Safety and Quality

TOOL 3

Open Disclosure

Comprehensive guide on open disclosure process for clinical leads / facilitators

Government of South Australia

SA Health

Contents

1. Introduction

The SA Health Comprehensive Guide on Open Disclosure Process for Clinical leads / Facilitators (Tool 3) has been adapted from the Australian Commission on Safety and Quality in Health Care Australian Open Disclosure Framework[1] and 'Just-in-time' information for healthcare professionals[2] and contributes to the National Safety and Quality in Health Service (NSQHS) Standard 1 – Governance for Safety and Quality in Health Service Organisations

> Standard 1.16 – implementing an open disclosure process based on the Australian Open Disclosure Framework.

The SA Health Comprehensive Guide on the open disclosure process for clinical leads / facilitators is to be read in conjunction with the SA Health Patient Incident Management and Open Disclosure Policy Directive. The policy directive establishes a consistent approach to open disclosure enabling health care services and clinicians to communicate openly and honestly with patients / consumers when an incident occurs. All SA Health employees or persons who provide health services on behalf of SA Health must adhere to the SA Health Patient Incidents – Management and Open Disclosure Policy Directive.

The SA Health Comprehensive Guide on the open disclosure process for clinical leads / facilitators (Tool 3) provides more detailed information on the formal open disclosure process, and tools for open disclosure clinical leads and facilitators.

The SA Health Open Disclosure Comprehensive Guide (Tool 3) is to be read in conjunction with the SA Health Patient Incident Management and Open Disclosure Policy Directive. The comprehensive guide provides information on the level 1 and level 2 responses to open disclosure and the process.

The SA Health Saying sorry – a guide to expressing regret during open disclosure (Tool 2) provides staff with information and examples on appropriate wording and phrasing for the open disclosure process, as an expression of regret.

Patient / consumer information has been developed to provide information on the open disclosure process. Resources include:

> A brochure for patients / consumers on open disclosure (Tool 4)
> A guide for patients / consumers beginning an open disclosure process (Tool 5)
> A flowchart for patients / consumers on the open disclosure process (Tool 6)
> Frequently asked questions for patients / consumers on open disclosure and the process. (Tool 7)

What is open disclosure?

Open disclosure describes the way clinicians communicate with, and support, patients and/or their families, carers or other support persons (from here on referred to as 'the patient and their support persons') 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 incidents. Being open about incidents also helps organisations learn and provide safer and higher quality care.

Open disclosure is complex, and can be challenging and difficult for all participants. However, its systematic practice can assist health service organisations to manage incidents compassionately and provide broader benefits through improved clinical communication and systems improvement.

1 Australian Open Disclosure Framework, Australian Commission on Safety and Quality in Health Care (ACSQHC)
2 Open Disclosure: 'Just-in-time' information for healthcare providers, Australian Commission on Safety and Quality in Health Care

Open disclosure is:

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

Open disclosure is an open discussion with a patient / consumer about an incident(s) that resulted in harm to that patient / consumer. while they were receiving health care. Open disclosure discussions also include the patient's family, carer and / or support person.

An incident might be identified:

- by a clinician or staff member at the time of the incident
- by clinicians respectively when an unexpected outcome is detected
- by a patient / consumer, their family, carer and / or support person at the time of the incident or retrospectively
- through established consumer feedback or complaints mechanisms
- through incident detection systems, such as the Incident Management module in Safety Learning System or patient medical / case note record review
- from other sources such as detection by other patients, visitors, students or other staff.

Open disclosure is the open discussion of incidents that result in harm to a patient while receiving health care with the patient and their support persons. The elements of open disclosure are:

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

It is important to note that open disclosure is not a one-way provision of information, although providing information to the patient is important as is hearing their view of events. Open disclosure is a discussion between two parties that may take place in several meetings over a period of time.

What is an 'incident', patient 'harm' and 'no harm / near miss'

The Australian Open Disclosure Framework uses the World Health Organization definition of harm:

> *'[i]mpairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological'* [3]

An **incident** means: any event or circumstance which could have (near miss) or did lead to unintended and/or unnecessary psychological or physical harm to a person or patient/consumer and/or to a complaint, loss or damage during an episode of health care.

A **harmful incident (harm)** means any event or circumstance which resulted in unintended and/or unnecessary psychological or physical harm to a patient and/or to loss or damage during an episode of health care.

A **near miss incident or no harm** means: a patient incident that did not cause harm, but had the potential to do so. An arrested or interrupted sequence where the incident was intercepted before causing harm. The incident cannot be a near miss if the pati ent / consumer was harmed or injured.

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

3 World Health Organization. The International Classification for Patient Safety WHO, 2009

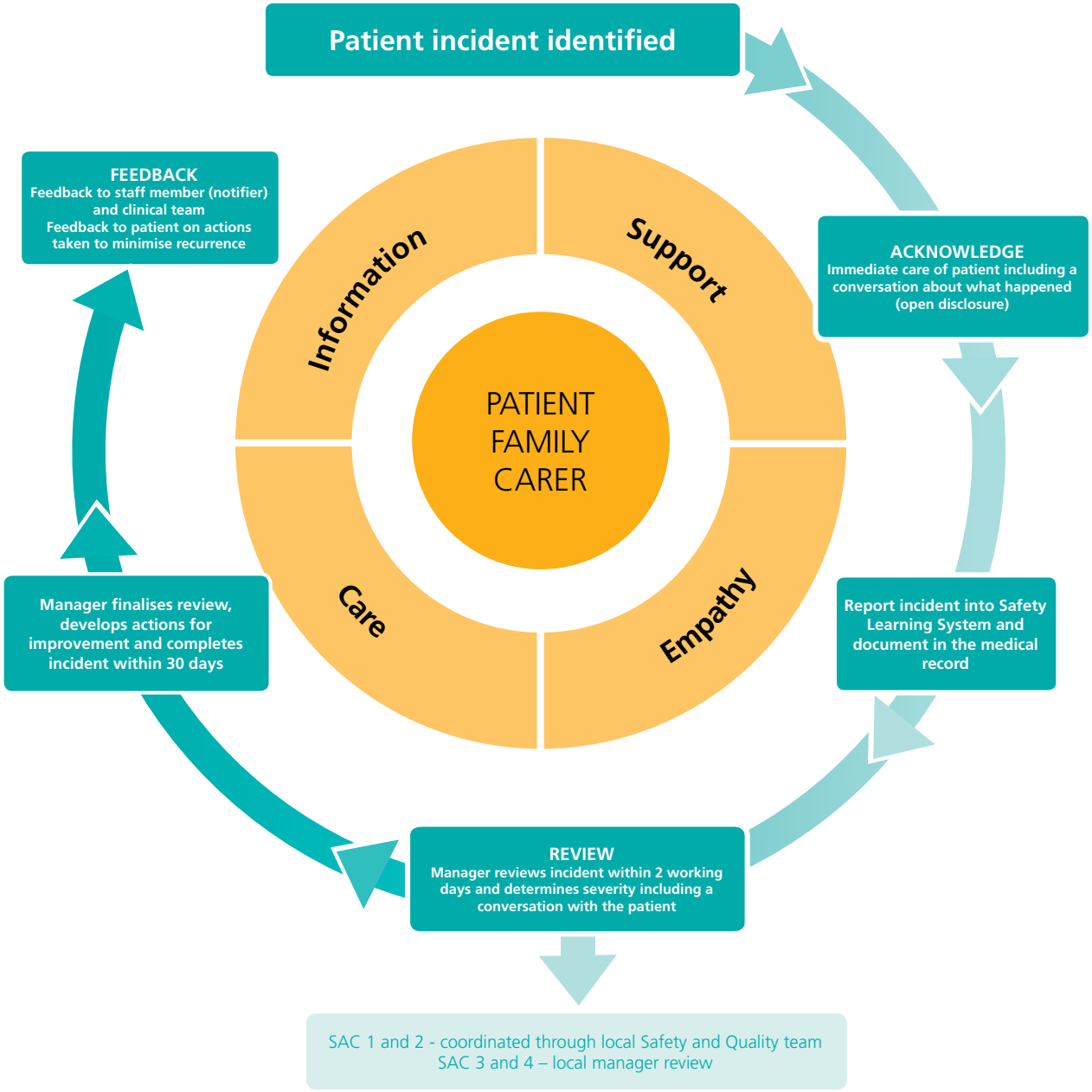
Incident management and open disclosure

After an incident, two (2) separate but integrated processes are initiated, both of which are essential to all people involved.

- Open disclosure – that will assist the patient / consumer, family, carer and /or support person in their recovery from the incident
- Incident reporting, investigation, analysis and action to improve practices – these benefit staff, the health service and the patient / consumer through improvement of safety and quality of services.

Diagram 1 summarises these processes.
Horizontal arrows indicate where the two processes can link.

Patient Incident Management and Open Disclosure Process



2. Principles

Open disclosure principles and processes are as follows:

Open and timely communication
The patient / consumer, their family, carers and / or support person should be provided with information about what happened in a timely, open and honest manner. The open disclosure process is fluid and will often involve the provision of ongoing information.

Acknowledgement
All incidents should be acknowledged to the patient / consumer, their family, carer and / or support person as soon as practicable. Health service organisations should acknowledge when an incident has occurred and initiate open disclosure.

Expression of regret
As early as possible, the patient / consumer, their family, carers and / or support person receive an expression of regret for any harm that resulted from an incident. An expression of regret should include the words *I am sorry'* or *'we are sorry that this has happened. I realise it has caused great pain / distress / anxiety or worry'*, but must not contain speculative statements, admission of liability or apportioning of blame.

Supporting, and meeting the needs and expectations of patients / consumers, their family, carers and /or support person
The patient / consumer, their family, carer and / or support person can expect to be:

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

Supporting, and meeting the needs and expectations of those providing health care
Health service organisations should create an environment in which all staff are:

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

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

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

Confidentiality
Policies and procedures should be developed by health service organisations with full consideration for patient / consumer 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.*

3. Level 1 (SAC 1 and 2) and Level 2 (SAC 3 and 4) open disclosure criteria and response

There are two (2) levels of responses to open disclosure, that is level 1 and level 2 responses, linked to criteria for harm that may be used to delineate level 1 and level 2 responses.

It is important to consider that patients / consumers, their families and carers can potentially suffer further emotional harm if post incident communication is managed insensitively. A level 2 response should only be initiated if the risk of further harm (from not conducting level 1 open disclosure) is unlikely. Where uncertainty exists, a level 1 response should be initiated.

Flow charts on the level 1 and level 2 responses are presented on pages 10 and 11.

Table 1: Criteria for determining the appropriate level of response - outlines the incident type, level response and criteria.

Incident type	Criteria
Level 1 = SAC 1 or 2 **Harm incident**	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 (eg admission to hospital, surgical intervention, a higher level of care, or transfer to intensive care unit) 4. Major psychological or emotional distress 5. Significant patient / consumer, family and / or concern arising from incident. 6. Incidents which may involve media interest or cluster incidents.
Level 2 = SAC 3 or 4 **Near miss or no harm incident**	1. Near misses and no-harm incidents 2. No permanent injury 3. No increased level of care (eg transfer to operating theatre or intensive care unit), required 4. No, or minor, psychological or emotional distress

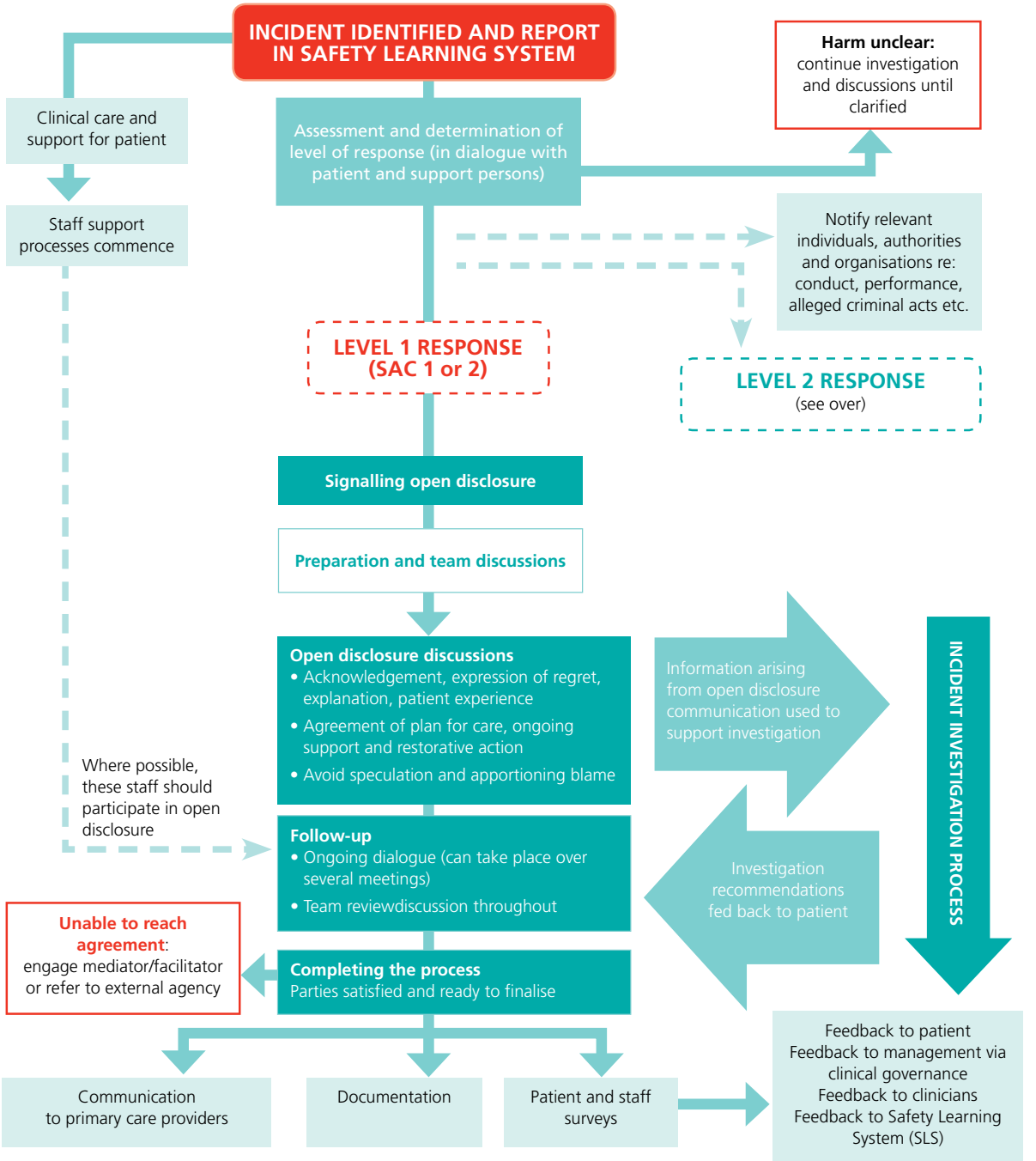
The incident response will be determined by the effect, severity or consequence of the incident.

Examples of incident types and suggested responses are described in table 2.

Table 2: Potential responses to various situations and incidents

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

4. Flow chart - Level 1 open disclosure for SAC 1 and 2 incident



Level 1 response

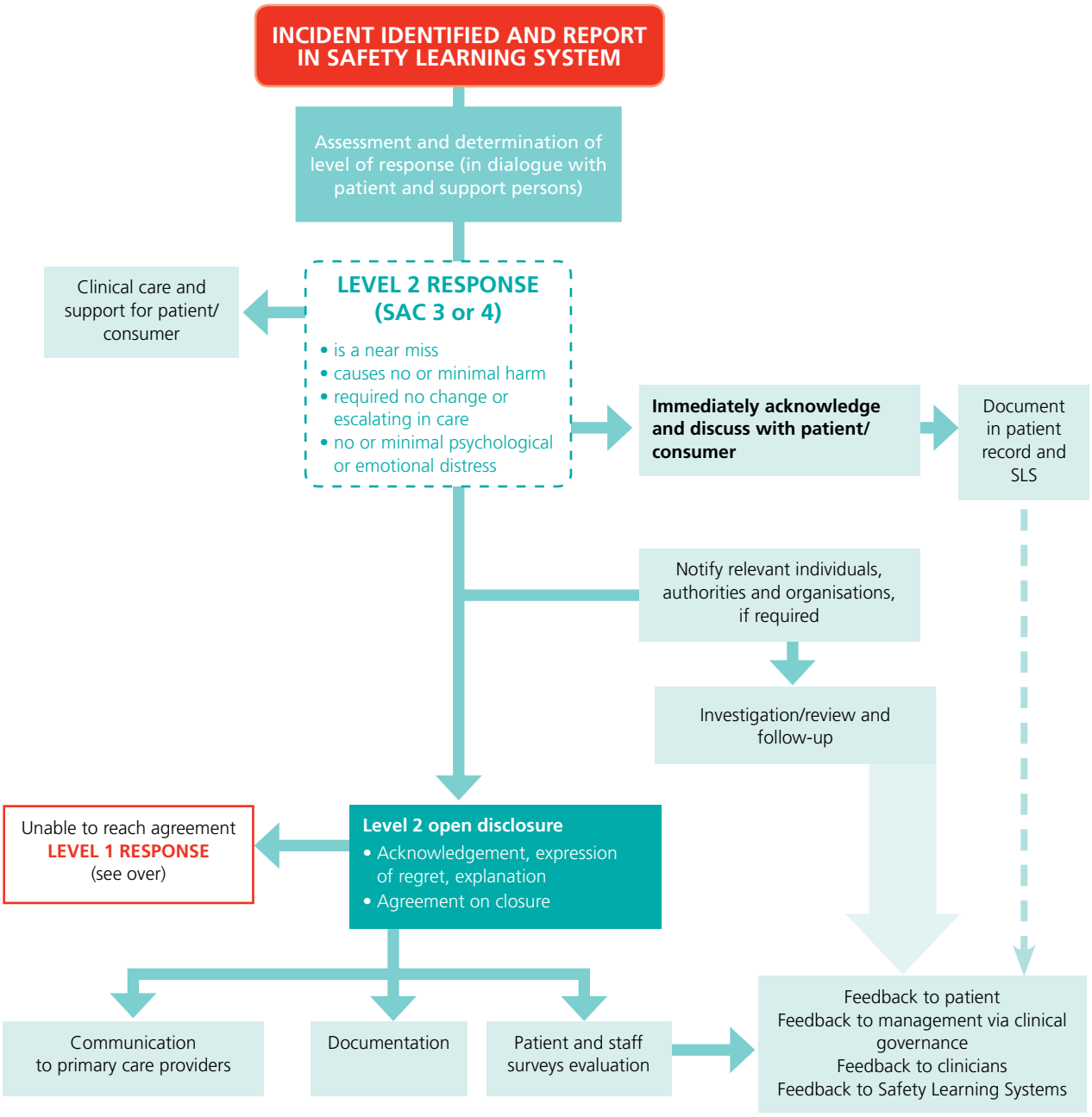
1. Death or major permanent loss of function
2. Permanent or considerable lessening of body function
3. Significant escalation of care/change in clinical managment
4. Major psychological or emotional distress
5. Significant patient/consumer, family or carer concern arising from incident
6. Incidents which may involve media interest
7. Cluster incidents
8. Extreme and unexpected poor outcome or avoidable complication of care

Level 2 reponse:

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

Australian Commission on Safety and Quality in Health Care (2013) *Open disclosure principles, elements and process* ACSQHC, Sydney

5. Flow chart – Level 2 open disclosure for SAC 3 and 4 incident



Australian Commission on Safety and Quality in Health Care (2013) *Open disclosure principles, elements and process* ACSQHC, Sydney

6. Open disclosure process, key considerations and actions

The open disclosure process is summarised in table 3, which outlines the elements of key considerations and actions during the open disclosure process.

Table 3: Key considerations and actions during the open disclosure process

Process	Key considerations and actions
1. Detecting and assessing incidents All incidents	> detect incident 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 level 1 and 2 > notify relevant personnel and authorities > ensure privacy and confidentiality of patients / consumers and clinicians are observed.
2. Signalling the need for open disclosure SAC 1 and 2 incidents Further information is available in the SA Health Comprehensive Guide on open disclosure process for clinical leads / facilitators	> acknowledge the incident to the patient / consumer, their family, carer and / or support person including an expression of regret > **a level 2 response can conclude at this stage** **Level 1 response** > signal the need for open disclosure > negotiate with the patient / consumer, their family carer and / or support 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 / consumer, their family, carer and / or support person > avoid speculation and blame > maintain good verbal and written communication throughout the open disclosure process.

Level 1 response

Incidents which have caused significant harm (SAC 1 and 2) will require level 1 responses for open disclosure. This will involve the Open Disclosure Clinical Lead / Facilitator to lead the process.

An overview of the level 1 response formal open disclosure process is available in table 4.

Table 4: Level 1 response process

Process	Key considerations and actions
Preparing for open disclosure	> 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 patient / consumer, their family, carers and / or support person > gather all the necessary information > identify the health service contact for the patient / consumer, their family, carer and / or support person (if this is not done already).

Process	Key considerations and actions
Engaging in open disclosure discussions	> provide the patient / consumer, their family, carer / and or support person with the names and roles of all attendees > provide a sincere and unprompted expression of regret including the words *'I am sorry'* or *'we are sorry that this has happened. I realise it has caused great pain / distress / anxiety / worry'*. > clearly explain the incident > give the patient / consumer, their family, carer and / or support person the opportunity to tell their story, exchange views and observations about the incident and ask questions > encourage the patient / consumer, their family, carer and / or support person to describe the personal effects of the incident > agree on, record and sign an open disclosure plan > assure the patient, their family and carers and / or support that they will be informed of further investigation findings and recommendations for system improvement > offer practical and emotional support to the patient / consumer, their family, carers and / or support person > support staff members throughout the process > if the incident took place in another health service organisation, include relevant staff if possible > if necessary, hold several meetings or discussions to achieve these aims.
Providing follow up	> 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 / consumer, their family, carers and / or support person the opportunity to discuss the process with another clinician (eg a general practitioner).
Completing the process	> reach an agreement between the patient / consumer, their family, carer and / or support person and the clinician, or provide an alternative course of action > provide the patient / consumer, their family, carers and / or support person with final written and verbal communication, including investigation findings > communicate the details of the incident, and outcomes of the open disclosure process, to other relevant clinicians > complete the patient / consumer and staff evaluation surveys.
Maintaining documentation	> keep the patient record up to date > maintain a record of the open disclosure process using the Safety Learning System Incident Management Module > file documents relating to the open disclosure process in the patient record > provide the patient with documentation throughout the process.

7. Patient and staff considerations

Open disclosure describes the way clinicians communicate with and support patients / consumers, their family, carers and / or support person, who have experienced harm during health care.

Open disclosure is a patient right, and is anchored in professional ethics, considered good clinical practice, and is part of the care continuum.

Patient considerations

After experiencing harm, patients / consumers expect prompt acknowledgement and open communication. It is important that patients / consumers, their family, carers and / or support person are shown empathy, openness and honesty, and are given reassurance and support.

Patient / consumers, their family, carers and / or support person should be encouraged to ask questions.

Patient / consumer information

Patient / consumer information has been developed to provide information on the open disclosure process. Resources include:

- A brochure for patients / consumers on open disclosure
- A guide for patients / consumers beginning an open disclosure process
- A flowchart for patients / consumers on the open disclosure process
- Frequently asked questions for patients / consumers on open disclosure and the process.

Further information is available in Tools 4 – 7 Patient / consumer information.

Key patient considerations:

- communication (verbal and written) and consider patient needs including:
  - children
  - mental health conditions
  - interpreter for the cultural and linguistically diverse
  - aboriginal and torres strait islander liaison officer
  - hearing or vision impaired
  - people with a disability
  - cognitive impairment
- show empathy, openness, honest and give reassurance
- advocacy and support
- reimbursement of out-of-pocket expenses
- avoidance of repeat harm to another
- other individual circumstances

Communication

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

Ensuring that communication after an incident is open, honest and timely is important to improving patient safety. Open disclosure is already occurring in many areas of the health system, and the SA Health Patient Incidents – Management and Open Disclosure Policy Directive and tools form a basis for more consistent and effective communication following an incident. This includes communication between clinicians and:

- patients / consumers, family, carer and / or support person
- their colleagues and peers
- the non-clinical workforce.

Communicating early

Communicating early as part of the open disclosure process is paramount, all care (including how well the patient / consumer – clinician relationship is established) can influence the outcome of open disclosure. This may include the following:

- ensuring that the consent process is thorough and the patient understands all the aspects of the procedure and treatment
- formally nominating support person/s
- engendering trust through open communication and other behaviours
- providing information on the roles and responsibilities of patients / consumers in decision-making (while at the same time respecting any decision to defer this to the healthcare team)
- providing information on open disclosure in the event that things go wrong
- documenting all relevant information in the patient record and on the Safety Learning System Incident Management module.

Communication is essential

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

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

The following outcomes include:

- ensuring early identification of the patient's needs by documenting at the time of admission:
  - the name of the patient's nominated contact, this person may not be the same as the patient's next of kin or other support person.
  - whether the patient may require an interpreter.
- encouraging patients / consumers to be actively involved in their care, and to notify the clinical team of any issues or conditions that may affect their care
- providing assurance that ongoing care plan will be developed in consultation with the patient / consumer, their family, carer and / or support person and that the plan will be followed through
- providing information about open disclosure at the beginning of the episode of care
- include the patient's / consumer's family, carer and / or support person in discussions about an incident, where the patient agrees
- provide information about the incident to the patient / consumer, their family, carer and / or support person
- provide information about the open disclosure process to the patients / consumers, their family, carer and / or support person, verbally and in writing, and in a language or communication style that they understand throughout the process
- ensure that, if a patient / consumer chooses to refrain from active engagement in their care and defer decision making to the clinical team, the patient remains informed of the care process at all times.

Particular patient circumstances

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

When a patient dies

It is crucial that communication with people who were close to the patient / consumer is sensitive, empathic and open.

- establish open channels of communication to allow support persons to indicate if counselling or other assistance is needed
- in the cases of untimely, unexpected or unexplained death, explain the process for reporting to the coroner and provide them with information they can expect to receive, and the timeframes for the coronial process
- ensure families', carers and other persons are kept up to date with what is happening, and that personal contact is maintained by the health care service throughout the coronial process.

Children

When an incident involves a child, the clinical team will, together with parents need to make informed but complex assessments of what the child should be told.

In the case of young people who may have legal competency, the involvement of parents in the process will be comparable to that of consent for treatment involving the child, and the team will need to weigh up the young person's maturing.

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

Patients with a mental health conditions

Disclosure of information relating to treatment, including open disclosure of incidents, applies equally to people with a mental health condition.

- consider the timing of the disclosure, with the clinical team's assessment on how this will affect the patient's health and their ability to understand what is said.

Patients with cognitive impairment

Patient with cognitive impairment should be involved directly in communications about what has happened to them.

Consider carefully in assessing whether disclosure of an incident and the decisions to be made to (or by) a third party in the absence of the patient's informed consent to do so.

- work with the relevant support or other persons to determine the most accessible type and format of communication for the individual
- a third party who understands the communication needs of the patient / consumer may be required to assist
- legal guardian, or attorney appointed under an enduring power of attorney

Aboriginal and Torres Strait Islander patients

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

Every effort needs to be made to ensure that the appropriate people (in the context of the patient's / consumer's, their family, carer and / or support person needs and with their agreement) are included in discussions regarding the incident and their investigation and management.

If available, an Aboriginal / Indigenous Liaison Officer should be involved from the outset to ensure the process occurs in a culturally appropriate manner.

Culturally and linguistically diverse patients

Ensuring appropriate and effective communication is an important consideration particularly when patients / consumers, their family, carer and / or support person come from culturally and linguistically diverse backgrounds to the clinician.

For example, the patient / consumer may have difficulty understanding medical terms, even if they are otherwise proficient in English. Similarly, English may be the second language of the patient / consumer, their family, carer and / or support person and or the clinician.

When a patient has difficulty communicating in English, or at the patient's request, a professional interpreter should be engaged.

Patients with other requirements

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

Advocacy and support

Patients / consumers will often need help and support after experiencing an incident. Support may be provided by family members, carers, support person, social workers, religious representatives and trained patient advocates.

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

Health service organisations should provide patients, their family, carers and/or support person with the following:

- **information** (including contact details) about service provided by social workers, religious representatives and trained patient advocates who can provide emotional support and help patients, their family, carer and support person identify issues of concern, provide information about appropriate community services and support patients meeting with these services.
- **contact details of a staff member** (the health service contact) who will maintain an ongoing relationship with the patient / consumer, their family, carer and/or support person. Where possible restrict telephone usage to arrange meetings or conveying specific information. More detailed discussion or explanation should be conducted in face-to-face meetings.
- **information about how to make a complaint**, including contact details for the relevant health service, and the patient's / consumer's (and their nominated contact person), right to access their medical record.

Substitute patient support

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

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

The person(s) can have a role in communicating to their extended family and other relevant individuals.

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

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

Reimbursement of 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 / consumers, families, carers and/or support person 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 limited to, transport, child care, accommodation and meals.

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

It is generally accepted that practical support made on ex gratia basis does not imply responsibility or liability. The context for financial reimbursement will vary, and health service organisations and clinicians should liaise with legal counsel, insurers and other stakeholders and refer to local guidelines for providing assistance to harmed patients, their family, carers and/or support person 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 insure is to meet the cost).

Ongoing care: cost and other considerations

Patients who have been harmed will often require ongoing treatment or care, which may be provided at the same health service organisation, or at another. Agreeing on matters of ongoing treatment, such as billing and other costs (eg 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 care organisations should engage in these discussions with the patient / consumer, their family, carer and/or support person, as soon as practicable after harm is identified.

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

Saying sorry

Expression of regret is a key component of open disclosure, but also the most sensitive. 'Saying sorry' requires great care.

The exact wording and phrasing of an expression of regret will vary in each case.

The following points should be considered:

- the words 'I am sorry' or 'we are sorry' should be included
- it is preferred that, wherever possible, people directly involved in the incident also provide the expression of regret
- sincerity is the key element for success. The effectiveness of an expression of regret hinges on the way it is delivered, including the tone of voice, as well as non-verbal communication such as body language, gestures and facial expressions. These skills are often innate and may need to be practiced.
- the expression of regret should make clear what is regretted, and what is being done to address the situation.
- an expression of regret is essential in helping patients / consumers, their family, carers and / or support person cope with the effects of a traumatic event. It also assists clinicians in their recovery from incidents in which they are involved.

It is important to note that an expression of regret alone is insufficient, and must be backed up with further information and action to ensure effective open disclosure.

How to make an expression of regret

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

- acknowledge that an incident has occurred or that something didn't go to plan
- acknowledge that the patient / consumer, their family, carer and / or support person are unhappy with the outcome
- express regret for what has occurred (including the words 'I am / we are sorry').
- provide known clinical facts and discuss ongoing care (including any side effects to be aware of)
- indicate that a review or investigation is being or will be undertaken to determine what happened and to prevent the incident from happening again
- agree to provide feedback information from this when available.

Further information is available in Tool 2 Saying sorry – a guide to expressing regret during open disclosure

Examples of appropriate phrases during an expression of regret:

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

Examples of appropriate phrases to avoid during an expression of regret:

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

Factual explanations and speculative statements:

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

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

An expression of regret and admission of liability and the legal aspects of open disclosure:

An expression of regret are central to open disclosure.

Section 75 of the *Civil Liability Act 1936*, states 'expressions of regret':

In proceedings in which damages are claimed for a tort, no admission of liability or fault is to be inferred from the fact that the defendant or a person for whose tort the defendant is liable expressed regret for the incident out of which the cause of action arose.

Discuss the legal aspects of open disclosure with the LHN Safety and Quality or Risk Management Unit.

Further information is available in the Australian Open Disclosure Framework – Appendix 1, page 62.

Feedback to patients / consumers, their family, carers and / or support person:

Recommendations from incident investigations should not only be disseminated and implemented to prevent recurrence.

In addition, patients / consumers, their family, carers and / or support person should be kept informed of progress of investigations during the open disclosure process.

They should be made aware of outcomes from investigations including:

1. the system causes of the harm they experienced
2. the role of individual clinicians (without apportioning blame)
3. findings and recommendations
4. changes to the systems as a result of the investigation.

Further information is available in the providing follow up section.

Further information is available in Tool 2 Saying Sorry – A guide to expressing regret during open disclosure

Follow up

Follow up with the patient, their family and carers is an important step in level 1 response to open disclosure. Level 2 responses may require no or minimal follow up.

Completing the process

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

Patient evaluation of the open disclosure process

Patients / consumers, their family, carer and / or support person 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 standardised open disclosure evaluation survey should be provided Sensitivity around how this is conducted will be required.

Further information is available in Tool 15 Patient / consumer evaluation survey.

Survey results should be reported to the organisation's management at regular intervals, along with internal open disclosure measures.

Staff considerations

Clinicians (and the non-clinical workforce) may be affected by being involved in an incident, and may require emotional support and advice in the aftermath of the incident.

It should be noted that clinicians and staff who were involved in an incident can benefit from participating in open disclosure, including an expression of regret where appropriate.

The staff involved in the open disclosure process should be provided with access to assistance and support, and with information they need to fulfil the role required of them.

To support staff, health service organisations should endeavour to ensure the following:

Key staff considerations:

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

Staff rights and responsibilities

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

- acknowledging their role in incidents and conveying an expression of regret
- participating in open disclosure training and education as required
- participating in open disclosure processes as required
- supporting their colleagues following an incident, and refrain from blame and potentially defamatory actions. This needs to be balanced with ethical behaviour and principles of transparency and openness.
- open disclosure should be an inter professional process, and participants will vary depending on circumstances.

Clinicians involved in incidents should be given the option to participate in the disclosure. The stage at which it occurs will depend on a range of factors including circumstances surrounding the incident, the experience of the clinician, and their confidence and preparedness for open disclosure.

Clinicians should be provided with the appropriate support and preparation to participate in open disclosure. However there will be circumstances where staff may identify that they do not feel prepared to participate, and these should be acknowledged and respected.

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

Use of a substitute clinician to lead open disclosure

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

Assistance with initial disclosure discussion

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

Facilitators

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

Legal counsel

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

Junior clinicians

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

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

Staff evaluation of the open disclosure process

Staff involved in open disclosure should also provide feedback through a standardised survey where possible. Ideally patient and staff feedback should be completed within four (4) weeks of the end of the open disclosure process. However, sensitivity is required depending on the circumstances.

Further information is available in Tool 16 Staff evaluation survey.

Survey results should be reported to the organisation's management at regular intervals, along with internal open disclosure measures.

8. Detecting and assessing incidents

Open disclosure formally begins with the recognition that the patient / consumer has suffered / experienced harm during treatment or care. Health service organisations should have appropriate mechanism to identify incidents.

Key considerations and actions:

- detect incidents through a variety of mechanisms
- provide prompt clinical care to the patient to prevent further harm
- assess the incident for severity of harm and level of response
- provide support for staff
- initiate a response, ranging from level 1 to level 2
- notify relevant personnel and authorities
- ensure privacy and confidentiality of patients / consumers and clinicians are observed

Identifying an incident

An incident might be identified:

- by a clinician or staff member at the time of the incident
- by clinicians retrospectively when an unexpected outcome is detected
- by a patient / consumer, their family, carer and / or support person at the time of the incident or retrospectively
- through established consumer feedback (complaint) mechanisms, ie Safety Learning System Consumer Feedback module
- through incident reporting via the Safety Learning System Incident Management module (refer to SA Health Patient Incidents – Management and Open Disclosure Policy Directive and tools) or patient record review
- from other sources, such as detection by other patients, visitors, students or other staff.

Incidents can be detected in a variety of ways. These include formal incident reporting (refer to Safety Learning System (SLS) Topic Guide on Open Disclosure), patient / consumer feedback (complaints), review of the patient record and informally, for example, by a colleague or even a visitor or student.

Formal mechanisms are known to miss incidents from time to time

All incidents reports should be followed up. The patient's treating clinicians should be informed as soon as possible and prompt clinical care should be provided as required.

The treating clinicians should perform preliminary investigations into what has occurred. This will most often include a discussion with the patient / consumer, their family, carer and / or their support person.

You may be asked to participate in determining the level of response. Generally, responses are graded as level 1 and level 2. When assessing an incident it is important to remember that an incident does not always result in *physical* harm. See level 1 and level 2 open disclosure responses as outlined on page 9.

If you have been involved in an incident, your employer has an obligation to provide you with support. You should openly discuss how you feel about what has happened.

If you are not involved, you should observe your colleagues who have been involved for signs of emotional distress.

It is important that all incidents are considered, regardless of the mechanism through which they are detected and reported in the Safety Learning System Incident Management module.

Supporting patient and clinician as a priority

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

Notifications are made and evidence gathered that will assist in the incident investigation. Where appropriate this should occur in consultation with the clinical risk team and executive.

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

Initial assessment to determine the level of response

The individual who detected the incident should make an initial assessment of the incident, usually in consultation with a senior clinician. This level of response required will be determined by the effect, severity or consequence of the incident.

Delayed detection of harm

In some cases patient / consumer harm may not be detected for some time and may have originated elsewhere. It is important to consider the principles of open disclosure in these circumstances including:

- notify the patient / consumer, their family, carers and / or support person of what has occurred
- inform other healthcare providers (eg General Practitioner, residential care facility or community care provide) of the incident
- notify the clinicians who were involved in the incident
- commence and investigation of the incident and establish the facts.

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

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

Open disclosure checklist

The Open disclosure checklist will assist staff to follow the open disclosure process from incident detection and notification to maintaining documentation.

Further information is available in Tool 9 Open disclosure process checklist.

Patient / consumer information

Patient / consumer information has been developed to provide information on the open disclosure process. Resources include:

- A brochure for patients / consumers on open disclosure
- A guide for patients / consumers beginning an open disclosure process
- A flowchart for patients / consumers on the open disclosure process
- Frequently asked questions for patients / consumers on open disclosure and the process.

Further information is available in Tools 4 – 7 Patient / consumer information.

9. Signalling the need for open disclosure

The initial discussion should occur as soon as possible after recognising harm, even if all the facts are not yet know. A full explanation should be given to the patient / consumer, their family, carer and / or support person.

The fact that something has happened should be acknowledged to the patient and their support persons as soon as possible, even if you and your colleagues don't yet know the full story.

Discussing the incident with the patient to gather a better picture of what happened will acknowledge the incident and reassure the patient that it is being taken seriously. Open disclosure research shows a relationship between timeliness of the initial response and positive outcomes.

Delaying acknowledgement can be counterproductive.

The acknowledgement should include, in most cases, an expression of regret including the word 'sorry'. Only in cases where it is very unclear whether an incident has occurred should an expression of regret not occur.

Apologising is *not* an admission of liability or fault, but an ethical and humane act. However, you should be careful:

> not to apportion blame to anyone including yourself
> not to speculate as to the causes and effects of the incident
> to be professional, empathic and courteous.

Key considerations and actions:

> acknowledge the incident to the patient / consumer, their family, carers and / or support person including an expression of regret
> **a level 2 response can conclude at this stage.**
> signal the need for open disclosure
> negotiate with the patient / consumer, their family, carers and / or support person 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 / consumer, their family, carers and / or support person
> avoid speculation and blame
> maintain good verbal and written communication throughout the open disclosure process.

During the initial discussion:

> the incident is acknowledged to the patient / consumer, their family, carer and / or support person
> an expression of regret is given
> the effect of the incident, including all known facts and the consequences, are described.

Level 2 response

Example of appropriate wording for low level response in initial discussion:

'I am / we are sorry for what has occurred. It is clear that something unexpected has occurred / things don't go to plan but fortunately it was recognised immediately and we have ensured that you did not suffer any harm from it. However, we will keep an eye on you for the next 24 hours and will ask you to let us know if you feel anything unusual. We do not expect that you will need to stay here any longer than originally planned'.

Examples of appropriate phrases during an expression of regret:

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

See also examples of useful phrases for open disclosure discussions.

Examples of appropriate phrases to avoid during an expression of regret:

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

Factual explanations and speculative statements:

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

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

Level 2 responses for minor incident can conclude at this stage. The conclusion should always be noted in the patient record and a written summary provided to the patient.

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

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

Reporting to management will occur through standard mechanisms consisted with local clinical governance, risk management and quality improvement policy and practice. Level 2 responses should be analysed to detect high-frequency events.

Patients / consumers, their family, carers and / or support person and participating staff members should be surveyed so that their open disclosure experience can inform quality improvement.

As an opportunity to provide feedback, 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.

Level 1 response

For level 1 responses, the acknowledgement conversation signals that a formal open disclosure meeting will be convened. The time and place, as well as attendees and participants in the meeting, should be negotiated.

A health service contact should be provided to the patient / consumer, their family, carer and / or support person. This will be a staff member whom they can call for further information.

If a level 1 response is indicated, the initial discussion will have an additional two (2) actions:

1. signal the need for an open disclosure
2. negotiate (where possible) with the patient / consumer, their family, carer and / or support person about:
    a. the format required for discussions and meetings
    b. the logistical details of the open disclosure.

Example of appropriate wording for level 1 response in initial discussion:

'I am / we are 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'.

Avoid speculation and blame

It is important not to speculate, attribute blame to yourself or other individuals, criticise individuals or imply legal liability when signalling the need for open disclosure, or during the formal open disclosure discussions.

All known facts relevant to the incident can be made available to the patient / consumer, their family, carer and / or support person, subject to any legal restrictions that may apply.

An expression of regret and admission of liability and the legal aspects of open disclosure:

An expression of regret are central to open disclosure.

Section 75 of the *Civil Liability Act 1936*, states 'expressions of regret':

In proceedings in which damages are claimed for a tort, no admission of liability or fault is to be inferred from the fact that the defendant or a person for whose tort the defendant is liable expressed regret for the incident out of which the cause of action arose.

Discuss the legal aspects of open disclosure with the LHN Safety and Quality or Risk Management Unit.

Further information is available in the Australian Open Disclosure Framework – Appendix 1, page 62.

10. Preparing for open disclosure

Level 1 (SAC 1 or 2) response of open disclosure will vary depending on circumstances and harm severity. The two (2) main types of level 1 responses are:

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

Key considerations and actions:

- hold a multidisciplinary team discussion to prepare for open disclosure
- consider who will participate in discussions
- appoint an individual to lead the open disclosure based on previous discussion with the patient / consumer, their family, carer and / or support person
- gather all the necessary information
- identify the health service contact for the patient / consumer, their family, carer and / or support person (if this is not done already).

Team discussion

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

- establish the basic facts (clinical and other facts)
- assess the event to determine the appropriate response
- identify who will take responsibility for discussion with the patient / consumer, their family, carer and / or support person
- consider the appropriateness of engaging patient support at this early stage, including the use of a facilitator
- identify immediate support needs for everyone involved
- ensure that all team members maintain a consistent approach in any discussions with patient / consumer, their family, carer and / or support person
- consider legal and insurance issues, both for the organisation and the clinicians, and notify the relevant staff (ie Clinical risk personnel, insurers, management, other clinicians, coroner, relevant statutory and other appropriate authorities). Refer to local procedures in relation to notifying relevant individuals, authorities and organisations.
- consider how to address issues regarding ongoing care such as billing and other costs, which should be addressed at the earliest opportunity
- update the patient record / case note, and record in the Safety Learning System Incident Management module.

Choosing the individual to lead the discussion

The individual leading the disclosure, where possible be the most senior clinician responsible for the care of the patient / consumer, and ideally the lead person should:

- be known to the patient / consumer, their family, carer and / or support person
- be familiar with the facts of the incident and the care of the patient
- be of appropriate seniority to ensure credibility
- have received training in open disclosure
- have good interpersonal skills, and be able to communicate clearly in everyday language
- be able and willing to offer reassurance and feedback to the patient / consumer, their family, carer and / or support person

- where possible and appropriate be willing to maintain a medium to long-term relationship with the patient / consumer, their family, carer and / or support person

The decision about who will make the disclosure should, where possible, be made in consultation with the patient / consumer, their family, carer and / or support person, clinical risk personnel and (if appropriate) senior management (in relevant health service organisations).

Arranging the first meeting: timing, location and attendees

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

The patient / consumer, their family, carer and / or support person should be consulted about which clinician and health service staff will participate in the open disclosure meeting.
Factors to consider include:

- patient's clinical condition
- availability of key staff
- availability of the patient's / consumer's family, carer and / or support person
- availability of support for staff
- patient's / consumer's preferences (and those of their family, carer and / or support person)
- patient's privacy and comfort
- patient's physical and mental health.

The patient / consumer, their family, carer and / or support person may need time to consider these matters.

If for any reason it becomes apparent that the patient / consumer, their family, carer and / or support person would prefer to speak to a different clinician(s) than those designated to lead the open disclosure, the patient's / consumer's wishes should be respected, and if possible, an acceptable substitute provided.

Health service contact

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

The patient should identify their nominated contact person, if they have not already done so.

Written information

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

Further information on the open disclosure process is available for patients / consumers in Tool 4 – 7 Patient Information (brochure, guide, flowchart and frequently asked questions).

Further information on the open disclosure process is available in:

- Tool 9 Open disclosure process checklist
- Tool 10 Patient considerations
- Tool 11 Staff considerations
- Tool 12 Open disclosure meeting checklist
- Tool 13 Open disclosure meeting plan and preparation
- Tool 14 Documentation and discussion summary
- Tool 15 Patient / consumer evaluation survey
- Tool 16 Staff evaluation survey

11. Engaging in open disclosure discussions

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

Participating in open disclosure meetings require that you remain professional but not distant or cold. Sometime this can be challenging in an emotionally strained situation. However, and in general, patients and their support persons will appreciate a 'human face'.

It is important for patients / consumers, their family, carer and / or support person to be heard and be able to convey their thoughts as it is for you and your colleagues to convey your information and an expression of regret.

Key considerations and actions:

- provide the patient / consumer, their family, carer and / or support person with the name and the roles of all attendees
- provide a sincere and unprompted expression of regret including the words '*I am*' or '*we are sorry*'
- clearly explain the incident
- give the patient / consumer, their family, carer and / or support person the opportunity to tell their story, exchange views and observations about the incident and ask questions
- encourage the patient / consumer, their family, carer and / or support person to describe the personal effects of the incident
- agree on, record and sign an open disclosure plan
- assure the patient / consumer, their family, carer and / or support person that they will be informed of further investigation findings and recommendations for system improvement
- offer practical and emotional support to the patient / consumer, their family, carer and support person.
- support staff members throughout the process
- if the incident took place in another health service organisation, include relevant staff if possible
- if necessary, hold several meetings or discussions to achieve these aims.

Key components of open disclosure discussions:

1. **Introductions**
   The patient / consumer, their family, carer and / or support person are **told the name and role of everyone attending the meeting**, and this **information is also provided in writing**.

2. **Saying sorry**
   A sincere and unprompted expression of regret is given on behalf of the health service organisation and clinicians, including the words 'I am' or 'we are sorry'. Examples of suitable and unsuitable phrasing of an expression of regret are provided below.

3. **Factual explanation: providers**
   A **factual explanation** of the incident is provided, including the **known facts and consequences of the incident**, in a way that ensures the patient / consumer, their family, carer and / or support person understand the information related earlier by the patient / consumer, family, carer and / or support person. Speculation should be avoided.

4. **Explanation: patient / consumer, family, carer / support person**
   The patient / consumer, family, carer and / or support person have the **opportunity to tell the clinicians their story** about the incident to **explain their views on what happened, contribute their knowledge and ask questions** (the patient's factual explanation of the incident). It will be important for the patient / consumer, their family, carer and / or support person that **their views and concerns are listened to, understood and considered.**

5. **Personal effect of the incident**
   The patient / consumer, their family, carer and / or support person are **encouraged to talk about the personal effect** of the incident on their life.

6. **Plan agreed and recorded**
   An **open disclosure plan is agreed and recorded** in which the patient / consumer, their family, carer and / or support person **outline what they hope to achieve from the process** and **any questions they would like answered.** This should be documented and filed in the appropriate place.

7. **Pledge to feedback**
   The patient / consumer, their family, carer and / or support person are assured that they will be **informed of any further reviews** to **determine why the incident occurred, the nature of the proposed process and the expected time frame.** The patient / consumer, their family, carer and / or support person are **given information about how feedback will be provided on the investigation findings**, by whom and in what timeframe, including any changes made to prevent recurrence.

8. **Offer of support**
   An **offer of support** to the patient / consumer, their family, carer and / or support person should include:
   a. ongoing support including reimbursement of out-of-pocket expenses incurred as a result of the incident.
   b. assurance that any necessary follow-up care or investigation will be provided promptly and efficiently
   c. in relevant settings, clarity on who will be responsible for providing ongoing care resulting from the incident
   d. contact details for services they may need to access
   e. information about how to take the matter further, including any complaint processes available to them.

9. **Support for patients / consumers and staff**
   The patient / consumer, their family, carer and / or support person engage in open disclosure with staff. Staff are supported by their colleagues, managers and health service organisation, both personally (emotionally) and professionally (including through appropriate training, preparation and debrief).

10. **Other health service organisations**
    In cases where the incident spans more than one location or service, health service staff will ensure that, where possible, all relevant individuals from these additional institutions are involved in the open disclosure process.

Other considerations:

It is not necessary to cover every component in the first disclosure meeting. For instance, a full explanation of why an incident occurred may not be possible until the causative factors are known.

A written account of the open disclosure meeting should be provided to the patient / consumer, their family, carer and / or support person.

Further information is available in Tool 2 Saying sorry – a guide to expressing regret during open disclosure

12. Providing follow up

Follow up with the patient / consumer, their family, carer and / or support person is important in relation to a level 1 response to open disclosure. Level 2 responses may require no or minimal follow up.

Level 1 response open disclosure is a process and not a single discussion. Follow up is important and may occur over a considerable period of time, even after the patient / consumer has been discharged.

Follow up will be done by a senior staff member but it may be delegated to more junior staff depending on the circumstances. It is important that follow-up is active and not reactive.

It is important to ensure patients / consumers, their family, carer and / or support person have an opportunity to ask further questions and request further information. It is also important that agreement is reached on providing, or monitoring, ongoing care related to the incident.

Importantly, follow up is an opportunity for the health service organisation to provide information on changes that been implemented as a result of an incident, and how the changes are improving patient safety. Patients / consumers respond very positively to their misfortune resulting in improved safety and better outcomes for others.

The patient / consumer, family, carer and / or their support persons should be offered an opportunity to discuss the process with another relevant professional such as a general practitioner, residential care facility or community care provider.

Key considerations and actions:

- ensure follow-up by senior clinicians or management, where appropriate
- agree on future care
- share the outcomes of investigations and the resulting practice changes
- offer the patient / consumer, their family, carer and / or support person the opportunity to discuss the process with another clinician (eg a general practitioner).

Key components of open disclosure discussions

The senior clinician involved in the incident (or senior management, if appropriate) should be involved in the follow-up discussion, which should occur at the earliest practical opportunity.

The patient / consumer, their family, carer and / or support person should be assured of receiving further information and follow-up care, and should be readily provided with any information they request (without contravening legal constraints).

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

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

The patient / consumer, their family, carer and / or support person should be provided with details of a person to contact if further issues arise.

Completing the process at this stage

If the process of open disclosure is complete at this point, the patient / consumer, their family, carer and / or support person should be asked if they agree that the process is complete and a note of this should be made in the patient record / case note, as well as the Safety Learning System Incident Management module.

Written information about the incident and it's management should be provided to the patient / consumer, their family, carer and / or support person.

Further information is available in the Tool 14 Open disclosure documentation and discussion summary.

The patient / consumer, their family, carer and / or support person should be offered an evaluation survey or, where it is considered more appropriate, a face to face interview, or both.

Further information is available Tool 15 Open Disclosure patient / consumer evaluation survey.

13. Completing the process

The open disclosure process concludes with shared agreement between the patient / consumer, their family, carer and / or support person and the healthcare team. In a majority of cases, this will occur after the incident review or investigation is completed.

If a satisfactory conclusion cannot be negotiated, the patient / consumer, their family, carer and / or support person should be offered alternative courses of action.

Key considerations and actions:

- reach an agreement between the patient / consumer, their family, carer and / or support person and the clinician, or provide an alternative course of action
- provide the patient / consumer, their family, carer and / or support person with final written and verbal communication, including investigation findings
- communicate the details of the incident, and outcomes of the open disclosure process, to other clinicians
- complete the patient / consumer / family / carer / support person evaluation survey
- complete the staff evaluation survey.

When the relevant review or investigation is complete, the patient / consumer, their family, carer and / or support person should be provided with feedback through face-to-face interview or equivalent (e.g. videoconference) and in writing. The interview and document should include:

- details of the incident, including the clinical facts and other relevant facts
- the patient's concerns or complaints
- an expression of regret (including the word 'sorry') for the harm suffered
- a summary of the factors contributing to the incident
- information about what has been and will be done to minimise the risk of recurrence of the incident, and how these improvements will be monitored.

If further issues are identified after the process is completed, the patient / consumer, family, carer and / or support person should have the opportunity to re-contact the open disclosure clinician for a response to their questions.

Key components for completing the process

Communication

When the relevant review or investigation is complete, the patient / consumer, their family, carer and / or support person should be provided with feedback through face-to-face interview and in writing.

The interview and document should include the following:

- details of the incident, including the clinical facts and other relevant facts
- the patient's / consumer's concerns or complaints
- an expression of regret (including the word 'sorry') for the harm suffered
- a summary of the facts contributing to the incident
- information about what has been and will be done to avoid recurrence of the incident, and how these improvements will be monitored.

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

Disclosure of review and investigation of findings

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

In some exceptional circumstances it may be considered that disclosure of information will adversely affect the patient / consumer, their family, carer and / or support person's health.

In these cases:

- the rationale must be clearly documented in the patient record
- where possible, the decision should be independently verified by a practitioner or colleague who was not involved in the incident. If possible, this verification must also be documented in the patient record / case note, and recorded in the Safety Learning System Incident Management module.

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

- investigations are awaiting conclusion of coronial process
- contractual arrangements with insurers preclude disclosure of specific information
- information is protected from disclosure

In these cases, the patient / consumer, their family, carer and / or support person will be informed of the reasons for restricting information. This will be documented in the appropriate place. Further information is available in the maintaining documentation section.

Continuity of care

When a patient / consumer has been harmed during treatment and requires further therapeutic management or rehabilitation, the patient / consumer, their family, carer and / or support person should be clearly informed of their proposed ongoing clinical management. Discharge planning should ensure that ongoing care is provided where it is required as a consequence of the incident.

Communication with the general practitioner, residential facility and other clinicians

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

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

Unable to reach agreement

Sometimes the relationship between the patient / consumer, family, carer and / or support person, and the healthcare team can break down. It is important that this not be seen as failure if all of the necessary steps and components of open disclosure are followed.

In these situations it is important to try to rebuild patient trust. The following strategies may assist:

- deal with the problem earlier rather than later.
- with the patient's agreement, ensure that their family and support persons are involved in discussions from the beginning.
- ensure the patient and support persons have access to support services.
- to ensure the appropriate staff member (e.g. a senior clinician) is aware of a potential relationship breakdown, communicate early warning signs.
- offer the patient and support persons another health service contact with whom they may feel more comfortable. This could be another member of the treating team or personnel responsible for clinical risk.
- use a mediation or conflict resolution service to help identify the issues between the health service organisation and the patient and support person and to look for a mutually agreeable solution.
- involve the Consumer Advisor (or delegate), if the patient and their support persons want to lodge a formal complaint.
- assess whether sufficient weight has been given to the patient's / consumer's version of events and whether reasonable efforts have been made to seek information from all key witnesses, including witnesses identified by the patient and their support persons.

Monitoring improvements

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

Where appropriate and possible, this information should be given to the patient / consumer, their family, carer and / or support person.

Communication and continued support for clinicians

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

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

Evaluation of the open disclosure process

Patients / consumers, their family, carer and / or support person 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 standardised open disclosure evaluation survey should be provided Sensitivity around how this is conducted will be required.

Further information is available in Tool 15 Patient / consumer evaluation survey.

Staff involved in open disclosure should also provide feedback through a standardised survey where possible. Ideally patient and staff feedback should be completed within four (4) weeks of the end of the open disclosure process. However, sensitivity is required depending on the circumstances.

Further information is available in Tool 16 Staff evaluation survey.

Survey results should be reported to the organisation's management at regular intervals, along with internal open disclosure measures.

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

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

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

14. Maintaining documentation

Comprehensive documentation contributes significantly to successful open disclosure. The disclosure of an incident 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 / case note, incident reports and records of the thorough review of the incident.

All incidents should be reported and documentation maintained in the management section of SLS Safety Learning System Incident Management and Consumer Feedback module via the web form at http://inside.sls.sa.gov.au or click green start button > Corporate programs > SAH applications > Safety Learning System

Key considerations and actions:

- keep the patient record / case note up to date
- keep the SLS Incident Management module up to date
- maintain a record of the open disclosure process
- file documents relating to open disclosure in the patient record / case note
- provide the patient with documentation throughout this process

Documenting the open disclosure process

It is important that a record of open disclosure is to be recorded and maintained in the Safety Learning System Incident Management module Open Disclosure section / panel and patient medical record / case note including:

- patient / consumer, their family, carer and support person contact details
- all discussions
- all information provided
- logistical details, plans proposed
- agreements and commitments made

Further information is available in the Safety Learning System (SLS) Topic Guide for Open Disclosure.

Key considerations for documentation

The patient medical record / case note and SLS Incident management module open disclosure section / panel must be up to date before the first meeting, including a comprehensive account of the incident as it is initially understood.

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

The patient medical record / case note and SLS Incident Management module should document the:

- time, date and place of the disclosure discussion and the names and relationships of those present
- plan for providing further information to the patient / consumer, their family, carer and / or support person
- offers of support and the responses received
- questions posed by the patient / consumer, their family, carer and / or support person
- progress notes relating to the clinical situation and accurate summaries of all points explained to the patient / consumer, their family, carer and / or support person
- copies of letters sent to the patient / consumer, their family, carer and / or support person and their general practitioner.

Without breaching legal and privacy requirements documentation should be made available to the patient / consumer, their family, carer and / or support person.

A contact point at the health service organisation should be available to answer staff questions regarding the documentation and sharing of information.

After the open disclosure process is completed a written summary is offered to the patient / consumer, their family, carer and / or support person.

This summary includes:

- date of incident
- date of discussion
- name and position of staff member who led the open disclosure discussion
- name of health service contact (staff member assigned to the point of contact for patient / consumer)
- names and positions of other staff present
- name of patient / consumer, their family, carer and / or support person who attended the meeting and their relationship to the patient / consumer
- brief factual summary of incident
- summary of all points explained to the patient / consumer, their family, carer and / or support person
- was an expression of regret offered
- summary of support offered and response
- plan for follow up.

Consumer feedback process

Once open disclosure has been identified as part of the consumer feedback process, the consumer feedback process is ceased and transferred to and undertaken by the open disclosure process and recorded in the SLS incident management module.

15. References

Australian Open Disclosure Framework, Australian Commission on Safety and Quality in Health Care (ACSQHC)

Just-in-time' information for healthcare professionals, Australian Open Disclosure Framework, Australian Commission on Safety and Quality in Health Care

National Safety and Quality Health Service Standards, Australian Commission on Safety and Quality in Health Care

For more information

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