

TITLE	Open Disclosure
TARGET AUDIENCE	All Staff
SCOPE	All Cabrini Health Clinical Sites and Services

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OPEN DISCLOSURE PROCEDURE STEP GUIDE

IMMEDIATE MANAGEMENT OF INCIDENT:

TRIGGER

Incident occurs resulting in unintended patient harm

▶ Step 1

Follow 'Clinical Incident Management Procedure' (available on PROMPT)

OPEN DISCLOSURE STEPS:

▶ Step 2

Assess incident for severity of harm and level of response

Severity of harm can be determined using the 'Severity Matrix - Incident Outcome Decision Support Tool' in the 'Clinical Incident Management (non-WHS) Procedure.

An incident will **either** require a lower-level response or a higher-level response depending on the severity of harm. Follow step 3a **or** 3b below according to incident severity

Where uncertainly exists a higher-level response should be initiated.

▶ Step 3a

Lower Level Response

(full detail available within Open Disclosure Procedure)

A Lower Level Response is to be led by the local service or department manager, with support from the Nurse Director.

1. Initial discussion with the patient and/or family should occur ASAP after recognising harm.
For a lower level response, it is likely that the disclosure process will be completed after this initial discussion.
2. Document in Medical Record
3. Update related RiskMan incident report
4. Follow up meetings should occur as necessary



▶ Step 3b

Higher Level Response

A Higher Level Response will involve the Director of Service/Nurse Director and multidisciplinary team members involved in adverse event, the relevant Executive Director, treating physician and Clinical Risk Team representative.

1. Initial discussion with the patient and/or family should occur ASAP after recognising harm, including providing the patient and family with the name and details of a nominated key liaison Cabrini Health person
2. Convene a higher level open disclosure meeting
3. Team discussion to take place (key meeting considerations, roles and responsibilities, actions to take place during meeting, timing, location and attendees of the first meeting)
4. First meeting to take place.
Guide for Open Disclosure meeting available on pg.12 of the Open Disclosure Procedure
5. Follow up with the patient and/or family to be provided by the nominated key liaison Cabrini Health person or delegate. Follow up may occur over a considerable period of time even if patient has been discharged.
6. Completing the process
The Open Disclosure Procedure concludes with a shared agreement between the patient and their support person, and Cabrini Health.

PURPOSE

- To facilitate open communication with patients and/or their family about an incident that resulted in harm to the patient whilst receiving care.
- To ensure a formalised process is in place to manage communication of adverse events and unexpected outcomes of care
- To provide persons using Cabrini Health services with relevant information about what happened to them and why, if they have been adversely affected during receipt of care
- To ensure the open disclosure of adverse events in an environment where patients and staff feel supported and which provides the opportunity for system improvements to be identified and acted upon

POLICY

- Cabrini Health follows the principles of open disclosure, and will inform patients and/or their family of any incident that resulted in harm
- Open disclosure reflects Cabrini Health's values of compassion, integrity, courage and respect, in recognising and addressing the needs and rights of patients and their families by providing appropriate information and support when an adverse event occurs
- All clinical adverse events must be notified in a timely manner to allow for early identification, reporting, and investigation, consistent with the ['Clinical Incident Management \(non-Work Health and Safety\) Procedure'](#) and [Serious Incident Review Protocol](#)
- Cabrini Health recognises the importance of supporting staff through the open disclosure process

PRINCIPLES

The eight key principles of open disclosure are:

1. Open and timely communication

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

2. Acknowledgment

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

3. Apology or expression of regret

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

4. Supporting, and meeting the needs and expectations of the patient and/or their family

The patient and/or their family can expect to be:

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

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

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

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

6. Integrated clinical risk management and systems improvement

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

7. Good governance

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

8. Confidentiality

Policies and procedures should be developed by health service organisations with full consideration for patient and clinician privacy and confidentiality, in compliance with relevant law (including Commonwealth, state and territory privacy and health records legislation). However, this principle needs to be considered in the context of Principle 1: Open and timely communication.

MEDICO-LEGAL CONSIDERATIONS

- Consideration of legal and insurance issues, both for Cabrini Health and the healthcare professionals involved:
 - The Clinical Risk Manager in consultation with the relevant Group Director will notify the hospital's medical indemnity insurers and lawyers as necessary
 - The Clinical Risk Manager will involve Cabrini Health insurers for an initial discussion about the information to be disclosed prior to communication with the patient
 - Medical clinicians should be advised to notify their Medical Defence Organisation

NOTE: A written account of higher-level open disclosure meeting(s) must be provided to the Clinical Risk Manager for review by the Cabrini Medical Indemnity Insurers prior to providing a copy to the patient.

PROCEDURE

1. IDENTIFICATION OF INCIDENTS AND ASSESSMENT OF RESPONSE

The open disclosure process commences with the recognition that a patient has suffered unintended harm during their treatment, which is unrelated to the natural course of the illness or differs from the immediate expected outcome of the person's management

An adverse event might be identified by:

- a clinician or staff member at the time of the incident
- a staff member when an unexpected outcome is discovered
- a patient and/or their family who expresses concern or dissatisfaction with the patient's health care, either at the time of the incident or retrospectively
- through patient feedback mechanisms
- the use of incident detection systems, such as RiskMan™, or clinical audit process
- other hospital patients, students, visitors or other staff.

2. INITIAL RESPONSE

As soon as an adverse event is identified, the first priority is the provision of prompt and appropriate clinical care and prevention of further harm, as per the [Clinical Incident Management \(non-Work Health and Safety\) Procedure](#)

3. ASSESSING THE INCIDENT FOR SEVERITY OF HARM AND LEVEL OF RESPONSE

3.1 Criteria for determining the appropriate level of response

The level of response required will be determined by the effect, severity or consequence of the incident. All incidents are to be reported via the incident management system RiskMan™. The open disclosure section of the incident report is mandatory for Managers to complete.

3.1.1 Lower-level response

Severity of harm

1. Near misses and no-harm incidents
2. No permanent injury
3. No increased level of care (e.g. transfer to operating theatre or intensive care unit) required
4. No, or minor, psychological or emotional distress

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

When a lower-level response is indicated:

- The open disclosure process is led by the local service/department manager, with the support from the Nurse Director/Clinical Service Director where appropriate
- The Clinical Risk team will be notified that open disclosure has occurred via the incident entry in RiskMan™

3.1.2 Higher-level response

Severity of harm

1. Death or major permanent loss of function
2. Permanent or considerable lessening of body function
3. Significant escalation of care or major change in clinical management (e.g. admission to hospital, surgical intervention, a higher level of care, or transfer to intensive care unit)
4. Major psychological or emotional distress
5. At the request of the patient
6. Any sentinel event
7. Any incident under the Serious Incident Reporting Scheme (SIRS) (Ashwood – Aged Care)

When a higher-level response is indicated:

- The Director of Service or the Nurse Director will have oversight of the open disclosure process to ensure the correct process is followed, in consultation the multidisciplinary team involved in the adverse event, the relevant Executive Director, the treating physician and the Clinical Risk Team.

4. INITIAL DISCUSSION

- The initial discussion with the patient and/or their family should occur as soon as possible after recognising harm, even if all the facts are not yet known and be:
 - Face-to-face
 - At a location and time that is suitable, convenient and accessible for the patient and/or their family
 - In a quiet, comfortable private area to maintain confidentiality, away from the clinical area and free from interruptions e.g. telephones / pager
 - With sufficient time to apologise, explain the known facts of the incident, listen, and address any questions and concerns
 - In a manner that empowers the patient and/or their family and encourages their openness to ask questions in an environment that is non-threatening and avoids intimidation
- During the initial discussion:
 - The adverse event is acknowledged to the patient and/or their family
 - An apology or expression of regret is given (including the word 'sorry') for the harm suffered
 - The effect of the incident, including all known facts and the consequences, are described
 - Avoid speculation or blame
 - Explain the type of review that will be undertaken and estimated timeframes for completion
- The initial discussion must be recorded in the RiskMan™ incident report and the patient's medical record.

When a **lower-level response** is indicated, it is likely that the disclosure process will be completed after the initial discussion, if all parties agree

When a **higher-level response** is indicated, three additional actions will be included in the initial discussion with the patient and/or their family:

1. Signal the need to convene a higher- level open disclosure meeting
2. Negotiate the time and place, as well as identifying all the attendees or participants that will be involved and / or present in the meeting
3. Provide the patient and/or their family with the name and details of a nominated key liaison Cabrini Health person who they can contact for further information

5. PREPARING FOR HIGHER-LEVEL OPEN DISCLOSURE

5.1 Team Discussion

A meeting will be convened as soon as possible after the event by the Director of the Service / Nurse Director, including the multidisciplinary team involved in the adverse event, the relevant Executive Director, the treating physician and Clinical Risk Team representative.

The purpose of the meeting is to:

- Complete the [Serious Incident Management Huddle Checklist which will then be stored by the Clinical Risk team](#)
- Decide who will lead the discussion and who will participate – (see below)
- Ensure that all the necessary facts are established
- Identify immediate support needs for staff involved (See [Employee Welfare Policy and Guidelines](#))
- Determine if an interpreter will be necessary and involve as required
- Identify potential areas of conflict or disagreement
- Agree on a basic plan or agenda
- Give consideration and discussion to how the incident is conveyed to the patient and/or their family, ensuring that all team members maintain a consistent approach in their discussions
- Consideration is given to:
 - Legal and insurance issues, both for the organisation and the clinicians
 - Issues regarding ongoing care such as billing and other costs should be addressed at the earliest opportunity.

A detailed summary of the open disclosure discussions should be entered into the patient’s medical record.

Note: While careful scripting is not recommended, it is important to have a basic idea of what will be discussed to avoid saying something that may need to be retracted later

5.2 Choosing the individual to lead the disclosure

The individual leading the open disclosure should, ideally, be the most senior clinician who is responsible for the care of the patient and meets the following criteria:

- Be known to the patient, their family and carers
- Be familiar with the facts of the adverse event and the care of the patient
- Be of appropriate seniority to ensure credibility
- Have received training in open disclosure
- Have good interpersonal skills
- Be able to communicate clearly in everyday language
- Be able and willing to offer reassurance and feedback to the patient and/or their family
- Where possible and appropriate, be willing to maintain a medium to long-term relationship with the patient and/or their family
- Be informed of any future legal implications

The decision about who will make the disclosure should, where possible, be made in consultation with the patient and/or their family, the Clinical Risk Manager, Director of the Service and the relevant Group Director.

If for any reason the senior clinician is unable to lead the open disclosure, a substitute will need to be selected but, ideally, the senior clinician should still be present at the discussion.

NOTE: The person leading the open disclosure may require the support of a senior staff member with appropriate skills.

5.3 Timing, location and attendees of the first meeting

The timing and location of open disclosure meetings should be decided in consultation with the patient and/or their family.

The patient and/or their family should be consulted about which members of the multidisciplinary team will participate in the open disclosure meeting.

If it becomes apparent that the patient would prefer to speak to a different clinician(s) than those designated to lead the open disclosure, the patient's wishes should be respected and, if possible, an acceptable substitute provided.

6. ENGAGING IN OPEN DISCLOSURE

See [Appendix 2 -Guide for the Open Disclosure Meeting](#)

Key considerations and actions of the open disclosure meeting are:

- Provide the patient and/or their family with the names and roles of all attendees
- Provide the patient and their family with written information explaining the open disclosure process
- Provide a sincere and unprompted apology or expression of regret including the words: 'I am sorry' or 'we are sorry'
- Clearly explain the incident
- Give the patient and/or their family the opportunity to tell their story, exchange views and observations about the incident and ask questions

- Encourage the patient and/or their family to describe the personal effects of the adverse event on their well-being
- Where possible, a plan for the open disclosure process should be agreed by all parties involved in the process
- Agree on and record an open disclosure plan including the expected outcomes of the open disclosure process for both patient and/or their family and Cabrini Health
- Assure the patient they will be informed of further investigation findings and recommendations for system improvement
- Offer practical and emotional support to the patient and/or their family
- Support staff members through the process and prepare to link with staff support programs
- If the adverse event took place in another health service organisation, include relevant staff from that organisation if possible
- If necessary, hold several meetings or discussions to achieve the above aims.

NOTE: A written account of all higher-level open disclosure meetings must be provided to the Clinical Risk Manager for review by the Cabrini Medical Indemnity Insurers prior to providing a copy to the patient.

7. PROVIDING FOLLOW-UP

- Higher-level response open disclosure is a process and not a single discussion
- Follow-up is important and may occur over a considerable time period, even after the patient has been discharged
- Follow-up will be done by the individual leading the open disclosure, however it may be delegated to another member of the multidisciplinary team, depending on the circumstances
- It is important that:
 - Follow-up is active and not reactive
 - Patients and/or their family have an opportunity to ask further questions and request additional information
 - Agreement is reached between relevant parties on providing, or monitoring, ongoing care related to the incident
 - Cabrini Health will provide information on changes that have been implemented as a result of an adverse event and how the changes will improve patient safety
 - The patient and/or their family are offered an opportunity to discuss the process with another relevant professional such as a general practitioner, residential care facility or community care provider.

8. COMPLETING THE PROCESS

- The open disclosure process concludes with shared agreement between the patient and/or their family and the healthcare team. In most cases, this will occur after the adverse event review or investigation is completed
- When the relevant review or investigation is complete, the patient and/or their family should be provided with the opportunity to review the outcome in their preferred manner, either face to face or in writing
- The interview and document should include:
 - Details of the incident, including the clinical facts and other relevant facts
 - The patient’s concerns or complaints
 - An apology or expression of regret (including the word ‘sorry’) for the harm suffered
 - A summary of the factors contributing to the adverse event

- Information about steps that have been taken to minimise the risk of recurrence of the adverse event, and how these improvements will be monitored
- An opportunity for the the patient and/or their family to ask questions
- If further issues are identified after the process is completed, the patient and/or their family should have the opportunity to re-contact the open disclosure clinician for a response to their questions.

8.1 Communication with primary care providers

If the patient agrees, a discharge letter will be forwarded to their general practitioner, residential facility or community care provider upon discharge from Cabrini Health.

8.2 Unable to reach agreement

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

If a complaint cannot be resolved, the patient and/or their family should be provided with the contact details of the [Health Complaints Commissioner](#)

9. MAINTAINING DOCUMENTATION

- Maintain a detailed record of the open disclosure process
 - Whilst the patient is an inpatient, a record of all meetings will be documented in the patient's medical record, including a list of attendees
 - Once the patient is no longer an inpatient, a record of all meetings will be documented on a meeting transcript supplied by the Clinical Risk Team. The ongoing documentation will be kept in a secure file in the Clinical Risk office
- Retain a copy of all documents relating to the open disclosure
- Provide the patient and/or their family with documentation throughout the process

EVALUATION

Number of senior clinicians trained in open disclosure process

Number of serious adverse events (Major or Catastrophic) managed using the open disclosure process

Participant feedback from education sessions

REFERENCES and ASSOCIATED DOCUMENTS

Cabrini Health Policies Procedures & Protocols

[Clinical Incident Management \(non-Work Health and Safety\)](#)

[Serious Incident Management Huddle Checklist](#)

[Serious Clinical Incident Review](#)

[Serious Incident Reporting Scheme \(SIRS\) - Ashwood](#)

[Patient, Resident and Family Feedback, Complaints and Compliments Management](#)

[Employee Welfare Policy and Guidelines](#)

Key Legislation & Standards

National Safety and Quality Health Service Standards (second edition) (Updated May 2021)) Australian Commission on Safety and Quality in Health Care Std 1.12 (p8)
<https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-safety-and-quality-health-service-standards-second-edition>

[Australian Commission on Safety and Quality in Health Care \(2013\) *Saying sorry: a guide to apologising and expressing regret in open disclosure* ACSQHC, Sydney](#)

Australian Open Disclosure Framework Australian Commission on Safety and Quality in Health Care (2014) ACSQHC, Sydney

References

[Sentinel Event program, Safer Care Victoria](#)

[Australian Open Disclosure Framework Australian Commission on Safety and Quality in Health Care \(2014\) ACSQHC, Sydney](#)

[Open Disclosure Handbook Clinical Excellence Commission \(Oct 2014\) Sydney: Clinical Excellence Commission](#)

www.safetyandquality.gov.au/opendisclosure:

- [Australian Commission on Safety and Quality in Health Care – Open disclosure: just in time information for clinicians](#)

Health Complaints Commissioner <https://hcc.vic.gov.au/>

Executive Sponsor	Group Director Medical Services and Clinical Governance	
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Appendix 1 Guide for the Open Disclosure Meeting

<p>Beginning the meeting</p> <ul style="list-style-type: none"> <input type="checkbox"/> Find a suitable place to hold the meeting, in consultation with the patient <input type="checkbox"/> Turn off mobile telephones, beepers (if possible) <input type="checkbox"/> Be conscious of positioning and body language <input type="checkbox"/> Introductions and participants names and titles are provided in writing to patient <input type="checkbox"/> Describe the purpose of the conversation
<p>Listen and empathise throughout</p> <ul style="list-style-type: none"> <input type="checkbox"/> Assess the patient’s understanding of what happened <input type="checkbox"/> Identify the patient’s key concerns <input type="checkbox"/> Actively listen (repeat back in your own words what the patient is saying) <input type="checkbox"/> Acknowledge and validate the patient’s feelings
<p>Apology / expression of regret</p> <ul style="list-style-type: none"> <input type="checkbox"/> The lead will say they are sorry for the adverse event in a sincere manner early in the conversation, even if an apology was provided in an earlier discussion
<p>Explain the facts</p> <p><i>What happened and the role of team members? What are the consequences?</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Identify the adverse event early in the discussion <input type="checkbox"/> Explain what happened in plain language <input type="checkbox"/> Explain what is known about why the adverse event happened; <ul style="list-style-type: none"> <i>Do not speculate on causes, or blame others.</i> <i>Do not pre-empt results of investigations or reviews.</i> <i>Work with colleagues to provide a consistent approach.</i> <input type="checkbox"/> Tell the patient what should have happened <input type="checkbox"/> Explain your role in the incident and the role of other members of the clinical team; <ul style="list-style-type: none"> <i>Do not blame others or ‘the system’</i> <input type="checkbox"/> Explain how the short-term consequences will be treated or managed <input type="checkbox"/> Explain how the event is likely to impact the medium, and long-term health care and what will be done to care for the patient <input type="checkbox"/> Explain how billing and other cost of consequent care will be managed (if applicable) <input type="checkbox"/> Explain what will be done to ensure that a similar event doesn’t happen to others.
<p>Invite patient response <i>How do they feel about what happened?</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Patient and/or their family tell their story about incident <input type="checkbox"/> Patient and/or their family ask questions <input type="checkbox"/> Patient and/or their family describe personal effects and impact of adverse event <input type="checkbox"/> Cabrini team listen and explore patient/family concerns and respond to questions.
<p>Closing the discussion</p> <ul style="list-style-type: none"> <input type="checkbox"/> Discuss the next steps and plan for a follow-up conversation <input type="checkbox"/> Confirm how results and information is best provided – meeting/ letter <input type="checkbox"/> Ask the patient if they have any questions and provide responses <input type="checkbox"/> Provide the details of the Cabrini contact person in writing
<p>Following up</p> <ul style="list-style-type: none"> <input type="checkbox"/> Provide a written meeting summary to the patient and/or their family (- via Clinical Risk Manager / Medical Defence Organisation) <input type="checkbox"/> File a copy of this summary in the appropriate place in the patient record and with Clinical Risk Manager

Appendix 2 Definitions

Admission of liability: A statement by a person that admits, or tends to admit, a person's or organisation's liability in negligence for harm or damage caused to another.

Apology: An expression of sorrow, sympathy and (where applicable) remorse by an individual, group or institution for a harm or grievance. It should include the words 'I am sorry' or 'we are sorry'. Apology may also include an acknowledgment of responsibility, which is not an admission of liability

Expression of regret: An expression of sorrow for a harm or grievance. It should include the words 'I am sorry' or 'we are sorry'. An expression of regret may be preferred over an apology in special circumstances (e.g. when harm is deemed unpreventable).

Higher-level response: A comprehensive open disclosure process usually in response to an incident resulting in death or major permanent loss of function, permanent or considerable lessening of body function, significant escalation of care or major change in clinical management (e.g. admission to hospital, surgical intervention, a higher level of care or transfer to intensive care unit), or major psychological or emotional distress. These criteria should be determined in consultation with patients, their family and carers A higher-level response may also be instigated at the request of the patient even if the outcome of the adverse event is not as severe.

Lower-level response: A briefer open disclosure process usually in response to incidents resulting in no permanent injury, requiring no increased level of care (e.g. transfer to operating theatre or intensive care unit), and resulting in no, or minor, psychological or emotional distress (e.g. near misses and no-harm incidents). These criteria should be determined in consultation with patients, their family and carers.

Adverse Event: An incident that resulted in harm to a person receiving care (*Australian Commission on Safety and Quality in Health Care [ACSQHC]*)

Clinical Incidents: unintended or unexpected events that could have or did lead to harm for one or more patients receiving care (*Department of Health (2008), VHIMS data set specification, State Government of Victoria, Melbourne*).

Clinical incidents include adverse events, near misses and hazards in the environment that pose a clinical risk.

Harm: Harm includes disease, suffering, impairment (disability) and death:

- disease: a psychological or physiological dysfunction
- suffering: experiencing anything subjectively unpleasant. This may include pain, malaise, nausea, vomiting, loss (any negative consequence, including financial) depression, agitation, alarm, fear or grief
- impairment (disability): any type of impairment of body structure or function, activity limitation and/or restriction of participation in society, associated with a past or present harm

Open Disclosure: An open discussion with a patient about an incident(s) that resulted in harm to that patient while they were receiving health care. The elements of open disclosure are an apology or expression of regret (including the word 'sorry'), a factual explanation of what happened, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.

Open disclosure is a discussion and an exchange of information that may take place over several meetings (*Australian Commission on Safety and Quality in Health Care [ACSQHC]*)

Patient: Includes inpatients, outpatients, clients, consumers and residents

Family: A family may include:

- individuals of various ages who are biologically related
- related by marriage or
- not related at all but share common goals and the patient regards them as significant others

Sentinel Event: all catastrophic clinical incidents where following initial review, the outcome of the patient or resident (harm) was directly related to the incident (and not their pre-existing condition or disease process).

Sentinel events are relatively infrequent, clear-cut events that occur independently of a patient's condition, commonly reflect hospital (or agency) system and process deficiencies; and result in unnecessary outcomes for patients. It is mandatory for public and private hospitals to report sentinel vents to Safer Care Victoria

The eleven sentinel events categories in Victoria are:

1. Surgery or other invasive procedure performed on the wrong site resulting in serious harm or death
2. Surgery or other invasive procedure performed on the wrong patient resulting in serious harm or death
3. Wrong surgical or other invasive procedure performed on a patient resulting in serious harm or death
4. Unintended retention of a foreign object in a patient after surgery or other invasive procedure resulting in serious harm or death
5. Haemolytic blood transfusion reaction resulting from ABO incompatibility resulting in serious harm or death
6. Suspected suicide of a patient in an acute psychiatric unit or acute psychiatric ward
7. Medication error resulting in serious harm or death
8. Use of physical or mechanical restraint resulting in serious harm or death
9. Discharge or release of an infant or child to an unauthorised person
10. Use of an incorrectly positioned oro- or naso- gastric tube resulting in serious harm or death
11. Other – All other adverse patient safety events resulting in serious harm or death

Sub-categories under 11:

- Clinical process or procedure
- Falls
- Deteriorating patients
- Self-harm (behaviour)
- Communication of clinical information
- Medical device or equipment
- Nutrition
- Resource or organisational management
- Healthcare associated infection
- Patient accidents

Serious Incident Reporting Scheme (SIRS):

The Serious Incident Response Scheme (SIRS) is an initiative commencing 1 April 2021 to help prevent and reduce incidents of abuse and neglect in residential aged care services. This is as a result of changes to the Aged Care Act 1997, specifically the introduction of the Aged Care Legislation Amendment (Serious Incident Response Scheme) Instrument 2021.

The incidents include:

1. Unreasonable use of force
2. Unlawful sexual contact or inappropriate sexual conduct
3. Psychological or emotional abuse
4. Unexpected death of a resident
5. Stealing or financial coercion by a staff member
6. Neglect
7. Inappropriate physical or chemical restraint
8. Unexplained absence from care

Near Miss: An incident that did not cause harm, but has the potential to cause harm but didn't due to timely intervention and/or luck and/or chance