PURPOSE

TITLE	Open Disclosure Protocol and Procedure
SETTING	*All Staff and Consumers, All Clinical Sites and Services*

To ensure open disclosure processes are aligned with better practice and legislative requirements, including the Australian Open Disclosure Framework, and that Cabrini employees understand the principles of open disclosure and are aware of, and compliant with, their responsibilities.

DEFINITIONS

Adverse Event: An event referred to in Table 1: Adverse Event Responses, including an Adverse Patient Safety Event or Serious Adverse Patient Safety Event.

Adverse Patient Safety Event (or clinical incident)**:** A clinical incident that results, or could have resulted in, harm to a patient or consumer. This includes 'near miss' events.

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'. An apology may also include an acknowledgement 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 such as an unpreventable event. It does not include an acknowledgement of responsibility.

Open Disclosure: An open discussion with a patient and/or their families, carers and next of kin (**support person(s)**) about an incident 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 re-occurrence. Open Disclosure is a discussion between two parties and an exchange of information that may take place in several meetings over a period of time. (Australian Commission for Safety and Quality in Health Care, 2014).

Serious Adverse Patient Safety Event (SAPSE): A serious adverse patient safety event as defined in section 3(1) of the *Health Services Act* 1988 (Vic), being an event of a prescribed class or category that results in harm to one or more individuals. A prescribed class or category is an event that:

- occurred while the patient was receiving health services from a health service entity; and
- in the reasonable opinion of a registered health practitioner, has resulted in, or is likely to result in unintended or unexpected harm being suffered by the patient.

Statutory Duty of Candour (SDC): A legal obligation under the *Health Services Act* 1988 (Vic) for Victorian health service entities to ensure that patients, or their support person, receive an apology and are communicated with openly and honestly when a SAPSE occurs. SDC builds on the Australian Open Disclosure Framework currently utilised for all cases of harm and near misses, and which will continue to operate where there is an adverse event which is not defined as a SAPSE.

PRINCIPLES

The following eight principles should be applied when conducting Open Disclosure with a patient and/or support person:

1. **Open and timely communication**
   If an Adverse Event occurs or an issue arises, the patient and/or their support person should be provided with information about what happened in a timely, open and honest manner. The Open Disclosure process is fluid and will often involve the provision of ongoing information.

2. **Acknowledgement**
   All Adverse Events should be acknowledged to the patient and/or their support person as soon as practicable.

3. **Apology or expression of regret**
   As early as possible, the patient and/or their support person 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 any speculative statements, unverified facts, admission of liability or apportioning of blame.

4. **Supporting and meeting the needs and expectations of patients, their families and carers**
   The patient and/or their support person(s) 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, including the choice to opt out of receiving further information about the open disclosure process if that is their wish; and
   - offered the opportunity to ask any questions related to the adverse event.

5. **Supporting and meeting the needs of those providing health care**
   Cabrini aims to create an environment in which all staff are:
   - encouraged and able to recognise and report Adverse Events;
   - not exposed to blame or other pecuniary actions for reporting Adverse Events;
   - prepared through training and education to participate in Open Disclosure; and
   - supported through the Open Disclosure process.

6. **Integrated clinical risk management and system improvement**
   Once identified, an Adverse Event will undergo a thorough clinical review and investigation. The purpose of this review is to identify opportunities to improve systems and / or processes. The information obtained through the Open Disclosure and incident review process should be incorporated into quality improvement activities and recommendations should be reviewed for their effectiveness.

7. **Good governance**
   Open Disclosure requires good governance frameworks, along with sound clinical risk and quality improvement processes. Through these systems, Adverse Events should be investigated and analysed to, as far as reasonably practicable, prevent them recurring. Good governance involves a system of accountability through a health service organisation's employees, senior management, executive and 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**
   Cabrini has policies and guidelines which meet our obligations relating to patient privacy and confidentiality laws (including privacy and health records legislation). However, confidentiality and privacy needs to be considered in the context of Principle 1: Open and timely communication and Statutory Duty of Candour legislation, which encourages honest, open and timely disclosure of information to patient and their support persons when an Adverse Event has occurred. *See link to Privacy Policy in References and Associated Documents.*

PROTOCOL

All Adverse Events require Open Disclosure to occur with the patient or their support person. This disclosure and conversation with the patient or their next of kin should occur as soon as possible after recognising the event, even if all the facts are not yet known, however, there should be consideration given to the clinical condition of the patient, availability of the patient's support person and the patient's emotional and psychological state.

Open Disclosure may involve multiple conversations or interactions with a patient and their support person as the facts become known.

The response level required is determined by the severity of harm or potential harm and the consequences of the incident. A patient's individual circumstances and concerns will be taken into consideration when determining the level of response and the requirement for further conversations. Apology must never be delayed due to any uncertainty regarding the level of response required.

Table 1: Adverse Event Responses should be used as a guide in determining the level of response required. The procedure following the table outlines what is required for a lower level and higher level response.

Table 1: Adverse Event Responses		
Adverse Event Type	**Harm Considerations**	**Response**
Adverse Patient Safety Event with a severity rating of near miss*, minor or moderate	• Near misses and no-harm incidents • No permanent injury • No increased level of care (e.g., transfer to operating theatre or intensive care unit) required. • No, or minor, psychological, or emotional distress * A near miss event which does not reach the patient, does not need to be disclosed.	Lower-level Response
Adverse Patient Safety Event with a severity of major or catastrophic	• 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) • Major psychological or emotional distress • At the request of the patient	Higher Level Response
Serious Adverse Patient Safety Event (SAPSE) with a severity rating of major or catastrophic	• In the reasonable opinion of a registered health practitioner, has resulted in, or is likely to result in, unintended or unexpected harm (which includes moderate harm, severe harm **or** prolonged psychological harm) being suffered by the patient • Moderate harm means harm that requires a moderate increase in treatment to a patient, such as an unplanned or unexpected return to surgery, but does not include harm that causes permanent damage or injury to an individual • Severe harm means harm that causes a permanent lessening in the functioning of an individual that is unrelated to the natural course of a person's illness or underlying condition including harm that can lead to a person experiencing a permanent impairment or disability, or death	Higher Level Response extending to include Statutory Duty of Candour

	• Prolonged psychological harm means psychological harm which a patient has experienced, or is likely to experience, for a continuous period of at least 28 days[1]	
Sentinel event	• An unexpected and adverse event that occurs infrequently and results in the death of, or serious physical or psychological injury to, a patient as a result of system and process deficiencies • An event which meets one of the 11 sentinel event classifications: https://www.safercare.vic.gov.au/report-manage-issues/sentinel-events/what-to-report	Higher Level Response which must include Statutory Duty of Candour

PROCEDURE

OPEN DISCLOSURE LOWER-LEVEL RESPONSE

- To be completed for **ALL** Adverse Events.
- Undertaken through clinician disclosure or clinical team disclosure.
    - Medical events or complications should be disclosed by the treating physician; events relating to nursing care should be disclosed by the nursing team.
    - Safety events relating to equipment, personal safety or other will be disclosed by a relevant senior staff member involved in the care team.
- The person leading the disclosure should have received training in Open Disclosure, be able to offer reassurance to the patient / next of kin and should have good interpersonal and communication skills.
- For Adverse Events requiring a lower-level response, the Open Disclosure process is usually complete after the initial conversation.
- Consider:
    - Language and diversity, and whether an interpreter is required.
    - Patient's cognitive state or decision-making capability and whether a support person is required to be present or should the conversation instead take place with the patient's next of kin.
- Allocate responsibility for further patient follow up or ongoing dialogue if required.

STEP 1. Identification of event and notification
• APSE is identified and notified to senior clinician, nurse in charge or line manager. • Notification of event in incident management system, RiskMan (this may occur following the initial disclosure to the patient / next of kin).

[1] Regulation 3A of the *Health Services (Quality and Safety) Regulations 2020.*

STEP 2. Initial disclosure to patient and / or next of kin

• Initial disclosure sits with a member of the clinical team who is known to the patient and is familiar with the circumstances of the Adverse Event.
• Two staff members should be present, junior staff must be supported by a senior staff member.
• Open Disclosure must include:
  ○ An introduction
  ○ Acknowledgement of the event
  ○ Genuine apology or expression of regret including the words '*I am sorry / We are sorry…'*
  ○ A discussion of the known facts as agreed by the team
  ○ An opportunity for the patient or next of kin to ask questions
  ○ A plan for further clinical care (if required)
  ○ A plan for further follow up / information sharing (if required)
• Open Disclosure should occur as soon as possible with consideration of the patient's emotional and psychological state, clinical needs and active treatment.

STEP 3. Documentation
• The conversation must be documented in the progress notes within the patient's medical record with the date, time, names of staff members present and names of patient's support people present • Documentation should reflect the conversation that occurred including details of the apology given, facts provided and any further follow up required. • Documentation of all APSEs must occur in the incident management system (RiskMan).

OPEN DISCLOSURE HIGHER LEVEL RESPONSE

- A high-level Open Disclosure response will be completed **IN ADDITION to the lower-level response** for Adverse Patient Safety Events with an outcome / severity rating of major or catastrophic and for Serious Adverse Patient Safety Events.

- A follow up meeting will be arranged with the patient and / or support person. Responsibility sits with a senior member of the clinical care team (often the Nurse Unit Manager). The meeting may involve the Quality and Patient Safety Team, the Senior Medical Practitioner and / or the relevant Clinical Director.

- When an event is classified as a SAPSE, the Associate Director, Patient Safety will coordinate further meetings and will provide information to the patient and support person on the review process steps and timelines.

- Communication throughout and following the Adverse Event review may take the form of a face-to face discussion, a letter, report or combination of these. Where the Adverse Event is categorised with a severity rating of major or catastrophic, the patient should always be offered the opportunity for a face-to-face meeting.

- Feedback should always include:
  - A view of the facts (clinical and other)
  - Cabrini's response to any concerns or complaints expressed by the patient and support person
  - An expression of regret and an Apology for the harm and distress suffered
  - A summary of the factors that contributed to the adverse event
  - An explanation of the investigation process that was conducted
  - Information on what actions will be taken to reduce the incidence of recurrence
  - Use of health literacy principles in all communication with patients and their support persons to ensure that they understand the feedback

- The Open Disclosure process concludes with shared agreement between the patient, their family and carers and the healthcare team that concerns, issues and any improvements have been explained and addressed. In the majority of cases, this will occur after the adverse event review is completed.

Note: there are specific requirements when a SAPSE has occurred to complete the requirements of the Statutory Duty of Candour. In these situations, advice must be sought from Executive Sponsor and the Quality and Patient Safety team. See **Statutory Duty of Candour**

EVALUATION
The Open Disclosure procedure will be evaluated through incident review processes and feedback from patients and families.

REVIEW
This document will be reviewed every two years, or more frequently if there are changes in associated standards or legislation.

REFERENCES and ASSOCIATED DOCUMENTS
Cabrini Policies Procedures and Protocols
Privacy Policy

Key Legislation and Standards
Health Services (Private Hospitals and Day Procedure Centres) Regulations 2013
Health Services (Quality and Safety) Regulations 2020
Health Services Act 1988 (Vic)

References
Safer Care Victoria, Adverse Patient Safety Event Policy (2023)
Australian Commission on Quality and Safety in Health Care, Australian Open Disclosure Framework (2014)
Australian Commission on Quality and Safety in Health Care, Incident Management Guide (2021)

REVISION HISTORY

Version	Revision date	Revision notes
7.0	25 July 2025	Document revised in line with SDC legislation and to provide clarity on response types and responsibilities for these responses. References updated

Executive Sponsor	**Group Director, Medical Services and Clinical Governance**	
Approved By:	Quality and Safety Management Committee	**Date:** 13 August 2025
Authorised By:	Group Director, Medical Services and Clinical Governance	**Date:** 13 August 2025