Open Disclosure & Statutory Duty of Candour

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1. Objective

The purpose of this policy is to outline the approach to undertaking 'Open Disclosure' and/or 'Statutory Duty of Candour' following an incident or complaint.

2. Scope

All Staff

3. Policy Statement

Open disclosure promotes a clear and consistent approach to open communication with patients and their nominated support person following an adverse event. It includes guidelines for discussion about what has happened, why it happened, and what is being done to prevent it happening again.

Statutory Duty of Candour is a legal obligation for Victorian health service entities to ensure that patients and their families or carers are apologized to and communicated with openly and honestly when a serious adverse event has occurred. It builds on the Open Disclosure Framework currently utilized for all cases of harm and near miss.

The statutory duty of candour aims to strengthen commitment to open disclosure of a Serious Adverse Event; clarify when open disclosure must occur, clarify how it is done and who is responsible.

Level of Response

Minor Adverse Event open disclosure responses can be conducted at the time of the incident.

Serious Adverse Event open disclosure responses will be conducted as part of the Statutory Disclosure of Candour process.

The criteria for determining the appropriate level of response is presented in Table 1

Table 1

	Criteria
Minor Adverse Event	1. Near misses and no-harm incidents 2. No permanent injury 3. No increased level of care (e.g. transfer to operating theatre or intensive care unit) required 4. No, or minor, psychological, or emotional distress
Serious Adverse Event	1. Surgery or other invasive procedure performed on the wrong site resulting in serious harm or death 2. Surgery or other invasive procedure performed on the wrong patient resulting in serious harm or death 3. Wrong surgical or other invasive procedure performed on a patient resulting in serious harm or death 4. Unintended retention of a foreign object in a patient after surgery or other invasive procedure resulting in serious harm or death 5. Haemolytic blood transfusion reaction resulting from ABO incompatibility resulting in serious harm or death 6. Suspected suicide of a patient in an acute psychiatric unit or acute psychiatric ward 7. Medication error resulting in serious harm or death 8. Use of physical or mechanical restraint resulting in serious harm or death 9. Discharge or release of an infant or child to an unauthorised person 10. Use of an incorrectly positioned oro- or naso- gastric tube resulting in serious harm or death 11. All other adverse patient safety events resulting in serious harm or death

Maryvale Private Hospital follows the eight guiding principles of Open Disclosure as set out below:

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/complaints will be acknowledged to the patient and their support person as soon as practicable. Maryvale Private Hospital will acknowledge when an adverse event has occurred and initiate the open disclosure process.

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

Maryvale Private Hospital has created an environment in which all staff are:

- encouraged and able to recognise and report adverse events
- supported through the open disclosure process.

Integrated risk management and systems improvement

Thorough review and investigation of adverse events and complaints should be conducted through processes that focus on the management of 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 Events and complaints from the open disclosure process will be incorporated into quality improvement activity and will be reviewed for their effectiveness.

Good governance

Open disclosure requires good governance frameworks, and clinical risk and quality improvement processes. Through these systems, adverse events & complaints are investigated and analysed to prevent them recurring. Good governance involves a system of accountability through Maryvale Private's senior management and executive to ensure that appropriate changes are implemented, and their effectiveness is reviewed. Good governance should include internal performance monitoring and reporting.

Confidentiality

Maryvale Private Policies and procedures are developed with full consideration of the patient's, carers and staff's privacy and confidentiality, in compliance with relevant law, including Commonwealth and state/territory privacy and health records legislation.

Key Elements of Process

The key elements of an open disclosure/SDC process are presented in Table 1, if incident is a complaint this process needs to be in conjunction with the complaints process – see CORP-023 Consumer Feedback

Table 2

Incident Detection	• Detect adverse event/complaint through a variety of mechanisms • If Adverse event/outcome 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 (including Executive) and authorities • Ensure privacy and confidentiality of patients and clinicians are observed
Stage 1: **Apologise and provide initial information**	Acknowledge the adverse event/outcome to the patient, their family and carers including an apology or expression of regret **A minor adverse event response can conclude at this stage** More serious incident - Signal the need for SDC **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. **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.

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.
	- **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.

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. **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.

4. Definitions

SDC: Statutory Duty of Candour

SAPSE: Serious Adverse Patient Safety Event

5. Related Policies and References

- HOSP-006 Incident and non-conformance management
- CORP-020 Clinical Governance Framework
- CORP-025 Risk Management Framework
- HOSP-008 Patient and Consumer Centered Care
- RCA template
- Statutory Duty of Candour Workbook
- Patient information Safer Care Victoria-Next steps pamphlet
- Safer Care Victoria: Victorian Duty of Candour Guidelines: August 2022 https://www.safercare.vic.gov.au/support-training/adverse-event-review-and-response/duty-of-candour
- Health Services Act 1988
- Health Services Establishment Regulation 2003
- National Safety and Quality Health Service Standards 1, 2 & 8

Version Control				
Version	**Date created**	**Creator**	**Reviewer/Approval**	**Summary Changes**
1	02/10/2014	Quality & Risk Manager	CEO/DON	New Policy
2	25/05/2018			Regular review
3	24/08 2021			New logo new format **Level of Response** The Chief Executive Officer is the Official Open Disclosure Officer, unless otherwise delegated to an appropriate person (ie: Director of Clinical Services)
4	07/12/2022	Director of Clinical Services	Quality & Risk Manager/Chief Executive Officer	New Format Policy name changed to reflect the introduction of the 'Statutory Duty of Candour' in Victoria. Policy updated to reflect the newly implemented legislation and the requirements to ensure adherence and compliance.