



Safety and Quality

TOOL 1

Open Disclosure

Quick guide
to the open
disclosure
process



Government
of South Australia

SA Health

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1. Introduction

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.

The SA Health Open Disclosure Quick Guide 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 Open Disclosure Quick Guide (Tool 1) 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 Incident Management and Open Disclosure Policy Directive.

The SA Health Open Disclosure Quick Guide provides information on the level 1 (SAC 1 and 2) and level 2 (SAC 3 and 4) 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.

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 clinical leads and open disclosure facilitators.

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)

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](#)

What is open disclosure?

Open disclosure describes the way clinicians communicate with, and support, patients and / or their families, carers and / or other 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 / consumers, family, carers 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.

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.

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 or complaints mechanisms
- > through incident detection systems, such as the incident report Safety Learning System or patient record review
- > from other sources such as detection by other patients, visitors, students or other staff.

The elements of open disclosure are:

- > an expression of regret, which 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'*.
- > a factual explanation of what happened
- > an opportunity for the patient, their family and/or carers 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. Open disclosure is a discussion between two parties and an exchange of information that may take place in several meetings over a period of time.

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.

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

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 patient / 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.

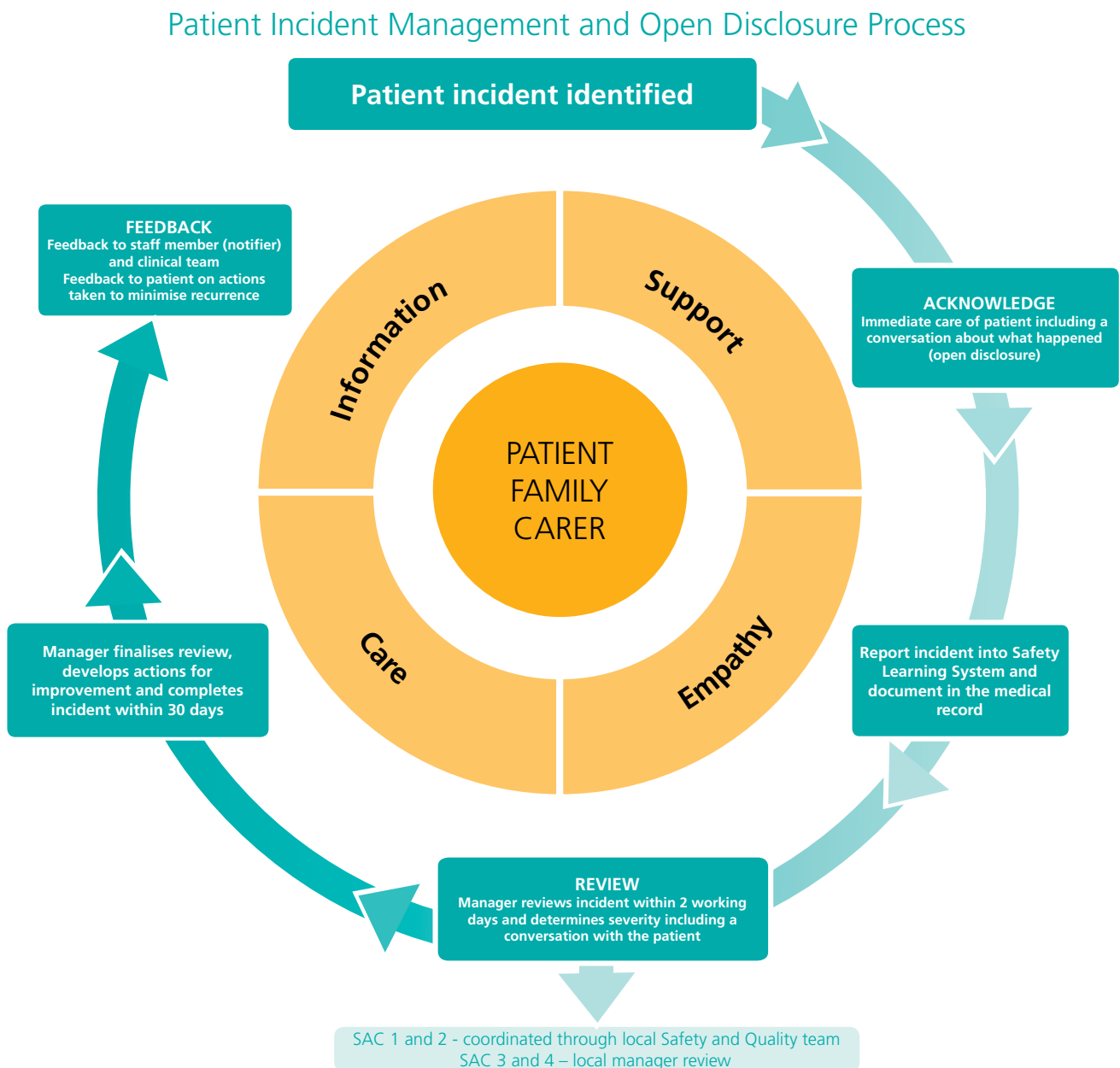
Incident management and open disclosure

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.



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 2 responses. Table 1 outlines the incident type, level response and criteria. Level 1 and Level 2 flowcharts are presented on pages 9 and 10.

Table 1: Criteria for determining the appropriate level of response

Incident type	Criteria
Level 1 = SAC 1 or 2 Harm incident	<ol style="list-style-type: none"> 1. Death or major permanent loss of function 2. Permanent or considerable lessening of body function 3. Significant escalation of care or major change in clinical management (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 7. Cluster incidents. 8. Extreme and unexpected poor outcome or avoidable complication of care.
Level 2 = SAC 3 or 4 Near miss or no harm incident	<ol style="list-style-type: none"> 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

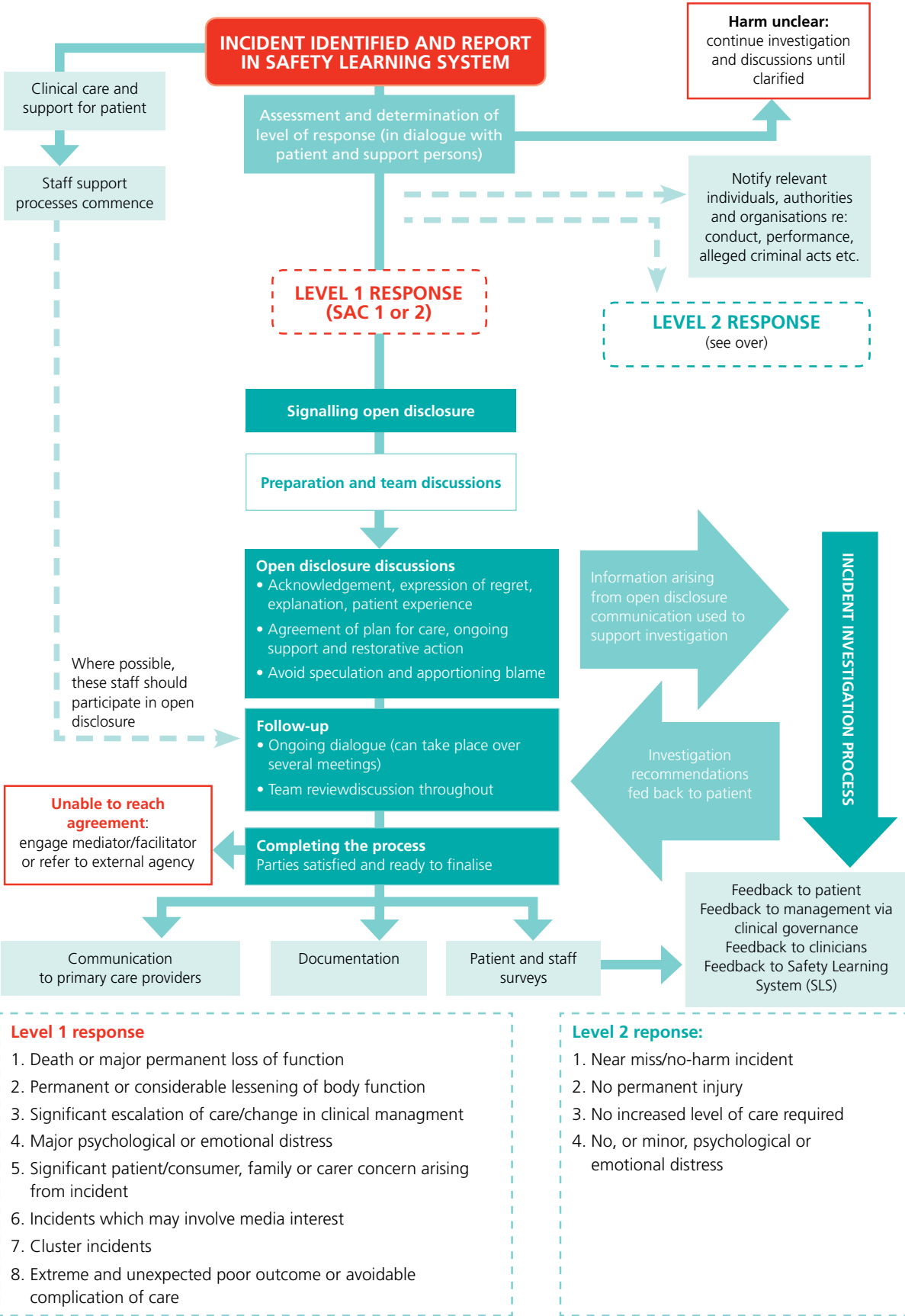
Quick Guide to the Open Disclosure process

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

Table 2: Potential responses to various situations and incidents

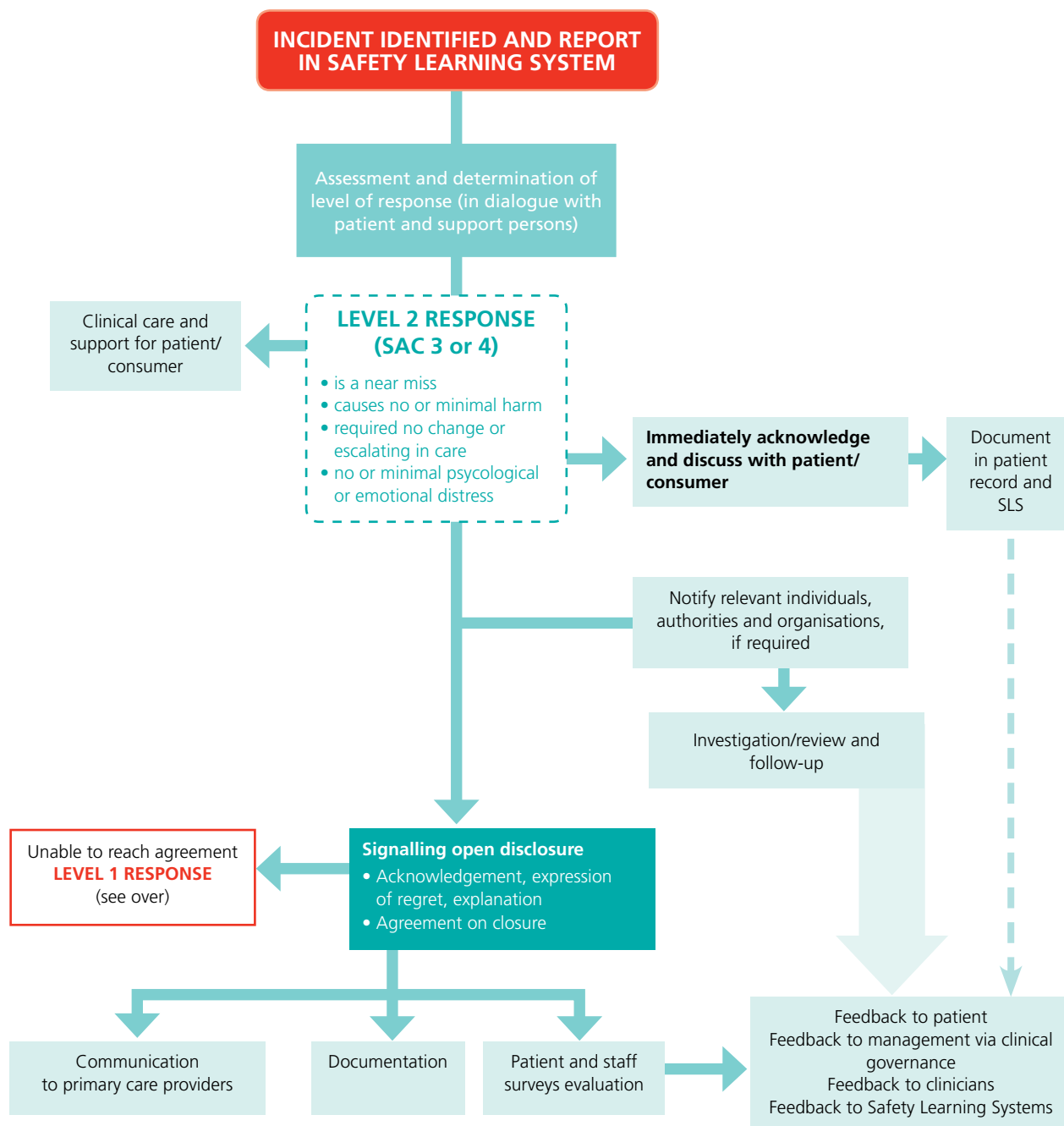
Incident type		Response
1.	Harm from natural progression of condition or disease process <i>eg a treatment for cancer was unsuccessful</i>	Discuss and explain (Level 2)
2.	Complication or natural disease progression a. Anticipated by patient / consumer via education and consent process b. Not anticipated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

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



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



6. Open disclosure process, key considerations and actions

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

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

Steps	Key considerations and actions
<p>1. Detecting and assessing incidents</p> <p>All incidents</p>	<ul style="list-style-type: none"> > 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.
<p>2. Signalling the need for open disclosure</p> <p>SAC 1 and 2 incidents - Level 1</p> <p>Further information is available in the SA Health Comprehensive Guide on open disclosure process for clinical leads / facilitators</p>	<ul style="list-style-type: none"> > 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 <p>Level 2 response</p> <ul style="list-style-type: none"> > signal the need for open disclosure > negotiate with the patient / consumer, their family carer and / or support person: <ul style="list-style-type: none"> • the formality of open disclosure required • the time and place for open disclosure • who should be there during open disclosure > provide written confirmation > provide a health service contact for the patient / consumer, their family, carer and / or support person > avoid speculation and blame > maintain good verbal and written communication throughout the open disclosure process.

Further information on the other elements of Level 1 response is available in Section 9 – Level 1 response for open disclosure (SAC 1 and 2).

Further information on the open disclosure process is available:

- > Tool 2 Saying sorry – a guide to expressing regret during open disclosure
- > Tool 3 Comprehensive Guide on open disclosure process for clinical leads / facilitators
- > Tool 4 – 7 Patient / consumer information (brochure, guide, flowchart and frequently asked questions)
- > 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 Open disclosure documentation and discussion summary
- > Tool 15 Open disclosure patient / consumer evaluation survey
- > Tool 16 Open disclosure staff evaluation survey
- > Tool 17 Level 1 Open disclosure response flowchart
- > Tool 18 Level 2 Open disclosure response flowchart

7. Detect and assess incident

Incidents can be detected in a variety of ways, and the care of the patient / consumer to prevent further harm is paramount.

Key points: Detecting and assessing incidents

- > 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 levels 1 and 2
- > notify relevant personnel and authorities
- > ensure privacy and confidentiality of patients and clinicians are observed

These include formal incident reporting (refer to Safety Learning System 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 2. When assessing an incident it is important to remember that an incident does not always result in physical harm.

See Level 1 (SAC 1 and 2) and Level 2 (SAC 3 and 4) open disclosure responses as outlined on page 7.

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.

8. Signal the need for open disclosure

The fact that something has happened should be acknowledged to the patient / consumer, family, carer and / or 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 / consumer 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.

Expressing regret 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.

Further information is available:

Open disclosure toolkit: Tool 2 - Saying sorry: A guide to expressing regret during open disclosure.

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)

Patient considerations

After expressing harm, patients 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. Patients / consumers, their family, carers and / or support person should also be encouraged to ask questions.

Key patient considerations are:

- > 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

Further information is available in Tool 10 Patient considerations.

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.

Useful phrases for open disclosure discussions

The open disclosure process does not need to be a tightly scripted. However, it is important to practise the words you will use so you feel comfortable and natural with the language when the need arises, without appearing to be rehearsed, defensive or concealing,

The following text provides phrases to use with the patient in an open disclosure conversation.

- > *'Let me tell you what happened. There has been a significant lapse in quality and we failed to follow up with you and tell you about your diagnosis.'*
- > *'Let me tell how sorry I am that this has happened.'*
- > *'I want to discuss with you what this means for you, but first I'd like to express my regret'*
- > *'I want to discuss with you what this means for your health.'*
- > *'I'm sorry, this shouldn't have happened. Right now, I don't know exactly what happened, but I promise you we're going to find out and do everything we can to make sure it doesn't happen again.'*
- > *'I will get back to you as soon as we know what happened and we can talk about the steps we will take to prevent it happening again.'*
- > *'Our organisation takes this very seriously and we will look into it to find out exactly what happened and what we can do to prevent it happening again.'*
- > *'Do you have all the information you need? I'm here if you have any other questions.'*
- > *'I know it's hard to take it all in so I'm happy to go over this again another time.'*
- > *'Would you like us to contact you to set up another meeting to talk about what has happened and answer any questions you may have?'*

Level 2 responses for minor incident can conclude at this stage. The conclusion should always be noted in the patient record.

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. Further information is available in Tool 3 SA Health Open Disclosure Comprehensive Guide on Open Disclosure Process for Clinical Lead / Facilitators.

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.

Key points: Signalling the need for open disclosure

- > acknowledge the incident to the patient / consumer, family, carer and / or support persons including an expression of regret
- > signal the need for open disclosure if a level 1 response is required
- > negotiate arrangements for the open disclosure meeting
- > provide a health service organisation contact
- > avoid speculation and blame

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 the 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 are:

- > provide advice and training on the 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.

Further information is available:

- > Tool 9 Open disclosure checklist,
- > Tool 11 Staff considerations.

9. Level 1 responses for open disclosure (SAC 1 and 2)

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.

Further information is available:

- > Tool 3 SA Health Open Disclosure Comprehensive Guide for Clinician Leads / Facilitators.

Table 4: Level 1 response process

Steps	Key considerations and actions
Preparing for open disclosure	<ul style="list-style-type: none"> > hold a multidisciplinary team discussion to prepare for open disclosure > consider who will participate in open disclosure > appoint an individual to lead the open disclosure based on previous discussion with 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).
Engaging in open disclosure discussions	<ul style="list-style-type: none"> > 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>I am sorry</i>' or '<i>we are sorry that this has happened. I realise it has caused great pain / distress / anxiety / worry</i>'. > 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, carers 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, 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	<ul style="list-style-type: none"> > ensure follow up by senior clinicians or management, where appropriate > agree on future care > share the findings of investigations and the resulting practice changes > offer the patient / consumer, their family, carers and / or support person the opportunity to discuss the process with another clinician (eg a general practitioner).

Process	Key considerations and actions
Completing the process	<ul style="list-style-type: none"> > 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	<ul style="list-style-type: none"> > keep the patient record up to date > maintain a record of the open disclosure process using the Safety Learning System Incident Management Module – Open disclosure tab > file documents relating to the open disclosure process in the patient record > provide the patient with documentation throughout the process.

10. References

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

[Saying sorry: a guide to apologising and expressing regret during open disclosure](#), 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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