OPEN DISCLOSURE

AIM:

To provide a nationally recognized formal and structured framework for communication following unexpected healthcare outcomes and harm. It is designed so that patients are treated respectfully after an adverse event, fully informed, and provided with an opportunity for questions and support. It also provides guidance and expectations for healthcare professionals.

ASSOCIATED RISKS:

1. That unqualified, uninformed, and unauthorized members of the workforce provide information to patients/parent(s)/legal representative.
2. That speculative and subjective information is provided, not facts.
3. That defamation occurs.
4. That inconsistent and contradictory information is included in the documentation.
5. Positions of authority are not aware of the adverse event.
6. Key personnel are not involved in the process.
7. Regulatory requirements are not met.
8. That events escalate to avoidable litigation.

RISK MANAGEMENT:

1. Formal policies and procedures guide work practice.
2. Formal education in regards to Open Disclosure is in place.
3. Formal orientation of new employees and Visiting Medical Officers.
4. Formal systems and processes are in place to monitor and report.
5. Governance systems are in place.

POLICY:

GIH Access Endoscopy Day Procedure Centre promotes and supports a formal, well structured, "best practice" approach to "Open Disclosure". All aspects of disclosure will take place in a fair manner, without bias, in keeping with the ethos of "patient centredness", with full support for the patient, involved members of the work force, and participating clinicians.

The "Open Disclosure" process will be invoked whenever a patient has suffered an adverse event that is rated in the moderate to catastrophic category, with flexibility to be considered for lower level events, or near misses, which have the potential to evolve into a moderate to catastrophic category, or where a patient/parent/legal representative has requested so.

The CEO and Director of Clinical Services must be notified of an adverse event immediately. The process is facilitated and managed by an Executive Member, namely the Director of

Clinical Services, with leadership roles being occupied by the Chairman of the Medical Advisory Committee, and attending Medical Practitioner. All participants are involved in ensuring the required documentation and reports are completed, and that reports are received by the appropriate key personnel, committees, and external regulatory bodies. The CEO is to receive ongoing information and status.

All members of the clinical workforce, including Accredited Medical Practitioners, are expected to have a full understanding of the "Open Disclosure" process, and to have completed the Victorian Government on-line education session on "Open Disclosure", or similar education.

Internal reporting through the formal human resource hierarchy; Quality, Risk, and Safety systems and process; and the committee structure is to take place. External reporting to regulatory bodies is to take place.

The Formal structure and process of "Open Disclosure" forms part of the Clinical Governance Programme.

THE OPEN DISCLOSURE PROCESS:

(Reference: Australia Open Disclosure Framework, 2013,pages14-17)

The Open Disclosure Process will be outlined within:

1. An Open Disclosure Framework
2. Three (3) tables.
   i) Table One (1) provides a flow chart for Lower level responses;
   ii) Table Two (2) provides a flow chart for Higher Level responses; and
   iii) Table Three (3) is in a narrative format, which provides the necessary detail for the workforce to initiate timely action, and follow a successful process.
3. A copy of the *Australian Open Disclosure Framework* is attached for more detail, and as a reference point. Reference to the literature is made throughout this policy & procedure.

The following lists provide a guide to events that are considered to "trigger" a **Lower-Level Response** and those that would be considered to "trigger" a **Higher Level Response.** They are guides only and clinical judgement and consideration must take place on an individual basis. (S=Section.)

A. General indications – Higher Level Response:
S7.3

1. Death or major permanent loss of function.
2. Permanent or considerable lessening of body function.
3. Significant escalation of care/change in clinical management.
4. Major psychological or emotional distress.
5. At the request of the patient.

B. General indications – Lower-Level Response:
S7.3

1. Near miss/no-harm incident.
2. No permanent injury.
3. No increased level of care required.
4. No, or minor, psychological or emotional distress.

OPEN DISCLOSURE FRAMEWORK:

(Reference: Australia Open Disclosure Framework, 2013,page13)

1. OPEN & TIMELY COMMUNICATION

If things go wrong, the patient, their family & carers will be provided with information about what happened in a timely, open & honest manner. The open disclosure process is fluid & will often involve the provision of ongoing information.

2. ACKNOWLEDGEMENT

All adverse events will be acknowledged to the patient as soon as practicable. & the Open Disclosure process initiated

3. APOLOGY OR EXPRESSION OF REGRET

As early as possible, the patient will 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, admissions of liability or apportioning of blame.

4. SUPPORTING AND MEETING THE NEEDS & EXPECTATIONS OF PATIENTS, THEIR FAMILY & CARERS

The patient, (their family and carers –if relevant) can expect to be:

- **fully informed of the facts surrounding an adverse event and its consequences.**
- **treated with empathy, respect & consideration.**
- **supported in a manner appropriate to their needs.**

OPEN DISCLOSURE

5. SUPPORTING & MEETING THE NEEDS & EXPECTATIONS OF THOSE PROVIDING HEALTH CARE

An environment will be provided in which members of the workforce are:

- **encouraged and are able to report adverse events.**
- **prepared through training & education to participate in Open Disclosure.**
- **Supported through the Open Disclosure process.**

6. INTEGRATED CLINICAL RISK MANAGEMENT & SYSTEMS IMPROVEMENT

Thorough clinical review & investigation of adverse events and adverse outcomes will be conducted through processes that focus on the management of clinical risk and quality improvement. Findings of these reviews will focus on improving systems of care & be reviewed for their effectiveness. The information obtained about incidents from the Open Disclosure process should be incorporated into quality improvement projects.

7. GOOD GOVERNANCE

Open Disclosure requires good governance frameworks, and clinical risk and quality improvement processes. Through these systems, adverse events will be investigated & analysed to prevent them re-occurring. Good governance involves a system of accountability through executive management & the governing body to ensure that appropriate changes are implemented & their effectiveness is reviewed. Good governance will include internal performance monitoring & reporting.

8. CONFIDENTIALITY

Policies & procedures will be developed with full consideration for patient & clinician privacy & confidentiality, in compliance with relevant law (including Commonwealth, State & Territory privacy & health records legislation). However, this principle needs to be considered in the context of Principle 1: open & timely communication

S=Section: within the Australian Open Disclosure Framework Reference

Table 1: Flow Chart outlining the Key Steps of Open Disclosure-Lower Level of Response

(Reference: Australia Open Disclosure Framework, 2013,page17)

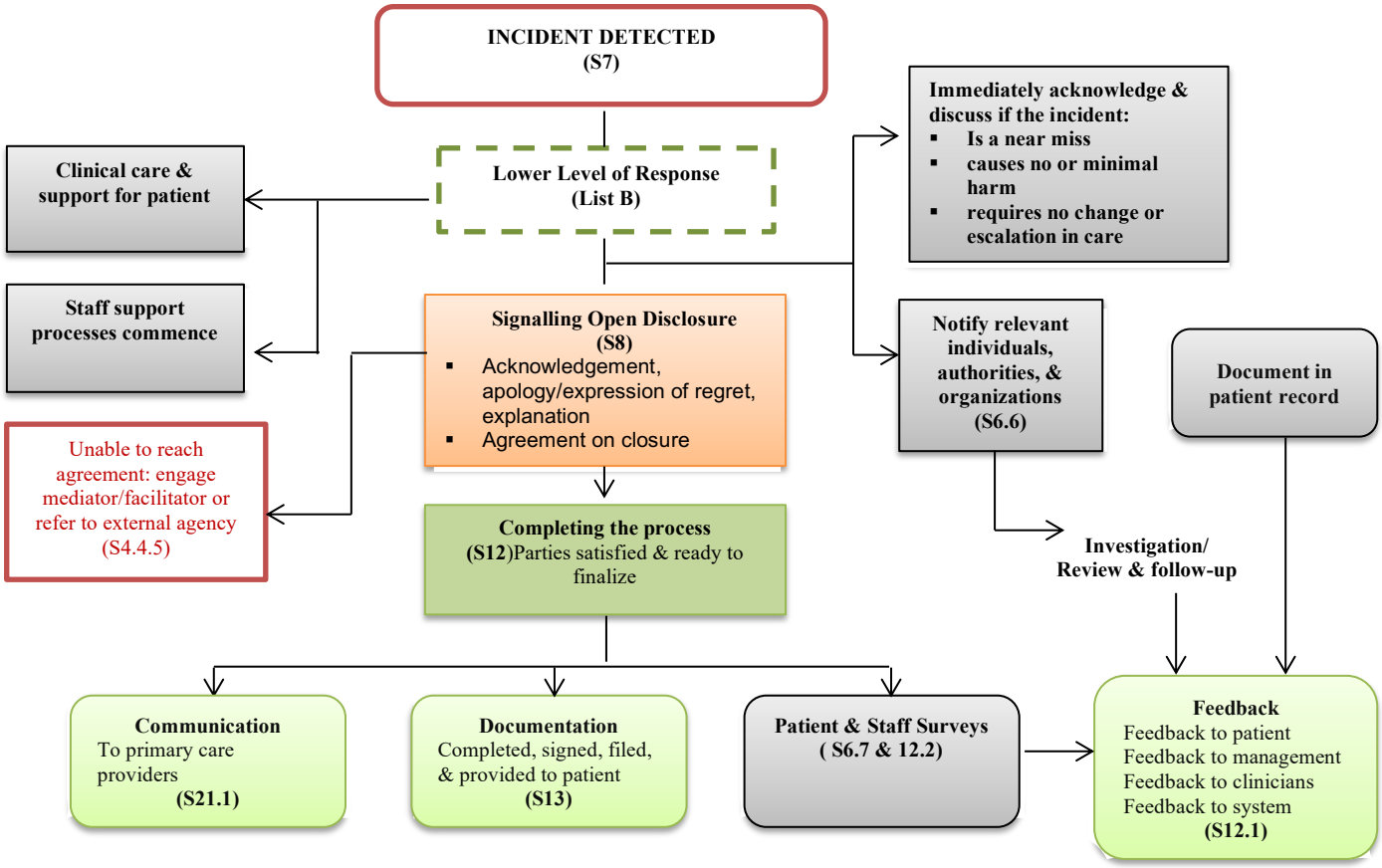

Table 1: Flow Chart outlining the Key Steps of Open Disclosure-Higher level of response

(Reference: Australia Open Disclosure Framework, 2013,page16)

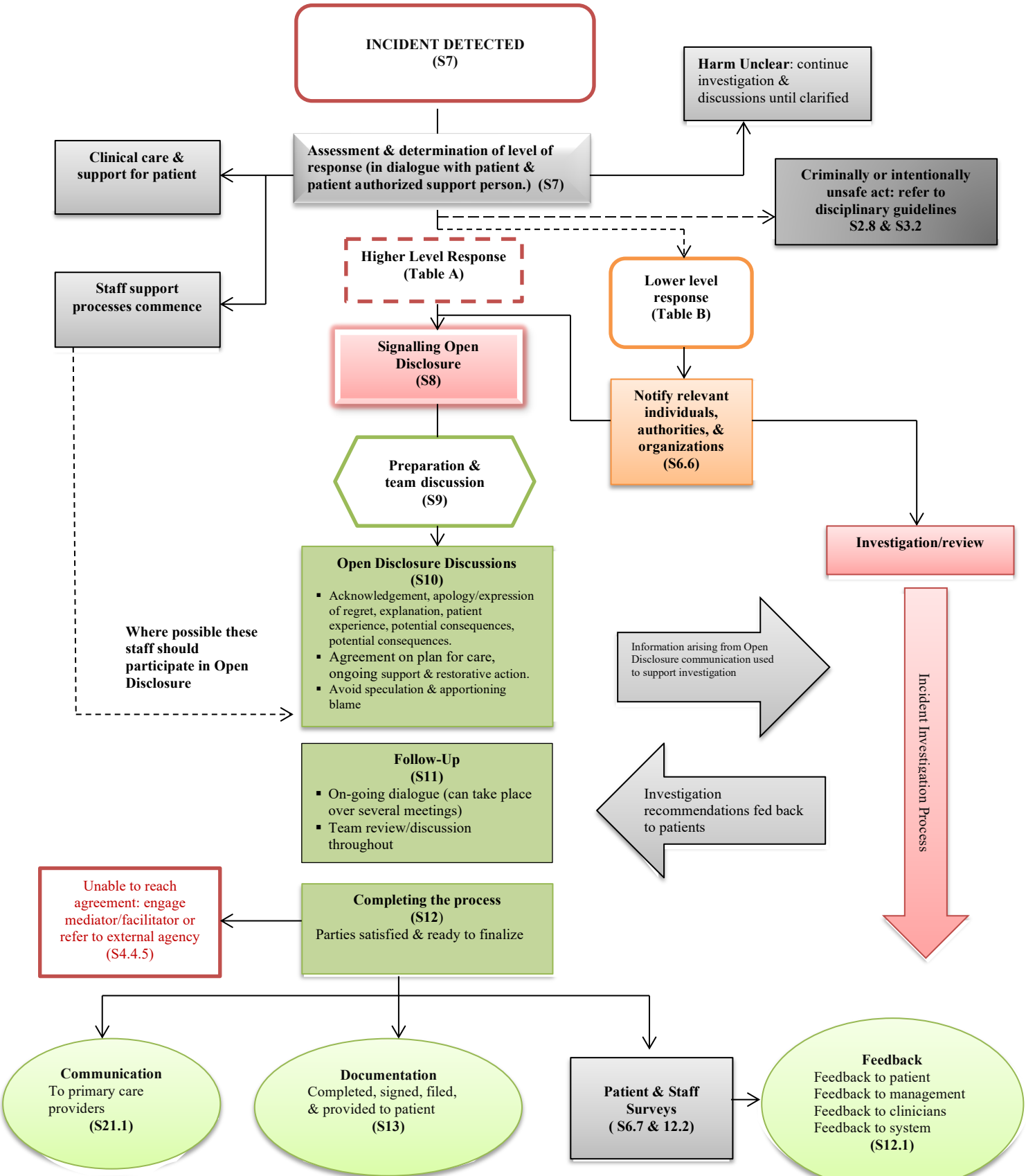

Table 2: Key considerations & actions during the Open Disclosure Process

Step 1. **Detecting & assessing incidents** *(Section 7)*	**Make the patient safe** ▪ Provide prompt clinical care to the patient to prevent further harm; ▪ Assess the incident for severity of harm and level of required response; ▪ Prompt medical assistance as required e.g. MET call or emergency ambulance; ▪ Notify Director of Clinical Services; ▪ Provide support for staff ; ▪ Ensure documentation is complete, accurate, & clear. **Assessment of situation for level of Open Disclosure process** ▪ Assess the incident for severity of harm and level of response; ▪ Initiate a response, ranging from lower to higher levels; ▪ Notify relevant personnel and authorities accordingly; ▪ Ensure privacy and confidentiality of patients and clinicians are observed.
Step 2. **Signalling the need for Open Disclosure** *(Section 8)*	**Lower-level Incidents & Adverse Events** Where the presentation fits within Category B: ▪ The Attending Medical Practitioner will acknowledge the adverse event to the patient, parent/legal representative including an apology or expression of regret. ▪ A full discussion will take place with encouragement and accommodation of questions by the patient/parent/legal representative. A translator is to be arranged as required. **Where all parties agree, a lower-level response can conclude at this stage.** **Documentation must be completed, signed, and filed.** **For a moderate-higher level response:** Where the presentation fits within Category A, or a Lower Level Incident cannot be resolved: ▪ Signal the need for a formal in-depth process of Open Disclosure; ▪ The Director of Clinical Services (DCS) will be immediately notified. The DCS will notify the CEO & Chairman of the MAC. The CEO will notify the Chairman of the BOD. ▪ An urgent meeting is arranged; ▪ A formal structured process will commence; ▪ Negotiate with the patient, patient/parent/legal representative or nominated contact person - the formality of Open Disclosure required. - the time and place for an Open Disclosure meeting(s) - who should be there during the Open Disclosure meeting(s). ▪ Provide written confirmation; ▪ Provide the DCS's contact details, or the nominated representative, to the patient/parent/legal representative or nominated person; ▪ Avoid speculation and blame; ▪ Maintain good verbal and written communication throughout the Open Disclosure process; ▪ Maintain dignity, respect, & courtesy; ▪ Ensure documentation is complete; ▪ Notify required authorities and complete reports as stipulated.
3. Preparing for Open Disclosure *(Section 9)*	▪ The Director of Clinical Services is responsible for gathering all required information, formulating the Open Disclosure multidisciplinary team, and convening a meeting

	as soon as reasonably possible. The meeting will occur with the following membership:

3. Preparing for Open Disclosure (cont.) *(Section 9)*	CEO, Director of Clinical Services (DCS), Chairman of the Medical Advisory Committee (MAC), Medical Practitioner of the patient, and any other identified relevant personnel e.g. Anaesthetist and/or employee(s) involved; ▪ Appoint an individual to lead the Open Disclosure based on previous discussions with the patient; ▪ Meet with members of the workforce involved in, or a witness to, the incident; ▪ Complete the Open Disclosure Checklist & Plan; ▪ Ensure information is factual and objective, not speculative or subjective; ▪ Once the initial checklist has been competed, those present need to agree on the approach and information to be provided before the first meeting takes place with the patient/parent/legal representative; ▪ Concerns that may be raised by the patient and family should be identified so that appropriate answers can be prepared, and additional information or the need for other personnel to be involved in the process can be anticipated; ▪ Identify which health professionals need to be involved in the first meeting. ▪ Prepare the dialogue and plan the dialogue to avoid risks associated with: • admissions of liability (see section 6.1) • blaming an individual • defamation.
4. Engaging in Open Disclosure discussions (*Section 10)* *Please refer to separate section on meeting documentation within this policy & procedure*	**Meeting with patient/parent/legal representative or nominated person:** ▪ Arrange for a meeting location which is private and comfortable; ▪ Ensure a professional translator is present if required; ▪ Identify the need for support from other personnel such as social workers, or pastoral care workers; ▪ Provide the patient/parent/legal representative or nominated person with the names and roles of all attendees. Introductions take place; ▪ Provide a sincere and unprompted apology or expression of regret including the words 'I am sorry' or 'we are sorry'; ▪ Clearly explain the incident, providing documents/reports; ▪ Give the patient/parent/legal representative or nominated contact person 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/parent/legal representative or nominated person that they will be informed of further investigation findings and recommendations for system improvement; ▪ Offer practical and emotional support to the patient/parent/legal representative or nominated person.
5. Providing follow-up *(Section 11)*	▪ The planning process will include the nominated organizational executive personnel to follow-up with the patient/parent/legal representative or nominated person; ▪ Follow-up will occur; ▪ Share the findings of investigations and the resulting practice changes; ▪ Agree on future care where required. ▪ If necessary, hold several meetings or discussions to achieve expected outcomes.

6. Completing the process *(Section 12)*	▪ Reach an agreement with the patient/parent/legal representative, or nominated person, that the process has been completed; or ▪ Arrange for an external mediation process where an agreement cannot be reached.
7. Maintaining documentation *(Section 13)* *Please refer to the separate section on documentation within this policy & procedure*	▪ Keep the patient record up to date; ▪ Maintain a record of the Open Disclosure process for organizational administrative purposes, including minutes of meetings; ▪ Ensure the documentation for *Root Cause Analysis* requirements have been met (refer to policy & procedure) ▪ File documents relating to the Open Disclosure process in the patient record; ▪ Provide the patient with documentation throughout the process; ▪ Maintain Privacy & Confidentiality at all times. ▪ Great care is to be taken to ensure that all documentation is accurate, factual, and does not offer opinions that may turn out to be misleading or formed on the basis of incorrect, or erroneous, information. Statements or opinions about possible causes of the adverse event together with any admission of liability (see section 6.1) should be avoided.
8. Internal & External Reporting	▪ Ensure timely reporting to external authorities. ▪ Ensure timely reporting to approved internal Quality, Risk & Safety forums. ▪ Review Risk Register if required. ▪ Ensure that the insurance company is fully aware.
9. Education & Continuous Improvement	▪ The analysis and planning process will include the assessment of whether education sessions are required and for whom; ▪ The analysis and planning process will include an assessment of whether any changes need to made to work practice, policies and procedures, or processes and systems; ▪ Any changes made will be fed back to the work force.

10. Performance Appraisal &/or Management	▪ Where the incident/adverse event has occurred through a criminal act, or intent, disciplinary procedures will occur (please refer to policy & procedure and/or By--Laws). External regulatory bodies will be notified. This will include:
	  ▪ The police force
	  ▪ AHPRA and relevant Registration Board
	▪ Where the incident/adverse event is a result of an unintentional action, then a performance appraisal and management process will occur, with follow-up and review.

RECORD KEEPING OF MEETINGS HELD:

Multidisciplinary Team meeting

A full record of agenda and minutes will be taken and filed appropriately. These will be read by external bodies e.g. legal representatives in the event they are subpoenaed, and regulatory bodies under the Quality Principles. The content therefore needs to be formal and professional, with only factual and objective content included. Consistency in information, times, and dates are essential.

Meeting with Patient/parent/legal representative

A full documented record is to be taken of the meeting(s) with the Patient/parent/legal representative. Professional interpreters are to be arranged to be present if required. A copy of the minutes will be provided to the Patient/parent/legal representative, with a request to confirm the accuracy in writing.

Documentation should include, but not restricted to the following:

1. brief details of the background to the Open Disclosure discussion with the patient such as factual information describing the adverse event.
2. detailed factual information reflecting what was said to the patient including where appropriate, the actual words used; areas to be included are:
    - the apology or expression of regret;
    - the explanation of what occurred, including actual and potential consequences;
    - the steps being taken to manage the event and prevent its recurrence

    (care should be taken to ensure that dates and times are consistent with other documents such as observation charts and medication charts);
3. the names of personnel present at the meeting, including the patient's family and support people;
4. the questions asked by the patient and information provided in response to the question;
5. a description of the ongoing plan of care discussed with the patient including referrals and further treatments;
6. how the patient appears to be taking the information and the perceived level of understanding;
7. other information provided for the patient such as information brochures;
8. how the patient is to receive additional information, and any representations made by those present in relation to how this will be supplied/provided, such as further meetings, a letter, phone call or at a subsequent outpatient appointment;
9. any comments that the patient may make that indicate some contribution to the outcome, such as failure to take medication/treatment prescribed;
10. any other issues that are relevant to the process and the ongoing care of the patient.

LEGAL ISSUES:

(Reference: Open Disclosure in Victorian Health Services 2008,page21)

The following information is provided in general terms only as an information point, and is not intended to provide legal advice. Legal advice is to be obtained from a legal source.

Legal Action

- After any adverse event, there is a risk that a patient who has sustained a psychiatric or physical injury, or experienced economic loss, may commence legal action against the health service and/or relevant health professional
- Seeking compensation for injuries that may have been the result of a breach in the expected standard of care is a patient's legal right and, although there is no obligation on the part of the hospital to appraise a patient of his or her legal rights, the patient must not be discouraged or dissuaded from taking legal action.
- A patient may seek legal redress regardless of whether the Open Disclosure process has taken place

Documentation

One of the greatest concerns to all involved in the process of incident investigation and Open Disclosure is that the potential exposure to legal risks is unnecessarily increased by erroneous, careless, and inaccurate documentation, or through providing inaccurate, conflicting, or confusing information to the patient. A health service may be compelled to disclose information or a document unless the information is exempted by a privilege scheme or by statute. This can occur, for example, under the *Freedom of Information Act* or *Health Records Act*, through a subpoena issued by a court or tribunal and via the process of 'discovery' once litigation has commenced.

'Documentation' referred to above includes the following:

- hospital records, meeting minutes,
- the results of investigations such as *Root Cause Analysis* (RCAs), personal and hospital file notes or journal entries, emails, memos and other forms of written communication.

Great care should be taken to ensure that all documentation is accurate, factual, and does not offer opinions that may turn out to be misleading, or formed on the basis of incorrect or erroneous information. It also should not contain statements, or opinions, about possible causes of the adverse event together with any admission of liability (see section 6.1 of the Australian Open Disclosure Framework, page 36).

Freedom of Information

Under the Freedom of Information Act (FOI), a patient of a public health service has the right (subject to the exemptions outlined in the Act) to access certain documents such as the medical
record. Applications can also be made by members of the public for certain documents if releasing the documents is in the public interest and the exemptions do not apply.

The Health Records Act contains similar provisions to enable patients to access their personal health record when held by a non-public sector health service.

Legal professional privilege, also known as client legal privilege, protects oral and written confidential communications between a client and lawyer where the dominant purpose of the communication is to seek legal advice in anticipation of litigation, or when legal proceedings are in process. The privilege extends only to documents and not individuals and is generally invoked to protect documents that would be otherwise disclosed through 'discovery' or other devices.

Relevant to the Open Disclosure process is that the privilege is automatically 'waived' by the client if the details of the communication are disclosed and the confidential nature of the communication is then lost.

Apologies and admissions of liability

An admission of liability can be defined as the assumption of legal responsibility (either verbally or in writing) by the health service, or one of its employees or agents, for the harm or injury to a patient arising as a result of an adverse event.

Insurance policies generally contain clauses restricting admissions of liability made by or on behalf of the insured (the health service or one of its employees). An admission, or inference, of liability in relation to an adverse event may be grounds for an insurer to deny indemnity to

the insured. That is, the health service or health practitioner may not be 'covered' in the event that the patient initiates legal proceedings.

An apology is defined as an expression of sorrow, regret, or sympathy but does not include a clear acknowledgment of fault. Legislation in Victoria specifically protects health professionals and health services that offer an apology to a patient who has suffered an adverse event.

Under the Wrongs Act an apology to the patient, or a family member(s) of a patient, who has sustained harm or injury as the result of an adverse event does not constitute an admission of liability; or of unprofessional conduct, carelessness or incompetence (for the purposes of a complaint to a health professional registration board). If, however, a factual matter is disputed during legal proceedings, the statements used in the apology may be admissible to the extent that they prove or disprove a fact.

Defamation and libel

Claims of defamation and libel arise when a person's reputation has been damaged, or he or she feels insulted or aggrieved by the written or spoken comments of another.

Blaming another health professional for incompetence, or any other fault that reflects upon his/ her professional competence, or reputation, may result in a formal complaint of a legal claim
against the person making the comments. This risk can be avoided by:

- stating the facts of what happened without insinuating that there is a causal link between the health professional's standard of practice, or competence, and the adverse event;
- ensuring that any statements made are not exaggerated but are factual and can be verified (care should be taken when providing information that is yet to be confirmed by the RCA investigation);
- avoiding 'hearsay' and opinions, or conclusions, that cannot be logically supported.

Blaming individuals for adverse events is not helpful to the open disclosure process as it both discourages health professionals from being open about adverse events and it creates additional
legal risks. Adverse events that raise concerns about a health professional's competence or professional conduct are best managed through the health service's disciplinary process.

EXPECTED OUTCOMES:

- Responsibility & Accountability
- Effective Consultative approach with Patients/Parents/Guardians/Carers
- Patient Safety
- Effective Risk Management
- Quality & Continuous Improvement of care & service provision
- Transparency
- Open Disclosure
- Prevention of the incident, adverse event, occurring again.
- The maintenance of excellence in quality & safe service delivery.
- Compliance with Governing legislation, standards, codes of conduct, codes of practice, and evidence based best practice.

- Effective Governance

ASSOCIATED FORMS, POLICIES & PROCEDURE, FRAMEWORKS:

Governance- Clinical-Policy & Procedure & Framework
Open Disclosure Booklet for Patients – Victorian Government published literature
Open Disclosure Plan & Checklist – Form
Open Disclosure Patient Questionnaire – Form
Open Disclosure Staff Questionnaire – Form
Open Disclosure Summary Sheet for Patients - Form
Victorian Government supportive literature and Open Disclosure Framework

SUPPORTING REFERENCES:

- Australian Commission on Safety & Quality in HealthCare (2017): *National Safety & Quality Health Service Standards –Guide for Day Procedure Services*, Commonwealth of Australia. https://www.safetyandquality.gov.au/about-us/governance/

- Australian Commission on Safety & Quality in HealthCare (2017): National Model-*Clinical Governance Framework*, Commonwealth of Australia. https://www.safetyandquality.gov.au/about-us/governance/

- Australian Commission on Safety & Quality in HealthCare (2017): Open Disclosure Framework https://www.safetyandquality.gov.au/about-us/opendisclosure/

- DUCKETT,S;CUDDIHY,M;NEWNHAM,H. (2015)*Targeting zero Supporting the Victorian hospital system to eliminate avoidable harm and strengthen quality of care Report of the Review of Hospital Safety and Quality Assurance in Victoria,* Department of Health & Human Services, published by the Victorian Government, 1 Treasury Place, Melbourne. https://www.dhhs.vic.gov.au/publications/targeting-zero-review-hospital-safety-and-quality-assurance-victoria

- Freedom of Information Act 1982
https://www.legislation.gov.au/Details/C2018C00016

- Victorian Charter of Human Rights and Responsibilities Act 2006

- Victorian State Government (2017): *Delivering High Quality Health Care-Victorian Clinical Governance Framework*, Department of Health & Human Services, published by the Victorian Government, 1 Treasury Place, Melbourne https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/clinical-risk-management/clinical-governance-policy

- Victorian Government (1988): *Health Services Act (Victoria)1988, (Amendments 2012),* Victorian Government Printing Office, *www.legislation.vic.gov.au/Domino/Web_Notes/.../88-49aa133%20authorised.pdf*.

- Victorian Government (2013): *Health Services (Private Hospitals and Day Procedure Centres) Regulations 2018,* Victorian Government Printing Office, https://srhr.org/.../03-Australia-Victoria-Health-Services-Private-Hospitals-and-Day-Regulations-2018.

- Victorian Government (2008): Open Disclosure in Victorian Health Services www.health.vic.gov.au/clinrisk

- Wrongs Act 1959 (Vic), http://www.legislation.vic.gov.au/

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1	April 2021	Initial document	May 2019	Board of Directors	April 2024