobility impairment, discussions should be held in a readily accessible place.

### 4.2 Advocacy and support

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

Where a patient needs more detailed long-term emotional support, the health service organisation should advise the patient about how to access appropriate counselling or support services.

Health service organisations should provide patients with:

- information (including contact details) about services provided by social workers, religious representatives and trained patient advocates who can provide emotional support, help patients identify issues of concern, provide information about appropriate community services and support patient’s meeting with these services
- contact details of a staff member (the contact person) who will maintain an ongoing relationship with the patient. 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 right to access their medical records.

### 4.3 Reimbursement of out-of-pocket expenses

Open disclosure is most effective if it is coupled with restorative action. This includes a pledge to support patients to cope with the effects of harm. Patients who have been harmed often indicate that bearing the cost of care is the determining factor in initiating litigation. Costs may include transport, child care and meals.
Open disclosure between patients and clinicians can break down because of delays in financial 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 to the patient.

The context for financial reimbursement will vary. Health service organisations should liaise with legal counsel, insurers and other stakeholders to develop guidelines for providing assistance to patients who have been harmed during care 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 with prior consultation with the insurer (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. Ensure that family, carers or the patient’s support 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 will be subject to requirements of the coroner and the legislation.a

Health service organisations should ensure that all staff are aware of coronial legislation and requirements relevant to their jurisdiction and sector.

### 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 close to the age of capacity, 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.

There is often conflict between a young person asserting (or entitled to) autonomy and parental authority. State and territory legislation generally protects clinicians who act on the instructions of parents of children under 18 years old from civil liability if the young person did not consent.

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a The functions of the coroner include determination of the identity of the deceased person, as well as the manner and cause of death. The coroner has the power to require a post-mortem and the production of medical records, including private clinical records and hospital records, for the purpose of the coronial inquiry. The coroner does not determine any criminal or civil liability. However, the investigation can provide valuable insight into causes of the adverse event. The coroner can make recommendations on public health and safety which should be channelled into the appropriate mechanisms for improving systems throughout the health sector.
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 10.2).

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 and the clinician breaks down. The patient may not accept the information provided or may not wish to participate in the open disclosure process. The following strategies may assist:

- Deal with the problem earlier rather than later.
- Where the patient agrees, ensure that their support persons are involved in discussions from the beginning.
- Ensure the patient has access to support services, as described in Section 4.2.
- Where the senior clinician is not aware of the relationship breakdown, provide mechanisms for early warning signs (e.g. patient communicating concern to other members of the team, lodging a Freedom of Information application).
- Offer the patient and support persons another contact person 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, 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 wants to lodge a formal complaint.
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.

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:

- 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 are aware that personal information about clinicians that is not related to the incident 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, hospital 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.\(^{b}\)

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\(^{b}\) 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.
Criticism and adverse findings against individuals should be avoided. If adverse findings must be made, treat the professional fairly and afford 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).

Recognise the obligation or right of professionals 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 also needs to be balanced with ethical behaviour and principles of transparency and openness.

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.

5.2 Involvement in open disclosure

Open disclosure should be a multidisciplinary 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 incident, the experience of the clinician, and their confidence and preparedness for open disclosure. However, there will be circumstances where staff do not feel prepared to participate, and these should be acknowledged.

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

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 or their support persons without jeopardising the rights of clinicians or their relationship with the patient. The substitute person may be responsible for clinical risk or be someone of similar expertise.

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
If there is difficulty with conducting open disclosure or finding a resolution, 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. However, at times, it may be appropriate for a legal representative of the patient or the health service to attend an open disclosure meeting. The purpose of the legal representative’s presence should be explained to the other party.

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 agrees
- the junior clinician has received adequate training to undertake the disclosure
- the junior clinician is willing to participate in the process.

5.3 Saying sorry
Apology is a key component of open disclosure, but it is also the most sensitive. Apology must be practised and executed with 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.
- The people who were directly involved in the incident do not necessarily have to be involved in providing the apology or expression of regret, although feedback from patient groups suggests that this is the preferred approach.
- 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 6.4).
- The apology or expression of regret should make clear what is regretted or being apologised for, and what is being done to address the situation.
- An apology or expression of regret is essential in helping patients cope and achieve closure following 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.

5.3.1 Apology and admission of liability
Appendix 2 details legal aspects of open disclosure, including apology and admission of liability.
5.3.2 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, making too many promises or making statements that are subsequently retracted can further undermine trust.

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

It is important that clinicians avoid making speculative statements during an initial disclosure. The following points should be considered when signalling open disclosure and preparing for 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 investigations must not be pre-empted.
- How remuneration or compensation will be decided should not be discussed until all the facts are known.

6 Organisational considerations

6.1 Governance and risk management

Every health service organisation 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 Organisational responsibilities

The Framework assumes that health service organisations will have integrated clinical governance, risk management, and incident notification and investigation systems and processes, as required under the National Safety and Quality Health Service Standards.

Health service organisations should ensure that they:

- 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 6.4)
- 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)
- 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)
- have established systems to identify adverse events
- 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 or indicators of open disclosure performance (see Section 6.6)
- advise clinicians of their obligation to notify their insurer(s) about an incident and planned response.

6.3 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 uptake and implementation of open disclosure, organisational leadership should:

- explicitly support open disclosure as an
  - 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 6.6)
- participate in open disclosure training and open disclosure (when required and appropriate).
6.4 Open disclosure education and training

Health service organisations should provide open disclosure education and training as part of professional development programs.

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.

Successful current practice suggests a modulated approach consisting of:

1. General introductory (and refresher) training for all clinicians.
2. 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.
3. ‘Just in time’ training to prepare staff immediately before an open disclosure dialogue begins.

Open disclosure education and training should:

- promote a multidisciplinary approach
- reflect consumer-centred values and principles
- cover the legal aspects of open disclosure (see Section 7)
- 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.

6.5 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. Health services should ensure that notification requirements for adverse events align with local open disclosure policy and practice.

6.5.1 Clinical risk personnel

Clinical risk management staff should always be informed of an adverse event. This will begin the process of responding to the incident and the formal investigation.

Senior management should be notified in smaller health service organisations without a clinical risk manager.

6.5.2 Insurers

Insurers of health service organisations and insurers of individual practitioners will need to be notified in accordance with timely notification requirements. This requirement should not interfere with prompt communication with patients (see Section 6.7).

6.5.3 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.
6.5.4 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.

6.5.5 Coroner
Cases of untimely or unexplained death and suspected unnatural deaths must be reported to the coroner as required by local legislation (see Section 4.4.1). Health service organisations and their management should ensure that all staff are aware of coronial legislation and requirements relevant to their jurisdiction and sector.

6.5.6 Notification to relevant statutory and other appropriate authorities
Where there are adverse outcomes, health service organisations may need to respond to a variety of external requirements, reviews or queries, including requirements of state, territory and federal regulatory bodies. The health service organisation’s policy on incident management and open disclosure should clearly state these requirements to ensure that its legal and insurance needs are met.

6.6 Measurement, evaluation and reporting
Measurement is a key component of clinical governance, risk management and quality improvement. It contributes to and fosters 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 and participating staff members should be surveyed so that their open disclosure experience can inform quality improvement.

Suggested open disclosure process and outcome measures are provided in Appendix 3. Suggested patient and staff survey templates can be found in the open disclosure supporting materials on the Australian Commission on Safety and Quality in Health Care website: www.safetyandquality.gov.au/our-work/open-disclosure/

6.7 Insurance considerations
Indemnity insurance providers can play a key role in the successful uptake of open disclosure by influencing clinician and health service behaviour in their responses 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.

6.7.1 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.
6.7.2 Independent indemnity providers

Independent insurers can similarly 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.

6.7.3 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 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.

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.

Indemnity insurance providers can play a key role in the successful uptake of open disclosure by influencing clinician and health service organisation behaviour (particularly in incident management responses). It is recommended that insurers promote open disclosure to clients as an appropriate strategy in adverse event management.
7 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 2.

7.1 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 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. Flexibility is required to meet specific circumstances and the needs of patients and clinicians. Open disclosure policies and procedures will need to adapt to each situation to ensure it is handled appropriately.

Part B should be read as a guiding framework for open disclosure. Its contents are summarised in Appendix 1, which also includes a flow chart of open disclosure.

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 2).

8 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 and level of response
- Provide support for staff
- Initiate a response, ranging from low to high level
- Notify relevant personnel and authorities

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

8.1 Identifying an adverse event

An adverse event might be identified:

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

It is important that all incidents are considered, regardless of the mechanism through which they were detected.
8.1.1 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 managers should be advised and should gather any evidence that will assist in investigating the event.

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

8.2 Initial assessment to determine the level of response

The member of the clinical team who detected the incident should make an initial assessment of the incident. This will consider the severity of harm and the level of response required. Ordinarily, a senior clinician will be contacted to confirm this initial evaluation. The level of response required will be determined by the effect or consequence of the incident.

8.3 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>
<thead>
<tr>
<th>Incident type</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Harm from natural progression of condition or disease process (e.g. a treatment for cancer was unsuccessful)</td>
<td>Discuss and explain (low level)</td>
</tr>
<tr>
<td>2. Complication or natural disease progression</td>
<td></td>
</tr>
<tr>
<td>a. Anticipated by patient/family via education and consent process</td>
<td>a. Discuss and explain (low level)</td>
</tr>
<tr>
<td>b. Not anticipated by patient/family via education and consent process (go to 3)</td>
<td></td>
</tr>
<tr>
<td>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</td>
<td>b. Open disclosure (high or low level depending on severity)</td>
</tr>
<tr>
<td>3. Patient harm/adverse event (e.g. wrong-site surgery)</td>
<td>Open disclosure (high or low level)</td>
</tr>
<tr>
<td>4. Clinical (‘no harm’) incident: reaches patient but no harm (e.g. wrong medication dose with no effect on patient)</td>
<td>Generally disclose (low level)</td>
</tr>
<tr>
<td>5. Clinical (‘near miss’) incident: does not reach patient (e.g. an intercepted wrong-patient biopsy)</td>
<td>Team decision based on:</td>
</tr>
<tr>
<td>• context</td>
<td></td>
</tr>
<tr>
<td>• circumstances</td>
<td></td>
</tr>
<tr>
<td>• potential ramifications (low level)</td>
<td></td>
</tr>
<tr>
<td>6. Patient perception or report of harm (e.g. patient perception of delay in diagnosis resulting in poor patient outcome)</td>
<td>Discuss and agree on appropriate form of disclosure (high or low level)</td>
</tr>
</tbody>
</table>
Table 2 describes low-level and high-level responses linked to harm criteria. It outlines some criteria that may be used to delineate low-level and high-level responses. 

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Lower level response</th>
<th>Higher level response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Near misses and no-harm incidents</td>
<td>1. Death or major permanent loss of function</td>
</tr>
<tr>
<td>2.</td>
<td>No permanent injury</td>
<td>2. Permanent or considerable lessening of body function</td>
</tr>
<tr>
<td>3.</td>
<td>No increased level of care (e.g. transfer to operating theatre or intensive care unit) required</td>
<td>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)</td>
</tr>
<tr>
<td>4.</td>
<td>No, or minor, psychological or emotional distress</td>
<td>4. Major psychological or emotional distress</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. At the request of the patient</td>
</tr>
</tbody>
</table>

Patients and their support person can potentially suffer further emotional harm if post-incident communication is handled insensitively. A low-level response should only be initiated if the risk of further harm (from not conducting formal open disclosure) is deemed negligible. Where uncertainty exists, a high-level response should be initiated.
9 Signalling the need for open disclosure

Key considerations and actions

- Acknowledge the incident to the patient, 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
  - 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 contact person for the patient
- Avoid speculation and blame

9.1 Initial discussion

All open disclosures commence with an initial discussion, which should occur as soon as possible after recognising harm, even if all the facts are not yet known. It acknowledges the incident to the patient and includes an apology or expression of regret (see Section 5.3). It will describe the effect of the incident, including all known facts and the consequences.

It is likely that, in most cases where a lower level response is indicated, the disclosure process will be completed after the initial disclosure discussion with the patient.

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 an error was made 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 in hospital any longer than originally planned.'

The person conducting the initial discussion may be a nurse manager, nurse specialist, staff specialist, registrar, resident medical officer or allied healthcare professional. This should be determined by the circumstances and the health service organisation’s particular policy.

Unless there are specific indications, or the patient requests it, the disclosure process will occur at the local service delivery level, with participation of those directly involved in the event. Reporting to management will occur through standard incident reporting 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 6.6 and 13.1.7.

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d For a high-level incident, this will be the senior clinician responsible for the patient.
e The organisation’s policy should also specify when to notify and involve the CEO and other management.
If a higher level response is indicated, the initial discussion will have an additional two actions:

- Signal the need for open disclosure.
- Negotiate (where possible) with the patient about
  - the formality of disclosure required
  - the logistical details of the open disclosure.

### 9.1.1 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, subject to any legal restrictions that may apply (see Section 7 and Appendix 2).

An example of appropriate wording for a high-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.’

### 10 Preparing for open disclosure

#### Key considerations and actions

- Hold a multidisciplinary team discussion to prepare for open disclosure
- Consider which clinicians will participate in discussions
- Appoint an individual to lead the open disclosure based on previous discussion with the patient
- Gather all the necessary information
- Identify the designated contact person for the patient

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

- initial discussion followed by a formal open disclosure meeting at which all facts are made available and the process is concluded
- 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.

### 10.1 Team discussion

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:

- 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 and their support persons (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 and their support persons
• consider legal and insurance issues, both for the organisation and the clinicians, and notify the relevant people (see Sections 6.5 and 7).

10.1.1 Choosing the individual to lead the disclosure
The individual conducting the disclosure should be the most senior clinician who is responsible for the care of the patient. That person should have the support of a senior staff member with good communication skills. Ideally, the person disclosing should:

• be known to the patient
• be familiar with the facts of the incident and the care of the patient
• be of sufficient seniority to be credible
• 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 and their support persons
• be willing to maintain a medium to long-term relationship with the patient, where possible.

The decision about who will make the disclosure should be made in consultation with the patient, their support persons, clinical risk personnel and (if appropriate) senior management. If for any reason the senior clinician is unable to make the disclosure, a substitute will need to be selected but, ideally, the senior clinician should still be present at the discussion.

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

10.2 Deferring open disclosure
Prompt open disclosure is not indicated in every adverse event 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 and their support persons 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’s medical record
• the decision must be independently verified by a practitioner or colleague who was not involved in the incident. This verification must also be documented in the patient’s medical record.
If open disclosure is deferred with the patient but is held with the patient’s support persons, the process should recommence with the patient at a later date.

10.3 Arranging the first meeting

10.3.1 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. 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 should be consulted about which health service professionals 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 support persons
- availability of support for staff
- the patient’s preferences
- the patient’s privacy and comfort
- the patient’s physical and mental health.

The patient may need time to consider these matters.

If for any reason it becomes clear that the patient would prefer to speak to a different clinician, the patient’s wishes should be respected and an acceptable substitute provided, if possible.

10.3.2 Contact person

The patient should be provided with the name and details of a health service contact person who should provide information and support to the patient throughout the open disclosure process, and manage the open disclosure to its completion. It is preferable that a single contact 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 formally nominate their open disclosure support person if they have not already done so.

10.3.3 Written information

The patient 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.
11 Engaging in open disclosure discussions

Key considerations and actions

- Provide the patient with the names and roles of all attendees
- Provide a sincere and unprompted apology or expression of regret
- Clearly explain the incident
- Give the patient the opportunity to tell their story, exchange views and observations about the incident and ask questions
- Encourage the patient to describe the personal effects of the adverse event
- Agree on, record and sign an open disclosure plan
- Assure the patient that they will be informed of further investigation findings and recommendations for system improvement
- Offer practical and emotional support to the patient
- Support staff members throughout the process
- If necessary, hold several meetings or discussions to achieve these aims

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

11.1 Key components of open disclosure discussions

The key components of open disclosure discussions are:

1. The patient is 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 healthcare service and clinicians (see Section 5.3).

3. The patient has the opportunity to tell the clinicians their story about the incident to explain their views on what happened, contribute their knowledge and ask questions. It will be important for the patient that their views and concerns are listened to, understood and considered.

4. The patient is encouraged to talk about the personal effect of the adverse event on their life.

5. A clear explanation of the adverse event is provided to the patient, including the known facts and consequences of the incident, in a way that ensures the patient understands this information. Speculation should be avoided.

6. An open disclosure plan is agreed on and recorded, in which the patient outlines what they hope to achieve from the process and any questions they would like answered.

7. The patient is assured that they will be informed of any further investigation that will determine why the adverse event occurred, the nature of the proposed process and the expected time frame. The patient is given information about how feedback will be provided on the investigation findings, including any changes made to prevent recurrence.

8. An offer of support to the patient and their support persons should include
   a. ongoing support including reimbursement of out-of-pocket expenses incurred as a result of the incident (see Section 4.3)
b. assurance that any necessary follow-up care or investigation will be provided promptly and efficiently

c. contact details for any relevant service they wish to access

d. information about how to take the matter further, including any complaint processes available to them.

9. The patient engages in open disclosure with staff. Staff are supported by their colleagues, managers and health service organisation, both personally (emotionally) and professionally (through appropriate training, preparation and debrief; see Section 6.4).

10. In cases where the healthcare incident spans more than one institution or service, health professionals will ensure that all relevant health professionals 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 incident occurred may not be possible until the causative factors are known.

Consideration should be given to providing a written account of the open disclosure meeting to the patient if requested.

12 Providing follow-up

<table>
<thead>
<tr>
<th>Key considerations and actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ensure follow-up by senior clinicians or management, where appropriate</td>
</tr>
<tr>
<td>• Agree on future care</td>
</tr>
<tr>
<td>• Share the outcomes of investigations and the resulting practice changes</td>
</tr>
<tr>
<td>• Offer the patient the opportunity to discuss the process with another clinician (e.g. a general practitioner)</td>
</tr>
</tbody>
</table>

Follow-up with the patient and their support persons is an important step in high-level responses to open disclosure. Lower level responses may require no or minimal follow-up.

12.1 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 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).

The patient should be kept informed of the progress and results of any investigation, including whether the results are delayed, pending or uncertain. The healthcare organisation should notify the patient 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 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 should be provided with details of a person to contact if further issues arise.
12.1.1 Completing the process at this stage

If the process of open disclosure is complete at this point, the patient and their support person should be asked if they are satisfied by the investigation and explanation, and a note of this should be made in the patient’s records (see Section 14). Written information about the adverse event and its management should be provided to the patient and their support person.

The patient and/or their support persons should be offered an evaluation survey, which should preferably be completed within four weeks of the open disclosure process (see Section 13.1.7).

13 Achieving closure

Key considerations and actions

- Reach an agreement between the patient and the clinician, or provide an alternative course of action
- Provide the patient with final written and verbal communication, including investigation findings
- Communicate the details of the event to the patient’s primary care provider
- Complete the evaluation surveys

The process of open disclosure concludes with shared agreement between the patient and the healthcare team. In the majority of cases, this will occur after completion of the incident investigation.

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

13.1 Key components of closure

13.1.1 Communication

When the investigation is complete, provide feedback to the patient through face-to-face interview or equivalent (e.g. videoconference), and in writing. The interview and document will include:

- 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 closure, the patient can re-contact the open disclosure health professional for a response to their questions.
13.1.2 Disclosure of investigation findings

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

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

- it is considered that disclosure of information will adversely affect the patient’s health
- investigations are pending coronial processes
- contractual arrangements with insurers preclude disclosure of specific information
- information is protected from disclosure (see Section 4.4.1 and Appendix 2).

In these cases, the patient will be informed of the reasons for restricting information.

13.1.3 Continuity of care

When a patient has been harmed during treatment and requires further therapeutic management or rehabilitation, the patient 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.

13.1.4 Communication with the general practitioner, residential facility and other care clinicians

When the patient is leaving the care of the 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. Subject to the patient’s consent, the 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.

13.1.5 Monitoring improvements

Any changes implemented as a result of an 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 and/or their support persons.

13.1.6 Communication and continued support

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.

13.1.7 Evaluation

Patients, support persons and staff involved in open disclosure should complete open disclosure evaluation surveys. Patient and staff surveys should be completed within four weeks of the end of the open disclosure process.
Survey results should be reported to the organisation’s management (see Section 6.6) at regular intervals, along with other open disclosure measures (see Appendix 3).

13.1.8 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 the 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.

14 Maintaining documentation

<table>
<thead>
<tr>
<th>Key considerations and actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Keep medical records up to date</td>
</tr>
<tr>
<td>• Maintain a record of the open disclosure process</td>
</tr>
<tr>
<td>• Provide the patient with documentation</td>
</tr>
</tbody>
</table>

The disclosure of an adverse event and the facts relevant to it must be properly recorded. Documentation includes medical records, incident reports and records of the investigation process. This commences at the beginning of open disclosure and continues throughout the entire process. Health service organisations should have an open disclosure documentation management process in place.

14.1 Key considerations for documentation

Keep a record of the open disclosure process, including all relevant patient, family and support person contact details, all discussions, all information provided, logistical details, plans proposed, and agreements and commitments made.

Ensure the patient’s medical record is 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 medical record will remain accessible to all those who will be involved in the open disclosure process. The medical record should document:

- the time, date and place of the disclosure discussion and the names and relationships of those present
- the plan for providing further information to the patient and their support persons
- offers of support and the responses received
- questions posed by the patient or their support persons and the answers given
- plans for follow-up as discussed with the patient
- progress notes relating to the clinical situation and accurate summaries of all points explained to the patient and their support persons
- copies of letters sent to the patient, their support persons and their general practitioner.

Without contravening legal and privacy constraints, documentation should be made available to the patient.
# Appendix 1 Summary of the steps involved in open disclosure

1. **Detecting and assessing incidents** (Section 8)
   - Detect incidents through a variety of mechanisms
   - Provide prompt clinical care to the patient to prevent further harm
   - Assess the incident for severity and level of response
   - Provide support for staff
   - Initiate a response, ranging from low to high level
   - Notify relevant personnel and authorities

2. **Signalling the need for open disclosure** (Section 9)
   - Acknowledge the incident to the patient, 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:
     - 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 contact person for the patient
   - Avoid speculation and blame

3. **Preparing for open disclosure** (Section 10)
   - Hold a multidisciplinary team discussion to prepare for open disclosure
   - Consider which clinicians will participate in discussions
   - Appoint an individual to lead the open disclosure based on previous discussion with the patient
   - Gather all the necessary information
   - Identify the designated contact person for the patient

4. **Engaging in open disclosure** (Section 11)
   - Provide the patient with the names and roles of all attendees
   - Provide a sincere and unprompted apology or expression of regret
   - Clearly explain the incident
   - Give the patient opportunity to tell their story, exchange views and observations about the incident and ask questions
   - Encourage the patient to describe the personal effects of the adverse event
   - Agree on, record and sign an open disclosure plan
   - Assure the patient that they will be informed of further investigation findings and recommendations for system improvement
   - Offer practical and emotional support to the patient
   - Support staff members throughout the process
   - If necessary, hold several meetings or discussions to achieve these aims

5. **Providing follow-up** (Section 12)
   - 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 the opportunity to discuss the process with another clinician (e.g. a general practitioner)

6. **Achieving closure** (Section 13)
   - Reach an agreement between the patient and the clinician, or provide an alternative course of action
   - Provide the patient with final written and verbal communication, including investigation findings
   - Communicate the details of the event to the patient’s primary care provider
   - Complete the evaluation surveys

7. **Maintaining documentation** (Section 14)
   - Keep medical records up to date
   - Maintain a record of the open disclosure process
   - Provide the patient with documentation
**Figure 1** Flow chart outlining the key steps of open disclosure

1. **Incident detected S8**
   - Clinical care and support for patient
   - Assessment and determination of level of response (in dialogue with patient and support persons) S8
   - Harm unclear: continue investigation and discussions until clarified S8
   - Criminal or intentionally unsafe act: refer to disciplinary guidelines S2.7 and S3.2

2. **HIGH-LEVEL RESPONSE**
   - Signalling open disclosure S9
   - Preparation and team discussion S10
   - Open disclosure discussions S11
     - Acknowledgement, apology/expression of regret, explanation
     - Agreement on plan for care, ongoing support and restorative action
     - Avoid speculation and apportioning blame
   - Follow-up S12
     - Ongoing dialogue (can take place over several meetings)
     - Team review/discussion throughout
   - Investigation

3. **LOW-LEVEL RESPONSE** (See Figure 2)
   - Notify relevant individuals, authorities and organisations S6.5
   - Information arising from open disclosure communication used to support investigation
   - Investigation recommendation fed back to patients

4. **Closure** S13
   - Parties satisfied and ready to finalise
   - Communication to primary care providers S13.1.4
   - Documentation completed, signed, filed and provided to patient S14
   - Patient and staff surveys S6.6 and 13.1.7
   - Feedback to patient
   - Feedback to management
   - Feedback to clinicians
   - Feedback to system S13.1

5. **Unable to reach agreement:**
   - Engage mediator/facilitator or refer to external agency 4.4.5

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**Notes:**

- **A** General indications — high-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
  6. S8.2

- **B** General indications — low-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
  5. S8.2
Figure 2  **Low-level response**

**LOW-LEVEL RESPONSE**

- Immediately acknowledge and discuss if the incident:
  - is a near miss
  - causes no or minimal harm
  - requires no change or escalation in care

- Notify relevant individuals, authorities and organisations
  - S6.5

- Investigation and follow-up

- Document in medical record

**Unable to reach agreement**

**HIGH-LEVEL RESPONSE**

(See Figure 1)

- Communication to primary care providers
  - S13.1.4

- Signalling open disclosure
  - S9
  - Acknowledgement, apology/expression of regret, explanation
  - Agreement on closure

- Documentation completed, signed, filed and provided to patient
  - S14

- Patient and staff surveys
  - S6.6 and 13.1.7

- Feedback to patient
- Feedback to management
- Feedback to clinicians
- Feedback to system
  - S13.1
Appendix 2 Legal aspects of open disclosure

1 Apology and open disclosure

Apology and/or expression of regret are central to open disclosure (see Section 5.3). All Australian jurisdictions have enacted laws\(^1\) that are designed to protect statements of apology or regret made after a variety of ‘incidents’ from subsequent use in certain legal settings. It should be noted that these laws were enacted without open disclosure in mind, and relate to various situations and legal contexts.

The protective value of apology laws in relation to open disclosure is constrained by:

- varying apology legislation across jurisdictions, especially with regard to *mea culpa* statements
- exclusion in five jurisdictions (Victoria, Tasmania, Western Australia, Northern Territory and South Australia) of statements containing acknowledgements of fault or liability
- the fact that an apology or expression of regret is only one element of open disclosure.

Health service organisations must consider their respective jurisdictional legislation when developing their open disclosure policies and procedures, including training and development of their staff.

There is scant empirical evidence from health care and other settings that apology laws restrict what can be said in these situations. Numerous examples in Australian common law indicate that an apology, including one that conveys or implies fault, is not admissible, does not constitute an admission of liability and is unlikely to be given weight in an Australian court.\(^5-7\)

1a How to make an apology

In discussions with the patient and their support persons during the open disclosure process, clinicians should, as appropriate:

- acknowledge that an adverse event has occurred
- acknowledge that the patient is unhappy with the outcome
- apologise 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 an investigation is being or will be undertaken to determine what happened and to prevent such an adverse event happening again
- agree to provide feedback information from the investigation when available
- provide contact details of a person or persons within the health service organisation whom the patient can contact to discuss ongoing care.

Healthcare professionals need to be aware of the risk of making an admission of liability during the open disclosure process. In any discussion with the patient and their support persons during the open disclosure process, the clinician should take care not to speculate on the causes of an incident or pre-empt the results of any investigations. They must also 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.

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\(^1\) Civil Liability Act 2002 (NSW), Wrongs Act 1958 (Vic), Civil Liability Act 2003 (Qld), Civil Liability Act 1936 (SA), Civil Liability Act 2002 (WA), Civil Liability Act 2002 (Tas), Personal Injuries (Liabilities and Damages) Act 2003 (NT), Civil Law (Wrongs) Act 2002 (ACT)
These restrictions should be balanced against the benefits that a full and sincere disclosure can provide to both patient and clinician.

**Examples of recommended 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 fix it 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.

Supporting materials about open disclosure on the Australian Commission on Safety and Quality in Health Care website offer more guidance on the apology aspect of open disclosure.


2 Protection of communications and documents from disclosure

Communications and documents (including emails) produced in response to an adverse event may have to be disclosed later in any legal proceedings or, for public hospitals, 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 some circumstances (which should be detailed in the health service organisation’s open disclosure policy) it may be necessary to undertake the open disclosure process in tandem with other legal or investigative processes so as to appropriately utilise legal professional privilege or qualified privilege legislation.

2a Legal professional 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 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 is the health service organisation that is obtaining the legal advice. Healthcare professionals, both those employed by the organisation and
those who are independent contractors, may have sought their own legal advice and then claimed legal professional privilege for communications between them and their lawyers.

The client 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 discloses the communication or document so that it is no longer confidential.

2b Qualified privilege legislation

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.

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

There is considerable variation between these statutes and the protection they afford to information generated during an investigation.

Many of the adverse events that trigger the open disclosure process will not trigger a quality assurance activity under the legislation (assuming that the legislation applies in a particular case), and accordingly, in many cases of an adverse event, that legislation and the qualified privilege will not apply.

Where the quality assurance 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 those circumstances where qualified privilege will apply to the investigation, health service organisations and clinicians need to be aware that their ability to disclose information to a patient or support persons who are part of the open disclosure process will be restricted.

In some jurisdictions, it is possible to release some information.

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

A health service organisation that has qualified privilege legislation available to it should include in its internal open disclosure policy the circumstances where it is likely that a quality assurance activity under the legislation will be invoked.

3 Freedom of information legislation

Public hospitals are subject to freedom of information (FOI) legislation, which varies across jurisdictions. The Commonwealth and the states and territories have all enacted FOI legislation.

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 healthcare professionals create documents as part of the open disclosure process, they should keep in mind that the document may become available to

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8 Health Act 1993 (ACT), Health Administration Act 1982 (NSW) (ss.20D-20K), Health Services Act 1991 (Qld) (ss. 30-38), Health Commission Act 1976 (SA) (s. 64D), Health Act 1997 (Tas), Health Services Act 1988 (Vic) (s. 139), Health Services (Quality Improvement) Act 1994 (WA) and Health Insurance Act 1973 (Cwlth) (Part VC).

the patient. 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 for accuracy, as far as possible, and should not:

• attribute blame to any healthcare professional or the health service organisation
• record opinions about staff, patients, support persons 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.

4 Privacy and confidentiality

In some jurisdictions and in some circumstances, patients have legislative rights to privacy and confidentiality of personal information, and a right to access their health records.\(^1\)

There is also an implied obligation of confidentiality in common law (because of the nature of the relationship between a healthcare professional 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 legislatively required to protect the privacy of patients, clinicians and others when conducting investigations, creating reports and making any disclosures during the open disclosure process. Patients should be informed of these requirements. Information obtained as part of the open disclosure investigation should be recorded and stored in accordance with the legislation.

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 medical 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 incident, 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 care professional. For example, this could occur by a health care professional alleging that a colleague is incompetent.

For an action for defamation to arise, the communication only needs to be made to one other person. It is not even 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 healthcare professionals are informed, in their training in open disclosure, that they must be careful about information recorded and what is said to and about others during the open disclosure process.

\(^1\) Privacy Act 1988 (Cwlth), For information on state and territory privacy laws see [www.privacy.gov.au/privacy_rights/laws](http://www.privacy.gov.au/privacy_rights/laws)
## Appendix 3 Measures of open disclosure

### Outcome measures

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<tr>
<th>Measure</th>
<th>Details</th>
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<td>Percentage of reported clinical incidents disclosed</td>
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<td>Percentage of sentinel events formally disclosed</td>
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<td>Percentage of open disclosure vs. open disclosure requests through:</td>
<td>• patient initiations</td>
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<td></td>
<td>• complaints</td>
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<td>Percentage of clinicians trained in open disclosure:</td>
<td>• general</td>
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<td></td>
<td>• specialised</td>
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<tr>
<td>Results of feedback to training / development</td>
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<td>Results of feedback to open disclosure</td>
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<td>Results of patient feedback / satisfaction surveys</td>
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### Process measures

<table>
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| The health service has an official open disclosure policy based on the  | • the steps for open disclosure described in the Framework  
| Framework that contains:                                               | • provisions for ongoing support for the patient and loved ones or carers  
|                                                                      | • provisions for ongoing support of staff involved in open disclosure and clinical incidents; this includes a 'debrief' with suitably qualified staff.                                                     |
| The health service has an identified open disclosure support officer    | in place with a capacity to respond to clinical incidents.                                                                                                                                           |
| The health service has an official and regular program for open        | disclosure training and education including, where appropriate, role-playing and simulation with structured feedback, which includes:  
| disclosure training and education including, where appropriate, role-  | • open disclosure as part of orientation of all clinical and management staff  
| playing and simulation with structured feedback, which includes:      | • basic open disclosure training for all staff, with regular refresher workshops  
|                                                                      | • comprehensive training for selected individuals from various professions.                                                                                                                            |
| The health service has a standardised survey for patients, family and  | to elicit impressions and satisfaction with the open disclosure process.                                                                                                                                  |
| support persons involved in open disclosure                            | The health service has a standardised survey for staff involved in open disclosure to elicit impressions and satisfaction with the open disclosure process.                                                      |
| The health service can trigger open disclosure through a variety of    | The patient, family and carer are provided with open disclosure information in an appropriate format.                                                                                                       |
| methods including:                                                    | The health service has a record of all communications made about healthcare incidents that are discussed with patients, families and carers.                                                          |
|                                                                      | The health service has official counselling and support service for staff involved in clinical incidents and consequent open disclosure processes.                                 |
References