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Patient incident management and open disclosure Policy Directive

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1. Policy Statement

SA Health recognises that effective incident management and open disclosure processes are attributes of high-quality health service organisations, and important parts of healthcare quality improvement and a patient-centred approach to care.

A patient incident is any event or circumstance which could have (near miss) or did lead to unintended and/or unnecessary psychological or physical harm to a patient, that occurred during an episode of health care.

Open disclosure is the process of providing an open, consistent approach to communicating with patients/consumers, their family, carer and/or support person following a patient incident. This process includes expressing regret or saying sorry.

SA Health is committed to continuous quality improvement and an environment, in which there is:

- recognition that patient incidents usually have many contributing factors that are mostly related to the systems of care, rather than an individual, and that active reporting and management of patient incidents by the whole clinical team lead to timely action to eliminate or reduce risk
- conduct and documentation of an appropriate open disclosure process, irrespective of whether or not harm resulted from the incident, and this is :
  - a critical element of clinical communication,
  - a patient/consumer right,
  - a core professional requirement and
  - a health service obligation
- an expectation that the patient and carers will be supported to recover from a patient incident through being:
  - informed of the facts surrounding a patient incident, its consequences for them, and the steps being taken to prevent recurrence, and provided opportunity to ask questions
  - treated with empathy and respect and supported in a manner appropriate to their needs
  - offered and/or assisted to access support or make a complaint, in addition to treatment and care provided by the clinical treating team
  - assured of their privacy and confidentiality
- a focus on quality improvement in an open, just and transparent culture of patient incident management that includes support for staff affected by the incident
- a system of accountability through which a health service organisation's senior management, executive or governing body ensures that:
  - appropriate system improvements are implemented and their effectiveness is monitored
  - individual staff are held accountable for their role
  - patients and carers are supported to participate, and
  - the effectiveness of the patient incident management and investigation systems is reviewed
- education and training and support to maintain a competent and capable workforce, and recognition that teamwork and mutual respect are key defences against system failure.

All health services will have established systems for safety and quality improvement that focus on the timely reporting of all incidents and near misses and take action to reduce patient harm. This will also include regular review of the open disclosure processes and patient experience from incidents.

This policy directive describes a standardised system for managing patient incidents that ensures all staff:

- use the SA Health incident management reporting system called Safety Learning System (SLS) for reporting and documenting the management and open disclosure of patient incidents

- provide appropriate feedback to, and engage with patients/consumers, their family, carer and/or support person, including open disclosure
- respond effectively to patient incidents, and promote safety and quality improvement through sharing lessons learned from single (or groups of) patient incidents
- take action, in collaboration with consumers, and service providers external to SA Health to improve the safety and quality of services; and
- maintain compliance with relevant law and codes of conduct in relation to transparent and fair treatment, privacy and confidentiality of both patient and clinician.

This policy directive is to be read / administered in conjunction with:

- the accompanying toolkit for patient incident management and open disclosure
- SA Health Lookback Review policy directive
- *Health Care Act* and Regulations 2008 and SA Government Gazette 11 July 2019
- Australian Open Disclosure Framework (Australian Commission on Safety and Quality in Health Care - ACSQHC)
- Version 2 of the National Safety and Quality Health Service Standards.

2. Roles and Responsibilities

2.1 Chief Executive (CE) - SA Health is responsible for:

- ensuring services across SA Health operate in accordance with this policy.

2.2 Local Health Network (LHN) governing boards and Chief Executive Officers will:

- ensure that the open disclosure and reporting and management of patient incidents across SA Health is in accordance with this policy and legislative requirements
- explicitly supports incident management and open disclosure as a patient or consumer right, organisational requirement and opportunity to learn from incidents
- ensure that resources are available to enable implementation of incident management and open disclosure including the education and training of appropriate staff
- participate in the SA Health response and management of complex and/or serious or cluster incidents that carry organisational risk, including public communication and briefing to the Minister of Health.

2.3 Chief Medical Officer, Chief Public Health Officer and Chief Psychiatrist

- provide advice, lead or participate as required in review of patient incidents and/or review of services where incidents have occurred, in order to fulfil relevant legislative requirements.

2.4 Chief Executive Officers or Chief Operating Officers of Local Health Networks, SA Ambulance Service and statewide clinical support services

- ensure the health services within their area of control have systems in place which facilitate the effective reporting and management of all incidents and open disclosure in accordance with this policy, National Safety and Quality Health Service Standards and legislative requirements
- allocate sufficient human and material resources to enable effective incident management and open disclosure to operate across all areas within their area of control, and appropriate data capture and analysis to inform planning and evaluation
- delegate the day-to-day responsibility for establishing and monitoring the implementation of this policy to the relevant senior managers
- ensure that all incidents that have the potential to result in substantial liability and/or have the potential to attract significant media attention and or require external review are immediately escalated to the Chief Executive SA Health using RIB and recommended process (section 3.9)

- provide advice and assistance to Chief Executive SA Health and Director of Safety and Quality, DHA about the SA Health response and management of complex and/or serious incidents that carry organisational risk.
- have staff training programs in place for incident reporting, different types of investigation, appropriate escalation to senior managers, review and open disclosure of patient incidents, including the use of the SLS.

2.5 Directors, heads of service/departments and other senior managers

- assign appropriate levels of responsibility for the timely investigation, review, management and open disclosure of incidents, and for implementation of activities to improve safety and quality of services
- ensure that there are procedures in place to guide the investigation, review and open disclosure of patient incidents
- support staff to participate in patient incident investigations, reviews and open disclosure, including Part 7 committee, mortality review and RCA investigations as appropriate.

2.6 Director, Safety and Quality, Department for Health and Wellbeing

- establish, maintain and review the effectiveness of the Patient Incident Management and Open Disclosure Policy Directive
- support the implementation of the policy through facilitating the development, dissemination and implementation of training, tools, resource materials and evaluation of these
- support the continual improvement of the Safety Learning System, by maintaining systems for;
  - governance of the SLS, including approval of change requests
  - review of data quality and data integrity
  - data security and protection of personal information
- support the Safety and Quality Unit role as SLS System Administrator, including management of vendor contracts and liaison with eHealth
- support the development and publishing of a suite of data indicators relating to incident management that will be used to monitor trends and inform planning. This will include, but not be limited to incident data, hospital, ambulance, and emergency department data
- review reported incidents and investigation reports, conducting trend analysis and develop and disseminate statewide strategies for system improvement
- provide advice to health services in response to specific queries about incident management and management
- provide advice and assistance to CE and LHN and CEOs of statewide clinical support services about the SA Health response and management of complex and/or serious incidents that carry organisational risk.

2.7 LHN / SA Ambulance Service (SAAS) Safety and Quality Risk Managers / Clinical Governance

- ensure that patients and carers are involved in the analysis of incidents, and the planning of activities to improve safety and quality
- monitor all SAC 1 and 2 incidents and other harmful incidents within their area of responsibility, to ensure correct investigative processes are followed
- provide advice (Clinical Incident Briefing) and assistance to LHN CEOs and Director Safety and Quality, Department for Health and Wellbeing about the response and management of complex and/or serious incidents that carry organisational risk
- SLS User Administration role - ensure that staff have appropriate level of log-in access to SLS and user profiles that enable notification of incidents as required by their role
- ensure that all managers are investigating incidents to the level required, and the patient incident module of SLS is used to document the investigation processes
- ensure that managers and committees are able to access reports and data to identify trends and areas requiring support for quality improvement
- ensure that all staff are aware that personal information in SLS must be protected and kept securely in the same way as personal information in a medical record

- data security – data custodians ensure that any internal or external requests for data or information from the SLS are considered for approval by LHN Safety and Quality Manager and/or Director Safety and Quality Unit, DHA, and are in accord with *Health Care Act* 2008, *Mental Health Act 2009* and *Freedom of Information Act* 1991.
- ensure data quality and integrity, including correct classification of patient incidents and adequate information provision
- participate in governance of the SLS system assist staff to formulate SLS Change requests, for local endorsement and submission to DHA SLS Support team for approval and action
- collaborate with clinical educators to ensure that
  - all staff have skills and knowledge required to record an incident (be an SLS notifier)
  - all managers have skills and knowledge required to review and manage patient incident types, including those requiring escalation to senior managers and/or Safety and Quality managers

2.8 Clinical Educators

- assist Safety and Quality staff and SLS Administrators to ensure that staff have skills and knowledge about reporting, managing and openly disclosing patient incidents, required for their role through including these topics in training curricula.

2.9 All SA Health staff, students and contractors

- report all identified patient incidents into the SLS
- participate in relevant patient incident management and open disclosure training
- support consumers/patients and carers to report patient incidents, and to engage with the process of incident investigation
- commence and/or participate in the open disclosure process as appropriate
- participate in the investigation of incidents as required
- participate in the implementation of recommendations arising from the investigation of incidents
- encourage colleagues to report and/or notify incidents and near misses that have been identified.

All SA Health employees or persons who provide health services on behalf of SA Health will comply with this policy directive.

This policy directive does not apply to the management of incidents that are reported into other modules of the SLS such as:

- the Consumer Feedback module such as complaints and commendations
- the Security Incident module, such as fire, flood, or other emergency code incidents and notification by security officers to SA Police about weapon possession or alleged criminal acts
- the Work Health and Safety module, such as hazards and harm to workers, or notification to SafeWork SA.

A patient incident investigation will not involve the review, investigation or management of issues related to the competence of individual health practitioners. These matters must be separately investigated and resolved by Workforce staff, in accordance with the SA Health (Health Care Act) Human Resources Manual.

3. Policy Requirements

3.1 Standards

The National Safety and Quality Health Service Standards set criteria against which health services are assessed and accredited.
The health service organisation has a patient incident management and investigation system that:

- supports staff, patients and family/carer to recognise and report patient incidents, and use the patient incident management module of the SLS to document the investigation and analysis of incidents and open disclosure processes in an accurate and timely manner
- initiates and provides open and timely communication, that is, an appropriate open disclosure response, with the patient, and carers where appropriate, after a patient incident, and that this includes an acknowledgement of the incident, an expression of regret and provision of ongoing information as required
- ensures that staff have the skills and knowledge required for their roles and are supported after distressing incidents
- involves staff and patients and family/carer in the investigation and analysis of patient incidents when appropriate
- provides timely feedback from the analysis of patient incidents to the governing body, staff and consumer groups; and ensures that recommendations for quality improvement are implemented and monitored
- recommends that organisational risks identified during the analysis of patient incidents are referred to the Risk Manager
- meets statutory and other requirements for:
  - reporting or notification to external organisations and bodies of incidents involving patients
  - investigation, analysis, documentation and protection of information gained during these processes.

3.2 Components of incident management and open disclosure

After a patient incident, two separate but linked and related processes are initiated:

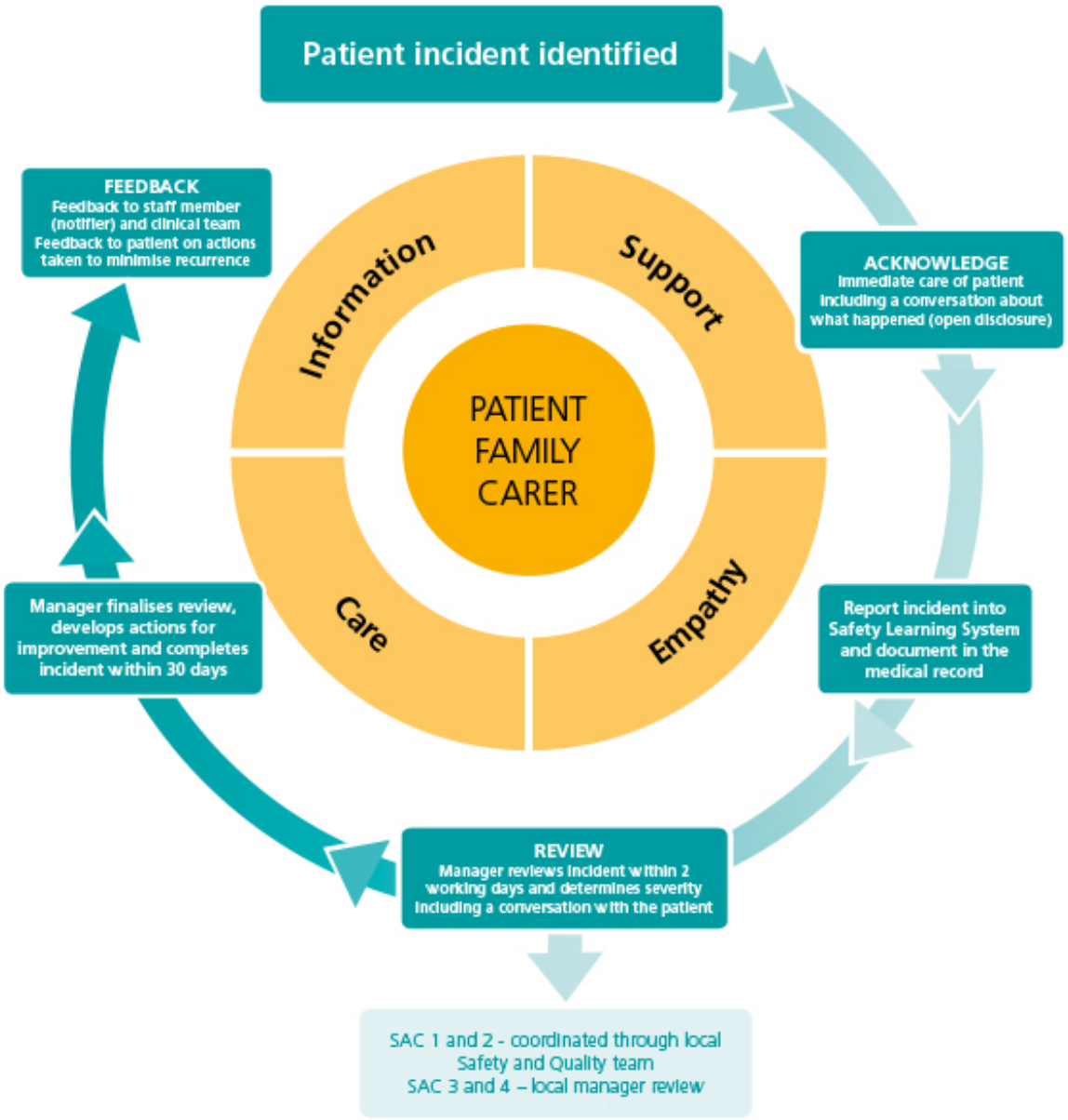
- open disclosure - that will assist the patient and carers in their recovery from the incident, and guide the health workforce and health service organisations in supporting patients who have experienced harm
- incident reporting, investigation, analysis and action to change practices - these benefit staff, the health service and the patient through improvement of safety and quality of services and the opportunity to support staff who have been involved in a distressing incident.

The linking of open disclosure and incident management is essential to ensure that:

- patients and family/carer can contribute to the investigation, and are informed of the recommendations arising and actions taken or planned to prevent recurrence and improve safety and quality of the service
- health service organisations learn from the investigation of incidents and from the patient and family/carer perspectives.

Professional codes of conduct require participation in incident management and open disclosure, for example Good medical practice: a code of conduct for doctors in Australia, 2014.

Diagram 1 – Summary of patient incident management and open disclosure



The patient incident management and investigation system has a number of steps and processes that include open disclosure with the patient (Diagram 1). The toolkit that accompanies this policy includes additional information. These steps are:

- identification, and immediate action
- care of, and communication with the patient, including open disclosure and management of a complaint, if required
- care of staff involved
- reporting into SLS, documentation and/or onward notification to senior managers
- review of the notifiers report
- classification, investigation and analysis of the individual patient incident, including decision about type of investigation required
- assisting in analysis of groups of patient incidents, or data arising, in conjunction with the relevant governance committee, for example all incidents in one part of a health service, or a group of like incidents such as pressure injuries
- implementing action(s) to improve safety and quality, both locally, across health services and across SA Health as applicable.

Where an incident has occurred sensitive, empathetic, open and honest communication with the patient and their family/carer is essential. Open disclosure steps include:

- acknowledgement of the incident, and offering, initiating or signalling the need for open disclosure
- preparing for, and engaging in open disclosure discussion, including expressing regret
- providing follow up to patient and family/carer, including actions taken as a result of the investigation
- completing the process and maintaining documentation.

3.3 Initial steps after a patient incident

3.3.1 Identification and immediate action after a patient incident

A patient incident might be identified:

- by a clinician, staff member or student at the time of the incident, or when an unexpected outcome is detected
- through established consumer feedback or complaints mechanisms
- through other review systems, such as audit or review of medical records
- by the patient and family/carer, other patients, visitors, students or other staff, at the time of the incident or later.

All SA Health employees or those providing a service on behalf of SA Health including students and staff of a health service that is providing services under contract with SA Health, who observe or become aware that a patient incident or near miss has taken place are required to:

- ensure that any person affected by the incident is safe and all necessary steps are taken to support and treat the person/s and prevent further injury
- inform a line manager
- preserve evidence (section 3.3.2), within the constraints of providing safe clinical care in the situation
- report the incident into SLS, and document information in the medical record.

Patients and their family/carer should be encouraged to report incidents to the clinical team. Staff are required to act on such reports, by reporting into the SLS.

The line manager or the treating clinician may be responsible for the initial acknowledgement and completion of a Level 2 open disclosure process.

Managers are required to provide or arrange support, team or individual de-briefing and/or counselling services to staff involved in a distressing patient incident.

3.3.2 Preservation of evidence surrounding incidents

If the matter has been referred to the SA Coroner, SafeWork SA or SA Police or other external agencies, there are requirements for preservation of evidence that should be adhered to.

If this cannot be done, use a SA Health owned digital camera to document the scene prior to the environment being disturbed. Images should be uploaded into the Documents tab in the managers section of the SLS incident report.

Any relevant equipment, disposables and the environment involved must be left as it was at the time the incident occurred, where practicable. Avoid altering equipment settings and connections. If, for safety reasons this is not possible:

- document any changes and attach this documentation to relevant equipment, and
- isolate and secure the relevant equipment, accessories, disposables and associated packaging.

If there is no feasible alternative to the continued use of the equipment or clinical environment, preservation of evidence will take second place to the provision of safe services to clients and the emotional well-being of those involved.

3.4 Open disclosure (OD)

Open disclosure is defined as a process of providing an open, consistent approach to communicating with consumers/patients and their carer/support persons following a patient incident.

Open disclosure is:

- a patient and consumer right, and a legal obligation. Part 3 of *Health and Community Services Complaints Act* 2004 includes a Charter of Health and Community Services Rights (the HCSCC Charter). The HCSCC Charter of Rights states that any incidents involving consumers are managed openly to ensure improvements.
- a core health professional requirement (Good medical practice: a code of conduct for doctors in Australia 2014 section 6.2) and other Australian health professional codes
- an attribute of high-quality health service organisations (required by the NSQHS Standard 1) and an important part of healthcare quality improvement
- guided by the Australian Open Disclosure Framework (Australian Commission on Safety and Quality in Health Care - ACSQHC).

Aims of open disclosure include continuation or restoration of a therapeutic relationship and patient trust in clinicians and the healthcare system. To this end:

- all patient incidents except near misses should be acknowledged or openly disclosed to the patient and their carer/support person within 24 hours if practicable, and unless there are reasons for deferral (section 3.4.3).
- the treating clinical team has the primary responsibility for open disclosure.

If the incident occurred during the episode of care that was provided by a health service under contract with SA Health or an LHN, the service is expected to provide open disclosure. The exception is for SAC 1 and 2 incidents, when it is expected that both the contracted service and the referring LHN or SA Health representative service responsible will actively participate in the Level 1 Open Disclosure process.

There are circumstances in which the service that is primarily responsible for the incident has no relationship with the patient, or is unable to provide open disclosure, for example due to location. Examples include the statewide services such as SA Pathology, or emergency services such as SA Ambulance or MedStar. These services must provide relevant information about the incident to enable the treating clinical team to provide open disclosure on their behalf. The exception is for SAC 1 and 2 incidents, when it is expected that the service responsible will actively participate in the Level 1 Open Disclosure process.

Open disclosure Tools 4. 5, 6, and 7 provide information for consumers and family/carers. Open disclosure is not a one-way provision of information – it is a discussion between two parties and an exchange of information that may take place in several meetings over a period of time.

The offer of open disclosure may be refused, and this can be documented in the SLS incident. As part of these discussions, patients should be informed about processes and options for making a complaint, if they wish to. Open disclosure may not resolve patient or carer concerns.

3.4.1 Direct Personal Response

A Direct Personal Response (DPR) is an element of the National Redress Scheme; the scheme provides acknowledgment and support to people who experienced child sexual abuse in institutions across Australia. If a victim of child sexual abuse applies to the scheme and are offered redress they can also ask for a DPR from the institution responsible for the abuse. Whilst a DPR is very similar to open disclosure there are specific requirements that support the process of providing a DPR, for more information visit the SA Health web site

3.4.2 Level 1 and Level 2 Open disclosure

The level of open disclosure process required will depend on the outcome and circumstances of the incident (Table 1):

- Level 1, which is a response to a patient incident with a Safety Assessment Code rating of 1 or 2 (actual SAC) that is, more serious incidents or significant patient or family/carer concern, and
- Level 2, which is a response to incidents with a Safety Assessment Code rating of 3 or 4 (actual SAC) that is, less serious incidents.

Table **1: Criteria for levels 1 and 2 Open disclosure response**

Open Disclosure	**Incident type Criteria**	**Requirements, timelines and documentation**
Level 1 High level response	SAC 1 or 2 incidents and others where there is: • death or major permanent loss of function • permanent or considerable lessening of body function • 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) • major psychological or emotional distress • significant patient or carer concern arising from any incident • actual or potential media attention • cluster incidents • extreme and unexpected poor outcome or avoidable complication of care.	An Open Disclosure Facilitator must be present or lead the process. The senior treating clinician must be present. The process must be initiated in a timely manner, and should be within hours of the incident when practicable. The health service must nominate a contact person who is not part of the treating team for the patient and family/carer. A professional interpreter must be present if English is not the primary language. A consumer advocate or equivalent support person can be present if the patient requests. The process and the outcome must be recorded in the SLS in the managers section of the patient incident. The Safety, Quality and Risk Manager can provide advice.
Level 2 Low level response	SAC 3 or 4 incidents where there is : • no permanent injury • no increased level of care required (eg no transfer to operating theatre or intensive care unit) • no, or minor, psychological or emotional distress.	The OD process can be conducted by the patient incident manager or a senior member of the patient's clinical team. The process can occur at or near the time that the incident is identified, but should be completed within 24 hours if practicable. The process and the outcome should be documented in the SLS in the managers section of the incident.

Level 1 open disclosure cannot be delegated to junior staff. An open disclosure cannot be delegated to administrative staff or students.

The steps staff take through Open disclosure process for Level 1 and 2 are illustrated in flowcharts (Tools 18 and 19). Steps include preparation, engaging in open disclosure, providing follow-up and completing and documenting the process.

3.4.3 Patient considerations in preparing for open disclosure

There is preparation required to ensure that the open disclosure discussion includes the most appropriate people and an optimal outcome is achieved. Preparation is described in detail in Tool 1 Quick guide and Tool 3 Comprehensive guide. The checklist in Tool 9 will assist in tracking the completion of open disclosure steps.

Tool 10 describes patient considerations to ensure that the individual's needs are best addressed, including when application for deferment of the process may be warranted.

A professional interpreter, communication aid or device, or a third party who understands the communication needs of the patient may be required.

If an incident involves a person under 18 years, the clinical team will, together with the parents or authorised caregivers, need to make informed but complex assessment of their involvement. A psychologist can assist. In the case of young people who may have legal competency, the involvement of parents in the process will be comparable to that of consent for treatment involving the child, and the team will need to weigh up the young person's maturity, age and the wishes of the young person and the parents, where appropriate.

Disclosure of information relating to treatment, including open disclosure of any incident applies equally to people with a mental health condition, irrespective of whether the patient has capacity and/or is subject to an inpatient or community treatment order. Similarly, patients with a cognitive impairment should be involved directly in communications about what has happened to them. The timing of the disclosure is subject to the clinical team's assessment of how this will affect the patient's health, and their ability to understand what is said.

The Chief Psychiatrist and Community Visitors have powers of inspection under the *Mental Health Act* 2009, and may be involved with incidents occurring in mental health treatment centres.

Incidents that resulted from actions to a patient by other patients or other persons such as visitors, may require consideration of level 1 open disclosure to restore trust in the safety of the service. An example may be where a patient is pushed to the floor and harmed by another patient or visitor.

If the incident resulted in a death is required to be reported by the appropriate medical officer to the SA Coroner, families may need information about the coronial process and autopsy (if applicable).

3.4.4 Deferral of open disclosure

Prompt open disclosure may not be indicated in every situation. For example, if the physical or mental health of the patient precludes them participating.

If staff consider that deferral is in the best interests of the patient:

- the rationale for deferral and plans for when open disclosure will take place must be clearly documented in the patient's medical record and the management section of the SLS
- the patient incident manager or treating clinician needs to seek approval from local Safety and Quality or Risk Manager, using the SLS email tab for communication.

The patient, their family/carer may also request deferral. In this case, a decision not to openly disclose must be justified as being in the patient's best interest, and:

- the rationale for deferral and plans for when open disclosure will take place must be clearly documented in the patient's medical record and the management section of the SLS
- where possible, the decision should be independently verified by a practitioner or colleague who was not involved in the incident. This verification must also be documented in the patient's medical record and the management section of the SLS.

If there is a disagreement or dispute, advice should be sought from Safety and Quality or Risk Manager in the LHN or Statewide Support Service, or the Safety and Quality Unit of the Department for Health and Wellbeing or HealthSentinelEvents@sa.gov.au . If open disclosure with the patient is deferred, but is held with the patient's family/carer or other relevant persons in the meantime, the process must recommence with the patient at a later date.

There are rare situations when Open Disclosure may not be appropriate, including some instances of self-harm, suicide or criminal acts. It is recommended that advice is sought from the Safety and Quality Unit and/or the Office for the Chief Psychiatrist. Other forms of counselling or debriefing for persons involved may be required.

In rare circumstances a cluster incident may occur and following investigation it is apparent that no harm has occurred. In these circumstances the Chief Executive SA Health may give consideration to the requirement for open disclosure to be waived. Any consideration of waiving must be briefed to the Chief Executive and include a description of the incident and subsequent investigation and rationale for waiving the open disclosure process.

3.4.5 Engaging in open disclosure discussions

The important elements of open disclosure from a patient or consumer perspective are:

- an expression of regret, which should include the words 'I am sorry' or 'we are sorry that this has happened'
- a factual explanation of what happened
- an opportunity for the patient, their family/carer to relate their experience and ask questions
- a discussion of the potential consequences of the incident
- an explanation of the steps being taken to prevent recurrence.

Resources have been developed to assist the patient and family/carer to understand and engage with the open disclosure process (Tools 4, 5, 6, and 7). Tool 2 describes appropriate communication for saying sorry, that should be used by staff.

Information arising from open disclosure may be used in the investigation of the incident. Staff can advise the patient and family/carer about what is being done to investigate the incident. Tools 13, 14 and 15 assist staff to track and document the process.

3.4.6 Completing and documenting the open disclosure process

Completing the open disclosure process with patients and carers includes:

- reaching an agreement regarding future care, ongoing support and restorative action between the patient, their family/carer and health service
- offering the patient, their family/carer final written and verbal communication, including recommendations arising from the investigation findings.

Additional steps that may be required include:

- offering the patient, their family/carer the opportunity to discuss the process with another clinician (eg a general practitioner)
- additional meetings and following up any outstanding concerns that the patients or family/carer have
- providing information to support the patient and family/carer to take an alternative course of action if an agreement cannot be reached
- encouraging patients and staff to complete open disclosure evaluation surveys (Tools 15 and 16).

Completing the open disclosure process includes communicating the recommendations for minimising recurrence that have arisen from the incident investigation and outcomes of the open disclosure process to patient, carer and staff. Communicating with staff is achieved through:

- documentation of the incident management and open disclosure process in the medical record
- recording the completion of Open Disclosure in SLS. The SLS Topic Guide and SLS Guide How to manage a patient incident provide further information.

3.5 Legal aspects of open disclosure

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

However, clinicians must be aware of the risk of making an admission of liability during open disclosure. In any discussion with the patient during open disclosure, clinicians should take care not to:

- speculate on the cause of an incident
- pre-empt the results of any investigations
- attribute or apportion blame, or criticise individuals
- state, imply or agree that they, other clinicians or health service organisations are liable for the harm caused to the patient.

Further information is available through the training that is available for staff who have a role in leading Level 1 Open Disclosure processes (Open Disclosure facilitators) and the Australian Open Disclosure Framework (Australian Commission on Safety and Quality In Health Care). This resource also provides guidance on other legal issues such as freedom of information, privacy, defamation, and qualified privilege.

If the patient has a legal guardian or a substitute decision maker appointed through an advance care directive or enduring power of medical attorney or enduring power of guardianship it will be necessary for staff to determine the legal effect of any such relationships in assessing whether any decisions needed after disclosure of an incident can be made by a third party in the absence of the patient's informed consent to do so.

3.6 Reporting of patient incidents

There is a requirement for accurate and factual documentation in the patient's medical records, including care and treatment provided before, during and after an incident.

Any patient incident reporting required by legislation or relevant Department of Health or local health service policy or procedures, should be followed, for example some patient incident reporting is required by the *Mental Health Act* 2009.

All patient incidents must be reported into the patient incident module of the SLS, via the online web form, within 24 hours or as soon as practicable.

The staff member who becomes aware of, or observes the patient incident, or has the most information about the incident must make the initial report into the patient incident module. This task cannot be allocated to non-clinical staff unless they discover or are involved in the incident. Students can submit a report if they were involved in the incident, but must discuss with their supervisor and include their supervisor's name in the 'Other people involved' section of SLS. Local arrangements with contracted service providers to facilitate incident reporting into the SLS are required because they cannot access the SLS.

Many hospital acquired complications, side effects of treatment or unexpected poor outcomes from treatment or care are preventable or avoidable, and have serious impacts on patients and health services. These must be reported, openly disclosed and investigated in accordance with this policy

directive, so that contributory factors can be understood and risk treatments and controls put in place to reduce risk of recurrence.

The final long term outcome of a patient incident may be unknown at the time of reporting and investigation, for example incidents involving babies where there may be potential developmental delay, or delay in treatment of a progressive condition. Where there is potential for harm, that is, the longer term sequelae of the incident are unknown, a report should be made.

3.6.1 Using Safety Learning System (SLS) to report an incident

The SLS is the SA Health governance system for recording reports, management, analysis of all patient related incidents, including documentation of recommendations and actions taken to reduce likelihood of reoccurrence. The staff member who is reporting a patient incident is termed the SLS notifier.

A link to the SLS web form can be found by clicking the start button **> Corporate programs > SAH applications > Safety Learning System**.

All staff can access SLS to report an incident. SLS will prompt the notifier to provide the required information. This includes a brief, factual description of what happened and where; and what the outcome was – harm, no harm or near miss (as known at the time of the data entry).

The notifier assigns an initial Safety Assessment Code (SAC). This is done by assessing both the actual known consequence (harm) of that incident and the likelihood (frequency) of this type of incident occurring again.

Once the report is submitted, an email is automatically sent by the SLS to the patient incident manager to inform them that an incident has occurred in their area of responsibility.
There are SLS guides and topic guides to assist notifiers to report, classify and assign Safety Assessment Code ratings to incidents.

Patient incidents are classified according to a 3 tier classification (levels 1, 2, and 3). SLS Topic guides provide assistance with classification of some types of incidents.

The location of the incident is usually where the incident occurred, for example the fall occurred in x Local Health Network (LHN) or statewide service, y hospital, ward z. In SLS this is termed the 'location exact'. SA Ambulance Service defines the location by the team involved. The patient incident manager for the area where the incident occurred is given primary responsibility for the investigation and to take steps to prevent recurrence.

For a health service provided by a provider under a contract with SA Health, the location is the SA Health service that notifies the incident on behalf of that service, usually the referring SA Health service.

Some patient incidents are known to have occurred in one area, but are reported by another area, for example ward Y identifies that two doses of a medication were omitted by ward X, prior to the patient transfer. The incident location is entered as ward X, and the manager of ward X investigates.

The responsibility for patient incidents that involve more than one LHN or statewide service, or require transfer from one LHN to another is determined by relevant Managers of Safety, Quality and Risk and is described in the SLS Guide How to Manage a patient incident.

3.7 The patient incident manager

In general, the patient incident manager has responsibility for coordinating all the activities required for patient incident management, and for implementing any changes in the area for which they have responsibility that will result in safety and quality improvement. Examples of staff who can be

patient incident managers include the senior nurse on a ward, the head of a unit or the team leader for an allied health team.

To preserve security of the system, managers/supervisors are required to apply for log-in access (manager access) to be able to:

- receive email notification of incidents occurring in that area
- log in and read the notifiers report, and add information to the SLS incidents within their area of responsibility, and
- act as a reviewer as required for other incident managers
- document open disclosure processes.

Applications for patient incident manager access (log-in or user access) are made by completing the SLS User Access Request form and forwarding to the Clinical SLS Site Administrator who then verifies that, in order to fulfil the role of patient incident manager, the nominated staff member:

- holds a position that requires them to be a patient incident manager
- has completed the SA Health eLearning course Patient incidents and open disclosure
- has read and understood the SLS guide How to manage a patient incident, that includes practical information and information about legal aspects of incident management
- has access to other relevant training, mentoring and troubleshooting as required.

3.8 Initial review by the patient incident manager

The notifier's report of the patient incident should be reviewed by the patient incident manager as soon as practicable, or at least within two (2) working days of the incident being reported.

At a minimum, the initial review of an incident should include:

- verifying the incident classification
- updating what is known about the patient outcomes, for example a fracture resulting from the fall
- the status of the open disclosure process
- patient characteristics, for example age, co-morbidities
- incident characteristics, for example when, where the incident occurred
- contributing factors
- organisational outcomes– the potential effect of the incident on the organisation
- verifying the Safety Assessment Code (SAC) rating, especially if SAC 1 or SAC 2.

After this review the patient incident manager must decide:

- what further information, and what type of investigation is required?
- what level of open disclosure is required? If open disclosure has already occurred ensure that the process is completed. If the incident is serious, discuss with the LHN Safety, Quality and Risk team.
- who else should be involved in investigation of the incident, as a reviewer or a staff member with a more senior role?
- what other requirements there may be for additional notification or escalation to senior management?

There are some categories of incident that require more than one report. The patient incident manager should be aware of, and may be required to participate in other types of investigation in these situations. For example:

- a patient incident of challenging behaviour may require additional reporting of a Security incident if security officers attend. In this example, the security manager investigates the security response, and the patient incident manager investigates the events leading to the unsuccessful de-escalation
- when a patient incident also involved harm to an employee or student, there is a requirement to report into the Worker incident module of SLS.

The SLS allows for linkage of incidents. Advice and training can be sought from the relevant SLS Administrator or Managers of Safety, Quality and Risk, and additional information is included in the SLS guide How to manage a patient incident.

Events that are reported into the restricted access Notification module of SLS by designated senior managers, for example alleged criminal acts or alleged professional misconduct, may also require another report into the patient incident module:

- if there was a patient incident
- if there is a need to investigate if there were any systemic factors that contributed to the occurrence of the patient incident.

In these cases, the investigation of the patient incident is conducted and documented in accordance with this policy directive. Advice from the Department for Health and Wellbeing Safety and Quality Unit via HealthSentinelEvents@sa.gov.au should be sought to ensure that the investigation and documentation of the patient incident is limited to the appropriate scope, so as to not impede other investigative processes.

3.9 Level of escalation/notification for patient safety incident(s)

Patient incident managers need to be aware of the requirements for notifying senior managers of the health service about SAC 1 and SAC 2 patient incidents and suspected cluster incidents, both verbally and in writing (the SLS 'Send an Email' tab can be used). (Table 2)

Within 24 hours of confirmation that an incident is a SAC 1 or 2, or a Sentinel Event or adverse incident, the local Manager of Safety, Quality and Risk or delegated staff must email HealthSentinelEvents@sa.gov.au and provide the CEO of the LHN or statewide service with a briefing. The CEO notifies the Deputy Chief Executive and other relevant executive(s) using a Clinical Incident Briefing (CIB). The CIB is uploaded into SLS in the Documents tab. It can be uploaded as a level 1 secure document if it is judged to require this additional security.

Table 2 - Guiding principles for level of escalation of significant patient incidents

Written brief required	When
To LHN or statewide service CEO, or Chief Psychiatrist	• SAC 1 and SAC 2 (except falls incidents) • external agencies eg SAPOL, SA Coroner, SAICORP notified or involved with the patient incident. (Note for example that not all deaths requiring coronial notification have an associated patient incident). • the patient incident was a system error or failure but no patient has suffered actual or likely harm (cluster incidents without harm) and a lookback review is planned / required
To SA Health DCE or relevant Executive(s)	• the patient incident was a system error or failure, and more than one patient has suffered actual harm or potential for a future harmful outcome (cluster incidents with harm) and a lookback review is planned / required • media attention is probable • external agencies involved eg SAPOL, AHPRA, SA Coroner • an external or independent review is planned, eg by SA experts external to the LHN or statewide service • the patient incident involves more than one LHN, or LHN and statewide service • response and actions are required by more than one executive, eg People and Culture, eHealth

3.10 Patient incident investigation and analysis

Investigation of a patient incident leads to understanding about when and how the healthcare led to the adverse outcome for the patient. For example, was there treatment specific harm; psychological harm; or harm due to over-treatment, delayed or inadequate diagnoses or system failure?

Most patient incidents result from a complex system of interaction between healthcare professionals, treatment procedures and medical equipment. Analysis of incidents determines which contributing factors may have led to an incident occurring.

Investigation and analysis of avoidable complications of care, side effects of treatment or unexpected outcomes from treatment or care, enables:

- identification of contributory factor(s) or cause(s) such as a system issue for example delay, error or failure in patient assessment, staff or patient factors, equipment, information or communication, procedures or coordination of care
- identification of strategies to predict and/or prevent that complication or adverse outcome next time, or for other patients.

Methods that may be used for the review and investigation of patient incidents include interdisciplinary team review, root cause analysis (RCA), audits or reviews of medical records by peers or by committees such as mortality review committees, Part 7 Incident review committees or committees with these functions. These are described in detail in the SLS guide How to manage a patient incident.

3.10.1 Patient Incident Reviewers

Patient incident managers should use SLS to request other staff with log-in access to be a reviewer. Reviewers are expected to provide specialist comment and review or analysis of the incident. Some reviewers, for example Biomedical Engineers can also ensure that appropriate notifications are made, for example to the Therapeutic Goods Administration.

Patient incident reviewers can include content experts and managers from workgroups such as Work Health and Safety, Mental Health, Security Services, Biomedical Engineering, SA Pharmacy, SA Pathology, SA Medical Imaging, Infection control, Radiation Safety Officers, SA Ambulance or Drug and Alcohol Services SA, or Consumer Liaison officers (or equivalent).

3.10.2 Investigation of SAC 3 or SAC 4 incidents

All SAC 3 or 4 incidents should be investigated, analysed and closed within 30 calendar days of reporting.

The investigation or review of SAC 3 and 4 patient incidents can be managed by the relevant patient incident manager. This is called a managers review. As well as the review of the information provided by the notifier, investigation should include, at a minimum:

- discussion with notifier and other staff as appropriate
- discussion with patient involved (this can be part of the open disclosure process)
- review of careplan, medical record, and any physical evidence
- review of any relevant procedure(s) or protocol(s)
- contribution by patient incident reviewer(s) if required.

This investigation will assist in identifying the factors that contributed to the incident, and plan action that will reduce or eliminate risk of recurrence.

Interdisciplinary team review within 48 hours is recommended for harmful incidents and repeat incidents such as repeat falls and other SAC 3 and 4 rated patient incidents. This team activity promotes shared team learning, and engagement with the patient. Guidance about the conduct of a team review is provided in the SLS guide How to manage a patient incident.

The recommendations arising from a team review are documented in the managers' section of SLS. Changes to the patients care plan are documented in the medical record.

3.10.3 Investigation of SAC 1 and SAC 2 incidents

The most serious incidents will be rated as SAC 1 or SAC 2 by the patient incident manager (actual SAC). The steps are illustrated in the flowchart Reporting and management requirements for Safety Assessment Code (SAC) 1 notifiable incidents.

All patient incidents confirmed as SAC 1 or SAC 2 require:

- detailed and thorough investigation/review, possibly using RCA processes or review by Part 7 committee, to identify actions to minimise recurrence, to be completed within 70 calendar days. SAC 2 falls incidents only require post fall team review
- level 1 open disclosure response
- coordination with Safety and Quality or Risk Manager of the LHN or Statewide Support Service
- provision of a Clinical Incident Brief (CIB) to LHN or Statewide Service CEO or Chief Psychiatrist
- de-briefing or counselling as required for staff involved

The Structured review tab of the SLS includes functions for recording and tracking these investigations. Access to this tab has limited access. Use of this tab enables monitoring of types and completion of investigation of SAC 1 and SAC 2 incidents. Reports 1 and 2 that contain the outcome of any protected investigation must be uploaded into the SLS as a level 1 secure document.
Advice can also be obtained from the Department for Health and Wellbeing Safety and Quality Unit at email HealthSentinelEvents@.sa.gov.au.

3.10.4 Investigation of cluster incidents

These are a group of incidents or occurrences that have system-wide safety implications, that is, they involve a system failure or multiple systems failure that does, or has the potential to compromise the safety of more than five patients.

Examples of this type of incident include a missed diagnosis of a progressive condition due to a systemic issue/error with a test, or under- or over-dosing of medication due to an incorrect protocol. There are incidents where the eventual outcome or impact on an individual patient is unknown at the time, or the outcome for each individual may vary between patients, depending on their individual response.

If a cluster incident is identified, the Chief Executive Officer of the LHN or statewide service must be briefed within 24 hours using an RIB and the process described in 4.9.

A ‘master’ incident must be reported into SLS. Individual patient incidents will each then be linked to the master incident.

The appropriate investigation methodology for a cluster incident is a lookback review, initially to assess the scope and numbers of patients affected, and coordinate the appropriate response. Guidance on investigation and reporting into SLS is provided in the SA Health Lookback review policy directive.

3.10.5 Actions arising from investigation and analysis

Incident management is a key quality improvement activity, and as such has 2 main parts.

1. Incident reporting, providing the measures (the data).
2. Incident review, investigation, analysis, informing the action taken to minimise risk or prevent recurrence

After analysis, the patient incident manager is responsible for:

- implementing local changes or actions to reduce risk, and
- referring any recommendations for action to the relevant governance committee or senior manager(s). This includes recommendations for system change

- recording recommendations arising from investigation and analysis in the medical record and in the SLS.

3.11 Legal aspects of review, investigation and analysis of incidents

All entries made into the SLS should be written as factual objective statements.

Information contained in the SLS is not prohibited from disclosure unless:

- it is information gathered at the request of a Part 7 Committee; or
- it is information gathered as the result of an RCA commissioned under Part 8 of the *Health Care Act*; or
- it is personal information that is protected from disclosure by section 93 of the *Health Care Act* or s.106 or the *Mental Health Act 2009*; or
- it is personal information that meets the criteria for an exemption under the *Freedom of Information Act 1991*

Some committees are authorised under Part 7 of the *Health Care Act* to undertake quality improvement activities and may review patient incidents. The information gained by these committees is prohibited from disclosure. Activities of a Part 7 committee include:

- the assessment or evaluation of the quality of services provided by the health service
- the making of recommendations to improve the provision of services provided
- the monitoring of the implementation of any recommendations or other initiatives that are relevant to improving the quality of services provided.

It should be noted that both Part 7 and Part 8 of the *Health Care Act* prohibit the use of these parts to investigate the competence of a particular person in providing health services. The RCA policy and the Part 7 Committees policy provide further information.

It is the responsibility of all staff to identify and raise genuine complaints about a practitioner whose conduct or performance is a risk to patients and/or may meet the grounds for voluntary or mandatory notification under the *Health Practitioner Regulation National Law* or the National Code of Conduct for Unregistered Health Practitioners, or the legal requirement to report to the Independent Commissioner against Corruption (ICAC). It may be appropriate to report a health practitioner who has inappropriately reported or managed patient incidents to AHPRA or HCSCC.

3.11.1 Release of information about patient incidents

Parts 7 and 8 of the *Health Care Act 2008* protect information gained as the result of or in connection with an authorised activity, or a root cause analysis, from being disclosed, except in in the very limited circumstances allowed by the Act. There are substantial penalties under the *Health Care Act* for releasing information protected by Part 7 or 8 to someone who is not authorised to receive that information.

Section 93 of the *Health Care Act 2008* and Section 106 of the *Mental Health Act 2009* also protects personal information from disclosure.

Any staff receiving a request for information about an incident, a review done by a Part 7 Committee or an RCA must direct the request to the LHN Safety and Quality or Risk Managers or Department for Health and Wellbeing Safety and Quality Unit (HealthSentinelEvents@sa.gov.au). This includes, but is not limited to requests from:

- Freedom of Information officers
- Australian Health Practitioner Regulation Agency (AHPRA)
- SA State Coroner
- consumers
- lawyers
- the media
- SA Ombudsman.
- Health and Community Services Complaints Commissioner

Patient confidentiality and privacy are to be maintained in accordance with the SA Health Privacy Policy, and professional codes of conduct.

3.12 Education and training requirements

All staff involved with direct provision of services to patients must be able to report a patient incident into the SLS, and be able to participate in the investigation of incidents and level 2 open disclosure. All such staff must be aware of their responsibilities in reporting incidents, and providing an appropriate open disclosure response.
The interactive eLearning course is designed for completion by all staff, and introduces incident investigation and open disclosure. The SLS guide How to report a patient incident provides information for all staff.

All patient incident managers must acquire the skills and knowledge they require to fulfil their roles and responsibilities in patient incident management, including open disclosure, incident classification and SAC rating, investigation, using SLS, escalation of serious incidents, and taking action to improve safety. The SLS Guide How to manage a patient incident provides further information.

Patient incident managers require skills and knowledge in analysis of single incidents, serious incidents, and in analysis of aggregated incident types for the purpose of quality improvement.

Nominated Open Disclosure Facilitators, RCA team leaders and Part 7 committee chairs all require specialised training to equip them with knowledge and skills for these roles.

The managers and staff of a Safety and Quality and Risk Unit or equivalent, including the designated SLS Administrators, can provide advice to staff and executives, and have a role in staff education. These teams are able to authorise access to SLS for patient incident manager. Safety and Quality managers have considerable expertise in SLS and patient incident management. Further information for these staff is available from Department for Health and Wellbeing Safety and Quality Unit.

4. Implementation & Monitoring

Health services are required to evaluate the effectiveness of their incident management system, and the open disclosure processes outlined in this Policy Directive. Table 3 summarises a number of indicators and measures.

This includes evaluation or gap analysis of staff knowledge and skills to effectively use the features of the SLS as the key enabling tool for all phases of incident management, and to use the data and information for planning quality improvement.

Evaluation measures require linkage with regular committee-led activities for safety and quality, clinical governance and risk management. These provide a comprehensive picture of the impact of incident management, and monitoring of the progress with improvement initiatives.

The Local Health Network Analytic and Reporting System (LARS)and QIP Hub will be used to display indicators for patient incidents relevant to the National Safety and Quality Health Service Standards, and other indicators, drawing from data captured in the SLS. The SLS retains the more comprehensive set of data, and indicators can be reported directly from SLS in a variety of formats.
Health services should aim for minimisation of both numbers of patient incidents and harm resulting from patient incidents. An indicator of a positive safety culture is preparedness to report incidents and near misses. Decrease in harm is a useful measure of improvement.

Table 3 – Evaluation and indicators

A health service may require a number of measures to indicate its performance in patient incident management. These include:		**Data source**
Timely / appropriate reporting of patient incidents by notifiers	All patient incidents and near misses are recorded in SLS. All incident reports; • contain adequate and appropriate information All medical records include details of the incidents and any diagnosis and/or care provided as a result of the patient incident. All staff have knowledge and skills in principles and practice, including use of SLS appropriate to their role.	Clinical audit of medical record or Sunrise EMR and comparison with SLS reports Audits of SLS data quality Audits of staff knowledge, skills
Effective review and management of individual incidents	All patient incidents are reviewed within timelines. Incident managers are reviewing all incidents, and SLS is used to document the review. All incident managers are investigating patient incidents to the level required, and SLS is used to record the investigation processes. All recommendations and/or actions arising are documented in SLS. All SAC 1 and SAC 2 incidents have timely review according to this policy, and documentation uploaded into SLS. All recommendations and/or actions arising are completed in timely fashion. All incident managers have appropriate knowledge and skills in principles and practice, including use of SLS in reporting /documenting investigation and follow-up actions. All incident managers request input from reviewers appropriately. All incident managers are using SLS for documentation for individual patient incidents of; • post incident team review • other results of investigation • open disclosure processes • SAC 1 and 2 processes • implementation of recommendations / actions arising. All incident managers are using SLS to house relevant documents, eg documents generated during an investigation of a patient incident.	SLS Audits of SLS data quality Audits of staff knowledge, skills
SLS Administrators	All SLS Administrators have knowledge and skills to undertake their role. (SLS Administrators guide)	DHW SLS training records Records of IHI training completed
Relevant staff education and training	• Training provided that meets the skills and knowledge requirements of their role • Staff participation in training. • The quantity, quality and type of training offered, and to which staff, is monitored and evaluated. • All managers and committee members have	Records of clinical education Completion of on-line module

	appropriate knowledge and skills in principles and practice of data analysis and quality improvement. • There are sufficient staff with RCA training, and Open Disclosure Facilitator training	
Open disclosure	Proportion of all SAC1 and 2 incidents openly disclosed (target 95%) • Proportion of patient incidents where open disclosure discussion provided, by either the notifier or manager • Number of open disclosure processes that commenced and concluded in a reporting period • The number and percentage of open disclosure processes referred to mediation • The number and percentage of open disclosures triggered by complaints, incident notification, case note review, general observation or patient/consumer request. • Numbers of staff with OD facilitator training • Managers completions of the Open disclosure questions in the managers section of SLS. • Survey results of staff experience of open disclosure • Survey results of consumers experience with open disclosure	SLS – incident report Staff and consumer surveys regarding open disclosure
Consumer or patient feedback	Complaints or concerns relating to incident management and/ or open disclosure. Patients are encouraged to complete open disclosure evaluation surveys (Tool 15).	SLS - consumer feedback
Post incident follow-up with staff	Documentation of staff follow-up, eg team or individual de-brief, team learning, referral for counselling (EAP). Patients and staff are encouraged to complete open disclosure evaluation surveys (Tool 16).	SLS
Use of SLS data **Report or data generation**	There is regular review and analysis by clinical managers and committees of data from groups of incidents: • One, or a group of locations, eg surgical division • One or more classification, eg pressure injury Numbers and rates of incidents by • Area / location and • classification and • consequence / SAC rating Actions arising are documented, and completed in timely fashion. Quality improvement activities arising are documented, and completed in timely fashion.	Committee minutes, agendas

5. National Safety and Quality Health Service Standards

The Australian Commission on Safety and Quality in Health Care has developed the National Safety and Quality Health Service Standards (the Standards).

The Standards provide a nationally consistent and uniform set of measures of safety and quality for application across a wide variety of health care services. They propose evidence-based improvement strategies to deal with gaps between current and best practice outcomes that affect a large number of patients.

National Standard 1 Clinical Governance	National Standard 2 Partnering with Consumers	National Standard 3 Preventing & Controlling Healthcare-Associated Infection	National Standard 4 Medication Safety	National Standard 5 Comprehensive Care	National Standard 6 Communicating for Safety	National Standard 7 Blood Management	National Standard 8 Recognising & Responding to Acute Deterioration
☒	☒	☒	☒	☒	☒	☒	☒

This policy is relevant to all National Safety and Quality Health Service Standards. The Standards specifically require services to have the ability to monitor and respond to incidents for some Standards - medication safety, clinical handover, blood and blood products and falls.

Patient safety incidents must be recognised, reported and analysed, and this information used to improve quality of care and safety systems.

6. Definitions

A full glossary of terms, including additional explanations, is available.

In the context of this document:

- **actual SAC** means: the Safety Assessment Code rating applied to a patient incident by the patient incident manager after investigation and analysis (SAC matrix)
- **adverse event** means: a term used by Therapeutic Goods Administration (TGA) for reportable unwanted and sometimes harmful occurrences from using medicines, vaccines or medical devices (collectively known as therapeutic goods)
- **adverse outcome** means: a poorer than expected outcome for the patient from treatment
- **avoidable complication of care** (or potentially avoidable complication of care, or hospital acquired complication of care) means: a known or unexpected complication of care, or side effect of treatment that may have been prevented
- **carer(s)** means: a term that includes family, relative, support person, person responsible, substitute decision-maker and significant others, but not paid carers or volunteers
- **clinician** means: a healthcare provider. Clinicians include registered and non-registered health practitioners
- **contributing factors** means: the circumstances, actions or influences which are thought to have played a part in the origin or development of an incident, or to increase the risk of an incident. Examples include human factors or system factors
- **degree of harm** means: the severity and duration of any harm, and any treatment implications, that result from an incident
- **disclosure** means: the act of making something known or revealed or uncovered. To disclose, in relation to information, means to give, reveal or communicate in any way

- **error** means: a failure to carry out a planned action as intended, or application of an incorrect plan. An error can be by omission (not doing the right thing) or by commission (doing the wrong thing)
- **health service** means: all public health organisations, including statewide clinical support services that are the responsibility of SA Health
- **health service manager or supervisor** means: the staff member who is responsible for the activities of a particular location for example ward or team manager or medical head of unit
- **incident** (patient 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 consumer / patient that occurs during an episode of health care
- **harmful incident** means: any event or circumstance which resulted in unintended and/or unnecessary psychological or physical harm to a patient during an episode of health care
- **cluster incident** means: a type of adverse incident where there is a group or series of harmful incidents that are the result of one systemic error or issue, and that involves a systems failure or multiple systems failure that does or has the potential to place more than five patients directly at risk
- **near miss** means: a patient incident that did not cause harm, but had the potential to do so
- **no harm** means: the incident occurred and the patient was exposed but no harm resulted
- **adverse incident** means: any of the classes of patient incident, including Sentinel events, as defined by the South Australian Government Gazette
- **incident classification** means: the category of incident determined by its clinical features such as relating to a pressure injury or the provision of a treatment or procedure
- **incident investigation** means: a detailed systematic inquiry conducted to ascertain the underlying causes and facts of a patient incident
- **incident management** means: all the activities involved in the reporting, notification or documentation of an incident or near miss, including the review, investigation and analysis of the individual incident, and the analysis of groups of incidents, or data arising, for the purpose of improvement of the safety and quality of the health service and the care provided
- **incident review** means: the initial review of the notifier's report of an incident submitted into SLS, done by the patient incident manager
- **open disclosure** means: a process of providing an open, consistent approach to communicating with consumers / patients and their family or carer and/or support persons after an incident
- **open disclosure facilitator** means: an SA Health staff member who has completed the prescribed face to face open disclosure training to be able to conduct level 1 open disclosure
- **patient** means: a person currently receiving health services from an SA Health service or a service funded by SA Health. For the purpose of this document patients, consumers and clients and residents (of residential care facilities operated by SA Health) are equivalent terms
- **patient incident manager** means: the senior staff member of a clinical area or service who is responsible for the conduct of all activities to do with the management of the patient incident, and who has been verified by the SLS Administrator or Safety and Quality Manager(s) to have relevant knowledge and skills
- **patient outcome** means: the impact upon a patient which is wholly or partially attributable to an incident
- **Part 7 committee** means: a committee that is formed in accordance with the requirements of, and under the protection of, Part 7 of the Health Care Act 2008
- **quality** means: the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge (ACSQHC)
- **risk** means: the probability that an incident will occur

- **root cause analysis (RCA)** means: a method of investigating incidents, using a systematic iterative process whereby the factors that contribute to an incident are identified by reconstructing the sequence of events to elucidate underlying root causes (contributing factors or hazards)
- **safety** means: the reduction of risk of unnecessary harm associated with health care to an acceptable minimum (ACSQHC)
- **Safety Assessment Code (SAC)** means: a numerical score applied to a patient incident which is based on the consequence of the incident and its likelihood of a recurrence. The score is determined by the use of the SAC Matrix
- **Safety Learning System (SLS)** means: The electronic system and database used in SA Health for reporting information about all phases of patient incident management.
- **system failure** means: fault, breakdown or dysfunction within an organization's operational methods, processes or infrastructure
- **team review** means: a brief, informal team meeting that occurs as soon as possible after the incident and where the inter-professional team reviews the incident, with the patient and carer if possible.

7. Associated Policy Directives / Policy Guidelines and Resources

- Accreditation policy
- Advance Care Directives policy
- Complaints about a health practitioner policy directive
- Consent to Medical Treatment and Health Care policy guideline
- Consumer Feedback Management policy directive
- Coronial Process and *Coroners Act 2003* policy directive and policy guideline, and the Coroners Inquest procedure
- Framework for Active Partnership with Consumers and the Community directive
- Lookback Review policy directive
- The *Health Care Act 2008* Part 7 Committees policy directive
- The *Health Care Act 2008* Part 8 Root Cause Analysis policy directive
- Reporting and management of incidents of suspected or alleged sexual assault of an adult, or sexual misconduct by an adult, within SA Health facilities and services policy directive
- Root Cause analysis policy directive

South Australian legislation

- *Civil Liability Act 1936*
- *Consent to Medical Treatment and Palliative Care Act1995*
- *Coroners Act 2003*
- *Freedom of Information Act 1991*
- *Health and Community Service Complaints Act 2004*
- *Health Care Act 2008*
- *Health Care Regulations 2008*
- *Health Practitioner Regulation National Law (South Australia) Act 2010*
- *Independent Commissioner Against Corruption Act 2012*
- *Mental Health Act 2009*
- *Radiation Protection and Control Act 1982 and associated regulations*
- *South Australian Carers Recognition Act 2005*
- *Work Health and Safety Act 2012*

References and other resources

- AMA Position Statement on Quality and Safety in Hospital Practice (2013)
- Australian Open Disclosure Framework. Australian Commission on Safety and Quality in Health Care
- Code of Ethics for the South Australian Public Sector.
- SA Health Privacy Policy
- National Safety and Quality Health Service Standards June 2012. Australian Commission on Safety and Quality in Health Care
- National Codes of Conduct. Australian Health Practitioner Regulation Agency (AHPRA).
- SA Health Guide for Engaging with Consumer and the Community
- The South Australian Government Gazette
- Your Rights and Responsibilities – A Charter for Users of the South Australian Public Health System'

8. Document Ownership & History

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Approval Date	Version	Who approved New / Revised Version	Reason for Change
15/05/2020	V2.3	Director, Safety and Quality	Minor changes to reflect the introduction of the Governing Boards Insertion of clause in s3.4.4 so the CE can waive the requirement for OD in rare cases Insertion of clause 3.4.1 DPR Change of template
29/09/2017	V2.2	Executive Director, Quality Information and Performance	Minor changes to • s 4.11 relating to the protection of SLS information
03/01/2017	V2.1	Executive Director, Quality Information and Performance	Minor changes to • s4.4 open disclosure of near miss incidents, some criminal and self-harm incidents and for some service providers • s 4.11 after removal of protection of SLS information under Part 7 of Health Care Act 2008 • s 4.9 regarding notification to executives and briefing to DHA
14/07/2016	V2	Portfolio Executive	Updated information and integration of : • Incident Management Policy D0162 • Open Disclosure Policy D0247 • Incident Management Policy Guideline incorporating Open Disclosure Response G0075

01/07/12	V1.2	Operational Safety and Quality Committee	Amended to reflect Contact Centre (1800 NOTIFY) telephone number
06/10/11	V.1.1	Portfolio Executive - OOS	Amended to reflect intro of SLS and OD
06/10/09	V.1	Portfolio Executive – Incident Management(D0162)	PE Approved version.
22/11/14	V1.2	V3 - 22/11/14 - current - Updated review date	Updated review date
17/09/12	V.1.1	Operational Safety and Quality Committee	Update to reflect the restructures within the portfolio and are not material in nature
06/10/11	V.1	Portfolio Executive – Open Disclosure Policy Directive (D0247)	PE Approved version
dd/mm/yy	V2.0	<approving authority>	eg. Formally reviewed in line with 1-5 year scheduled timeline for review.
dd/mm/yy	V1.1	<approving authority>	eg. Amended department name to 'Department for Health and Wellbeing'.
dd/mm/yy	V1.0	<approving authority>	Original <approving authority> approved version.