PURPOSE

When and if there is an adverse event at Manningham 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 comply with the Statutory Duty of Candour (SDC) Framework and Guidelines when a Serious Adverse Patient Safety Event (SAPSE) as defined by the guidelines have occurred.

REFERENCES

Australian Open Disclosure Framework, 2014
Victorian Duty of Candour Framework, October 2022
Victorian Duty of Candour Guidelines, October 2022
Statutory Duty of Candour Data Collection - Reporting guideline, May 2023

DEFINITIONS

Adverse event is an incident that results, or could have resulted, in harm to a patient or consumer. A near miss is a type of adverse event.

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.

Chief Quality and Safety Officer (CQSO) means the person appointed as Chief Quality and Safety Officer under section 116 of the Health Services Act 1988.

Cultural safety is defined as an environment that is safe for Aboriginal people and Torres Strait Islanders, where there is no assault, challenge or denial of their identity and experience.

Harm is 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 are 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) is 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 is the highest incident severity rating category. These incidents result in severe adverse outcomes or death.

ISR 2 is the second highest incident severity rating category. These incidents result in moderate adverse outcomes.

Just Culture is 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 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.

Near miss is 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) is 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.

Parent is an adult in a significant primary caring role, whether they are a biological, adoptive, foster or step-parent, or the legal guardian of a child.

Patient refers 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.

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 has been 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) is a standardised dataset for the collection and classification of clinical, occupational health and safety incidents, near misses, hazards and consumer feedback.

POLICY

Statutory Duty of Candour (SDC) needs to be undertaken when a SAPSE has occurred to a patient at Manningham 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.

PROCEDURE

Requirements

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 within 3 business days of the SAPSE being identified.
3. The SDC meeting must be held within 10 business days of the SAPSE being identified. *(Refer SDC -MPH Initial meeting note template)*
4. The following must be provided in the SDC meeting:
    a. An honest, factual explanation of what occurred in a language that is understandable to the patient.
    b. An apology for the harm suffered by the patient.
    c. An opportunity for 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 within 10 business days of the SDC meeting. *(Refer SDC - MPH 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-MPH 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.

Reporting

Manningham Private Hospital will report their compliance with the SDC quarterly (commencing 30/9/2023) 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.

PRINCIPLES OF OPEN DISCLOSURE

Open disclosure describes the way clinicians communicate with and support patients, and their family and carers who have experienced harm from adverse events while receiving health care services. *NOTE that not all adverse events to which the Open Disclosure framework applies meet the criteria for application of the Victoria Statutory Duty of Candour.*

An initial assessment is required to determine the level of response.

The individual who detected the incident should make an initial assessment of the incident. This may be in consultation with a colleague. The consideration will include the severity of harm and the level of response required.

In small practices, the causation of most adverse events will be able to be determined immediately, or soon after detection. For some, a review and investigation will need to be conducted before all the facts are known. In the latter scenario the initiation of open disclosure, acknowledgement and open disclosure should not be delayed.

All relevant organisations and authorities, such as indemnity insurance providers, should be notified immediately following detection of an adverse event.

The level of response required will be guided by the effect, severity and consequence of the incident. Table 1 below provides potential responses to incidents in which patients have, or may have been harmed.

Table 1: Potential responses to incidents of patient harm or potential patient harm

Incident type	Response
1. Harm from natural progression of condition or disease process *e.g. management of diabetes was unsuccessful*	**Discuss and explain** ***(lower-level)***
2. Complication or natural disease progression a. Anticipated by patient/family via education and consent process b. Not anticipated by patient/family via education and consent process (**go to 3**) *e.g. patient not adequately informed of the possibility of side effects from beta blockers and feels that this would have altered their decision to proceed with treatment*	**a. Discuss and explain *(lower-level)*** **b. Open disclosure** ***(higher or lower-level depending on severity)***
3. Patient harm/adverse event *e.g. adverse drug event (wrong vaccination given)* *e.g. patient fall during rehabilitation exercises*	**Open disclosure *(higher or lower-level depending on severity and impact on patient)***
4. Clinical ('no harm') incident: reaches patient but no harm *e.g. medication error (no/minimal effect on patient)*	**Generally disclose *(lower-level)***
5. Clinical ('near miss') incident: does not reach patient *e.g. an intercepted failure to follow up test results*	**Decision based on:** • context • circumstances • potential ramifications ***(lower-level)***

6. Patient perception or report of harm *e.g. patient perception of delay in diagnosis resulting in poor patient outcome*	**Discuss and agree on appropriate form of disclosure** ***(higher or lower-level)***

Table 2 describes lower-level and higher-level responses linked to criteria for harm that may be used to delineate lower-level and higher-level responses.

Table 2: Criteria for determining the appropriate level of response to an incident

	Criteria
Lower-level response	1. Near misses and no-harm incidents 2. No permanent injury 3. No increased level of care (e.g. need for domiciliary care) required 4. No, or minor, psychological or emotional distress
Higher-level response	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. present to emergency department, surgical intervention, other higher level of care) 4. Major psychological or emotional distress 5. At the request of the patient

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.
2. **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.
3. **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.
4. **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.
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. 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
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 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.*

KEY ELEMENTS OF THE OPEN DISCLOSURE PROCESS

1. **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
2. **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
3. **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)

4. 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

5. 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)

6. 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

7. 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

KEY COMPONENTS OF OPEN DISCLOSURE DISCUSSIONS

1. **Introductions**
   - The patient, their family and carers are told the name and role of everyone attending the meeting, and this information is also provided in writing.
2. **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
3. **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.
4. **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.
5. **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.
6. **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.
7. **Pledge to feed back**

   The patient, their family and carers are 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.
8. **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

9. Support for patients and staff

The patient, their family and carers engage 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.

10. 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.

OUTCOME

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

SUPPORTING DOCUMENTS

MPH Checklist for SDC process
MPH Initial note meeting template
MPH Meeting report template
MPH Final Report template
MPH Statement template to opt out of the SDC process.
Open Disclosure Report
Open Disclosure Governance Statement
Risk Clear database
Minutes of O&Q and MAC Committee meetings.
Safer Care Victoria
Open Disclosure Framework