Policy Code: IDX-1309	Title: **Open Disclosure Policy**	
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CHANGE LOG:

Date	Vers #	Summary of changes made
09/03/2023	1.0	New document approved by ICLC and SLT
16/07/2024	2.0	Reviewed and revised as advised by external lawyer consultation

POLICY STATEMENT:

Open Disclosure is an open discussion with a patient regarding an incident(s) 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, 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.

Integral Diagnostics (IDX) recognises that Open Disclosure is:

- A patient and consumer right.
- A core professional requirement and obligation.
- A normal part of an episode of care in the event the unexpected occurs and is a critical element. of clinical communications.
- An attribute of high-quality health service organization and an important part of healthcare quality improvement.

IDX acknowledges that our patients, their families, and carers are entitled to timely, honest, and open communication about any unexpected event that may have caused harm and be provided with all the facts surrounding an unexpected event.

Our open disclosure policy is based on the Australian Open Disclosure Framework and provides guidance of when and the manner to which open disclosure should occur.

IDX will consider the legislation in force in the state or territory in which their businesses operate in this policy and procedure and training staff.

INTRODUCTION

The guiding principles of Open Disclosure are:

1. 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.
2. 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.
3. 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.

4. 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
     - listened to and supported in a manner appropriate to their needs
5. Supporting and meeting the needs and expectations of those providing health care
   - 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.
6. Integrated clinical risk management 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. The 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.
7. 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.
8. Confidentiality
   - Policies and procedures be developed by the organization giving full consideration for patient and staff privacy and confidentiality, keeping compliant with relevant law (including Commonwealth, State and Territory privacy and Health Records Legislation)

The Open Disclosure Process:

1. Detecting and assessing incidents
2. Signaling the need for open disclosure
3. Preparing for open disclosure
4. Engaging in open disclosure discussions
5. Providing follow-up
6. Completing the process
7. Maintaining documentation

Refer to **Appendix A** for Key Considerations and Actions During the Open Disclosure Process

SCOPE:

This policy applies to all IDX staff both employed and contracted.

RESPONSIBILITIES:

IDX Board of Directors

The IDX Board is responsible for overall governance and management and ensure that when an adverse event has occurred with a patient the Open disclosure process was initiated.

Upon completion of the Open disclosure process and review, the Board shall analyse the root cause analysis and corrective/preventative actions to ensure appropriate controls are in place to reduce the chance of recurrence. Should

the Board determine whether these corrective/preventative actions are not satisfactory, a request for any inadequacies to be addressed and rectified will be communicated.

Senior Management Group (SMG):

Responsible for leading and holding Management to account ensuring compliance with the IDX Open Disclosure policy. The following have been given Delegation of Authority to address the media in accordance with the IDX Media Relations Policy:

- Chief Executive Officer
- Chief Financial Officer
- Chief Medical Officer

Clinical Staff

All clinical staff are responsible for recognizing when a patient has experienced unexpected and unintended harm during their examination and reporting this immediately to their site supervisor and entering into CAMMS.

Local Leadership Team

The local leadership team are responsible for ensuring timely investigation, follow-up, and actions of incidents entered in CAMMS and escalating if required.

DEFINITIONS:

Admission of Liability

A statement by a person that admits, or tends to admit, a person's or organisation's liability in negligence for harm or damage caused to another.

Adverse Event

An incident in which harm resulted to a person receiving health care.
Note: This term is used interchangeably with 'harmful incident'.

Adverse Outcome

An outcome of an illness or its treatment that has not met the clinician's or the patient's expectation for improvement or cure.

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'. Apology may also include an acknowledgment of responsibility, which is not an admission of liability.

Clinical Risk

The combination of the probability of occurrence of harm and the severity of that harm.

Disability

Any type of impairment of body structure or function, activity limitation or restriction of participation in society.

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).

Harm

Impairment of structure or function of the body and/or any deleterious effect arising therefrom, including disease, injury, suffering, disability, and death. Harm may be physical, social, or psychological.

Harmful Incident

An incident that led to patient harm. Such incidents can either be part of the healthcare process, or occur in the healthcare setting (i.e., while the patient is admitted to, or in the care of, a health service organisation).

Note: This term is used interchangeably with 'adverse event'.

Higher-Level Response

A comprehensive open disclosure process usually in response to an incident resulting in 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), or major psychological or emotional distress. These criteria should be determined in consultation with patients, their family, and carers.

A higher-level response may also be instigated at the request of the patient even if the outcome of the adverse event is not as severe.

Liability

The legal responsibility for an action.

Lower-Level Response

A briefer open disclosure process usually in response to incidents resulting in no permanent injury, requiring no increased level of care (e.g., transfer to operating theatre or intensive care unit), and resulting in no, or minor, psychological, or emotional distress (e.g., near misses and no-harm incidents). These criteria should be determined in consultation with patients, their family, and carers.

Near Miss

An incident that did not cause harm but had the potential to do so.

No Harm Incident

An error or system failure that reaches the patient but does not result in patient harm.

Nominated Contact Person

Any individual who is formally identified by the patient as a nominated recipient of information regarding their care in accordance with local processes and legal requirements.

Qualified Privilege Legislation

Qualified privilege legislation varies between jurisdictions but generally protects the confidentiality of individually identified information that became known solely as a result of a declared safety and quality activity. Certain conditions apply to the dissemination of information under qualified privilege.

Quality Improvement

The continuous study and adaptation of a healthcare organisation's functions and processes to increase the probability of achieving desired outcomes and better meet the needs of patients and other users of services.

Risk Management

The design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors, and the institution.

<u>Clinical risk management</u>

Clinical, administrative, and manufacturing activities that organisations undertake to identify, evaluate, and reduce the risk of injury to patients and visitors, and the risk of loss to the organisation itself.

<u>Corporate risk management</u>

Activities of an organisation or corporation to identify and reduce potential financial or reputational liabilities, exposures, and dangers.

Support Person

- An individual who has a relationship with the patient. References to 'support person' in this document can include:

- Family members / next of kin
- Carers
- Friends, a partner or other person who cares for the patient
- Guardians or substitute decision-makers
- Social workers or religious representatives
- Where available, trained patient advocates.

System Failure

A fault, breakdown or dysfunction within operational methods, processes, or infrastructure.

System Improvement
The changes made to dysfunctional operational methods, processes, and infrastructure to ensure improved quality and safety.

PROCEDURE:

Key Essentials of Open Disclosure

*(Refer to **Appendix A** for Explanation on the key Considerations and Actions during Open Disclosure)*

Detecting and Assessing Incidents/Adverse Events

Identifying an Adverse Event
An adverse event can be identified:

- By a practitioner or staff member at the time of the incident.
- By a practitioner retrospectively when an unexpected outcome is detected.
- By a patient, their family or carer at the time of the incident or retrospectively.
- Through established complaint mechanisms.
- Through our internal incident detection systems, such as incident reporting or patient record review.
- From other sources, such as detection by other patients, visitors, or staff.

It is important that all incidents are considered and assessed, regardless of the mechanism through which they were detected.

Near Miss
In some cases, near misses should instigate open disclosure. Each case should consider the facts as well as:

- The psychological, physical, and clinical consequences of disclosure ('intrusive' near misses).
- The possibility of latent harm.
- Patient factors such as anxiety and willingness to be involved in clinical decision making (which may be apparent from earlier communication with the patient).
- The patient's personal and clinical history.

No-Harm
Clinicians must be certain that no harm has actually occurred. The only way to be certain of the absence of harm is to discuss the incident with the patient, their family, and carers. This will require acknowledgement that an incident occurred.

It is recommended that this course of action be followed for most no-harm incidents. The risk of doing this is small. In a 'false negative' situation (where harm actually occurred), the disclosure will serve as a way of identifying an adverse event and reassure the patient, their family and carers who may otherwise have felt let down by the service.

In a 'true negative' situation (where no harm occurred), the patient may appreciate the communication and contribute their perspective to the consideration. It is acknowledged that indiscriminate disclosure of near misses and no-harm incidents is not feasible. The following questions can be used to guide such decisions:

- Will the distress or psychological harm of disclosing the information outweigh the benefit that could feasibly be achieved by disclosure?
- Will disclosure reduce the risk of future incidents?
- Will disclosure maintain the patient, family, and carers in our service?

Supporting patient and clinician as a priority
As soon as harm is identified, the first priority is prompt an appropriate clinical care and prevention of further harm. Additional treatment should be provided if required and if reasonably practical, after discussion and with the agreement of the patient.

The local leadership team should be advised and should gather any evidence that will assist in investigating the event, with assistance from the relevant Risk and Quality Business Partner.

All staff involved in the adverse event should be monitored and supported as required.

Initial assessment to determine the level of response

The individual who detected the incident should make an initial assessment of the incident, usually in consultation with the clinical director. This process will consider the severity of harm, and the level of response required. The level of response required will be determined by the effect, severity, or consequence of the incident.

Examples in **Table 1 and Table 2** below.

Table 1: Potential responses to various situations and incidents.

Incident type	Response
1. **Harm from natural progression of condition or disease process** *e.g. a treatment for cancer was unsuccessful*	Discuss and explain ***(lower-level)***
2. **Complication or natural disease progression** a. Anticipated by patient/family via education and consent process b. Not anticipated by patient/family via education and consent process (**go to 3**) *e.g. patient not adequately informed of the possibility of respiratory complications of general anaesthesia and feels that this would have altered their decision to proceed with treatment*	a. Discuss and explain ***(lower-level)*** b. Open disclosure ***(higher or lower-level depending on severity)***
3. **Patient harm/adverse event** *e.g. adverse drug event (wrong dose medication)*	Open disclosure ***(higher or lower-level depending on severity and impact on patient)***
4. **Clinical ('no harm') incident: reaches patient but no harm** *e.g. medication error (no/minimal effect on patient)*	Generally disclose ***(lower-level)***
5. **Clinical ('near miss') incident: does not reach patient** *e.g. an intercepted wrong-patient biopsy*	Team decision based on: • context • circumstances • potential ramifications ***(lower-level)***
6. **Patient perception or report of harm** *e.g. patient perception of delay in diagnosis resulting in poor patient outcome*	Discuss and agree on appropriate form of disclosure ***(higher or lower-level)***

Source: Australian Open Disclosure Framework 2013

Table 2: Describes lower-level and higher-level responses which are linked to criteria for harm that may be used to determine a lower-level or higher-level response.

Incident type	Criteria
Lower-level response	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
Higher-level response	1. Death or major permanent loss of function 2. Permanent or considerable lessening of body function 3. 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) 4. Major psychological or emotional distress 5. At the request of the patient

Source: Australian Open Disclosure Framework 2013

It is important to consider that patients, their families, and carers can potentially suffer further emotional harm if post-incident communication is managed insensitively. A lower-level response should only be initiated if the risk of further harm (from not conducting higher-level open disclosure) is unlikely. Where uncertainty exists, a higher-level response should be initiated.

Delayed detection of harm

In some situations, patient harm may not be detected for some time and the adverse event may have occurred elsewhere. The principles of open disclosure should still be considered in these situations, and we should:

- Notify the patient, their family, or carers of what has occurred.
- Inform other healthcare providers, such as the patient's general practitioner or residential care facility or community care provider of the incident. This must only occur with the patient's permission.
- Notify staff who were involved in the incident.
- Commence an investigation of the incident and establish the facts.

Based on the particular circumstances, open disclosure should then proceed as outlined in this policy. Where possible the clinicians who were involved in the incident should participate in the open disclosure process.

Signaling the Need for Open Disclosure

The Initial Discussion

The initial discussion should occur as soon as possible after recognising harm, even if all the facts are not yet known. During this discussion:

- The adverse event is acknowledged to the patient, family, and carers.
- Establish with the patient their nominated contact person.
- Advise the patient with the name and details of the organisations contact (recommended this should be a person who was not directly involved in the incident).
- An apology or expression of regret is given.
    - Apology and/or expressions of regret are central to open disclosure. All Australian jurisdictions have enacted laws that are designed to protect statements of apology or regret made after 'incidents' from subsequent use in certain legal settings. Refer to **Appendix B** Apology or Expression of Regret acts.

- The effect of the incident, including all known facts and the consequences, are described.

Note: If a lower-level response is determined, it is likely that the disclosure process will be completed after the initial discussion.

If a higher-level response is determined, the initial discussion will have an additional two actions.

1. Signal the need for open disclosure
2. Negotiate (where possible) with the patient, their family, and carers about:
    a) The format required for discussions and meetings.
    b) The logistical details of the open disclosure.

Avoiding speculation and blame and Admission of Liability

It is important not to speculate, pre-empt the results of any investigations, attribute blame to yourself or other individuals, criticize individuals or imply legal liability when signaling the need for open disclosure, or during the formal open disclosure discussion. There is risk in making an admission of liability during open disclosure which could be used against us if the patient seeks to sue us.

Where you think an event could potentially result in a legal claim by a client, you should ensure you notify the Legal and Risk team so that they can notify IDX's insurers.

If you are unsure about what information you should be disclosing to a patient, please reach out to your Risk and Quality Business Partner.

These restrictions should not delay open disclosure or the benefits that a genuine and sincere apology or expression of regret can provide to both the patient and IDX staff.

Preparing for Open Disclosure

Team Discussion

Prior to any team discussion, the patient records must be up to date and all relevant information available.

The established team involved will meet as soon as possible after the event to achieve the following:

- Establish the basic facts (clinical and other facts).
- Assess the event to determine the appropriate response.
- Identify who will be the lead and take responsibility for discussion with the patient, their family, and carers.
- Consider the appropriateness of engaging patient support at this early stage, including the use of a facilitator or a patient advocate that is impartial.
- Identify immediate support needs for everyone involved.
- Ensure that all team members maintain a consistent approach in any discussions with the patient, their family, and carers.
- Consider how to address issues regarding ongoing care such as billing and other costs, which should be addressed at the earliest opportunity.

Notifying Relevant Individuals, Authorities and Organisations

- Consider legal and insurance issues, both for the organisation and the staff, and notify the relevant people.
- Upon agreement with the patient, other clinicians such as the referring practitioner, residential care facility so they can be informed and can offer their support and continuance of care to the patient.
- Cases of untimely or unexplained death and suspected unnatural causes must be reported to the Coroner. Each state and territory have legislation governing the coronial process. Refer to **Appendix C** – Coroners Acts
- Where there is an adverse outcome the need to respond to a variety of external requirements, reviews, or queries, including requirement of Commonwealth, State, territory, and regulatory bodies.

If you are unsure how to go about notifying relevant entities, reach out to the Legal and Risk team to assist.

Deferring Open Disclosure

Not every situation will require immediate open disclosure, and the process may need to be deferred. Examples are:

- Deferral may be requested by the patient, their family and career.
- Physical and mental health of the patient is not conducive to participating in open disclosure.

In these exceptional cases, a decision not to disclose can be justified as being in the patient's best interest. In this case:

- The decision to defer and rationale must be clearly documented in the patient record.
- Where possible, the decision to defer should be independently verified by a practitioner who was not involved in the adverse event. This verification must be documented in the patient record and CAMMS by the Operations Manager or local Clinical Director

Arranging the first meeting

The timing and location of the first face-to-face open disclosure meeting should be decided in consultation with the patient, their family or carers as well as advising who will be participating. Appropriately, the discussion should not occur where the harm occurred. Videoconferencing may be appropriate.

Other factors to take into consideration:

- Patient's clinical condition.
- Availability of key staff.
- Availability of the patient's family and carers and other relevant support persons.
- Availability of support for staff.
- Patient's preferences (and those of their family and carers).
- Patient's privacy and comfort
- Patient's physical and mental health.
- If patient wishes to speak to a different clinician than those designated to lead the open disclosure, their wishes should be respected and if possible, an acceptable substitute provided.

The patient, their family and carers may need time to consider these matters.

Engaging in Open Disclosure Discussions

The key components of the open disclosure discussion are:

1. The patient, their family, and carers are told the name and role of everyone attending the meeting, and this information is also provided in writing.
2. A sincere and unprompted apology or expression of regret is given on behalf of the health service organisation and clinicians, including the words 'I am' or 'we are sorry'.
3. A factual explanation of the adverse event is provided, including the known facts and consequences of the adverse event, in a way that ensures the patient, their family and carers understand the information, and considers any relevant information related earlier by the patient, family and carers. Speculation should be avoided.
4. The patient, family, and carers have the opportunity to tell the clinicians their story about the adverse event to explain their views on what happened, contribute their knowledge, and ask questions (the patient's factual explanation of the adverse event). It will be important for the patient, their family, and carers that their views and concerns are listened to, understood, and considered.
5. The patient, family and carers are encouraged to talk about the personal effect of the adverse event on their life.
6. An open disclosure plan is agreed and recorded in which the patient, their family, and carers outline what they hope to achieve from the process and any questions they would like answered. This should be documented and filed in the patient's record, CAMMS, and a copy provided to the patient, their family, and carers.
7. The patient, their family, and carers are assured that they will be informed of any further reviews to determine why the adverse event occurred, the nature of the proposed process and the expected time frame. They are to be given information about how feedback will be provided on the investigation findings, by whom and in what timeframe, including any changes made to prevent recurrence.
8. An offer of support to the patient, their family and carers should include:
    a) Ongoing support including reimbursement of out-of-pocket expenses incurred as a result of the adverse event

b) Assurance that any necessary follow-up care or investigation will be provided promptly and efficiently.
c) Contact details for services they may need to access.
d) Information about how to take the matter further, including any complaint processes available to them.

9. The patient, their family, and carers engage in open disclosure with staff. Staff are supported by IDX, their colleagues, and managers both personally (emotionally) and professionally (including through appropriate training, preparation and debrief.
10. In cases where the adverse event spans more than one location or service, staff will ensure that, where possible, all relevant individuals from these additional locations are involved in the open disclosure process.

It is not necessary to cover every component in the first disclosure meeting. For instance, a full explanation of why an adverse event occurred may not be possible until the causative factors are known.

A written account of the open disclosure meeting should be provided to the patient, their family, and carers as soon as practically possible.

Providing Follow-Up

Follow up is an important step in a higher-level response to open disclosure. Lower-level responses may require no or minimal follow-up.

The team involved in the adverse event and the initial open disclosure discussion should be involved in follow-up discussions. This should occur at the earliest practical opportunity. The patient, their family and carers should be assured of receiving further information and follow-up and should be provided with any information they request, without contravening legal constraints.

They should be:

- Kept informed of the progress and results of any investigation even if results are delayed, pending or uncertain.
- Notified of any changes to practice that are intended as a result of the investigation.
- Confirm these changes have been made and implemented to prevent recurrence of the adverse event.
- Offered the opportunity to discuss the situation with another relevant professional, where appropriate. This may include their general practitioner, residential care facility for community care provider. This must only occur with the patient's permission.
- Provided details of the person to contact if further issues arise.

Completing the process at this stage

If the process of open disclosure is complete at this point, the patient, their family, and carers should be asked if they agree that the process is complete, and a note of this should be made in the patient record and in CAMMS. Written information about the adverse event and its management should be provided to the patient, their family, and carers. Refer to "Completing the Process" documented below.

The patient, their family, and carers should be offered an evaluation survey or, where it is considered more appropriate, a face-to-face interview, or both.

Completing the Process

The open disclosure process concludes with shared agreement between the patient, their family carers and the IDX team involved in the open disclosure discussions.

If a satisfactory conclusion cannot be negotiated, the patient, their family and carers should be offered an alternative course of action.

Communication

When the relevant review or investigation is complete, the patient, family and carers should be provided with feedback through face-to-face interview or equivalent (e.g., videoconference) and in writing. The interview and document should include the following:

- Details of the incident, including the clinical facts and other relevant facts.
- The patient's concerns or complaints.

- An apology or expression of regret (including the word 'sorry') for the harm suffered.
- A summary of the factors contributing to the adverse event.
- Information about what has been and will be done to avoid recurrence of the adverse event, and how these improvements will be monitored.

If further issues are identified after the process is completed, the patient, their family and carers can re-contact the health service organisation for a response to their questions.

Disclosure of the review and investigation findings

In most cases there will be complete disclosure of the findings of relevant review or investigations. A formal, written report should be provided in a language and communication style that the patient, their family, and carers will understand.

In some exceptional circumstances it may be considered that disclosure of information will adversely affect the patient, their family, and carers' health. In these cases:

- The rationale must be clearly documented in the patient record and CAMMS
- Where possible, the decision should be independently verified by a practitioner or colleague who was not involved in the adverse event. If possible, this verification must also be documented in the patient record and CAMMS by the Operations Manager or local Clinical Director.

In addition, in some cases and jurisdictions, information may be withheld or restricted. This may occur, for example, where:

- Investigations are awaiting conclusion of coronial processes.
- Contractual arrangements with insurers preclude disclosure of specific information.
- Information is protected from disclosure.

In these cases, the patient, their family, and carers will be informed of the reasons for restricting information. This will be documented appropriately.

Monitoring Improvements

Any changes implemented as a result of a review or investigation should be monitored for their effectiveness. The Risk Management Team should develop a plan for monitoring the implementation and effectiveness of changes.

Communication and continued support for staff

Effective communication with staff is a vital step in ensuring that recommended changes are fully implemented and monitored. It will also increase awareness of patient safety and the value of open disclosure.

Staff who were involved in the incident must continue to be supported to minimise any residual emotional and professional harm. Continued support, including debrief, should be active but approached with sensitivity.

Evaluation of the open disclosure process

Patients, their families, and carers should be given the opportunity to provide feedback on the open disclosure process. This could be a face-to-face interview and/or a standardized open disclosure evaluation survey. Sensitivity to how this is conducted will be required.

Staff involved should also be given the opportunity to provide feedback through a standardized approach

If appropriate and depending on the sensitivity and other circumstances, the feedback for both patient and staff should be completed within four weeks at the end of the open disclosure process.

Maintaining Documentation

Comprehensive documentation contributes significantly to successful open disclosure. The disclosure of an adverse event and the facts relevant to it must be properly recorded. Recording commences at the beginning of open disclosure and continues throughout. Documentation includes:

- Patient records including family and carers contact details.
- All discussions.
- All information provided.
- Incident reports and records of the thorough review of the adverse event.
- Agreements and commitments made.

Without breaching legal requirements, all documentation related to open disclosure should be kept in the patient's record.

Key Considerations for Documentation

The patient record must be up to date before the first meeting, including a comprehensive account of the adverse event as it is initially understood. In the case of death due to an incident, a copy of the patient record will remain accessible to all those who will be involved in the open disclosure process.

The patient record should document the:

- Time, date and place of the disclosure discussion and the names and relationships of those present.
- Plan for providing further information to the patient, their family, and carers.
- Offers of support and the responses received.
- Questions posed by the patient, their family and carers and the answers given.
- Plans for follow-up as discussed with the patient, their family, and carers.
- Progress notes relating to the clinical situation and accurate summaries of all points explained to the patient, their family, and carers.
- Copies of letters sent to the patient, their family and carers and their general practitioner.

Without breaching legal and privacy requirements, documentation should be made available to the patient, their family, and carers. The risk team should be available to answer staff questions regarding documentation and sharing of information.

Associated Documents:
Open Disclosure Survey

Reference:
Australian Commission on Safety and Quality in Health Care Australian Open Disclosure Framework 2013

Appendix A – Key Consideration and Actions During the Open Disclosure Process

1. Detecting and assessing incidents	• Detect adverse event through a variety of mechanisms • 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 and authorities • Ensure privacy and confidentiality of patients and clinicians are observed

2. Signaling the need for open disclosure	• Acknowledge the adverse event to the patient, their family and carers including an apology or expression of regret.
	• **A lower-level response can conclude at this stage.**
	• Signal the need for open disclosure
	• Negotiate with the patient, their family and carers or nominated contact person
	  o the formality of open disclosure required
	  o the time and place for open disclosure
	  o who should be there during open disclosure
	• Provide written confirmation
	• Provide a health service contact for the patient, their family, and carers
	• Avoid speculation and blame
	• Maintain good verbal and written communication throughout the open disclosure process

3. Preparing for open disclosure	• Hold a multidisciplinary team discussion to prepare for open disclosure • Consider who will participate in open disclosure • Appoint an individual to lead the open disclosure based on previous discussion with the patient, their family, and carers • Gather all the necessary information • Identify the health service contact for the patient, their family, and carers (if this is not done already)
4. Engaging in open disclosure	• Provide the patient, their family and carers with the names and roles of all attendees • Provide a sincere and unprompted apology or expression of regret including the words *I am,* or *we are sorry* • Clearly explain the incident • Give the patient, their family, and carers 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, their family, and carers that they will be informed of further investigation findings and recommendations for system improvement • Offer practical and emotional support to the patient, their family, and carers • Support staff members throughout the process

	• If the adverse event took place in another health service organisation, include relevant staff if possible. • If necessary, hold several meetings or discussions to achieve these aims
5. Providing follow-up	• Ensure follow-up by senior clinicians or management, where appropriate • Agree on future care • Share the findings of investigations and the resulting practice changes • Offer the patient, their family, and carers the opportunity to discuss the process with another clinician (e.g., a general practitioner)
6. Completing the process	• Reach an agreement between the patient, their family and carers and the clinician, or provide an alternative course of action • Provide the patient, their family, and carers with final written and verbal communication, including investigation findings • Communicate the details of the adverse event, and outcomes of the open disclosure process, to other relevant clinicians • Complete the evaluation surveys
7. Maintaining documentation	• Keep the patient record up to date • Maintain a record of the open disclosure process • File documents relating to the open disclosure process in the patient record • Provide the patient with documentation throughout the process

Source: Australian Open Disclosure Framework 2013

Appendix B – Apology or Expression of Regret Acts

ACT	*Civil Law (Wrongs) Act 2002*
New South Wales	*Civil Liability Act 2002*
Northern Territory	*Personal Injuries (Liabilities and Damages) Act 2003*
Queensland	*Civil Liability Act 2003*
South Australia	*Civil Liability Act 1936*
Tasmania	*Civil Liability Act 2002*
Victoria	*Wrongs Act 1958*
Western Australia	*Civil Liability Act 2002*

Source: Australian Open Disclosure Framework 2013

Admission of liability

Health service organisation staff need to be aware of the risk of making an admission of liability during open disclosure. In any discussion with the patient, their family and carers during the open disclosure process, the clinician should take care not to speculate on the causes of an incident or pre-empt the results of any investigations. They must not apportion blame, or state or agree that they, other clinicians, or the health service organisations are liable for the harm caused to the patient.

These restrictions should not impede open disclosure or the benefits that a genuine and sincere apology or expression of regret can provide to both patient and clinician.

Appendix C – Coroners Acts

ACT	*Coroners Act 1997*
New South Wales	*Coroners Act 2009 No 41*
Northern Territory	*Coroners Act 2011*
Queensland	*Coroners Act 2003*
South Australia	*Coroners Act 2003*
Tasmania	*Coroners Act 1995*
Victoria	*Corners Act 2008 Revised Penalty Provisions*
Western Australia	*Coroners Act 1996*

Source: Australian Open Disclosure Framework 2013