AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

NSQHS STANDARDS

Australian Open Disclosure Framework

Supporting materials and resources

Implementing and practising open disclosure: Guide for health service managers

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Open Disclosure: A family's perspective

Mr Silvestro was admitted to hospital with pneumonia and Chronic Obstructive Pulmonary Disease. He lived with his wife in a retirement village and they had strong support from their children and families. While in hospital he had a fall and sustained a fractured femur that was not diagnosed for some time.

Eight days after the fall he was operated on. After the surgery he was transferred to the orthopaedic ward and Mr Silvestro's daughter asked the nurse looking after him why it took so long for the fracture to be discovered and acted on. The nurse was not sure so she said she would try to find out.

Three days later Mr Silvestro's daughter again asked for an explanation as to why her father's operation had been delayed. Because she was upset and angry that she hadn't received any information or explanation the ward nurse immediately referred her to the Senior Nurse Manager. A discussion with staff from the medical and orthopaedic teams followed. It was decided that the Senior Medical Specialist and Nurse Manager should discuss what had happened with Mr Silvestro, his wife and daughter. The Nurse Manager consulted with Mr Silvestro and his family regarding the need for an interpreter because Mr Silvestro and his wife were not fluent English speakers.

The Specialist apologised to Mr Silvestro for the delay and was frank in providing information about procedures that had not been followed in review and reporting of the fall. He also outlined changes to requirements for examining patients after a fall even where there is no obvious injury.

The ward initiated changes to ensure these procedures were followed and this was communicated to the Silvestros in a letter from the CEO.

Mr Silvestro and his family were pleased with the outcome as they felt that the hospital had, after the initial delay in response, taken the incident seriously and treated their concerns with sensitivity.

1 Introduction

Open disclosure has been practiced in Australian health service organisations since endorsement of the national *Open Disclosure Standard* (the Standard) by Australian Health Ministers in 2003.

The Standard was revised in 2012 and superseded by the *Australian Open Disclosure Framework*. The *Australian Open Disclosure Framework*, released in 2013, builds on the Standard but contains changes that reflect the latest evidence and research on open disclosure, as well as the changing landscape of Australian health care.

1.1 What is the purpose of this guide?

This guide is designed to assist health service managers implement the *Australian Open Disclosure Framework* (the Framework). It should be read in conjunction with the Framework its supporting resources.

The Framework and supporting materials can be accessed at www.safetyandquality.gov.au/opendisclosure

Implementation of open disclosure should be considered in the context of local policies and guidelines. As it is likely that open disclosure is already practiced in most Australian health service organisations, this guide is designed to:

a. complement existing local open disclosure policies and resources
b. help managers implement the new aspects of open disclosure contained in the Framework.

This guide will be relevant for clinical managers as well as individuals responsible for clinical risk and patient safety.

1.2 What is open disclosure?

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

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

The elements of open disclosure are:

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

Open disclosure is a discussion and an exchange of information that may take place over several meetings.

When developing open disclosure policies, and preparing staff for involvement in it, it is important to stress that that open disclosure is about providing an open, transparent and consistent approach to communicating with patients and their family and carers following an adverse event. This includes:

- saying 'sorry' for what has happened to them
- providing the facts about the event
- refraining from speculative statements and/or apportioning of blame to other individuals
- listening to their version of the event and how it has affected their lives
- providing information about their ongoing care
- communicating the steps taken to minimise the risk of recurrence
- maintaining an ongoing dialogue with them.

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

Managers are responsible for ensuring systems are in place that assist individual and organisational learning to minimise the risk of the adverse event recurring.

1.2 The ethical basis for open disclosure

The ethical basis for the disclosure of information to patients and their families following an adverse event are the principles of being truthful, open and honest, respecting patient autonomy and putting the welfare of the patient first. Openness and honesty is the basis for the relationship of trust that patients have with their clinician, their clinical team and the health service organisation in which they are being treated.

The eight principles of open disclosure, as described in the Framework, are detailed in Section 3 of this guide.

Health service organisations must facilitate the disclosure of information to patients regarding their care by virtue of the patient-clinician relationship which is based on trust. They are also required to implement open disclosure as part of the accreditation process for relevant Australian health service organisations (see Section 1.3 of this guide).

If a clinician refuses to disclose information to a patient and the health service organisation deems it to be the correct response, it is the ethical obligation of the health service manager to ensure that disclosure occurs despite the objections of the individual clinician. However there will be circumstances where staff may identify that they do not fell prepared to participate in open disclosure, and these should be acknowledged, respected and addressed in the appropriate manner.

1.3 The requirement to implement and practice open disclosure

Open disclosure has been endorsed by Australian Health Ministers on several occasions over the past decade and it now forms a part of health service accreditation under the second edition of the *National Safety and Quality Health Service (NSQHS) Standards*.

The NSQHS Standards (2nd ed.) were endorsed by Australian Health Ministers in 2011 and provide a clear statement about the level of care consumers can expect from health service organisations. Open disclosure is required under the NSQHS *Clinical Governance Standard*. This assessment tool is designed to fit into the overarching health service assessment requirements set out under the NSQHS Standards (2nd ed.). For more information visit www.safetyandquailty.gov.au

2 Implementing open disclosure in your organisation

Every organisation is unique due to its casemix, demographic factors, geographical location, and, most importantly, its culture. Developing the right culture, behaviours and attitudes for open disclosure is a key task for managers and executives. Some of the challenges are outlined below, followed by some general strategies. The most important aspects include leadership, communication, training and education, and measurement and evaluation.

It is also important that open disclosure be aligned with the organisation's clinical incident management policies and processes.

See end of Section 4.3 and Appendix 2 of this guide for some examples of open disclosure implementation.

2.1 Challenges

The challenges for managers may be to:

- facilitate clinical management systems that are designed around the patient's perspective
- foster a culture to support and encourage open discussion of adverse events and possible strategies for prevent them from recurring
- move away from focusing on individual error whilst focusing on a 'just' culture
- provide avenues for managers and clinicians to learn from adverse events
- develop patient-focused multi-disciplinary and inter-professional teams
- empower colleagues and clinicians to make changes that manage clinical risk
- describe a clear policy, regulatory and legal path for open disclosure.

2.2 How can good open disclosure practice be implemented and embedded?

Systems and process changes can be implemented in a relatively short timeframe but cultural transformation takes longer. General strategies to assist managers in achieving cultural change are outlined below. More specific actions are outlined in Section 2.4.

Leadership

Enlist a clinician leader to champion open disclosure and who will lead the open disclosure process by example. It takes leaders who are willing to create a clear vision of improved patient safety to change attitudes and model new behaviours.

It is also important to have the explicit and vocal support of executive and senior leadership of your organisation.

However, leadership can occur at all levels of an organisation. When building a coalition to support the implementation of good open disclosure practice it is important to enlist leaders among junior levels.

Support

Ensuring appropriate support for staff during open disclosure is critical for the individuals involved and for generating support. Deploying relevant open disclosure and legal expertise will assist and assure staff. It will also aid the open disclosure process and the patient who has been harmed.

Communication

Look for opportunities to get the message out, including meetings, telephone calls, email, memos and newsletters. Keep in mind the “teachable moments” when errors occur and clinicians are looking for answers and feedback these opportunities into the organisation to foster continuous improvement. Be persistent in order to encourage cultural change.

Enlist patients

Successes have been found when patients have been asked to become part of the solution. Clinicians often relate better to patients’ experiences and explore the issues together.

Continuous learning

Continue to learn and adapt, and involve clinicians in the learning process. Clinicians are curious and willing to learn about new ideas and approaches. Provide them with articles, run workshops and give them time out from normal duties to receive the training they need.

Listen

Listen carefully to clinicians’ concerns and try to understand their view of your efforts. For example, they may see this as “just one more” administrative project that will go away. You may need to find out if they are carrying around an old story or a grudge that is blocking their participation. You will need to explain to them the personal benefits of being involved in the open disclosure process. Invite experts from other organisations who have had success and learn from their experience, as sometimes it takes an outside expert delivering the same message that you have, for people to hear.

Training and development

All staff should be provided with general knowledge and information about open disclosure. This should be part of orientation for all clinical staff. Workshops utilising case studies are also useful to explore the open disclosure process. Ensure training sessions or workshops are conducted by someone sufficiently skilled to deal with difficult, and possibly emotional, issues that may arise.

Ideally a small cohort of clinical and administrative staff should be trained as 'experts' who can step in and support other staff during open disclosure. This training should, where possible, utilise facilitated role-playing scenarios.

Dispel myths and present a clear rationale

There are still a lot of myths surrounding open disclosure (e.g. that it increases litigation; that it adversely affects patients). Clinicians will engage in open disclosure if these myths are dispelled and an evidence-based rationale for conducting open disclosure is presented.

The *Open Disclosure Standard Review Report (2012)* contains useful material for based on the latest research and literature. New papers are published regularly and managers are advised to keep up with emerging literature in this area.

Measurement and evaluation

Measuring and evaluating open disclosure is a key aspect of fostering the right culture for open disclosure. Reporting outcomes is a strong signal that the organisation takes openness and transparency seriously. Clinicians are known to respond to feedback about their performance which is well grounded. The Framework suggests several measures that can be used to track performance including patient and staff surveys (see Section 4.9 of this guide). Reporting to executive can also generate a sense of engagement and urgency.

Recognising achievement

Recognising the efforts of individual clinicians at all stages of their careers to be open and truthful about adverse events is an important aspect of change management, and cultural transformation.

2.3 Key personnel for open disclosure implementation

Individual responsible for clinical risk

Health service organisations need to designate responsibility for the management of risks associated with the delivery of clinical care. The person responsible needs to be of sufficient seniority to have credibility and be able to drive change to effect improvements. He or she will oversee the implementation of the open disclosure process within the organisation. In a small organisation this may be a clinician leader or a senior manager.

Executive sponsor

To successfully implement open disclosure, executive support at the highest level is required. Executive sponsors at every level of your heath service organisation and the health system should be delegated with responsibility for overseeing implementation of the *Australian Open Disclosure Framework*.

Open disclosure support staff

Identifying and skilling individuals to assist open disclosure processes are critical for implementation success. They will either have sufficient knowledge, including legal expertise, to assist staff or work with others who have those skills.

Patient safety manager

We know that patients who have been harmed, and their families or carers, take comfort from a single, consistent contact person communicating on behalf of the hospital and assisting them through the open disclosure process (the Health Service Contact). A properly trained and resourced patient safety manager will assist successful open disclosures and implementation.

Senior clinicians

It is important to enlist the support of senior clinicians who will champion open disclosure and provide leadership to their peers

2.4 Specific actions to implement open disclosure

Specific strategies for supporting open disclosure implementation include:

- Presenting open disclosure cases at grand rounds, hospital inservices or peer review meetings that include medical, nursing and allied health staff.
- Scheduling an open disclosure session into orientation programs for all new staff.
- Including open disclosure as part of health service organisation ongoing performance appraisal.
- Providing training for clinicians on seeing a situation and acting from the perspective of the patient.
- Identifying and supporting of clinical open disclosure champions.
- Providing a facility for anonymous reporting of adverse events.
- Training clinicians to work effectively in teams.
- Ensuring that the teams involved in an adverse event have the opportunity to meet and informally debrief as soon as possible after the adverse event.
- Organising regular multi-disciplinary and inter-professional team meetings to discuss adverse events at a local level
- Rewarding those who report adverse events and who participate in open disclosure through available mechanisms such as improved career prospects
- Reducing disincentives to reporting adverse events.
- Include an open disclosure question during recruitment interviews.
- Evaluating and tracking open disclosure performance through process and outcome measures developed in partnership with clinicians and consumers.
- Reporting open disclosure performance to senior management through an established pathway or mechanism.
- Framing adverse events as opportunities to learn and improve.
- Including open disclosure as part of ongoing performance appraisals for staff.
- Identifying and supporting of clinical champions and opinion leaders in open disclosure.

- Providing appropriate leave from the workplace for clinicians affected by their involvement in an adverse event.

3 Open disclosure principles

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

The Framework's eight guiding principles are:

1. **Open and timely communication**

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

2. **Acknowledgement**

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

3. **Apology or expression of regret**

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

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

   The patient, their family and carers can expect to be:

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

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

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

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

6. Integrated clinical risk management and systems improvement

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

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 and clinician privacy and confidentiality, in compliance with relevant law (including Commonwealth, state and territory privacy and health records legislation). However, this principle needs to be considered in the context of *Principle 1: Open and timely communication*.

4 The open disclosure process and key considerations for managers

This section provides a summary of the open disclosure process and outlines some key considerations of the process for health service managers..

More detail on the open disclosure process can be found in Part B of the Framework. A flow chart illustrating the open disclosure process is provided in Appendix 3 of this guide.

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

1. Detecting and assessing incidents Section 7	• Detect adverse event through a variety of mechanisms • Provide prompt clinical care to the patient to prevent further harm • Assess the incident for severity of harm and level of response • Provide support for staff • Initiate a response, ranging from lower to higher levels • Notify relevant personnel and authorities • Ensure privacy and confidentiality of patients and clinicians are observed

2. Signalling the need for open disclosure
 	
Section 8
	• Acknowledge the adverse event to the patient, their family and carers including an apology or expression of regret.
	• **A lower level response can conclude at this stage.**
	• Signal the need for open disclosure
	• Negotiate with the patient, their family and carers or nominated contact person
	  ○ the formality of open disclosure required
	  ○ the time and place for open disclosure
	  ○ who should be there during open disclosure
	• Provide written confirmation
	• Provide a health service contact for the patient, their family and carers
	• Avoid speculation and blame
	• Maintain good verbal and written communication throughout the open disclosure process

3. Preparing for open disclosure Section 9	• Hold a multidisciplinary team discussion to prepare for open disclosure • Consider who will participate in open disclosure • Appoint an individual to lead the open disclosure based on previous discussion with the patient, their family and carers • Gather all the necessary information • Identify the health service contact for the patient, their family and carers (if this is not done already)
4. Engaging in open disclosure Section 10	• Provide the patient, their family and carers with the names and roles of all attendees • Provide a sincere and unprompted apology or expression of regret including the words *I am* or *we are sorry* • Clearly explain the incident • Give the patient, their family and carers the opportunity to tell their story, exchange views and observations about the incident and ask questions • Encourage the patient, their family and carers to describe the personal

	effects of the adverse event • Agree on, record and sign an open disclosure plan • Assure the patient, their family and carers that they will be informed of further investigation findings and recommendations for system improvement • Offer practical and emotional support to the patient, their family and carers • Support staff members throughout the process • If the adverse event took place in another health service organisation, include relevant staff if possible. • If necessary, hold several meetings or discussions to achieve these aims
5. Providing follow-up Section 11	• Ensure follow-up by senior clinicians or management, where appropriate • Agree on future care • Share the findings of investigations and the resulting practice changes • Offer the patient, their family and carers the opportunity to discuss the process with another clinician (e.g. a general practitioner)
6. Completing the process Section 12	• Reach an agreement between the patient, their family and carers and the clinician, or provide an alternative course of action • Provide the patient, their family and carers with final written and verbal communication, including investigation findings • Communicate the details of the adverse event, and outcomes of the open disclosure process, to other relevant clinicians • Complete the evaluation surveys
7. Maintaining documentation Section 13	• Keep the patient record up to date • Maintain a record of the open disclosure process • File documents relating to the open disclosure process in the patient record • Provide the patient with documentation throughout the process

4.1 Determining the level of response

See Framework Section 7

An important aspect of determining the level of response is to take into account the views of patients as well as the clinical facts. Clinicians and patients will are likely to have different versions of an event and the ensuing level of harm. Both views are legitimate and can contribute information to the incident review or investigation.

A key role of managers may include listening to both sides and determine the correct level of response.

Vexatious claims are possible but rare. In the majority of cases, patients' complaint and/or version of events will be legitimate. Indeed, in many cases a key purpose of open disclosure is to reduce tension that may be present between patients and clinicians, clear up any misunderstandings and facilitate open communication.

When determining the level of response it is important to consider that:

a. The definition of harm engenders a psychological and social dimension

b. Patients and their support persons can potentially suffer further emotional harm if post-incident communication is managed insensitively.

As such, lower-level response should only be initiated if the risk of further harm (from not conducting higher-level open disclosure) is unlikely. Where uncertainty exists, a higher-level response should be initiated.

In short, the response will be determined by various factors that will need to be weighed up.

Examples of incident types and suggested responses, and criteria to distinguish between lower-level and higher-level responses are provided in Appendix 4 of this guide.

4.1.1 Acting promptly

See Framework Section 8.1

A timely response to patient harm is a key ingredient in successful incident management and an important way to prevent a minor incident from escalating.

In the some of cases waiting for all the facts to emerge may take too long. Prompt acknowledgement that something has occurred is advised, with a reassurance that it is being followed up. An example of potential wording may be:

I am/we are sincerely sorry that this has occurred. It is clear that something went wrong and we are investigating it right now. 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

4.2 Supporting patients and staff throughout the process

See Framework sections 4.2 and 5.1

It is imperative that patients and their support persons are provided with proactive support as soon as an adverse event is identified and throughout the open disclosure process.

A health service contact should be allocated to the patient and their support persons, who can be called on at any time to answer questions, organise meetings and provide logistical support. This may in some cases be a health service organisation's clinical risk manager.

Equally important is the support of staff who were involved in the adverse event. Staff, especially clinicians, can often be strongly affected in these circumstances and should be monitored and offered professional counselling or other forms of support.

The organisation's culture will have a strong bearing on how staff are supported and able to cope following an adverse event (in turn, the level of support provided to staff in these circumstances can be a strong determinant of organisational culture).

It is part of the responsibility of management and executive to foster a 'just' culture that avoids any blaming of individuals.

4.3 Providing practical support to patients

See Framework Section 4.3

4.3.1 Reimbursement and out-of-pocket expenses

Open disclosure is most effective if it is coupled with restorative action. This includes a pledge of practical support for patients, families and carers to cope with the effects of harm. Those who have been harmed often indicate that bearing the cost of care

and out-of-pocket expenses can be determining factors in initiating litigation. Out of pocket expenses may include, but not be limited to, transport, child care, accommodation and meals.

An open disclosure process can break down because of delays in 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.

It is generally accepted that practical support made on an *ex gratia* basis does not imply responsibility or liability. The context for financial reimbursement will vary between sectors and jurisdictions.

Health service organisations should liaise with legal counsel and insurers to develop guidelines for providing assistance to patients who have been harmed and their support persons when preliminary investigation indicates that this would be appropriate.

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

4.3.2 Ongoing care and other considerations

See Framework Section 4.3.1

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

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

Health service organisations should engage in these discussions with the patient and their support persons as soon as practicable after harm is identified, and in liaison with the relevant indemnity insurers.

4.3.3 Compensation and settlement

An offer of fair compensation for harm is emerging as an important aspect of clinical incident management.[A,B] This issue is complex and has not been studied in much detail in the Australian context. While some health service organisations here and abroad have had positive results from combining compensation negotiations with open disclosure (see example at the end of this section), it should be noted that these organisations are usually captive, or self-insured. This allows more flexibility and responsiveness that may not be available to managers of other types of organisations.

[A] Bell SK, Smulowitz PB, Woodward AC, Mello MM, Duva AM, Boothman RC, et al. Disclosure, Apology, and Offer Programs: Stakeholders' Views of Barriers to and Strategies for Broad Implementation. *Milbank Quarterly* 2012;90(4):682-705

[B] Murtagh L, Gallagher TH, Andrew P, Mello MM. Disclosure-And-Resolution Programs That Include Generous Compensation Offers May Prompt A Complex Patient Response. *Health Affairs* 2012;31(12):2681-2689.

Particular circumstances and context will influence how to approach the matter of compensation, and how closely to align this process with open disclosure itself.

Managers must work together with legal counsel and insurers to determine the correct approach to these questions both as a matter of local policy and on a case-by-case basis.

Example of a successful open disclosure and clinical incident management program

The Mater Hospital Group, Australia

There are many open disclosure success stories in Australia. Mater Health Services Brisbane is among them. Mater recognises that openly discussing adverse events and near misses with patients and their families is an integral component of its mission and values, and is openly committed to the principles of open disclosure and the promotion of a safety culture that values transparency, honesty and respect.

Mater's Clinical Safety and Quality Unit (CSQU) was formed in 2002. The CSQU's role is broad, and includes responsibility for medico-legal advice relevant to open disclosure. The Mater's approach to open disclosure has included the introduction of inhouse medico-legal counsel to the Mater campus in September 2003, and inhouse claims management in January 2004.

These staff members play an important role in staff education, early liaison with patients and their families and, where indicated, early resolution of complaints, claims and compensation.

Other steps that Mater has introduced and are integral to comprehensive implementation of open disclosure include:

- Engagement of an external contractor in May 2004 to advise CSQU on how Mater might design and implement a communications and training package to educate and engage all clinicians in the roll out of open disclosure practices and clinical incident management.
- Subsequent engagement of the same contractor to assist with the training of senior clinical colleagues as leaders and mentors in open disclosure and clinical incident communication and management. This centred on development of advanced clinical communication skills to enable appropriate, open and honest conversations with patients and their families following serious adverse events.
- Development of a service-wide *Open Disclosure Policy* that was comprehensively promoted across the entire health service.

For the majority of reported clinical incidents, open disclosure now takes place as a matter of course, initiated by the clinicians involved in patient care. Mater recognises that ensuring early and comprehensive disclosure with the patient in relation to an event fosters a good rapport with the patient and their family and which ultimately will have a positive influence on patient clinical care and the rapid resolution of the patient's concerns.

During the past few years, Mater has received a considerable amount of positive feedback from patients and families on its approach to open disclosure. The advantageous interaction between patient safety, adverse events and adverse financial outcomes has emerged since the inception of the program.

4.4 Attendees and participants

See Framework Sections 5.2 and 9.1.1

Circumstances and context will determine the attendees of open disclosure meetings and discussions.

Patients should be encouraged invite support persons such as family members, carers or close friends. Managers should explain to patients that a smaller number of attendees is more conducive to a fruitful meeting. A 'cast of thousands' can prove difficult to manage.

Where patients do not have support available, a patient advocate may be engaged to fulfil this role.

In situations where patients are deceased the same principles should be observed but must be handled with great care and sensitivity.

From the health service organisation's perspective, it is advised that the staff involved in the adverse event attend open disclosure meetings at some stage. Too many attendees from the organisation should be avoided. Generally legal counsel will not be required to participate, especially during the initial meeting(s). However, legal counsel may be required to attend if open disclosure is combined with negotiations regarding compensation (see 4.3.3).

The patient and their support persons should be consulted on who is best to attend the open disclosure.

4.5 Preparation

See Framework Section 9

It is very important to stress to participants that preparation is a key component in successful open disclosure. It is important that:

- staff have already had basic training and education in open disclosure through their orientation and refresher courses
- A small cohort of 'experts' with experience in open disclosure be available to support less experienced participant throughout the process.

It is the responsibility of the health service organisations to have the necessary training and development processes in place.

It is also important that the participating personnel meet before the first open disclosure discussion in order to:

1. establish the basic facts (clinical and other)
2. assess the event to determine the appropriate response
3. identify who will take responsibility for lead discussions with the patient and their support persons
4. consider the appropriateness of engaging patient support at this early stage, including the use of a facilitator or a patient advocate
5. identify immediate support needs for everyone involved
6. ensure that all team members maintain a consistent approach in any discussions with the patient and their support persons
7. consider legal and insurance issues, both for the organisation and the clinicians, and notify the relevant people

8. consider how to address issues regarding ongoing care such as billing and other costs, which should be addressed at the earliest opportunity.

It may be appropriate to rehearse some aspects of the conversation, such as the apology or expression of regret with the team.

Often it may be useful to 'coach' the main protagonists prior to the first open disclosure meeting. Critical parts of the discussion (such as apology or expression of regret) can be rehearsed with a colleague taking the role of the patient, and another team member acting as a coach in providing constructive feedback to the open disclosure lead.

However, caution is urged. While it is very important to be prepared, patients may not feel that the discussion in sincere if it comes across as too scripted.

4.6 Apology and expression of regret

See Framework section 1.5 and 10.2; Appendix 1 section 1

See 'Saying Sorry: A guide to apologising and expressing regret in open disclosure'

Apologising and expressing regret are key components of open disclosure, but also the most sensitive. 'Saying sorry' requires great care.

A supporting resource titled *Saying Sorry: A guide to apologising and expressing regret in open disclosure* provides additional information to the Framework, including preparation, phrasing and key skills, is available at www.safetyandquality.gov.au/opendisclosure.

Managers are encouraged to use this resource to manage any apprehension held by clinicians and other colleagues in relation to apologising or expressing of regret. This includes perceived medico-legal risks, which should be approached in liaison with the relevant legal professionals.

A sincere and empathic apology or expression of regret is a valuable component of open disclosure and, based on evidence and case law available, entails very little medico-legal risk. However, care should be taken not to speculate on the causes of an incident or pre-empt the results of any investigations. No blame must apportioned, or statements in agreement anybody is liable for the harm caused to the patient.

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

"The way things are done"

Perspective of a Plaintiff Lawyer

I had numerous experiences where our firm would review a file and, in what we called the "sorry, we can't take your case because we don't believe there was malpractice" letter, I would explain just what had happened or what we had been able to piece together.

On many occasions I would get a tearful "thank you" from patients and their families because they finally had answers to their questions. No one in the hospital would talk to them. No one would say "I'm sorry this happened to you," and that, more than anything, made them angry and defensive about the situation.

I found it incredibly sad and an indictment of "the way things are done" that the only place a patient or family could get answers to questions was a plaintiff 's lawyer who

was saying “I’m sorry you went through this. There isn’t malpractice here but here’s what happened.” After that, we would get calls asking us “so why didn’t they just TELL us this in the first place?”

4.7 Documentation

See Framework Section 13

Health service organisations should have an open disclosure documentation management process in place. The principal reasons for this are to ensure transparency, consistency and accountability, and to enable review for quality improvement purposes.

Comprehensive documentation contributes significantly to successful open disclosure. The disclosure of an adverse event and the facts relevant to it must be properly recorded. Recording commences at the beginning of open disclosure and continues throughout. Documentation includes patient records, incident reports and records of the thorough review of the adverse event.

A record of all open disclosure meetings should be kept, including all relevant:

- patient, family and support person contact details
- all discussions
- all information provided
- logistical details, plans proposed
- 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
- agreements and commitments made
- offers of support and the responses received
- questions posed by the patient and their support persons and the answers given
- plans for follow-up as discussed with the patient and their support persons
- 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 and their support persons and their general practitioner.

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

Without breaching legal and privacy requirements, documentation should be made available to the patient and their support persons. In the case of death due to an incident, a copy of the patient record will remain accessible to all those who will be involved in the open disclosure process.

A documentation template is available at www.safetyandquality.gov.au/opendisclosure

4.8 Follow-up and completing the open disclosure process

See Framework Sections 11, 12 and 4.4.5

It is important for all staff to understand that open disclosure is often more than a one-off event. For lower level responses, it may be a conversation between the clinician and the patient. For higher-level responses, it may be a process that requires several meetings over a considerable period of time. Active follow-up by the organisation with

patients and their support is a key part of this process. Key considerations and actions of follow-up are:

- 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 and their support persons the opportunity to discuss the process with another clinician (e.g. a general practitioner).

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

If a satisfactory conclusion cannot be negotiated, the patient and their support persons should be offered alternative courses of action.

4.9 Evaluation and measurement

See Framework Sections 6.7 and 12.2 and Appendix 3

It is difficult to improve a process without measuring and monitoring performance. Any health service organisation seeking to improve the way open disclosure is practised will need to continually evaluate the process.

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

Patient and staff survey templates are available at www.safetyandquality.gov.au/opendisclosure

Evaluation alone is insufficient. First, results must be fed back to clinicians and staff involved in the open disclosure. Second, aggregate results should be collected to track progress over time, and should be provided to senior management or executive on a regular basis (ideally as part of broader performance monitoring processes).

Ensuring that each open disclosure is evaluated every time, that the results are fed back to relevant parties, and aggregate performance measures are provided to executive may be the responsibility of managers.

Suggested measures are presented in Table 2. These should be adapted to suit local settings and context. A suggested template for collection of data is available at www.safetyandquality.gov.au/opendisclosure

Table 2: Suggested open disclosure measures

Number of open disclosure processes commenced in a reporting period Number of open disclosure processes concluded in a reporting period Number and percentage of open disclosure processes referred to mediation
Number and percentage of open disclosure triggered by: • complaints • clinical incident notification • case note review

• general observation • patient request
Percentage of sentinel events formally disclosed

Percentage of open disclosure vs. open disclosure requests through: • patient initiations • complaints
Results of patient surveys Results of staff surveys
Percentage of clinicians trained in open disclosure
Results of feedback to training Results of feedback to open disclosure

4.10 Legal issues

See Framework Section 6.9 and Appendix 1

Open disclosure is not a legal process but, equally, does not take place in a legislative vacuum.

The legal context for open disclosure process will vary between jurisdictions and types of 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 interacts with qualified privilege, apology law, coronial legislation and any other relevant legislative requirements.

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.

A health service organisation's internal open disclosure policy and training materials need to be consistent with, and reflect, relevant legal obligations. These include:

- apology and expression of regret
- confidentiality
- protection of communications and documents (including legal professional privilege, client legal privilege and legislation to proctect quality improvement activities
- freedom of information
- privacy and confidentiality
- defamation
- coronial investigations.

For more detail, please refer to the Framework and seek legal advice.

4.11 Notification and referral to other bodies and processes

See Framework Section 6.6

When there are adverse outcomes, health care organisations may need to respond to a variety of external requirements, reviews or queries, including requirements of

State, Territory and Commonwealth regulatory bodies. The organisation's policy on adverse events and open disclosure should clearly state these requirements to ensure that an organisation's legal and insurance needs are met.

Organisations should have guidelines in place on how and when to make a referral to a disciplinary process. In developing and amending these guidelines, care should be taken to avoid potential conflict between disciplinary and open disclosure investigations. This includes ensuring that the rights of the person subject to the disciplinary process are recognised and respected, such as the right to be given an opportunity to respond to findings by the open disclosure investigation and to have legal, union or other representation.

5 Other considerations during an episode of patient care

Successful open disclosure is dependent, to a significant extent, on the environment in which it is conducted and on actions which precede it. While these matters are outside the scope of the *Australian Open Disclosure Framework*, they are important considerations for health service organisations implementing and practising open disclosure.

5.1 Providing information to patients

See Framework Section 1.4.2

Informing patients, families or support persons about what can be expected during their hospital stay is an important element in the duty of health service organisations. As well as informing them of what to expect normally, the information should also detail what to expect if something should go wrong. However it is important that this information be presented in the context of the larger framework of open communication with patients throughout their episode of care.

Possible communications strategies include:

1. Include the following information in a range of formats such as an information sheet, brochure or on the hospital website:

   > *If something goes wrong during your care at hospital you can expect that:*
   >
   > - *a member of your health care team will discuss with you what happened and any treatment that may be required as a result; and*
   > - *information will be provided to you on how the hospital is investigating what happened and what steps they are taking to prevent it from happening to someone else.*

   A patient information booklet and brochure have been developed for this purpose and are available from www.safetyandquality.gov.au/opendisclosure

2. Provide open disclosure information booklets and/or leaflets for patients and their carers when an adverse event occurs. These are available at www.safetyandquality.gov.au/opendisclosure

5.2 Informed consent

See Framework section 3.1

The informed consent process is outside the scope of the *Australian Open Disclosure Framework*, but it is important in establishing the patient–clinician relationship and setting patient expectations. Obtaining informed consent from a patient before starting treatment is a legal requirement, and the law imposes a duty on clinicians to do so.

The National Health and Research Council's *General Guidelines for Medical Practitioners on Providing Information to Patients* provide information on informed consent and is available at www.nhmrc.gov.au/guidelines/publications/a-z-list

6 Management of a serious or sentinel adverse event

Serious or sentinel events[C] are those which cause harm or death. While the first priority is to ensure an appropriate response to, and care for, the patient and their family and carers, and to staff affected by the event, there may be other matters to manage.

Other matters may include significant attention to the health service organisation as a result of the serious or sentinel event, either from the media, the legal profession, or both. Examples include events affecting multiple patients (incorrect interpretation of results from screening programs for cancer, incorrect interpretation of specimens, clinical workers infected with transmissible diseases), abducted neonates, suicide or murder on hospital premises, major transfusion reactions and equipment malfunction that may have implications for other patients.

Such events often produce significant legal, media and other interest, which, if not properly managed, may result in damage to the health service organisation's reputation or its assets.

The health service organisation should have guidelines for the rapid follow up of such incidents that cover:

- the responsibility for the management of the incident
- the detailed record keeping of the incident
- who should be informed
- media relations - who will be responsible for managing communication with the media (see Section 6.2)

[C] Sentinel events are adverse events that result in the death of, or serious harm to, a patient. (Steering Committee for the Review of Government Service Provision. Report on Government Services 2012. Melbourne. Productivity Commission, 2012). Australian health ministers have agreed on a national core set of sentinel events for which all public hospitals are required to provide data. States and territories define sentinel events differently. For the purpose of 'in house' measurement proposed here internal consistency of terminology is the main requirement.

- a strategy for dealing with multiple inquiries (e.g. a hotline)
- guidelines on the process for conducting a detailed investigation
- maintaining the confidentiality and privacy of individual patients in line with current privacy legislation.

The guidelines should detail that the health service organisation's principle concern is the best interest of the patient.

6.1 Management record

When a serious or sentinel adverse event occurs, in addition to documenting the open disclosure processes and patient records, a management record should be created. This should include:

- a chronological record of the information given, to whom and by whom
- an objective factual account of the investigation
- the name and job title of the individuals providing the information
- a record of all statements to media, politicians and other outside parties in chronological order
- itemised, timed contacts with patients (especially where patients are being traced for follow-up investigation)
- details of the progress of the investigations.

This is particularly important as a constant record when personnel managing an open disclosure process may change.

6.2 Guidelines for media communication and public relations

Health service organisations should have policies to deal with routine media enquiries to ensure, as far as possible, that any stories appearing in the media, are fair and balanced and based on an analysis of the true facts. As with the open disclosure process, it is important not to attribute blame, speculate as to the causes of the adverse event or admit liability. The positive outcomes of clinical risk management, where system improvement takes place, should be communicated to the media.

Health service organisations should have local guidelines on media training and public relations, which include:

- a strategic communications plan
- the identification of those on the management team who will take responsibility for media relations
- the provision of media training for selected individuals
- encouragement of a culture of good public relations
- co-operation with the media to provide feedback to healthcare users on improvements in healthcare services.

7 Frequently asked questions

Why is open disclosure important?

As knowledge about health grows and the use of new technologies increases, the provision of health care is becoming more complex. In this context, health service organisations need to create an environment that encourages identifying and reporting adverse events so that opportunities for learning can be identified and acted on. In working towards an environment that is as free as possible from adverse events, there is a need to move away from blaming individuals to focusing on establishing systems of organisational responsibility.

In this context open disclosure can:

- improve patient safety and quality of care through organisational learning
- increase trust between patients and their clinicians
- assist patients and their families and carers recover from healthcare harm
- support staff through understanding and managing unintended patient harm.

Is open disclosure practice mandatory?

Open disclosure is an accrediting activity in the NSQHS Standards (2nd ed.).

The *Clinical Governance Standard* aims to ensure that there are systems in place within health service organisations to maintain and improve the reliability, safety and quality of health care.

Criterion 1.12 of the standard describes implementing an open disclosure process. Health service organisations are required to have an open disclosure program that is consistent with the Australian Open Disclosure Framework, and monitors and acts to improve the effectiveness of open disclosure processes.

Information on the NSQHS Standards (2nd ed.) accreditation scheme is available at www.safetyandquality.gov.au

What information should be provided to patients regarding open disclosure?

See Section 5.1 of this guide for details of information to be provided to patients.

What information should be provided to staff regarding open disclosure?

A patient safety awareness culture should be fostered through communicating with staff about adverse events, including recommendations to minimise the risk of recurrence and consequent implementation of changes.

Health service organisations should identify a staff member responsible for communicating with staff on these issues.

Information may be provided by:

- electronic messages to all staff
- verbal reporting and discussions at staff meetings and shift handovers
- the immediate replacement of outdated policies and guidelines in departmental information sources

- regular clinical meetings to discuss recommendations, changes to be implemented and management of clinical risk as a routine part of the education and training of all staff
- clinical risk handbooks
- newsletters
- notice boards.

Where there has been a critical incident or sentinel event, or one that attracts media attention, a bulletin should be sent to staff to ensure that they have access to accurate information prior to seeing media reports. Staff should also be advised of the person responsible for media liaison and public enquiries.

As a manager, when should I be involved in the open disclosure process?

There will be some situations where you should take an active role in the disclosure interview. This may be where:

- A critical or sentinel event has occurred, and your participation may help to provide assurance to the patient and their family that the incident is viewed seriously by the organisation.
- The senior clinician involved requests your support.
- The investigation has revealed management issues in the causes of the event.
- Where there has been a breakdown in the relationship between the patient and the healthcare team.

What can I do as a manager to assist implementation of open disclosure?

The manager's role in assisting implementation of open disclosure is to create an organisational framework and culture that:

- puts patients' interests first, before that of the organisation, colleagues or self
- focuses on system improvement, not blaming individuals
- provides a supportive environment for staff involved in an adverse event
- ensures policies and guidelines that align with the *Australian Open Disclosure Framework* are developed and implemented.

Should adverse events be disclosed to patients where no harm is apparent?

While disclosure is required where harm has occurred, it may be appropriate to disclose even where no harm is immediately apparent. If there is reasonable likelihood of harm resulting in the future as a result of the adverse event, then disclosure should be initiated. This is a matter of judgement by the healthcare team.

Disclosing to the patient following the event allows them to take an active part in their care and to know potential signs and symptoms they should look out for. This will reduce the patient's concerns about any delays in their recovery and help to build trust between the patient and clinicians (see *Australian Open Disclosure Framework* Section 2.3).

How can I decide when something has happened that requires disclosure?

Open disclosure is required where a patient has suffered some unintended harm (physical or psychological) as a result of treatment. This may be a recognised complication, unanticipated incident, or a result of human or systems error. If the decision is made that the incident does not require disclosure this should be a decision that is defensible in public, and should be noted in the patient record (see *Australian Open Disclosure Framework* Sections 2 and 7).

Are there circumstances in which unintended harm has occurred and disclosure is not required?

The *Australian Open Disclosure Framework* advises that patient preference should be considered in relation to open disclosure, that is, there may be some cases where the timing of providing the open disclosure information could have a significant effect on the patient's ability to make decisions regarding their life. These decisions should be made on a case-by-case basis and the reasons for non-disclosure at that particular moment must be documented in the patient record. There is flexibility in determining the timing of disclosure to patients and their carers depending on several factors, including the condition of the patient and the availability of their support person (see *Australian Open Disclosure Framework* Section 9.2)

What should I do if a patient has suffered harm while under the care of a clinician or team from another institution or from outside your area of responsibility?

An adverse event may have occurred in an organisation or in another ward or department other than that in which it is identified. For example, it may be recognised that a post-operative patient in the ICU has suffered an adverse event during the surgery. First, establish whether the disclosure process has been initiated. If not, notify the senior clinician looking after the patient or the individual responsible for clinical risk in your own organisation (this should be determined by local policy). That person should establish whether:

- the adverse event has already been recognised
- the process of open disclosure has commenced elsewhere
- investigations are in progress.

If not, the open disclosure process should be initiated. Whenever possible, the investigation of the adverse event and the disclosure process should occur in the health care organisation where the adverse event originated. When this is not possible, the most senior clinician now looking after the patient should initiate the disclosure process. Care should be taken to disclose only known facts (see *Australian Open Disclosure Framework* Section 2.5).

What should I do where there has been an adverse event and the clinical team is unwilling to initiate the disclosure process?

Your organisation should have policies and guidance on the mechanism and reporting lines when this occurs, particularly in the case of the adverse event requiring immediate medical care. Maintain open communication with staff and explain the open disclosure process. Be supportive and help staff establish what to

discuss with the patient. If there is still an obvious reluctance to participate, you should explore the reasons why there is an unwillingness to disclose.

If staff members are concerned about litigation or loss of reputation, encourage them to contact their medical defence organisation or professional indemnifier to clarify their position. You may wish to facilitate the open disclosure process by offering to organise a meeting of the team or by providing assistance with the disclosure interview.

Does it cause more harm to let patients know when an adverse event has occurred?

All adverse events that have, or may have, caused harm or may have done so require disclosure. A patient may be unnecessarily concerned about a delay in their recovery or may not know why they are experiencing certain symptoms.

An example of this could be someone who bled more than expected in surgery. The patient feels tired and listless, and is unsure why. Several days later, blood tests indicate there is a need for a transfusion. Telling the patient of the blood loss and the potential signs and symptoms when it occurred initially, would have allowed the patient more active participation in their care and caused them less worry. They are then more able to watch for signs that will guide them to seek medical intervention that may be required to prevent further harm.

What are the rights of clinicians involved when an adverse event occurs and the open disclosure process is initiated?

Clinicians have rights that should be considered during the open disclosure process. The most relevant rights are:

- The right to seek appropriate legal advice and to disclose information to legal advisers in a manner that ensures that it attracts legal professional privilege
- The right to be treated fairly by the institution and to receive natural justice and procedural fairness
- The right not to be defamed
- The right – and on some occasions, the contractual obligation – to seek appropriate advice and guidance from their indemnity insurers or medical defence organisations.

What preparation is required for open disclosure discussions?

Preparation is important to ensure open disclosure meetings go as well as possible. Preparing for open disclosure will depend on your role in the process.

Firstly, open disclosure requires a specific set of skills. Health service organisations should ensure that:

- there is trained expertise amongst staff to lead open disclosure
- just-in-time information is provided to staff participating in open disclosure
- all staff are aware of the organisation's commitment to openly disclose adverse events and that they are encouraged, and will be supported, to do so.

When it is time to participate in open disclosure, the key elements which need to be in place include:

- establishing the facts (clinical and other facts)
- identifying immediate support needs for everyone involved
- assessing the event to determine the appropriate response
- identifying who will take responsibility for discussion with the patient
- considering the appropriateness of engaging patient support at this early stage, including the use of a facilitator or a patient advocate
- ensuring everyone involved maintains a consistent approach in any discussions with the patient
- considering legal and insurance issues and notify the relevant people
- considering how to address issues regarding ongoing care such as billing and other costs, which should be addressed at the earliest opportunity
- ensuring the patient record is up to date.

If participating with colleagues in open disclosure, preparatory meetings should be held to understand the issues and the individual responsibilities at the meeting.

It may be appropriate to rehearse some aspects of the conversation, such as the apology or expression of regret with the team. Often it is useful to go through the main elements of the information, including the apology or expression of regret.

Preparation should be balanced by responding appropriately to the patient and the way the meeting progresses. Patients may not feel that the discussion is sincere if it is stilted or otherwise perceived as insincere.

What contributes to successful open disclosure?

Following are some key actions by providers that can contribute to successful open disclosure:

- Establishing a good rapport and relationship with patients (and their support persons) from the very start of the episode of care.
- Ensuring informed consent is obtained and that the patient has reasonable expectations prior to undergoing the care, treatment or procedure.
- Accurately conveying the risks involved in the procedure and in health care generally.
- Ensuring that patient's support persons are identified formally.
- Acknowledging an unexpected event as soon as possible even if further investigation is required.
- Not speculating on the causes of an incident, making unrealistic promises or blaming yourself or others
- Being respectful to the patient, their support person and your colleagues at all times.
- Demonstrating remorse and compassion when talking to patients.
- Listening actively to the patient during disclosure discussions and being aware of your body language.

- Supporting your colleagues.
- Preparing for participation in open disclosure.

Does open disclosure create legal liability?

Open disclosure encourages clinicians to acknowledge that an adverse event has happened and to apologise or express regret for what has occurred.

Open disclosure does not, of itself, create legal liability. Acknowledging an adverse event, apologising or expressing regret, is not an admission of liability. Liability is established by a court and is based on an evidentiary matrix which may, in part, be based on statements made either before or after the event.

Health service organisation staff must be aware of the risk of making an admission of liability during open disclosure. In any discussion with the patient and their support persons during open disclosure, staff should take care not to speculate on the cause of an incident or pre-empt the results of any investigations. They must not apportion blame, or state or agree that they, other clinicians or health service organisations are liable for the harm caused to the patient.

The *Australian Open Disclosure Framework* provides guidance on what, and what not, to say when conducting open disclosure discussions, and highlights legal issues which should be considered, such as freedom of information, privacy, defamation, and qualified privilege.

Does an apology or an expression of regret mean admitting liability?

Legal advice suggests that an apology is not an admission of liability and that there are no legal impediments to an appropriately worded apology. It is not an admission of liability to:

- Say the words *I am* or *we are sorry*
- Explain how an adverse outcome occurred
- Acknowledge that the patient is not happy with the outcome
- Express your concern for the patient.

However, speculative statements and apportioning of blame to oneself, other individuals or institutions must be avoided.

Examples that may be useful are:

"I am very sorry this has happened";

"I am sorry that this hasn't turned out as expected".

For more information see *Australian Open Disclosure Framework* Section 1.5 and 10.2, and additional resources *Open disclosure: Guide for health service managers* and *Saying Sorry: a guide to apologising and expressing regret during open disclosure,* both available at www.safetyandquality.gov.au/opendisclosure

Will open disclosure increase litigation?

There is no conclusive evidence that open disclosure either increases or decreases litigation. Current literature states that if a patient is told about an adverse event and

they are treated quickly and harm prevented or minimised, the patient may be less inclined to pursue legal action.

In taking an active approach, you or your clinical staff may be able to talk to the patient in a way that defuses anger and restores trust. In some cases it may be appropriate, after consultation with the clinical team, management and insurers, to recommend a prompt and fair out of court settlement. When you offer support for follow up or additional treatment, it doesn't necessarily mean your organisation is accepting liability. For more information see *Australian Open Disclosure Framework* Section 4.3 *Open disclosure: Guide for health service managers* and *Saying Sorry: a guide to apologising and expressing regret during open disclosure,* both available at www.safetyandquality.gov.au/opendisclosure).

Litigation may be reduced if patients appreciate the fallibility and honesty of the clinician. If you or your clinical team do not disclose and serious mistakes come to light later on, the patient may think it is an attempt to cover up and become angry and litigious.

Appendix 1: Glossary

Accreditation	A status that is conferred on a health service organisation or individual when they are assessed as having met particular standards relating to quality of care and patient safety.
Admission of liability	A statement by a person that admits, or tends to admit, a person's or organisation's liability in negligence for harm or damage caused to another.
Adverse event	An incident in which harm resulted to a person receiving health care. Note: This term is used interchangeably with 'harmful incident'. See *Harm*
Adverse outcome	An outcome of an illness or its treatment that has not met the clinician's or the patient's expectation for improvement or cure.
Apology	An expression of sorrow, sympathy and (where applicable) remorse by an individual, group or institution for a harm or grievance. It should include the words 'I am sorry' or 'we are sorry'. Apology may also include an acknowledgment of responsibility, which is not an admission of liability. See also *Admission of liability, Expression of regret*
Carer	A person who provides unpaid care and support to family members and friends who have a disability, mental illness, chronic condition, terminal illness or general frailty. Carers include parents and guardians caring for children.[1] A person is not a carer if he or she provides this support and assistance under a contract of service or a contract for the provision of services, or in the course of doing voluntary work for a charitable, welfare or community organisation, or as part of the requirements of a course of education or training.[2]
Clinical risk	The combination of the probability of occurrence of harm and the severity of that harm.
Clinical risk management	See *Risk management*
Clinical workforce	The nursing, medical and allied health professionals who provide patient care, and students who provide patient care under supervision. This may also include laboratory scientists.
Clinician	A healthcare provider who is trained as a health professional. Clinicians include registered and non-registered practitioners, or a team of health professionals who spend the majority of their time providing direct clinical care.
Commission	Australian Commission on Safety and Quality in Health Care
Complication	A detrimental patient condition that arises during the process of providing health care.[3]
Consumer	Patients and potential patients, carers and organisations representing consumers' interests.[4]
Corporate risk	Potential liabilities, exposures and dangers faced by an organisation or corporation. These can be financial or reputational.

Corporate risk management	See *Risk management*
Disability	Any type of impairment of body structure or function, activity limitation or restriction of participation in society.
Error	Failure to carry out a planned action as intended or application of an incorrect plan through either doing the wrong thing (commission) or failing to do the right thing (omission) at either the planning or execution phase of healthcare intervention.[3]
Ex gratia	'Out of good will', usually referring to financial reimbursement or recovery payments. By definition, ex gratia payments are not an admission of liability.
Expression of regret	An expression of sorrow for a harm or grievance. It should include the words 'I am sorry' or 'we are sorry'. An expression of regret may be preferred over an apology in special circumstances (e.g. when harm is deemed unpreventable). See also *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.[3]
Harmful incident	An incident that led to patient harm. Such incidents can either be part of the healthcare process, or occur in the healthcare setting (i.e. while the patient is admitted to, or in the care of, a health service organisation). Note: This term is used interchangeably with 'adverse event'.
Health care	The prevention, treatment and management of illness and the preservation of mental and physical wellbeing through the services offered by the medical and allied health professions.
Healthcare record	See *Patient record*
Health service organisation	A separately constituted health service that is responsible for the clinical governance, administration and financial management of a service unit providing health care. A service unit involves a group of clinicians and others working in a systematic way to deliver health care to patients. This can be in any location or setting, including pharmacies, clinics, outpatient facilities, hospitals, patients' homes, community settings, practices and clinicians' rooms. Unless specified the term *health service organisation* includes all of these and other settings in which health care is provided.
Health service contact	A nominated employee of the health service organisation who acts as an ongoing point of contact and provides information and support to the patient throughout the open disclosure process.
Higher level response	A comprehensive open disclosure process usually in response to an incident resulting in death or major permanent loss of function, permanent or considerable lessening of body function, significant escalation of care or major change in clinical management (e.g. admission to hospital, surgical intervention, a higher level of care or transfer to intensive care unit), or major psychological or emotional distress. These criteria should be determined in consultation with patients, their family and carers. A higher level response may also be instigated at the request of the patient even if the outcome of the adverse event is not as severe. See also *Lower level response*

Incident	See *Adverse event*
Liability	The legal responsibility for an action.
Lower level response	A briefer open disclosure process usually in response to incidents resulting in no permanent injury, requiring no increased level of care (e.g. transfer to operating theatre or intensive care unit), and resulting in no, or minor, psychological or emotional distress (e.g. near misses and no-harm incidents),. These criteria should be determined in consultation with patients, their family and carers. See also *Higher level response*
Medical record	See *Patient record*
Multidisciplinary team	A healthcare team comprising individuals from various professions (nursing, medical, allied health, administrative, management) and disciplines within these professions.
National Safety and Quality Health Service (NSQHS) Standards	A set of standards which provide a clear statement about the level of care consumers can expect from health service organisations. They also play an essential part in accreditation arrangements which commenced in January 2013. See also *Accreditation*
Near miss	An incident that did not cause harm but had the potential to do so.[5]
Next of kin	Synonymous with family member and may include: • spouse or domestic partner • son or daughter who has attained the age of 18 • parent • brother or sister, who has attained the age of 18.
No-harm incident	An error or system failure that reaches the patient but does not result in patient harm.
Nominated contact person	Any individual who is formally identified by the patient as a nominated recipient of information regarding their care in accordance with local processes and legal requirements.
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 (including the word sorry), a factual explanation of what happened, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence. Open disclosure is a discussion and an exchange of information that may take place over several meetings.
Outcome	The status of an individual, a group of people or a population that is wholly or partially attributable to an action, agent (i.e. one who/which acts to produce a change) or circumstance (i.e. all factors connected with influencing an event, agent or person).

Patient	A person receiving health care. Synonyms for patient include 'consumer' and 'client'. In this document, patients can also refer to support persons such as family members and carers. See also *Support person*
Patient harm	See *Harm*
Patient record	Consists of, but is not limited to, a record of the patient's medical history, treatment notes, observations, correspondence, investigations, test results, photographs, prescription records and medication charts for an episode of care.
Patient safety	The reduction of risk of unnecessary harm associated with health care to an acceptable minimum. An acceptable minimum refers to the collective notions of current knowledge, resources available and the context in which care was delivered, weighed against the risk of non-treatment or other treatment.[3]
Qualified privilege legislation	Qualified privilege legislation varies between jurisdictions but generally protects the confidentiality of individually identified information that became known solely as a result of a declared safety and quality activity. Certain conditions apply to the dissemination of information under qualified privilege.
Quality (health care)	The degree to which health services increase the likelihood of desired outcomes and are consistent with current professional knowledge.
Quality improvement	The continuous study and adaptation of a healthcare organisation's functions and processes to increase the probability of achieving desired outcomes and better meet the needs of patients and other users of services.
Reimbursement	The act of paying for somebody's expenses without an admission of liability.
Risk	The chance of something happening that will have a negative effect. It is measured by consequences and likelihood.
Risk management	The design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the institution. **Clinical risk management** 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. **Corporate risk management** Activities of an organisation or corporation to identify and reduce potential financial or reputational liabilities, exposures and dangers.
Service recovery	The process used to 'recover' dissatisfied individuals or patients by identifying and fixing the problem, or making amends for the failure in customer or clinical services
Staff	Anyone working within a health service organisation, including self-employed professionals such as visiting medical officers.
Statute	A written law passed by a legislature at the state or federal level.

Support person	An individual who has a relationship with the patient. References to 'support person' in this document can include: • family members / next of kin • carers • friends, a partner or other person who cares for the patient • guardians or substitute decision makers • social workers or religious representatives • where available, trained patient advocates. References to support person 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.

Appendix 2: Examples of open disclosure implementation frameworks

A2.1 The 4-A framework

The 4-A Framework is a model for implementing and managing open disclosure in a healthcare organisation. It consists of the following components: awareness, accountability, ability, action. The model is summarised in the following table:

The 4-A Framework to assist organisational open disclosure (adapted from Gallagher 2007)[D]

Awareness	Heighten awareness of open disclosure and its importance through education, promotion and leadership. This may include: • conducting clinical-microsystem-level needs assessment and organisation-wide surveys • identifying gaps in practice — engage consumers and patients to provide their views and experiences directly to staff • sharing information and experiences, especially those of senior staff • including senior staff in workshops • providing comprehensive education for staff • make open disclosure part of official induction and orientation
Accountability	Create accountability, thereby promoting a transparent system Clearly delineate who is accountable and have a clear reporting structure Define accountabilities and responsibilities in policy Use structure, process and outcome measures (e.g. number of staff trained, percentage adverse events openly disclosed, clinician and patient satisfaction)
Ability	Furnish and build into the organisation the ability and confidence to disclose Integrate open disclosure with other clinical governance and quality improvement policies especially risk, clinical incident management and complaints Establish a comprehensive training and education strategy Train some experts and provide basic awareness to ALL staff Educate a cohort of staff to be open disclosure consultants Provide around-the clock support for patients and staff Foster a collegiate, team approach 'Normalise' open disclosure — make it routine
Action	Convert the ability into action Engage leadership in 'top down' support Actively champion open disclosure Provide simulation to develop and maintain confidence and skills Instil realistic expectations among staff Link open disclosure with other improvement activity

[D] Gallagher TH, Denham CR, Leape LL, Amori G, Levinson W. Disclosing unanticipated outcomes to patients: the art and practice. Journal of Patient Safety 2007;3(3):158-165.

A2.2 National Quality Forum guideline

In 2006 the National Quality Forum endorsed a 'safe practice guideline' for open disclosure. The key elements are shown in Table 9.

Key elements of the National Quality Forum safe practice guideline[E]

Content to be disclosed: • Facts about the event • Error or system failure, if known • Results of event analysis to support informed decision making by the patient • Regret for the unanticipated outcome • Formal apology if unanticipated outcome is caused by error or system failure
Institutional requirements Integrate disclosure, patient safety and risk management activities Establish disclosure support systems: • provide background disclosure education • ensure that disclosure coaching is available at all times • provide emotional support for health care workers, administrators, patients, and families • use performance improvement tools to track and enhance disclosure

A2.3 T.R.A.C.K.

The T.R.A.C.K acronym was proposed by Truog and colleagues for five core relational values that enable sound open disclosure. These are transparency, respect, accountability, continuity and kindness. An adapted version is presented in the table below.

The T.R.A.C.K. framework (adapted from Truog 2007)[F]

Value	Definition	Optimal patient and staff outcome
Transparency	Being frank, open and obvious	'I've had timely access to the information and input I needed'
Respect	Esteem for the intrinsic value of a person	'I've been valued as a human being by the people helping me' 'I've been respected throughout the process by my colleagues and management'
Accountability	Being answerable or called to account for intent, decision and actions	'The right people have assumed responsibility for their actions'
Continuity	Continuous and connected actions and activity over a period of time	'The care I've received makes sense and fits together'
Kindness	Acting in a caring, considerate and compassionate manner	'I've been treated with warmth, empathy and compassion'

[E] Gallagher TH, Studdert D, Levinson W. Disclosing Harmful Medical Errors to Patients. The New England Journal of Medicine 2007;356(2007):2713-9
[F] Truog RD, Browning DM, Johnson JA, Gallagher TH. Talking with Patients and Families about Medical Error: A Guide for Education and Practice. Baltimore: Johns Hopkins University Press, 2011

Appendix 3: Open disclosure process flowchart

Figure 1: Higher-level response (S = Section of Framework)

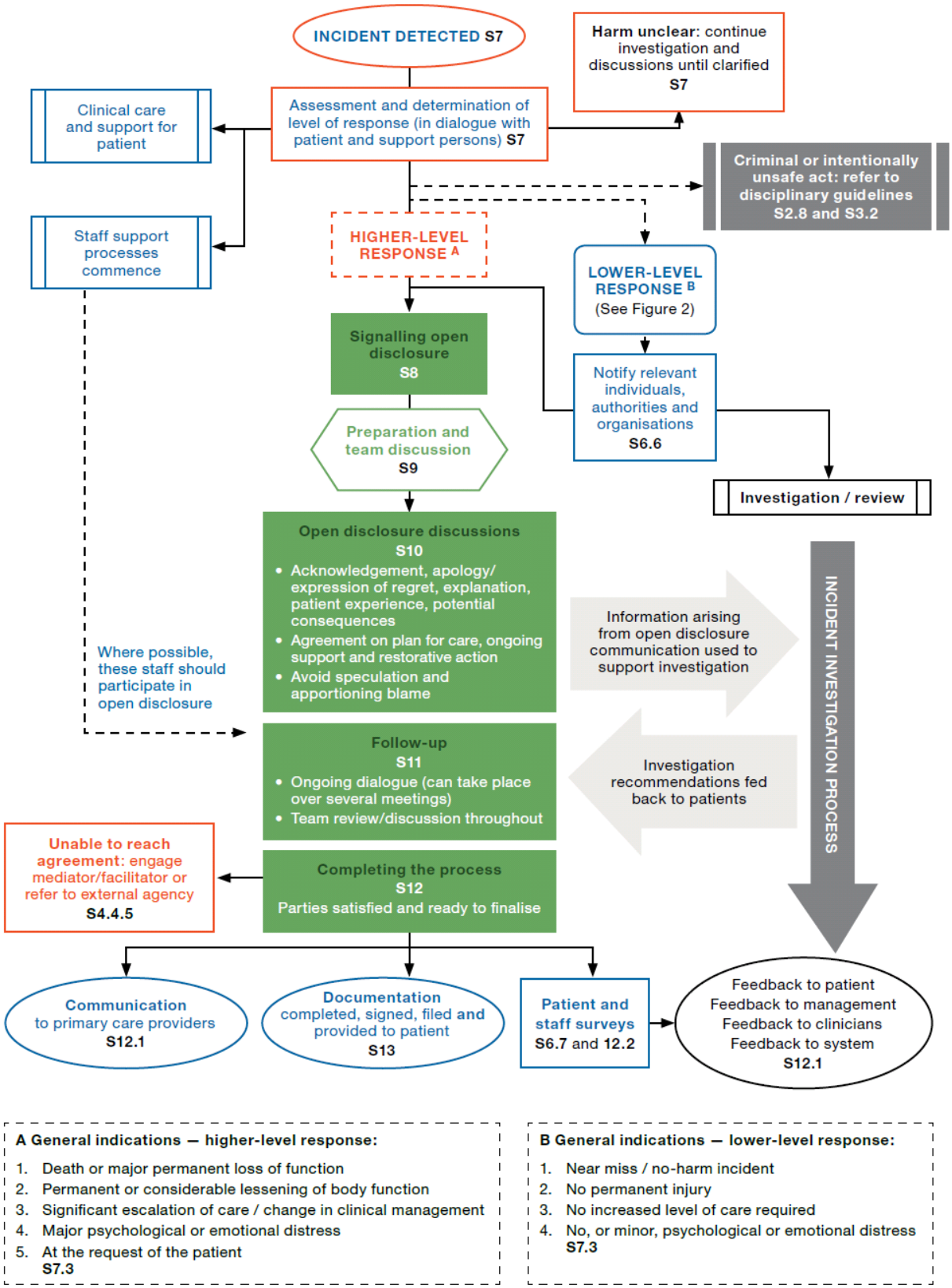
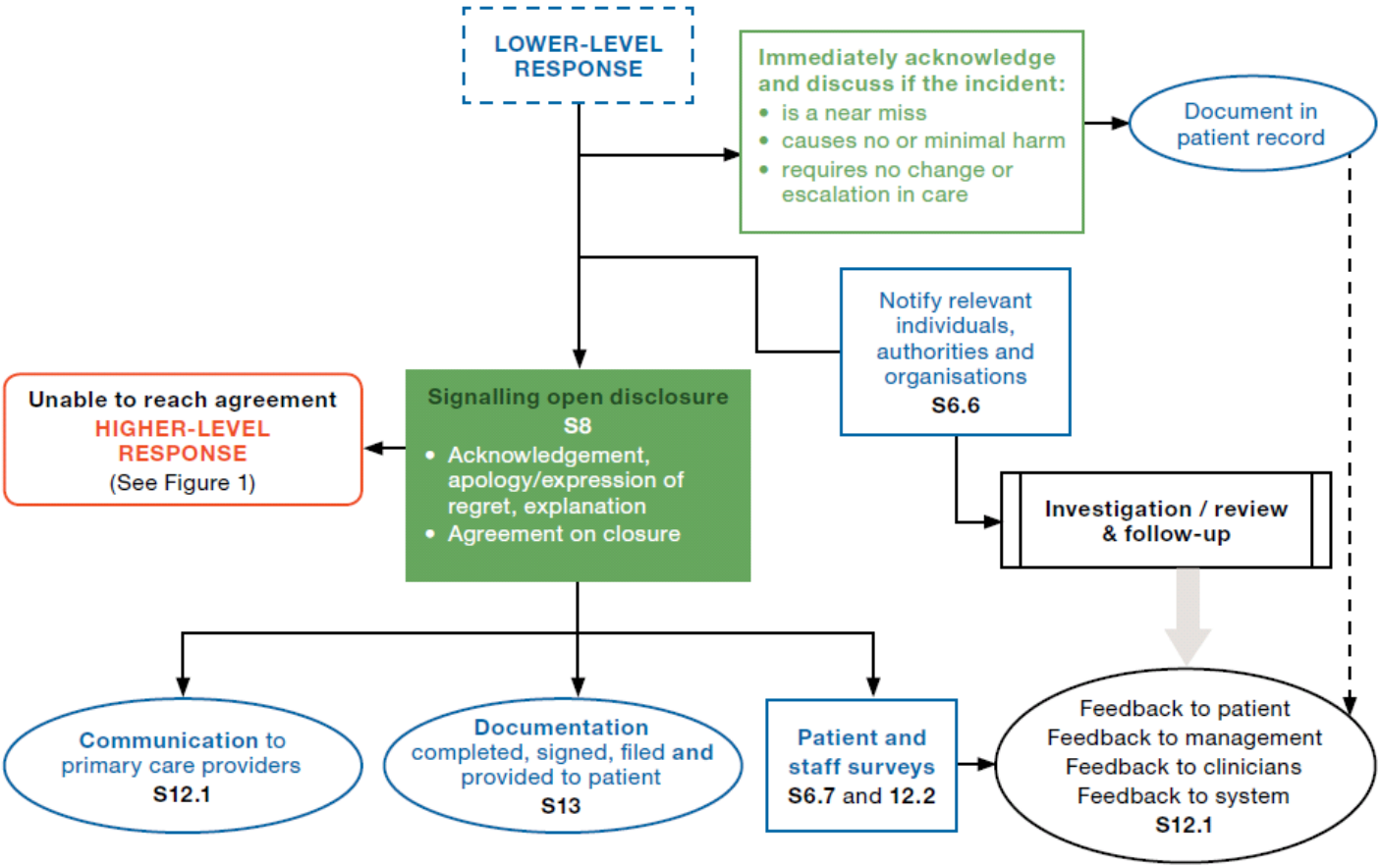


Figure 2: Lower-level response (S = Section of Framework)



Appendix 4: Examples and criteria for open disclosure responses following adverse events

Table A4.1: Potential responses to various situations and incidents

Incident type	Response
1. Harm from natural progression of condition or disease process *e.g. a treatment for cancer was unsuccessful*	**Discuss and explain** ***(lower-level)***
2. Complication or natural disease progression a. Anticipated by patient/family via education and consent process b. Not anticipated by patient/family via education and consent process (**go to 3**) *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*	**a. Discuss and explain** ***(lower-level)*** **b. Open disclosure** ***(higher or lower- level depending on severity)***
3. Patient harm/adverse event *e.g. Adverse drug event (wrong dose medication)*	**Open disclosure** ***(higher or lower-level depending on severity and impact on patient)***
4. Clinical ('no harm') incident: reaches patient but no harm *e.g. Medication error (no/minimal effect on patient)*	**Generally disclose** ***(lower-level)***
5. Clinical ('near miss') incident: does not reach patient *e.g. an intercepted wrong-patient biopsy*	**Team decision based on:** • context • circumstances • potential ramifications ***(lower-level)***
6. Patient perception or report of harm *e.g. patient perception of delay in diagnosis resulting in poor patient outcome*	**Discuss and agree on appropriate form of disclosure** ***(higher or lower- level)***

Table A4.2: Criteria for determining the appropriate level of response to an incident

	Criteria
Lower-level response	1. Near misses and no-harm incidents 2. No permanent injury 3. No increased level of care (e.g. transfer to operating theatre or intensive care unit) required 4. No, or minor, psychological or emotional distress
Higher-level response	1. Death or major permanent loss of function 2. Permanent or considerable lessening of body function 3. Significant escalation of care or major change in clinical management (e.g. admission to hospital, surgical intervention, a higher level of care, or transfer to intensive care unit) 4. Major psychological or emotional distress 5. At the request of the patient