Open Disclosure Protocol

Protocol

Open disclosure is the open discussion of adverse events that result in harm or a near miss to a patient while they were receiving care. It is a discussion held with the patient, their family and/or carers to facilitate open communication and transparency.

Open Disclosure's eight guiding principles are:

1. **Open and timely communication**

When things go wrong, the patient and/or their support person 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 and/or their support person as soon as it becomes practical. Epworth, in conjunction with the appropriate Senior Medical Staff, should acknowledge when an adverse event has occurred and initiate the open disclosure process.

3. **Apology or expression of regret**

As early as possible, the patient and/or their support person 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 any speculative statements, admission of liability or apportioning of blame.

4. **Supporting, and meeting the needs and expectations of the patient and/or their support person**

The patient and/or their support person(s) 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, and
- offered the opportunity to ask any questions related to the adverse event.

5. **Supporting, and meeting the needs and expectations of those providing health care**

Epworth aims to 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, and
- supported through the open disclosure process.

6. Integrated clinical risk management and systems improvement

Once identified, an adverse patient safety event, depending on its incident severity rating (ISR), will undergo a thorough preliminary assessment to determine level of harm, and this is followed by a formal investigation using an appropriate review methodology. The purpose of this review is to focus on identifying processes and systems relevant to the adverse event, which have failed and require improvement. The information obtained about adverse patient safety events from the open disclosure process should be used to inform quality improvement activities.

7. Good governance

Open disclosure requires good governance frameworks, and clinical risk and quality improvement processes. Through these frameworks and processes, adverse events should be investigated and analysed to prevent them from 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. Privacy considerations

Epworth is committed to open and timely communication in accordance with its statutory duty of candour. In conducting open disclosure, Epworth also has regard to its policies and protocols to respect and safeguard the privacy of personal information, including health information, in accordance with privacy and health records legislation.

Roles and Responsibilities

All staff have the reasonability to recognise that a patient has suffered unintended harm during their care and/or treatment at Epworth.

Process

1. When is open disclosure appropriate?

1.1 Commencing open disclosure process

- The open disclosure process commences with the recognition that a patient has suffered unexpected or unintended harm during treatment, a near miss or when the relevant senior staff deems the incident as an adverse event (regardless of outcome) warranting a response.
- Identifying that an adverse event has occurred can be through several ways including incidents reported directly into the Riskman, feedback and complaints (i.e., a patient identified adverse event), mortality and morbidity meetings and coroners' written findings.
- The response will vary according to the level of harm resulting from the adverse event. In the event of harm being identified, the priority is prompt and appropriate clinical care and prevention of further harm. Additional treatment should be provided if required and if reasonably practical, after discussion and with the consent of the patient.
- The treating team and responsible management personnel should be advised, and evidence should be gathered that will assist in investigating the event. Where appropriate this should occur in consultation with the Quality team and the Site Executive. Clinicians (and other staff) involved in the adverse event should be supported as required.
- Open disclosure should occur as soon as it becomes practical after staff become aware of the adverse event or near miss; best practice is within 24 hours after the adverse event has occurred.

1.2 Adverse events occurring elsewhere

An adverse event may occur during an inpatient admission such as when a patient is temporarily transferred to another organisation for treatment before returning to Epworth. If an adverse event has been identified that occurred in another organisation, the staff member who first identifies the possibility of an adverse event occurring external to Epworth should notify the site Quality Manager or Coordinator. The site Quality Manager or Coordinator will establish whether the:

- adverse event has already been recognised; and
- process of open disclosure has commenced elsewhere.

If the open disclosure process has not already commenced, Epworth will initiate the open disclosure process in consultation with the organisation in which the adverse event occurred.

1.3 Criteria for determining Open Disclosure vs Open Disclosure/Statutory Duty of Candour

	Incident Severity Rating	Level of harm considerations
Open Disclosure only	ISR 3 and ISR 4	• Near misses and no-harm incidents • No permanent injury • No increased level of care (e.g., transfer to operating theatre or intensive care unit) required • No, or minor, psychological, or emotional distress
Open Disclosure and Statutory Duty of Candour process	ISR 1 and ISR 2*	• Death or major permanent loss of function • Permanent or considerable lessening of body function • Significant escalation of care or major change in clinical management (e.g., admission to hospital, surgical intervention, a higher level of care, or transfer to intensive care unit)

ISR 2* - There are ISR 2 notifications used primarily for surveillance and therefore do not constitute a clinical incident, where Open Disclosure and or Statutory Duty of Candour is not required, for example: planned return to theatre with increased postoperative level of care**.** Where there is uncertainty, a decision support is provided by the Site Clinical Huddle and the Group Clinical Huddles.

2. Initial discussion with patient and/or their support person

2.1 Timing

The initial discussion with the patient and/or their support person (if the patient is unable to participate, or wants support person's involvement) should occur as soon as possible after the adverse event. However, consideration needs to be given to:

- the clinical condition of the patient;
- availability of key staff;
- availability of the patient's support person;
- the patient's preferences; and
- the patient's emotional and psychological state.

The apology should be documented in the progress notes with a clear reference that it is an Open Disclosure discussion.

2.2 Where should open disclosure discussion occur/location?

Unless there is a specific contra-indication or the patient requests a specific location, the open disclosure process will occur at the site level, with the participation of those directly involved in the event.
The Open Disclosure discussion with the patient and/or support person(s) should be held using means that are most convenient to the patient or their support person, including:

- face to face;
- videoconference (e.g., via Microsoft Teams or Zoom); or
- by telephone.

If being conducted face to face, ensure that there is a quiet, private area to maintain privacy.

2.3 Identification of appropriate individual to have the initial discussion.

The apology should be made by the relevant, experienced clinician (e.g., not by an intern or a graduate nurse). If the relevant clinician feels uncomfortable about making the apology, they should escalate to a more senior clinician. For serious adverse events, the apology would usually be made by the most senior clinician who is
responsible for the care of the patient, usually the treating medical practitioner. If they are unavailable, then their chosen delegate should have sufficient seniority and clinical experience to capably undertake the task. The lead clinician should also have the support of another staff member with good communication skills. The involvement of other clinicians may also be considered based on their ability to contribute to the process and provide support to the patient.

To facilitate the Open Disclosure discussion successfully the clinicians selected should:

- be known to the patient;
- be familiar with the care of the patient and circumstances of the adverse event
- be experienced and capable of managing a difficult conversation;
- have received training in open disclosure;
- have good interpersonal skills and the ability to communicate in everyday language;
- be able to offer reassurance and feedback to the patient and their support person; and
- be available to maintain an ongoing Open Disclosure dialogue with the patient, if required.

2.3.1 Protection of communications and documents from disclosure

Communications, staff statements and documents (including emails) produced in response to any adverse event may need to be disclosed later in legal proceedings. It is therefore important that any documents created should be factual and accurate.

Documents should not:

- attribute blame to any health care professional or health care organisation;
- record opinions about staff, patients, or support persons; or
- contain statements, which are, or are likely to be, defamatory.

Note that there are specific requirements when a SAPSE has occurred, and a 'protected review' is undertaken. In these situations, advice must be sought from site executive and quality team.

2.4 Content of Open Disclosure discussion

2.4.1 The initial discussion with the patient and/or their support person should include:

- an introduction of all people attending and their roles;
- the words 'I am sorry' that the event has occurred;
- an expression of regret and empathy for the harm that has occurred;
- discussion of the known facts at the time as agreed by the team;
- An opportunity for the patient and/or their support persons to be heard and to relate their experiences;
- an express acknowledgement that the views and concerns of the patient and/or their support person(s) are being heard and considered seriously;
- consideration of the potential impact on the patient; and
- identification of the immediate supports available to the patient (e.g., counselling; waiver of fees; key Epworth contact for ongoing communication; pastoral care etc.

The Open Disclosure discussion should not include speculation about unverified facts or causes for the adverse event and there should not be any attribution of blame.

Note that there are specific requirements when a Serious Adverse Patient Safety Event (SAPSE) has occurred to complete the requirements of the Statutory Duty of Candour.

The initial Open Disclosure discussion forms only a part of ongoing communication with the patient and must be documented in the medical record. Many of the issues raised in this first meeting may need to be re-explained or expanded on in subsequent meetings. Staff members participating in the initial discussion should make sure that the patient and any support person understand what is being said to them. This approach should also be taken in follow up meetings.

2.4.2 Language or Cultural Diversity Considerations:

Where use of an interpreter is specified in iPM, a patient and/or support person has difficulty communicating in English or requests, a professional interpreter should be used in the Open Disclosure process. An interpreter from the same cultural background may also be able to advise on other issues (e.g., whether the gender of the health care professional who makes the Open Disclosure is an issue that needs to be considered).

2.5 Support for clinicians and staff following an adverse event

If required, clinicians and staff should be provided with support immediately following the event and ongoing;

- advice and guidance
- an understanding of the systemic nature of adverse events and Epworth's commitment to shared accountability between the organization and the people in the system, supporting a fair and just approach to managing adverse events and creating a culture where employees feel safe to report adverse patient safety events. and/or
- management feedback including communication of the investigation outcomes and improvement actions to ensure confidence and engagement in the process of Open Disclosure.

3. Follow up meetings with patient and support person

- The Senior Medical Practitioner involved in the adverse event and the initial Open Disclosure discussion with the patient should also be involved in any follow up discussions required. Where aSAPSE has occurred, the Quality Managers will coordinate further discussions as required.
- Information should be given to the patient and support person on the investigation process steps and on the investigation progress to that point.

4. Completing the process

4.1 Communication with the Patient

After the adverse event review is completed, feedback to the patient may take the form of a face-to-face discussion, a letter or both. Where the adverse event is an ISR 1 or 2, the patient should always be offered the opportunity for a face to face meeting and always receive the feedback in writing. Feedback should include:

- the clinical and other relevant facts;
- Epworth's response any concerns or complaints expressed by the patient and support person;
- an expression of regret and apology for the harm suffered;
- a summary of the factors that contributed to the adverse event;
- an explanation of the investigation process that was conducted;
- information on what has been done and will be done to avoid repetition of the adverse event and how these improvements will be monitored and
- use of health literacy principles in all communication with patients to ensure that they understand the feedback.

Note that there are specific requirements when a SAPSE has occurred, and a 'protected review' is undertaken. In these situations, advice must be sought from site executive and quality team.

4.2 Documentation

The lead clinician is responsible for documenting a record of the Open Disclosure discussion in the patient's medical record. A record of the conduct of Open Disclosure discussions must be made via the incident management system (RiskMan) through the investigation field.

4.3 Expenses associated with managing and treating the adverse event

It is at the discretion of the relevant Site Executive to consider the waiver or reimbursement of patient expenses associated with managing and treating the adverse event.

Outcome

- Timely, clear, and effective communication/exchange of information between staff and patient/support person regarding any adverse event(s) or near miss.
- Consistent, transparent, caring, and empathetic approach is demonstrated in the process of Open Disclosure consistent with the Open Disclosure Framework and the Statutory Duty of Candour.

Appendices

Appendix A: Adverse events and Open disclosure, patient, family/carer brochure
Appendix B: Open Disclosure Flowchart for ISR 3, 4, Near Miss Incidents
Appendix C: Open Disclosure Flowchart for ISR 1 and 2

Definitions

Adverse Event: An unintended injury or complication, which results in disability, death or prolonged hospital stay and is caused by Epworth rather than the patient's disease.
Apology: An expression of sorrow, sympathy and (where applicable) remorse by an individual, group or institution for a harm or grievance. It should include the words 'I am sorry' or 'We are Sorry'. An apology may also include an acknowledgement of responsibility, which is not an admission of liability
Expression of Regret: An expression of sorrow for a 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).
Incident: An unintended event or outcome with the potential to cause, or that has caused, harm to a person(s) or loss or damage to Epworth. It applies to all events that result in actual or potential harm, including near misses and applies to patients, staff, visitors, volunteers, contractors, equipment, and Epworth.
Near Miss: An incident that did not cause harm but had the potential to do so
Open Disclosure: An open discussion with a patient and/or their support person(s) about an incident that resulted in harm to that patient while they were 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, an opportunity for the patient to relate their experience and an explanation of the steps being taken to manage the event and prevent recurrence.
Support Person: An individual who is authorised by a patient with decision making capacity to be informed about
SAPSE: A serious adverse patient safety event as defined in section 3(1) of the *Health Services Act 1988,* being an event of a prescribed class or category that results in harm to one or more individuals. A prescribed class or category is an event 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.
Statutory Duty of Candour: a legal obligation to ensure that consumers of health care and their families are apologised to, and communicated with, openly and honestly in the event of a SAPSE.
and be involved in their care. This can include family members, friends, partner, guardian, social worker, or religious representative. The support person may also have a legal right to be informed as the "nominated person" under the *Mental Health Act 2014* or the "medical treatment decision maker" under the *Medical Treatment Planning and Decisions Act 2016*.

Applicable Legislation and/or standards

Australian Commission on Safety and Quality in Health Care (ACSQHC). (2011). National Safety and Quality Health Service Standards, ACSQHC, Sydney. Standard 1, Criterion 1.16
Health Services Act 1988 (Vic)

References

Australian Commission on Safety and Quality in Health Care. (2013). *Australian Open Disclosure Framework*. ACSQHC, Sydney. Retrieved from https://www.safetyandquality.gov.au/sites/default/files/migrated/Australian-Open-Disclosure-Framework-Feb-2014.pdf

Safer Care Victoria. (2022). Victorian Duty of Candour Framework. Retrieved from https://www.safercare.vic.gov.au/sites/default/files/2022-10/Victorian%20Duty%20of%20Candour%20Framework%20-%20FINAL.docx

Safer Care Victoria. (2022). *Victorian Duty of Candour Guidelines*. Retrieved from https://www.safercare.vic.gov.au/sites/default/files/2022-10/Victorian%20Duty%20of%20Candour%20Guidelines%20-%20FINAL.docx

Safer Care Victoria. (2023). *Protections for serious adverse patient safety event reviews.* Retrieved from https://www.safercare.vic.gov.au/sites/default/files/2022-10/Protections%20for%20serious%20adverse%20patient%20safety%20event%20%28SAPSE%29%20reviews%20-%20FINAL.docx

Safer Care Victoria. (2023.) Adverse Patient Safety Event policy. Retrieved from https://www.safercare.vic.gov.au/sites/default/files/2022-10/Protections%20for%20serious%20adverse%20patient%20safety%20event%20%28SAPSE%29%20reviews%20-%20FINAL.docx

Relevant National Safety and Quality Health Service (NSQHS) Standards 2nd Ed.

- ☒ Clinical Governance
- ☐ Partnering with Consumers
- ☐ Preventing & Controlling Infections
- ☐ Medication Safety
- ☐ NSQHS Standards are not applicable
- ☐ Comprehensive Care
- ☐ Communicating for Safety
- ☐ Blood Management
- ☐ Recognising & Responding to Acute Deterioration

Linked Policies, Protocols or Procedures

Privacy Policy - 7961
Patient Complaint Protocol - 5790
Incident Management Protocol - 1280

Departments

All Epworth Staff including:

- Allied Health Services
- Academic and Medical Services
- Nursing & Midwifery

Document Control

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Change Log

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1.0	19/10/2018	Approved for publication by CPC 17 October 18
2.0	30/10/2018	Minor edit to include omitted amendment 'including written' under the 6th point in the OD conversation section.
3.0	04/12/2019	Links to archived Open Disclosure and Privacy of Health Information Policies removed from

		Linked PP section
4.0	15/10/2020	Removal of reference to ISR 1 and 2 ratings
5.0	19/12/2023	Endorsed at December 2023 CPC Approved at Group Clinical Governance Committee - date not provided Changed the language from "Low-Level Response" to "Open Disclosure." • Changed the language from "High-Level Response" to "Open Disclosure and Statutory Duty of Candor." • Updated the table with criteria for "Open Disclosure" vs. "Open Disclosure and Statutory Duty of Candour." • Added a new section called "Open Disclosure Guiding Principles." • Updated the list of definitions. • Updated the flowcharts for Open Disclosure in the event of an ISR 1 and/or 2. • Updated the flowchart for Open Disclosure in the event of an ISR 3 or 4 or a Near Miss. • Updated the references section