1. **Purpose:**

To inform all Macquarie Hospital Group (MHG) staff of their roles and responsibilities in undertaking Open Disclosure, Serious Adverse Event Review (SAER) and Statutory Duty of Candour (SDC) requirements following adverse patient safety events. The provision of information to patients, families, carers and/or support persons throughout the process and how this is supported and aligned with regulatory requirements. *Please note: SAER is a regulatory requirement for all New South Wales (NSW) Hospital sites and SDC is a regularly requirement for Victorian Hospital sites.*

Open disclosure is the open discussion of incidents that result in harm to a patient while receiving health care. The elements of open disclosure include a timely expression of regret, a factual explanation of what happened using language that is clear and free of medical jargon and acronyms, any potential consequences and the steps that are being taken to prevent recurrence.

Both the SAER and SDC require health entities to:

- apologise to any person seriously harmed while receiving care,
- explain what went wrong,
- describe what action will be taken and improvements put in place.

These requirements come with legal protections around health service apologies and reportable incident reviews.

2. **Scope:**

This policy applies to all MHG staff and should inform communications with patients, their families, carers and/or support persons following harm from an adverse event.

Note: *It is the responsibility of each Hospital Director to ensure that any serious adverse event is notice to the insurer.*

3. **Principles of Open Disclosure:**

3.1 Open and timely communication:

When something goes wrong, the patient, their family and carers need to be provided with information on what happened in a timely, open and honest manner. The open disclosure process will often involve the provision of ongoing information.

3.2 Acknowledgement:

All patients, their family, carers and/or support persons are to be informed of any adverse event as soon as possible post identification of an adverse event. If all the facts are not known, then an explanation of what is known along with the steps that will be undertaken to determine all facts should be discussed.

3.3 Apology or expression of regret:

As early as possible, the
patient, their family, carers and/or support persons will receive and apology or expression of regret for the harm resulting from an adverse event. The delivery of an effective apology or expression of regret requires certain

skills. High-level response apologies for serious adverse events will be provided by trained staff within twenty four hours of identification of the event.

3.4 Supporting and meeting the needs and expectations of patients, their families, carers and/or support workers:

The patient, their family, carers and/or support workers can expect to be:

- Fully informed of the facts surrounding the adverse event and its consequences discussed with them in language they can understand;
- Treated with empathy, respect and consideration;
- Supported in a manner that fits their needs;
- Offered a single point of contact to facilitate liaising with the review team;
- Offered the opportunity to ask questions related to the adverse event;
- Informed of MHG's response to the event and what improvements will made in an effort to prevent recurrence of this type of event in the future.

3.5 Supporting and meeting the needs of MHG staff providing health care:

MHG creates an environment in which staff are:

- Supported in recognising and reporting adverse events
- Prepared through training and education to participate in open disclosure conversations, and
- Fully supported through the open disclosure and SAER and SDC process.

3.6 Integrated clinical risk management and system improvement:

Thorough investigation and review of any adverse event will be conducted in line with the MHG Incident Management policies and procedures. All findings, recommendations and learnings from these reviews will be focused on system improvement and will be monitored and reviewed for effectiveness post implementation.

3.7 Good Governance:

Open disclosure is an integrated component of the MHG Clinical Governance Framework. This ensures that all adverse events are investigated, analysed and appropriate improvements are both implemented and monitored for effectiveness.

3.8 Confidentiality:

Both patient and staff privacy and confidentiality are maintained at all times and in accordance with MHG policies.

4. Policy:

MHG is committed to providing the required support to employees to enable them to apply the open disclosure principles as outlined in the Australian Open Disclosure Framework and

the obligations for open disclosure contained in the Australian Charter of Healthcare Rights. Additionally, MHG will adhere to the NSW requirements to undertake a SAER review and Victorian statutory requirements for a Sentinel Event and/or Duty of Candour when applied to identified SAPSE's as per the Health and Safety Act.

To achieve this:

- Staff will report adverse events into the RiskClear, as outlined in the Incident Management Policy and Procedure and promote timely open disclosure and SAER / SDC discussions.
- All incidents with a Harm Score of 1 are to be immediately escalated by the Hospital Director/Director of Nursing to direct line manager.
- All serious adverse events (those with a Harm Score of 1 or 2) will be reviewed by the Hospital Director/Director of Nursing, Legal Advisor, Corporate Quality Manager to confirm the severity of harm and determine if the adverse event meets the SAER/Sentinel Event and/or SDC criteria (moderate or severe physical harm or prolonged psychological harm).
- All low level adverse events (Harm score 3 or 4) still require open disclosure to advise the patient that either minor or no harm has occurred.
- Staff will be provided with access to training, resources and support to enact mandatory SDC requirements when a SAPSE has occurred.
- To comply with the mandatory SAER/Sentinel Event/SDC requirements patients, their families, carers and/or support workers will receive:
    - A genuine apology for the harm suffered within twenty four hours of identification of a SAPSE;
    - Information outlining the details of the adverse event and the next steps in the review process;
    - An invitation to an open disclosure meeting to be scheduled within ten business days of the identification of the SAPSE;
    - An opportunity during this meeting to discuss their experience and to ask any questions they may have;
    - An explanation of the review process and any improvements that may have been implemented;
    - An explanation of any implications as a result of the SAPSE;
    - A written report on any SAER/Sentinel Event/SDC meetings, and
    - A written report of the review of the adverse event and all identified areas for improvement.

5. Roles, Responsibilities and Delegations:

Role	Responsibility and Delegation
Quality Team	**Staff Training and Guides:** • Ensures all staff have access to and are trained in the use of the incident reporting system

	• Ensures the availability of training resources for staff for the principles and practice of Open Disclosure • Ensures staff are provided with resources and aides to assist with open disclosure and SDC discussions and how to record these discussions • Ensure policies and procedures are current and familiar to all staff **Incidents / Complaints:** • Monitor the incident and complaint system for events that meet the SAPSE requirements • Liaises with staff and the appropriate executive/legal advisor to confirm the incident severity (Harm score 1 and 2) and to agree if the event aligns with the SAPSE criteria • Ensures all appropriate stakeholders have been notified of the incident • Ensures the CEO is notified of all identified SAPSE events • Notify appropriate managers of a confirmed SAPSE and that the SAER/Sentinel Event/SDC process will begin. **Root Cause Analysis (RCA) Process:** • The staff member facilitating the review has completed the appropriate state specified training • All staff involved in the review were not directly involved in the adverse event • Coordinates and facilitates the complete the RCA; i.e. convening meetings, creating meeting reports, liaising with stakeholders, data collection and mandatory data reporting requirements • Liaising with other health care services if the patient was transferred after the adverse event occurred **Quality Improvement:** • Review both staff and patient experience with the SDC process • Provide reports to committees on the SDC process
Clinical Services Managers	**Incidents and Complaints:** • Ensure all their staff have access to and the required supportive tools to use the incident and feedback systems • Review incidents for their area(s) daily and liaise with the Quality team when Harm Score 1 or 2 incidents are logged to confirm severity **SAER/Sentinel Event/SDC Process:** • Complete the required training
Executive Director of Nursing / Director	**Incidents and Complaints:** • Review all alerts from RiskClear triggered from the incident and/or feedback system • Assist and support the review process when relevant to their area **SAER/Sentinel Event/SDC Process:** • Complete the appropriate training • Participates in open disclosure meetings as required
Executives	**Adverse Event / Level of Harm:** **Clinical Incidents – Harm score 2:** • Receives notification of Harm score 2 incidents via RiskClear alerts

	• Liaise with Quality team to confirm the harm score rating and determine if the event meets the SAPSE criteria • Discuss with Legal if any uncertainty remains for the level of harm or if the event meets the SAPSE criteria **Clinical Incidents – Harm score 1:** • Receives notification of Harm score 1 incidents via RiskClear alerts • Liaises with Quality team to confirm the harm score rating and with CEO/Deputy CEO for all Harm score 1 incidents to confirm level of harm and determine if the event meets the SAPSE criteria and agree the type of review required • SAPSE – support the SAER/Sentinel Event/duty of candour process for all identified SAPSE reviews **Open Disclosure:** • Complete relevant training modules • Ensure open disclosure is supported across the organisation and that all incidents are identified and reported into RiskClear to support the SDC process • Liaises with the Quality team to identify the appropriate staff to undertake open disclosure meetings
CEO	• Advised of all Harm Score 1 incidents • Ensures organisational structures, systems and processes are aligned with the relevant statutory and regulatory standards and requirements • Notified by the Quality team / Executive on all incidents meeting SAPSE criteria
Divisional Managers Meeting (DMM)	• Ensure the ongoing quality and safety of MHG through oversight of the integrated clinical risk management strategies and clinical effectiveness monitoring, including the system(s) used to identify serious adverse events and undertaking the statutory duty of candour • Monitor the implementation of MHG policies to ensure compliance with legislative, regulatory and government policies • Receive reports which provide assurance that the required compliance strategies are in place and effective

6. Definitions and Abbreviations:

Admission of liability: A statement by a person that proves, or tends to prove, a person's or organisation's liability in negligence for harm caused or damage caused.

Adverse event: An incident that resulted in harm (physical or psychological) to a person receiving care. Harm includes disease, suffering, impairment (disability) and death.

Apology: An expression of compassion, regret or sympathy in connection with any matter, whether or not the apology admits or implies an admission of fault in connection with the matter.

Apology not an admission of liability (NSW CLA Guidelines): In NSW, under section 68 of the CLA an apology is defined as an expression of sympathy or regret and may include an admission of fault.

Section 69 provides that an apology:

- (1)(a) does not constitute an admission of fault or liability in a matter;
- (1)(b) is not relevant to the determination of fault or liability in a matter; and
- (2) evidence of the apology is not admissible in civil proceedings as evidence of fault or liability.

Apology not an admission of liability (Victorian SDC Guidelines): In civil proceeding where death or injury of a person is in issue or is relevant to an issue, an apology:

(a) does not constitute an express or implied admission of liability for the death or injury; and
(b) 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.

Note: Nothing in this section affects the admissibility of a statement with respect to a fact in issue or tending to establish a fact in issue.

Duty of Candour: Is a statutory requirement (Health Services Act) in Victoria that requires health organisations, in the course of open disclosure, to follow the steps set out in the Victorian SDC Guidelines and to provide consumers impacted by a serious adverse event with:

- A written account of the facts regarding the serious event
- An apology for the harm suffered by the patient
- A description of MHG's response to the event
- The improvements that MHG has undertaken following the incident to prevent re-occurrence of the event

The statutory duty of candour does not replace current obligations to practice open disclosure under the Australian Open Disclosure Framework. Rather, the duty is a complementary legal obligation to support improved compliance within a defined set of circumstances.

The statutory duty of candour operates alongside existing incident response and reporting requirements.

Expression of regret: An expression of sorrow for harm or grievance. It should include the words 'I am sorry' or 'we are sorry'. An expression of regret may be preferred over an apology in special circumstances (e.g. when harm is deemed unpreventable).

Harm: Includes prolonged psychological harm, moderate harm and severe harm.

Incident: An event or
circumstance, which could have, or did lead to unnecessary harm to persons, complaint, loss or damage.

Incident / Complaint severity rating: All incidents and complaints notified in RiskClear are awarded a harm score on a scale of one (most serious) to four (near miss) that guides the level of investigation required.

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 cause permanent damage or injury to an individual.

Next of kin (NOK): The patient's next of kin which may be any partner, legal guardian, child or sibling of 18 years or older, or executor when a harm event results in death.

Nominated person / support person: An individual who is given permission by a competent patient to be informed about and be involved in their care. This can include family members, next of kin, friends, partner, guardian, social worker or religious representative. The support

person may also have a legal right to be informed if they are the legal treatment decision maker (Medical Treatment Planning and Decisions Act 2016).

Open disclosure: The open disclosure of an incident that results in harm to a patient whilst receiving health care.

The elements of open disclosure are:

- An apology or expression of regret (including the word 'sorry')
- A factual explanation of what happened explained in language that is understandable to the patient
- An opportunity for the patient to relate their experience
- An explanation of the steps being taken to manage the event and prevent recurrence
- The discussion(s) with the patient and family / carers may take place over several meetings.

Open disclosure is:

- The sharing of information via a two-way conversation between MHG clinicians and the patient / family / carer
- Not a legal process
- Does not imply that an individual or MHG has blameworthy facts to disclose.

Patient: Any person including inpatients, consumers, clients or residents who have incurred a SAPSE whilst utilising any MHG service.

Person centred care: Care that is respectful of, and responsive to, the preferences, needs and values of the individual patient. Key dimensions of person-centred care include respect, emotional support, physical comfort, information and communication, continuity and transition, care coordination, involvement of carers and family, and access to care.

Prolonged psychological harm:
Psychological harm experienced by or likely to be experienced by a patient, for a continuous period of less than 28 days.

Review: A formal process undertaken by MHG staff. A review is undertaken when there has been an adverse event, identified either through the incident reporting system or a patient complaint. The type of review tool employed may be an in-depth case review, a root cause analysis or might follow the London Protocol or ACCIMAP models.

SAPSE: Is defined as a serious adverse patient safety event that:

(a) Occurred while the patient was received 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.

To avoid doubt, an event may be identified following discharge from the health service entity.

SAPSE review (Victoria): Refers to a review of a SAPSE that is conducted in accordance with specific requirements in the Health Services Act 1988 (Division 8 of Part 5A of the Act). Not all SAPSE's will require a SAPSE review.

Severe (serious) harm: 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. Severe harm can lead to a person experiencing a permanent impairment, disability or death.

RiskClear: Electronic system utilised for capturing all incidents and patient feedback.

7. Governance:

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Approving authority	DMM		
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Legislation, Acts and Standards	National Safety and Quality Health Service Standards (Second edition 2017) NSW Private Health Facilities Regulation 2017 (NSW) Health Services (Health Service Establishments) Regulations 2013 (Vic) Australian Charter of Healthcare Rights (2020) Health Legislation Amendment (Quality and Safety) Act 2022 Health Services Act 1988 (www.legislation.vic.gov.au) NSW Civil Liability Act 2002 No 22 (www.legislation.nsw.gov.au)		
Key aligned documents	MHG Clinical Governance Framework MHG Incident Management Policy MHG Incident Management Procedure		
References	Australian Open Disclosure Framework – Better communication, a better way to care (Australian Commission on Safety and Quality in Health Care, 2014) Incident Management (PD2020_047, NSW Health, December 2020) Adverse Patient Safety Event policy (Safer Care Victoria, 2023) Victorian Duty of Candour Framework (Safer Care Victoria, 2022) Victorian Duty of Candour Guidelines (Safer Care Victoria, 2022)		
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