OPEN DISCLOSURE
(Including Statutory Duty of Candour)

NSQHS STANDARDS

	Clinical Governance	☑
	Partnering with Consumers	☑
	Preventing and Controlling Infection	
	Medication Safety	
	Comprehensive Care	
	Communicating for Safety	☑
	Blood Management	
	Recognising and Responding to Acute Deterioration	☑

1. PURPOSE AND SCOPE

When and if there is an adverse event at Sunshine Clinic Private Hospital, all personnel involved will be able to adhere to the principles of Open Disclosure as defined by the Australian Open Disclosure Framework.

In addition, from 30 November 2022, Victorian health service entities are legally required to provide patients or their next-of-kin/carer with a Statutory Duty of Candour (SDC) when they have suffered a serious adverse patient safety event (SAPSE).

2. TO WHOM DOES THIS POLICY APPLY?

This policy applies to all employees, contractors, and volunteers working at Sunshine Clinic Private Hospital.

3. DISTRIBUTION OF POLICY

a) Prior to implementation of this policy, all staff will be made aware of the policy at staff meetings and the policy will be made available on the staff notice board and the Sunshine Clinic Private Hospital SharePoint.

b) Following implementation of the policy, the policy will form part of the induction of new staff members.

4. POLICY

Statutory Duty of Candour (SDC) needs to be undertaken when a Serious Adverse Patient Safety Event (SAPSE) has occurred to a patient at Sunshine Clinic Private Hospital. The SDC process should occur with the patient and/or their support person(s), except when the patient has opted out.

SDC will need to be undertaken when a SAPSE has occurred and has been identified:

- by a registered health practitioner, or

- by a patient as self-reported harm which, in the opinion of a registered health practitioner, meets the definition of a SAPSE.

GLOSSARY OF TERMS

Term	Definition
Apology	is an expression of compassion, regret or sympathy in connection with any matter, whether the apology admits or implies an admission of fault in connection with the matter.
Harm	Physical or psychological damage or injury to a person. Examples of harm are 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.
Incidents	Events or circumstances that resulted, or could have resulted, in unintended and/or unnecessary harm to a person and/or a complaint, loss or damage.
Incident Severity Rating (ISR)	the four-tiered severity rating system for clinical incidents recorded in VHIMS. ISR ratings are determined by the level of harm, the required level of care, and the level of treatment required.
ISR 1	The highest incident severity rating category. These incidents result in severe adverse outcomes or death.
ISR 2	The second highest incident severity rating category. These incidents result in moderate adverse outcomes.
Just Culture	A part of safety culture with the major features being: – a systems-thinking mindset to adverse event review and improvement

	– provision of a psychologically safe workplace where employees feel safe to report adverse events and near misses · – acknowledging and managing the innate cognitive biases that we all have as part of being human – the concept of shared accountability between the organisation and an individual when adverse events occur.
Moderate Harm	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.
Near Miss	An incident that did not cause harm. A near miss is also an incident that had the potential to cause harm but didn't, due to timely intervention and/or luck and/or chance.
Next of kin (NOK)	The patient's next of kin which may be any partner, parent, legal guardian, child or sibling of 18 years or older, or executor when a harm event causes death.
Patient	Pefers to any patient including inpatients, consumers, clients or residents who have suffered a SAPSE in the course of receiving health services. In circumstances where the patient lacks capacity or dies, the term patient also includes others who may be involved in the SDC process including the patient's immediate family, carer, NOK, or any person nominated by the patient.
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.
Racism	Is that which maintains or exacerbates inequality of opportunity among ethnoracial groups.
Registered health practitioner	Means an individual who: (a) is registered under the Health Practitioner Regulation National Law to practise a health profession, other than as a student; or (b) holds non-practising registration under this Law in a health profession.
Secretary	Means the Department Head (within the meaning of the Public Administration Act 2004) of the Department of Health.12 Self-reported harm refers to if a patient identifies that they have experienced harm that has not yet been recorded by the health service entity.
Sentinel event	Means an unexpected and adverse event that occurs infrequently in a health service entity and results in the death of, or serious physical or psychological injury to, a patient as a result of system and process deficiencies at the health service entity.
Serious adverse patient safety event (SAPSE)	is an event of a prescribed class or category 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 (which includes moderate harm, severe harm or prolonged psychological harm) being suffered by the patient This includes an event that is identified following discharge from the health service entity.
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.
Sexual safety	Defined as a state in which physical and psychological boundaries of individuals are maintained and respected.
Statutory Duty of Candour (SDC)	must be performed if a patient suffers a SAPSE in the course of receiving health services. The health service entity responsible for providing those services must provide them with: – a written account of the facts – an apology for the harm suffered – a description of the health service entity's response to the event, and – the steps that the health service entity has taken to prevent re-occurrence of the event. They must also comply with the steps set out in the Victorian Duty of Candour Guidelines.
Victorian Health Incident Management System (VHIMS)	Standardised dataset for the collection and classification of clinical, occupational health and safety incidents, near misses, hazards and consumer feedback.

5. PROCEDURE

1. Provide a genuine apology for the harm suffered by the patient and initial information , as early as practicable (*and no longer than 24 hours*) after the SAPSE has been identified.
2. The SDC meeting must be organised with 3 business days of the SAPSE being identified.
3. The SDC meeting must be held with 10 business days of the SAPSE being identified. *(refer SDC Initial meeting note template)*
4. The following must be provided in the SDS meeting:
    a. An honest, factual explanation of what occurred in a language that is understandable to the patient
    b. An apology fo the harm suffered by the patient
    c. An opportunity fo the patient to relate their experience and ask questions
    d. An explanation of the steps that will be taken to review the SAPSE and outline any immediate improvements already made
    e. Any implications as a result of the sAPSE (if known) and any follow up for the patient
5. Provide a copy of the SDC meeting report to the patient with 10 business days of the SDC meeting. *(Refer SDC Meeting Report template).*
6. Complete a review for the SAPSE and produce a report outlining what happened and any areas identified for improvement. *(Refer SDC Final report template)*
7. The report created must be offered to the patient within 50 business days of the SAPSE being identified. However, if it involves more than one health facility, this may be extended to 75 business days.

6. REPORTING

Sunshine Clinic Private Hospital will report their compliance with the SDC quarterly via an AIMS form through the HealthCollect **portal.**

NB: To request a HealthCollect login for a new user or to have this new data collection assigned to an existing HealthCollect user, the staff member must complete the HealthCollect Portal User Request form.

If an event does not meet the definition of a SAPSE, and therefore does not trigger the legal obligations required of the SDC process, open disclosure should still be followed as outlined within the Australian Open Disclosure Framework below.

7. PRINCIPLES OF OPEN DISCLOSURE

- **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.

- **Acknowledgement**

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

- **Apology or 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.

- **Supporting, and meeting the needs and expectations of patients, their family and carer(s)**

The patient, their family and carers 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.

- **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.

- **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. Outcomes of these reviews should focus on improving systems of care and be reviewed for their effectiveness. The information obtained about incidents from the open disclosure process should be incorporated into quality improvement activity

- **Good governance**

Open disclosure requires good governance frameworks, and clinical risk and quality improvement processes. Through these systems, 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.

- **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 federal, 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.*

8. KEY ELEMENTS OF THE OPEN DISCLOSURE PROCESS

- **Detecting and assessing incidents**
  - Detect adverse event through a variety of mechanisms
  - Provide prompt clinical care to the patient to prevent further harm
  - Assess the incident for severity of harm and level of response
  - Provide support for staff
  - Initiate a response, ranging from lower to higher levels
  - Notify relevant personnel and authorities
  - Ensure privacy and confidentiality of patients and clinicians are observed
- **Signalling the need for open disclosure**
  - Acknowledge the adverse event to the patient, their family and carers including an apology or expression of regret.
  - A lower level response can conclude at this stage.
  - Signal the need for open disclosure
  - Negotiate with the patient, their family and carers or nominated contact person
    - the formality of open disclosure required
    - the time and place for open disclosure
    - who should be there during open disclosure
  - Provide written confirmation
  - Provide a health service contact for the patient, their family and carers
  - Avoid speculation and blame
  - Maintain good verbal and written communication throughout the open disclosure process
- **Preparing for open disclosure**
  - Hold a multidisciplinary team discussion to prepare for open disclosure
  - Consider who will participate in open disclosure
  - Appoint an individual to lead the open disclosure based on previous discussion with the patient, their family and carers
  - Gather all the necessary information
  - Identify the health service contact for the patient, their family and carers (if this is not done already)
- **Engaging in open disclosure**
  - Provide the patient, their family and carers with the names and roles of all attendees
  - Provide a sincere and unprompted apology or expression of regret including the words I am or we are sorry
  - Clearly explain the incident
  - Give the patient, their family and carers the opportunity to tell their story, exchange views and observations about the incident and ask questions
  - Encourage the patient, their family and carers to describe the personal effects of the adverse event
  - Agree on, record and sign an open disclosure plan
  - Assure the patient, their family and carers that they will be informed of further investigation findings and recommendations for system improvement
  - Offer practical and emotional support to the patient, their family and carers
  - Support staff members throughout the process

  - If the adverse event took place in another health service organisation, include relevant staff if possible.
  - If necessary, hold several meetings or discussions to achieve these aims
- **Providing follow-up**
  - Ensure follow-up by senior clinicians or management, where appropriate
  - Agree on future care
  - Share the findings of investigations and the resulting practice changes
  - Offer the patient, their family and carers the opportunity to discuss the process with another clinician (e.g. a general practitioner)
- **Completing the process**
  - Reach an agreement between the patient, their family and carers and the clinician, or provide an alternative course of action
  - Provide the patient, their family and carers with final written and verbal communication, including investigation findings
  - Communicate the details of the adverse event, and outcomes of the open disclosure process, to other relevant clinicians
  - Complete the evaluation surveys
- **Maintaining documentation**
  - Keep the patient record up to date
  - Maintain a record of the open disclosure process
  - File documents relating to the open disclosure process in the patient record
  - Provide the patient with documentation throughout the process

9. KEY COMPONENTS OF OPEN DISCLOSURE DISCUSSIONS

- **Introductions**
  - The patient, their family and carers is told the name and role of everyone attending the meeting, and this information is also provided in writing.
- **Saying sorry**

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

- **Factual explanation: providers**

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.

- **Factual explanation: patient, family and carer(s)**

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.

- **Personal effect of the adverse event**

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

- **Plan agreed and recorded**

An open disclosure 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.

- **Pledge to feed back**

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.

- **Offer of support**

An offer of support to the patient, their family and carers should include:

  - ongoing support including reimbursement of out-of-pocket expenses incurred as a result of the adverse event
  - assurance that any necessary follow-up care or investigation will be provided promptly and efficiently
  - in the relevant settings, clarity on who will be responsible for providing ongoing care resulting from the adverse event
  - contact details for any relevant service they wish to access information about how to take the matter further, including any complaint processes available to them

- **Support for patients and staff**

The patient, their family and carers engages in open disclosure with staff. Staff are supported by their colleagues, managers and health service organisation, both personally (emotionally) and professionally, including through appropriate training, preparation and debrief.

- **Other health service organisations**

In cases where the adverse event spans more than one location or service, relevant clinicians and staff will ensure, where possible, that all relevant staff from these additional institutions are involved in the open disclosure process.

OTHER CONSIDERATIONS

It is not necessary to cover every component in the first disclosure meeting. For instance, a full explanation of why an adverse event occurred may not be possible until associated investigations are completed and the causative factors are known.

A written account of the open disclosure meeting should be provided to the patient, their family and carers and a copy filed in the patient record.

10. EXPECTED OUTCOMES

Sunshine Clinic Private Hospital will act in accordance with the Australian Open Disclosure Framework when and if there is an adverse event.

11. REFERENCES

- Victorian Department of Health – Statutory Duty of Candour Guidelines
- Victorian Department of Health – Sentinel Event Guide
- Australian Commission on Safety and Quality in Health Care – Australian Open Disclosure Framework
- Safer Care Victoria – SAPSE Reporting Resources

12. REVIEW / CONSULTATION

- Medical Advisory Committee.
- Board of Governance
- Clinical Governance Committee

13. VERSION HISTORY

Version	Date from	Date to	Amendment
1.0	August 2025	Current	

APPENDIX 1

Open Disclosure Checklist – Low Level Disclosure

Low level Disclosure is for less serious incident or complaints and can be managed at the department/area manager level following a less serious incident or complaint which can then be documented in this form and uploaded into RiskClear.

Patient's full name		
File number		Date of birth:
Patient admission date		

Names and relationships of relevant next of kin/family members/carers (if applicable)	
Apology or expression of regret *Use the words " I am/we are sorry"*	
Description of what happened *Known facts only, avoid blaming individuals and self*	
Listening to patient, family/carer concerns (ensure they are offered the opportunity to express/relate their experience and is listened to)	
Discussion of what will happen next *(such as OR, further treatment, investigation into the incident)*	
Information to be provided about short/long-term effects	
Information about further support available to the patent and family	
Information provided in relation to how to take the matter further at any time *(such as internal and external complaint process. Avoid discussion about compensation without insurer consent, do not give legal advice but suggest patient seeks legal advice if information about compensation sought.)*	
Next meeting date and location (if applicable)	

APPENDIX 2

Open Disclosure Checklist – High Level Disclosure

High level Disclosure is for serious incident or complaints and must be managed at the Executive level, including the treating clinical. All personnel involved in the first meeting with the patient must read and agree upon the contents of this document which can then be documented in this form and uploaded into RiskClear.

Data

Patient's full name (including title)	
File number and date of birth	
RiskClear number	

Admission diagnosis and comments about management etc.	
Patient admission date	

Names and relationships of relevant next of kin/family members/carers	
Date of incident triggering the open disclosure process	
Incident description *Known facts only*	
Incident outcome *Known facts only, avoid cause and effect statements*	
Plan for further incident management and investigation *(such as RCA, report to department, Coroner)*	
Health professionals involved in patient care It is recommended that clinicians involved in adverse events be given the option to participate in the disclosure. (consultants, anaesthetist and others as appropriate.)	

First meeting

Does the patient require an interpreter? *If yes, provide details of language and arrangements that have been or to be made*	
Has the patient (if able) consented to sharing information with family members/others? *Give details*	
Has the insurer been notified? *Include date of notification*	
Date of first meeting	
Location of first meeting *Other details such as room booking, arrangements to ensure confidentiality if shared ward etc.*	
Patient/family understanding of the incident prior to the first meeting	
Person to be responsible for note taking	

Planning the disclosure dialogue	**Notes**
Who will speak first, provide introductions and so on?	
Anticipated patient concerns at this time if known	

Apology or expression of regret *Avoid admissions of liability*	
Description of what happened *Known facts only, avoid blaming individuals and self*	
Listening to patient, family/carer concerns (ensure they are offered the opportunity to express/relate their experience and is listened to)	
Discussion of what will happen next *(such as OR, further treatment, investigation into the incident)*	
Information to be provided about short/long-term effects	
Assurance for patient/support person that they will be informed when further information comes to hand	
Information about further support available to the patent and family	
Information provided in relation to how to take the matter further at any time *(such as internal and external complaint process. Avoid discussion about compensation without insurer consent, do not give legal advice but suggest patient*	

seeks legal advice if information about compensation sought.)	
Next meeting date and location	

First meeting outcomes

Actual date and location of meeting	
Names of all present at first meeting *Include titles/position/relationship to patient etc.*	
Concerns expressed by patient/family including requests for further information to be supplied	
Further support personnel identified *(such as pastoral worker, social worker)*	
Responsibility for documentation of the meeting in the medical record	
Name(s) of personnel given to patient/family if they have further questions prior to subsequent meetings	

Evaluation

Evaluation of this open disclosure process	