the glen endoscopy centre	**1.26 Open Disclosure & Statutory Duty of Candour for Serious Adverse Patient Safety Events**

Preamble

To ensure Clinicians communicate with and support patients, their family and carers who have experienced harm during healthcare and *follow Victorian Duty of Candour Guidelines for Serious Adverse Patient Safety Events (SAPSE)*

Guideline

What is Open Disclosure?

Open disclosure is the open discussion of adverse events that result in harm to a patient while receiving health care with the patient, their family and carers. The elements of open disclosure are:

- an apology or expression of regret, which should include the words 'I am sorry' or 'we are sorry'

- a factual explanation of what happened

- an opportunity for the patient, their family and carers to relate their experience

- a discussion of the potential consequences of the adverse event

- an explanation of the steps being taken to manage the adverse event and prevent recurrence.

It is important to note that open disclosure is not a one-way provision of information. Open disclosure is a discussion between two parties and an exchange of information that may

Open Disclosure should be used for the equivalent of an ISR 3 or 4 within public health services (VHIMS). SDC (Refer to Statutory Duty Of Candour Section) should be used be used for ISR 1 or 2.

Open Disclosure Principles

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.

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 carers

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. 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

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 Commonwealth, state and territory privacy and health records legislation).

When does the Open Disclosure Process begin?

Open Disclosure is part of Incident Reporting. As soon as an incident is identified and the risk level identified, the open disclosure response is graded as a **general level response** (usually low to medium risk) or a **high-level response** (usually high to very high risk).

General indications of a lower-level response are:

- Near Miss/ no-harm incident
- No permanent injury
- No increased level of care required
- No, or minor, psychological or emotional distress

General indications of a higher-level response are:

- Death or major permanent loss of function
- Permanent or considerable lessening of body function
- Significant escalation of care/ change in clinical management
- Major psychological or emotional distress
- At the request of the patient

See Open Disclosure Flowchart (Australian Commission on Safety and Quality in Health Care)

The Open Disclosure Checklist F-1.18 should be started.

The Open Disclosure Documentation and Discussion Summary F-1.19 should be completed for any discussions.

General Level Response

The purpose of the first meeting is to support and inform the patient. If direct communication with the patient is hindered because of the patient's clinical condition or language/cultural/disability difficulties or his/her emotional state, consideration should be given to initiating communication with the support person.

IN GENERAL LEVEL RESPONSES, the clinician directly involved in the incident is the most appropriate person to communicate with the patient and their support person. This may be a nurse, allied health professional or junior medical staff.

The general response involves:

- a meeting with the patient and their support person, where practicable
- an explanation of what happened, the immediate effects, and prognosis
- an apology
- The contact names and phone numbers of people in The Glen Endoscopy who are available to address concerns and complaints, including psychological and social support contacts
- For a general level response, this first meeting with the patient and their support person may be the only meeting about the incident.
- This meeting may simply be a conversation between the clinician and the patient at the bedside or a telephone conversation with the patient if discharged. It is up to the clinician to initiate a follow-up, if necessary.
- Regardless of the level of response, the patient and their support person must be advised of the known facts of the incident within 24 hours of identification of the incident by The Glen Endoscopy
- See Open Disclosure Framework Flow Chart
- The incident must be recorded in the patient's health care record and on the IIIR Form and IIIR Register
- If the incident escalates to a high or very high- risk incident, a high- level response should be initiated. A general level response can also be escalated to a high -level response at the discretion of the senior clinician and the senior manager.

High Level Response

The High -level response involves the full open disclosure process as follows:

Establish the open disclosure team. Senior Management forms an open disclosure team as soon as the severity of the incident has been established. The teams role is to support and assist with managing the open disclosure process and develop a robust plan to ensure that communication is consistent and accurate.

Team members may include the following:

- Patients senior clinician
- Director of Nursing/ Senior Manager or equivalent
- Another involved clinician
- A patient advocate
- If required, CEO

The team meets as soon as possible after the incident to discuss the following:

- Nominating the team leader who communicates with the patient and their support person

- Immediate patient care
- Ongoing patient care and support
- Basic clinical and other facts relevant to the incident
- Level of support for the patient's family and support person
- Level of support for staff and responsibility for providing that support
- How to maintain a consistent approach in discussions with the patient and their support person.

Reporting of very high- level risk to Department of Health.

The Department of Health has a schedule of Sentinel Events that require reporting. Refer to Incident Policy for further information. The Sentinel Event form must be completed via https://www.safercare.vic.gov.au/notify-us/sentinel-events

Notifying the Medical Defence Organisation

It the incident is significant or involves the high-level open disclosure response, it is recommended that Medical Practitioners contact their Medical Defence Organisation at the earliest practical opportunity for advice and support, at the same time meeting any insurance notification obligations.

Notifying other people/ groups

Other notifications may include (subject to observing applicable privacy requirements):

- The patient's General Practitioner
- The Coroner (note that the patients family and support person must be notified if the Coroner is notified)

Meeting with the patient

The initial disclosure meeting with the patient and their support person may involve the team leader, the person(s) directly involved with the treatment that resulted in the incident and the responsible Senior Clinician.

The discussion should include:

- An explanation of what happened and the known facts
- An apology
- The contact names and phone numbers of people in the health facility who are available to address concerns and complaints, including psychological and social support contacts
- Names of people on the open disclosure team
- How the incident will be investigated, what tools will be used
- Steps for ongoing feedback
- Anticipated timelines for investigating the incident

- A statement that an explanation of how or why the incident occurred may be delayed until investigations are complete.

If there is a breakdown in communication between the patient/support person and the team leader, the patient should be offered another person as the team leader.

Follow-up with the patient

The purpose of follow-ups with the patient and their support person is to inform them of the progress of any investigations. Follow-ups must be undertaken either in face-to-face interviews or by letter or both. If there are delays in the investigation, frequent updates should be supplied, together with an explanation of the reason for delays. Following discharge of the patient, a series of follow-up arrangements with the patient and their support person may need to be established to provide updates on findings of investigations.

Final follow-up interview and letter

Issues covered in the final follow-up interview and letter are:

- An apology and expression of regret for the harm suffered
- Acknowledgement of the concerns or complaints of the patient and their support person
- Details of the Root Cause Analysis Final Report and explanation of the report in plain English.
- A summary of the factors contributing to the incident and information on measures being implemented to prevent a similar incident from occurring.
- How improvements will be monitored.

See ACSQHC Open Disclosure Flowchart

Record Keeping

The Senior Clinician responsible for the care of the patient must record a summary of communication with the patient and their support person in the patient's healthcare record.

All ongoing developments and communication during and at the completion of the open disclosure process must be recorded.

The recordings include the date and time of each entry, what the patient was told and a summary of agreed actions. Confirmation that an apology was given must also be recorded.

The recording should include only known facts, be objective and not apportion blame.

The Open Disclosure Checklist F-1.18 and Open Disclosure Discussion F-1.19 should be used and kept with patient healthcare record.

Supporting the Clinician

When an incident occurs, the clinicians involved may require emotional and psychological support and advice on how to deal with their response to the incident. Each health facility should have systems in place to ensure that staff are aware and can access adequate support. Opportunities for staff debriefing should be provided as required. Staff involved in the incident should also be advised of the outcomes of the open disclosure process, including recommendations and implementation strategies.

STATUTORY DUTY OF CANDOUR (SDC) FOR SERIOUS ADVERSE PATIENT SAFETY EVENTS (SAPSE)

Victoria Duty of Candour Guidelines are in place that apply to all serious adverse patient safety events (SAPSE). A SAPSE is an event that:

a) *Occurred while the patient was receiving health services from a health service entity; and*
b) *In the reasonable opinion of a registered health practitioner, has resulted in, or is likely to result in, unintended or unexpected **moderate** or **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.*

A SAPSE is the equivalent of an ISR 1 or 2 event within public health services (VHIMS).

- *ISR 1 - Severe (including death)*

- *ISR 2 – Moderate*

SDC is a legal obligation for Victorian health service entities to ensure that patients and their families or carers are apologised to and communicated with openly and honestly when a SAPSE has occurred. It builds on the Australian Open Disclosure Framework currently utilised for all cases of harm and near miss.

If a patient suffers a SAPSE in the course of receiving health services, the health service entity responsible for providing those services owes a SDC to the patient and must do the following unless the patient has opted out:

(a) provide the patient with:

i. a written account of the facts regarding the SAPSE;

ii. an apology for the harm suffered by the patient;

iii. a description of the health service entity's response to the event;

iv. the steps that the health service entity has taken to prevent re-occurrence of the event;

v. any prescribed information; and

(b) comply with any steps set out in the Victorian Duty of Candour Guidelines

Stage 1**: **Apologise and provide initial information

***Requirement 1**: The health service entity must 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 by the health service entity. Refer to Form # F-1.27 Checklist for SDC Process*

The apology must be provided to the patient, or if the patient lacks capacity or has died, the patient's immediate family, carer, NOK or a person nominated by the patient, as early as practicable and clinically appropriate with regards to the needs of the patient. The health service entity may decide on the appropriate person to provide the apology, such as a suitably qualified health professional.

The health service entity should consider the following in providing the apology:

- *express compassion, regret or sympathy;*
- *say the words 'I am/We are sorry'; and*
- *avoid jargon or legalistic wording.*
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Apology not an admission of liability:

- *In a civil proceeding where the death or injury of a person is in issue or is relevant to an issue, an apology:*
- *does not constitute an express or implied admission of liability for the death or injury; and*
- *is not relevant to the determination of fault or liability in connection with that proceeding.*
- *This is relevant whether the apology is made orally or in writing or is made before or after the civil proceeding was in contemplation or commenced.*
- *Evidence of an apology made by or on behalf of a person or a health service entity in connection with any matter alleged to have been caused by the person or health service entity is not admissible in any civil or disciplinary proceedings as evidence of the fault or liability of the person or health service entity in connection with that matter.1*
- *The initial information may be provided with the initial apology, however, should ideally be performed by a suitably qualified health professional.*
- *When providing initial information, the health service entity must:*
- *provide factual information that is known at the time about the event;*
- *offer written patient information on the adverse event review process (e.g. information flyer); and*
- *provide the details of key contacts the patient can liaise with, including where relevant, an Aboriginal Hospital Liaison Officer (AHLO).*
- *When providing initial information, the health service entity should:*
- *be sensitive and empathetic;*

- *acknowledge that these events can be confronting matters for patients to deal with; and*
- *avoid inferring blame, admitting fault or offering opinion.*
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- *The health service entity may also consider providing further information including:*
- *confirming the patient knows how to access their health records if necessary;*
- *confirming any specific needs of the patient, including cultural or linguistic requirements;*
- *confirming how the patient would like to be communicated with;*
- *attempting to answer any questions the patient has since providing the initial information. If the questions cannot be answered immediately, the health service entity should record these questions and inform the patient they will be addressed as part of the SDC process; and*
- *outlining how the patient can raise concerns outside of the SDC process, including the health service entity's internal complaints process, or the Health Complaints Commissioner (HCC) or Mental Health Complaints Commissioner (MHCC).*
- *Where the harm has resulted in the patient's death, the health service entity should consider:*
- *advising the NOK that there may be additional processes involving third parties, such as the Coroner, and that coronial investigations or inquests may incur lengthy timelines; and*
- *providing psychological support for the NOK and any staff affected by the death*

***Requirement 2**: The health service entity must take steps to organise an SDC meeting **within 3 business days** of the SAPSE being identified by the health service entity. Refer Form # F-1.16 SDC Initial Meeting Note Template*

Stage 2: Hold the SDC meeting

***Requirement 3:** The SDC meeting must be held **within 10 business days** of the SAPSE being identified by the health service entity.*

***Requirement 4**: The health service entity must ensure that it provides the following in the SDC meeting:*

- *an honest, factual explanation of what occurred in a language that is understandable to the patient;*
- *an apology for the harm suffered by the patient;*
- *an opportunity for the patient to relate their experience and ask questions;*
- *an explanation of the steps that will be taken to review the SAPSE and outline any immediate improvements already made; and*
- *any implications as a result of the SAPSE (if known) and any follow up for the patient.*

  Refer to Form # F-1.17 SDS Meeting Report Template

At a minimum, the health service entity must confirm with the patient:

- *when and where the SDC meeting will be held;*
- *who will be at the meeting, including staff and representatives the patient would like to invite;*
- *details of the meeting, including informing them that they will have the opportunity to relate their experience and ask any questions they may have. The health service entity may recommend that the patient write these down in preparation for the SDC meeting; and*
- *details of key contacts, such as a family liaison person, if the patient has any questions before the meeting.*

In preparing for the meeting, the health service entity may consider the following:

- *designing the meeting with the attendee's needs in mind, such as having the meeting over video conference;*
- *the opportunity for further planning and discussions before the SDC meeting;*
- *offering the patient practical and emotional support at each stage of the process, such as paying for travel or parking costs to attend the SDC meeting;*
- *having an internal planning discussion before the SDC meeting, including who will lead the meeting;*
- *ensuring all relevant facts have been collected and understood, including seeking advice from relevant staff;*
- *seeking advice from an AHLO for any events involving Aboriginal and Torres Strait island patients; and*
- *patient preference in regard to relevant staff at the meeting, if the patient requests certain staff do not attend.*

At a minimum there must be:

- *one member from the health service entity who is experienced and suitably qualified in open disclosure or the SDC process; and*
- *a senior member of the clinical team that was involved (e.g. doctor or nurse).*

There may also be:

- *a member of the quality team; and*
- *a trainee or junior staff member from a development and organisational culture point of view.*

The SDC meeting is an opportunity for the health service entity to provide all required information, and for the patient to ask questions and relate their experience about the event.

In attending the SDC meeting, the health service entity must:

- *take measures to make the attendees feel supported in the meeting. For example, provide materials for them to take notes, and offering a comfortable, quiet environment to conduct the meeting;*
- *present a full, frank and honest explanation of what is known to have occurred. Use terminology and phrases that are likely to be understood by the attendees;*
- *apologise to the patient again for the harm suffered;*

- *allow the patient opportunity to relate their experience. Ask them to share their own thoughts on the event and the outcomes they are seeking from the SDC process;*
- *ensure there is sufficient time for the attendees to ask questions;*
- *explain the steps the health service entity is taking to review and manage the event, and any immediate improvements that have been made or will be made to prevent similar harm in the future (if applicable). This information may not be complete at the time of this meeting, however the patient should be informed that more details will be available in a subsequent review report; and*
- *inform those at the meeting about the implications of the SAPSE, especially any immediate or long-term health or other consequences (if known). Develop a plan to ensure the patient receives appropriate treatment, including notifying their local health service or general practitioner (if agreed).*

***Requirement 5**: The health service entity must document the SDC meeting and provide a copy of the meeting report to the patient **within 10 business days** of the SDC meeting.*

Immediately after the meeting

The health service entity may consider compiling the initial details of the meeting and provide this to the patient immediately following, including:

- *who was present;*
- *the time and date of the meeting;*
- *confirmation that all elements of the SDC were discussed;*
- *a point of contact for ongoing follow up;*
- *clear details of the future timelines and requirements of the SDC process; and*
- *any other comments or questions for noting.*
- *A copy of this note should then be filed in the appropriate records.*
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The meeting report must include a detailed account of all the different elements of SDC that were discussed. Documentation of the SDC meeting should follow usual clinical documentation conventions and expand on the initial note given after the meeting.

The health service entity may consider offering the meeting report in a language understandable to the patient. If the report requires translation, inform the patient that this may require more time and document any delay in the appropriate location.

A copy of the SDC meeting report must be stored in an appropriate location.

Stage 3: Complete a review of the SAPSE and produce report

Requirement 6*: The health service entity must complete a review for the SAPSE and produce a report outlining what happened and any areas identified for improvement. If the SAPSE is classified as a sentinel event, the health service entity must also outline in the report clear recommendations from the review findings.*

Requirement 7: *The report created from Requirement 6 must then be offered to the patient within 50 business days of the SAPSE being identified by the health service entity. If the SAPSE involves more than one health service entity, this may be extended to 75 business days of the SAPSE being identified by the initial health service entity.*

The report created as a result of the review must include the matters required by section 128ZC of the Health Services Act 1988, being:

- *a written account of the facts regarding the SAPSE;*
- *an apology for the harm suffered by the patient;*
- *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.2

As part of the SDC process, the review report must then be offered to:

- *the patient; or*
- *if the patient is deceased or lacks capacity, a person nominated by the patient, the immediate family, carer or NOK of a patient.*

The review is part of the ongoing information gathering process of the SDC. The resulting report forms part of the response to the patient. The health service entity must:

- *avoid jargon or legalistic wording, and*
- *ensure the patient is aware of the timeline for review.*

Following the review

When the relevant review or investigation is complete, the health service entity should consider providing the patient with feedback through face-to-face interview or equivalent (e.g. videoconference).

Documentation and reporting

Requirement 8*: The health service entity must ensure that there is a record of the SDC being completed, including clear dates of when the SAPSE occurred and when each stage of the SDC was completed.*

Requirement 9*: The health service entity must report its compliance with the SDC as legally required.*

The health service entity must ensure it:

- *has an appropriate reporting system to monitor compliance with the SDC such as a clinical incident management system; and*
- *report compliance with the SDC undertakings to the relevant bodies as legally required. These reports allow the health service entity's board to monitor the SDC and must be made available for auditing by the relevant bodies.*

Note: If it is identified through the review process that a health professional has acted in a way that constitutes notifiable conduct under the Health Practitioner Regulation National Law Act 2009, a staff member must submit a concern to the Australian Health Practitioner Regulation Agency (Ahpra). It is recommended that this referral take place after a discussion has occurred with the relevant staff member.

Where patients do not want to be involved in the SDC process

Patients may opt out from participating in the SDC process or from receiving information from a health service entity. If a patient confirms that they wish to opt out of the SDC process, the health service entity must:

ask them to sign a statement to this effect and store this in an appropriate location;3 and

provide a point of contact, such as a consumer liaison officer, if the patient wishes to re-initiate the SDC process at any time.

When a patient has opted out, the relevant health service entity does not have to comply with the Requirements in the Victorian Duty of Candour Guidelines. However, it is recommended that the health service entity conduct an adverse event review to ensure relevant information is recorded when relevant staff are available. This is recommended as the patient may later re-initiate their participation in the SDC process and elect to receive information required under the SDC.4 If this occurs, the commencement date must be clearly documented in an appropriate location, and the requirements within these Guidelines must then be followed.

Circumstances requiring a delay

There may be circumstances where the SDC process needs to be delayed, including:

if the patient lacks or has lost their capacity (either temporarily or permanently) through the harm; or

the patient is medically unable to participate (either temporarily or permanently through the progression of their medical condition).

If the above applies and has been assessed and documented by an appropriate medical professional, the health service entity must undertake SDC with:

the patient's immediate family, carer or NOK; or

a person nominated by the patient.

This must occur, unless the relevant person is not available, or they have opted out.

When the patient recovers capacity, regardless of whether the SDC has occurred with a person outlined in the list above or not, the health service entity must commence the SDC process again with the patient (unless the patient has opted out). The agreed commencement date must be clearly documented in the appropriate location, and the requirements within these Guidelines must then be followed.

Related Forms and Policies

ACSQHC Open Disclosure Flowchart

F- 1.18 Open Disclosure Checklist

F- 1.19 Open Disclosure Plan

F-1.15 SDC Checklist

F-1.16 SDC Initial Meeting Template

F-1.17 SDS Meeting Report Template

Legislation, Standards and References

Australian Commission for Quality & Safety Open Disclosure Framework

National Safety and Quality Health Services Standards Version 2 Standard 1

Australian Commission for Quality & Safety Open Disclosure Flowchart

Victorian Duty of Candour Guidelines 2022

Safer Care Victoria