Policy Risk Rating: (15)

1. Purpose

To ensure open disclosure is consistently and appropriately applied when an adverse event or serious adverse patient safety event (SAPSE) occurs.

Open disclosure is a discussion and exchange of information that may take place in one conversation or over multiple meetings. It involves timely, open, and honest communication that is sensitive, respectful, and responsive to patient needs.

This policy supports:

- A culture of transparency and accountability
- Continuous learning and systems improvement
- Compliance with Victorian Statutory Duty of Candour obligations
- Alignment with NSQHS Standards (Version 2)

An apology or expression of regret does not constitute an admission of liability.

2. Legislative and Regulatory Framework

This policy supports compliance with:

- NSQHS Standards (Version 2):
    - *Standard 1: Clinical Governance*
        - Action 1.03: Safety and quality systems are integrated with governance and business processes.
        - Action 1.11: The health service organisation regularly reviews safety and quality systems.
        - Action 1.12: The organisation uses reviews and audit findings to improve systems.
    - *Standard 2: Partnering with Consumers*
        - *Actions 2.04-2.10: Ensuring patients are engaged in planning, informed of incidents, and supported through the disclosure process.*
- Victorian Health Services (Private Hospitals and Day Procedure Centres) Regulations 2024
- Safer Care Victoria's Clinical Governance Framework (2020)
- Victorian Statutory Duty of Candour (2022)
- Australian Charter of Healthcare Rights (2nd Edition, 2020)
- Australian Open Disclosure Framework (ACSQHS, 2013)

3. Scope

This policy applies to:

- All clinical and administrative staff involved in patient care or incident response
- VMOs
- DON
- Quality Manager
- Patient Liaison

- Complaints Officer
- CEO
- MAC

3.1 Incident Integration

All incidents requiring open disclosure must also be managed with *PP22 – Incident, Issue and Improvement Reporting (IIIR),* including documentation within RiskClear, escalation pathways and audit compliance.

4. Definitions

4.1 Adverse Event

An incident resulting in harm to a patient.

4.2 Serious Adverse Patient Safety Event (SAPSE)

As defined under the Health Legislation Amendment (Quality and Safety) Act 2022 (Vic), a patient safety event resulting I n serious harm or death, including but not limited to Sentinel Events.

4.3 Sentinel Event

A subset of SAPSE requiring mandatory reporting to Safer Care Victoria within three (3) business days.

4.4 Open Disclosure

A structured process involving communication with patients and families following an adverse event, including acknowledgment, apology, and explanation.

4.5 Statutory Duty of Candour (SDC)

A legal obligation requiring health service to inform patients and families of a SAPSE, provide an apology, provide a written account of what occurred, outline steps taken, and offer an opportunity for questions.

5.0 Principles of Open Disclosure

5.1 Open and Timely Communication

If things go wrong, the patient, their family and carers 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.

5.2 Acknowledgement

All adverse events should be acknowledged to the patient, family, and carers as soon as practicable. Health service organisations should acknowledge wen an adverse event has occurred and initiate open disclosure

5.3 Apology and Expression of Regret

As early as possible, the patient, their family and carers 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.

5.4 Recognition of Reasonable Expectations

A patient may reasonably expect to be fully informed of the facts surrounding an adverse event and its consequences, treated with empathy, respect and consideration and provided with support in a manner appropriate to the patient's needs.

5.5 Staff Support

Health services create an environment where staff are encouraged to recognise and report adverse events and are supported emotionally and professionally. Open disclosure occurs within a just culture framework focused on learning and systems improvement.

5.6 Integrated Risk Management and Systems Improvement

Investigations of adverse events and outcomes are to be conducted through processes that integrate a focus on risk management and on improving systems of care and reviewing their effectiveness.

5.7 Good Governance

Accountability rests with the CEO and COM to ensure clinical risk and quality improvement processes prevent reoccurance of adverse events.

5.8 Confidentiality

All processes comply with Commonwealth and Victorian privacy and health records legislation.

6.0 Governance and Responsibilities

6.1 All Clinical Staff (including Visitors)

- Report adverse events
- Participate in open disclosure processes

6.2 Nursing Staff

- Initiate documentation through IIIR
- Escalate concerns
- Support patients during disclosure process

6.3 DON and Quality Manager

- Determine level of response
- Lead inverstigations
- Ensure SDC compliance
- Ensure accurate documentation in RiskClear and patient record
- Escalate to CEO and MAC

6.4 CEO

- Ensure organisational systems meet SDC obligations
- Ensure systems, training and monitoring are in place

- Ensure reporting to BOM

6.5 MAC

- Monitor serious incidents
- Review sentinel events
- Oversee clinical governance improvements

6.6 Patient Liaison Officer and Complaints Officer

- Coordinate patient communication
- Provide emotional and practical support
- Escalate feedback trends for investigation.

7. Procedure

All open disclosure activities must be carried out in conjunction with the incident response requirements outlined in *PP22 – Incidents, Issues and Improvement Reporting (IIIR)*, including recording in RiskClear, escalation to MAC, and audit compliance.

7.1 When Open Disclosure Applies

- Following any SAPSE
- Following any Sentinel Event
- Following an adverse outcome causing harm
- If a patient or carer requests further information after an incident.
- When clinical management is changed due to an error or unexpected event.

7.2 Immediate Actions

- Provide urgent clinical care to stabilise the patient.
- Notify the DON and Quality Manager.
- Record the incident in RiskClear and initiate IIIR (as per PP22).
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7.3 Determine Level of Response

7.3.1 High Level

- Required for:
  - Death
  - Permanent disability
  - Significant escalation of care
  - SAPSE
  - Sentinel Events
  - At patient request.

7.3.2 Low Level

- Minor harm
- No change in care
- Near miss.

7.4 Conducting Open Disclosure

7.4.1 Introductions

All attendees identify name and role.

7.4.2 Acknowledgement

Acknowledge the event promptly.

7.4.3 Apology

Provide a sincere and unprompted apology or expression of regret is given on behalf of the healthcare service and clinicians, including the words 'I am' or 'we are sorry'. Examples of suitable and unsuitable phrasing of an apology are provided in the resource titled Saying Sorry: a guide to apologising and expressing regret in open disclosure available at www.safetyandquality.gov.au/opendisclosure

7.4.4 Factual Explanation - Provider

A factual explanation of the adverse event is provided, including the known facts and consequences of the adverse event, in a way that ensures the patient, their family and carers understand the information, and considers any relevant information related earlier by the patient, family and carers. Speculation should be avoided.

7.4.5 Factual Explanation - Patient

The patient, family and carers have the opportunity to explain their views on what happened, contribute their knowledge and ask questions (the patient's factual explanation of the adverse event). It will be important for the patient, their family and carers that their views and concerns are listened to, understood and considered.

7.4.6 Personal Effect

The patient, family and carers is/are encouraged to talk about the personal effect of the adverse event on their life.

7.4.7 Plan Agreed and Recorded

A plan is agreed on and recorded, in which the patient, their family and carer(s) outline what they hope to achieve from the process and any questions they would like answered. This is to be documented and filed in the appropriate place and a copy provided to the patient, their family and carers.

7.4.8 Pledge to Feedback

The patient, their family and carers is assured that they will be informed of any further reviews or investigations to determine why the adverse event occurred, the nature of the proposed process and the expected time frame.

The patient, their family and carers are given information about how feedback will be provided on the investigation findings, by whom and in what timeframe, including any changes made to minimise the risk of recurrence.

7.4.9 Offer Support

May include:

- Ongoing support
- Reimbursement of out-of-pocket expenses where appropriate
- Follow-up care
- Complaint pathway information

7.4.10 Supporting Forms and Tools

- A discussion template and open disclosure checklist are in the Forms file under **F-36**
- Flowchart: "How to Prepare and What to Ask" is available under external documents **ED-36**
- Policy and Procedure -22 – Incidents, Issues and Improvement Reporting (IIIR) and accompanying forms

7.5 Statutory Duty of Candour

Relevant health service entities are legally required to provide a patient with a Statutory Duty of Candour (SDC) when they have suffered a SAPSE while receiving health services. The SDC builds on the principles of open disclosure as outlined in the Australian Open Disclosure Framework.

When a SAPSE occurs, the service must:

- Notify the patient or their representative of the event within 24 hours of identification of a SAPSE
- Provide a written account of the facts of what occurred
- Offer a sincere apology including the words "I am sorry" or "we are sorry"
- Provide information about the service's response to the event and steps taken to prevent recurrence
- Notify the patient/family/carer of their rights and provide written communication
- Deliver these elements as soon as practicable, or within legislated timeframes
- Provide the patient or their representative with the opportunity to ask questions and receive clear responses
- Comply with Safer Care Victoria guidelines: https://www.safercare.vic.gov.au/report-manage-issues/adverse-events/duty-of-candour
- File all SDC documentation in RiskClear and patient record
- Report sentinel events to Safer Care Victoria within three (3) business days via SCV portal

Patients want to understand what happened and why, feel there is genuine regret from the health service, and be assured that action will be taken to minimise the risk of recurrence.

7.6 Sentinel Events

In addition to 6.5, Sentinel Events must:

- Be reported to Safer Care Victoria within three (3) days via the SCV portal.
- Be logged in RiskClear.

- Be reviewed using a formal Root Cause Analysis (RCA) process. https://www.safercare.vic.gov.au/report-manage-issues/sentinel-events
- Be governed by audit obligations outlined in PP22

7.7 Multi-Service Events

Where events span multiple services, relevant clinicians must coordinate involvement of all affected services.

8. Documentation and Records

Document	Storage Location	Retention	Access
BOM Minutes	RiskClear	Life of document	DON/CEO/MAC
Open Disclosure Flowchart	RiskClear	Life of document	All staff
Open Disclosure Discussion Template (F-36)	RiskClear	Life of document	All staff
Open Disclosure Checklist	RiskClear	Life of document	All staff
Risk Register	RiskClear	Life of document	All staff
IIIR	RiskClear	Life of document	All staff
Risk Matrix	Dropbox DON GOV/Forms	Life of document	All staff
SDC Written Account	RiskClear & Patient Record	As per legislative requirement	Restricted
RCA Report	RiskClear	As per regulatory requirement	Restricted
SCV Submission Confirmation	RiskClear	As per regulatory requirement	Restricted

9. Monitoring and Compliance

Compliance with this policy is reviewed through:

- Internal audit schedule,
- MAC reviews
- Board of Management reporting
- SDC compliance monitoring
- Documentation audits
- Staff training in Open Disclosure

A risk assessment was undertaken at implementation and ongoing adherence is evaluated as part of te organisational risk management framework.

10. References and Resources

- Australian Open Disclosure Framework, ACSQHC: www.safetyandquality.gov.au/opendisclosure
- Victorian Duty of Candour Guidelines (2022), Safer Care Victoria
- Health Services (Private Hospitals and Day Procedure Centres) Regulations 2024 (Vic)
- Safer Care Victoria Clinical Governance Framework (2020)
- National Safety and Quality Health Service (NSQHS) Standards – Version 2
- Australian Charter of Healthcare Rights – 2nd Edition (2020)
- Health Legislation Amendment (Quality and Safety) Act 2022

https://www.health.vic.gov.au/quality-safety-service/open-disclosure-framework