Open Disclosure Policy and Procedure

GOV CORP 006

1. Purpose

This policy establishes a consistent approach when a patient is adversely affected during their treatment to ensure that there is effective and open communication between all involved parties, that the patient is supported, and that we learn from the incident.

2. Scope

This policy applies to all staff and Accredited Practitioners at all Adora Fertility sites and shall be adopted as standard practice.

3. Definitions

Term	Definition
Adverse Event	An unintended consumer injury or complication from treatment that results in disability, or death and is caused by health care management. A Serious Adverse Event is any event associated with ART treatment which causes harm, loss or damage to patients or their reproductive tissues, causes a significant medical or surgical condition to arise directly from ART treatment, results in hospitalisation following, and as a result of, the ART treatment. A Serious Notifiable Adverse Event is an event that might result in the transmission of a communicable disease, death or is life-threatening, disabling, or incapacitating condition, a gamete/embryo identification error or mix-up, might impact safety of people or their gametes/embryos, equipment or facilities as a result of a disaster, results in a potential or actual breach of legislation. The term 'adverse event' is not used in the policy as the more generic term "incident" is used
Apology	An expression of sorrow, sympathy and (when 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 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 (eg: when harm is deemed unpreventable)
Harm	Impairment of structure or function of the body and/or any deleterious arising therefrom, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological.
High 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 (eg: admission to hospital, surgical intervention, a higher level of care or transfer to intensive care), 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.
Lower Level Response	A briefer open disclosure process usually in response to incidents resulting in no permanent injury, requiring no increased level of care and resulting in no, or minor, psychological or emotional distress (eg: near misses and no-harm incidents). These criteria should be determined in consultation with patients, their family and carers

Open Disclosure	The open discussion of incidents that result in harm to a patient while receiving health care with the patient, their family, caregivers and other support persons.
Incident Management	Activities involved in reporting, notification and documentation of an incident.
Support person/s	Family members, next of kin, friends, partners, social workers or religious representatives

4. Open Disclosure

Open disclosure is an open discussion with a patient 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.
Open disclosure is a discussion and an exchange of information that may take place over several meetings.

5. Responsibilities in the Open Disclosure Process

Adora Staff and Stakeholders

- Inform a manager if there are concerns about safety
- Take immediate action to ensure the safety of the consumers, staff or facility; report incidents and participate in the incident management as defined in this policy and associated policies and procedures.
- Provide an apology to a patient and their support person/s following and incident, as appropriate or directed by their manager
- Participate in open disclosure as appropriate and directed by their manager
- Ensure activities relating to the policy are implemented, reported and adhered to
- Complete education and training on open disclosure

Managers

- Provide leadership to staff regarding policy implementation
- Undertake an initial, and if necessary, further, investigation and implementation and evaluation of recommendations as defined in this policy and associated procedures.
- Undertake open disclosure process with consumers and their nominated representative.
- Support staff following an incident including debriefing and /or counselling (external);
- Ensure incidents are recorded via the incident management system
- ensure compliance with reporting requirements to State/s Department of Health and other statutory bodies.
- Ensure all staff have completed training in the principles of open disclosure
- Monitor and assist with investigation of incidents and implementation and evaluation of associated recommendations
- Provide reports to the Governing Body, State & National Medical Advisory Committee and Consumer Advisory Committee on individual incidents and / or analysis of aggregate data as appropriate.

Senior Managers

- Determine the response level for open disclosure
- Monitor and assist with investigation of incidents and implementation and evaluation of associated recommendations
- Provide reports to the Chief Executive Officer, State & National Medical Advisory Committee and Consumer Advisory Committee on individual incidents and / or analysis of aggregate data as appropriate.

Chief Executive

- Provides leadership for an organisational open disclosure culture
- Notify insurer or medico-legal counsel of incidents that are part of, or have the potential to, result in legal proceedings.

6. Process

Detection of an incident

When an incident is detected the following immediate actions must be taken:

- Ensure patient safety and minimise the risk of further harm to the patient
- Provide prompt clinical care and support for the patient to prevent further harm
- Inform the line manager
- Report the incident in the incident management system.

Note: Serious Notifiable Adverse Events must also be reported in line with State Regulatory and Legislative requirements

Assessment of an incident

The incident must be assessed by Adora Accredited Practitioners and senior managers to determine if the level of response required is low or high level

Low and High Level Response

The level of open disclosure process required will depend on the outcome and circumstances of the incident. See table below:

Initiation of Open Disclosure

The incident should be acknowledged to the patient and/or their support person irrespective of the response level required as soon as possible and generally within 24 hours with a factual explanation of the incident including its impact on the patient.

An apology or expression of regret should be provided including the words ‘I am sorry’ or ‘we are sorry’

A plan should be agreed with the patient including ongoing support and further discussions or meetings.

Communication should be factual and clear. The patient and/or their support person should be given the opportunity to relate their experience of the incident

Completing the Open Disclosure Process

The patient and their support person should be provided with care and support for as long as required.

The patient and their support person should be given the opportunity to contribute to the investigation and actions to prevent recurrence.

A final written and verbal communication should be provided to the patient including details of the investigation, explanation of the report, and information on measures to be implemented to prevent a similar incident from occurring.

Relevant information must be communicated to other healthcare providers if required.

Please refer to Appendix 1 ***Open Disclosure Flow Charts***, Appendix 2 ***Open disclosure meeting planning and preparation template*** and Appendix 3 ***Open disclosure checklist*** for full details of the process

7. Documentation

Maintain all records of the incident and the open disclosure process within the patient chart BBS and the incident management software including all relevant discussions, information provided, details of plans proposed, and agreements and commitments made.

8. Training Requirements

On commencement of employment all staff and medical practitioners must undertake training in open disclosure and incident management. Records of training are held within the employee records or credentialling records of medical practitioners.

9. Appendix 1 *Open Disclosure Flow Charts*

Open disclosure flow chart

Figure 1: Higher-level response (S: section in the *Australian Open Disclosure Framework*)

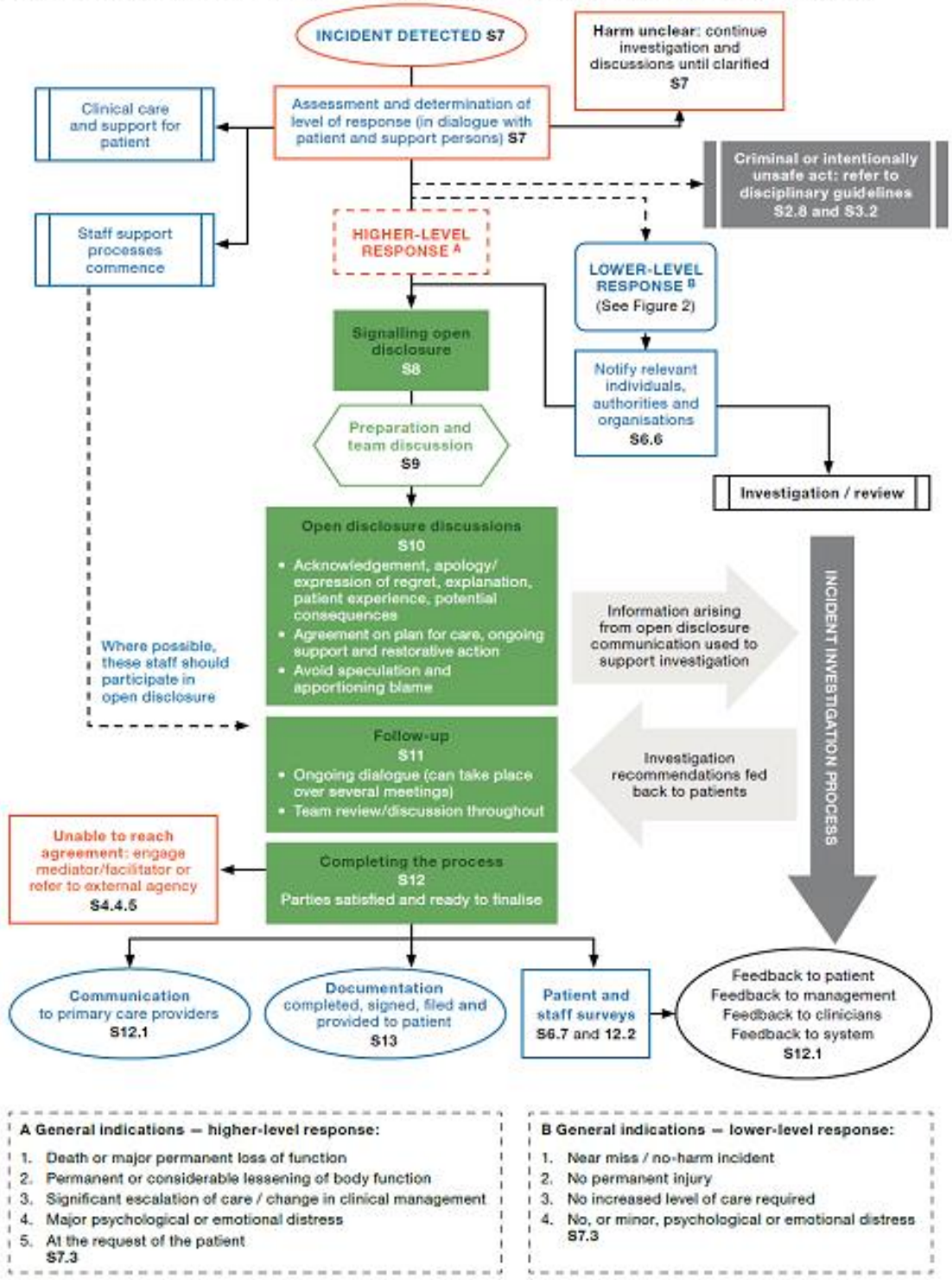
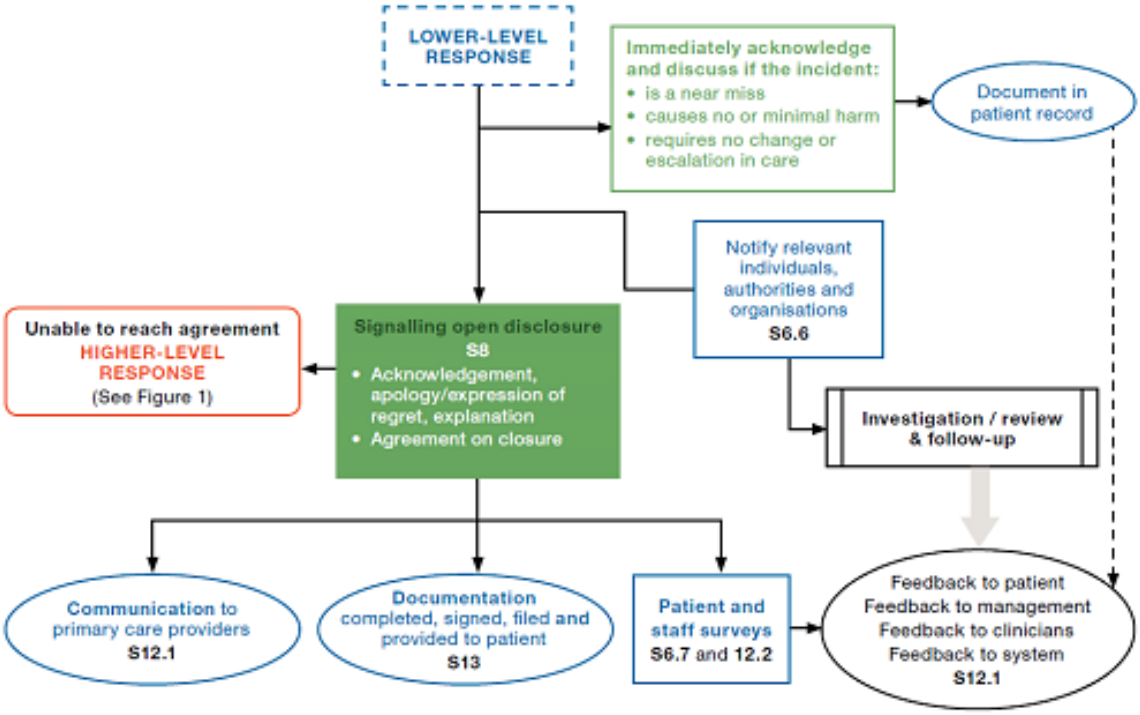


Figure 2: Lower-level response



10. Appendix 2 *Open disclosure meeting planning and preparation template*

1. Data & information

Patient's full name (including title)	
URN and date of birth	
Admission diagnosis and comments about management etc.	
Patient admission date	
Names and relationships of relevant next of kin/family/carers	
Date of incident triggering the open disclosure process	
Incident description *Known facts only*	
Incident outcome *Known facts only, avoid cause and effect statements*	
Plan for further incident management and investigation *(such as RCA, report to department, Coroner)*	
Healthcare providers/clinicians involved in patient care *Include consultants, anaesthetists and others as appropriate*	

2. First meeting

Interpreter required for patient *If so, provide details of language and arrangements that have been or to be made*	
Has the patient (if able) consented to sharing information with family members/others? *Give details*	

Has the insurer been notified? *Include date of notification*	
Date of first meeting	
Location of first meeting *Other details such as room booking, arrangements to ensure confidentiality if shared ward etc.*	
Patient/family/carers understanding of the incident prior to the first meeting	
Person to be responsible for note taking	
Who will be the health service contact for the patient/family/carers?	

3. Planning the disclosure dialogue

Nominated individual to lead the discussion	
Expected patient concerns	
Apology or expression of regret *Avoid speculation and apportioning of blame*	
Description of what happened *Known facts only, avoid blaming individuals and self*	
Listening to patient/family/carers concerns (ensure they feel listened to)	
Discussion of what will happen next *(such as OR, further treatment, investigation into the incident)*	
Information to be provided about short/long-term effects	
Information on out-of-pocket expenses and costs of ongoing care prepared with relevant parties	

e.g. indemnity insurer; see Australian Open Disclosure Framework Section 4.3	
Assurance for patient/family/carers that they will be informed when further information comes to hand	
Information about further support available to the patient/family/carers	
Information provided in relation on how to take the matter further at any time *(such as internal and external complaint process. Avoid discussion about compensation without insurer consent, do not give legal advice but suggest patient seeks legal advice if information about compensation sought.)*	
Next meeting date and location	

4. First meeting outcomes

Actual date and location of meeting	
Names of all present at first meeting *Include titles/position/relationship to patient etc.*	
Concerns expressed by patient/family/ carers including requests for further information to be supplied	
Further support personnel identified *(such as pastoral worker or social worker)*	
Responsibility for documentation of the meeting in the medical record	
Name(s) of personnel given to patient/family/carers if they have further questions prior to subsequent meetings	

5. Outcomes of subsequent meetings (if required)

Date and location of meeting(s)	
Names of all present *Include titles/position/relationship to patient etc.*	
Concerns expressed by patient/family/carers	
Further support personnel identified	
Responsibility for documentation of the meeting in the medical record	
Responsibility for providing documentation to the patient/family/carers	
Name(s) of personnel given to patient/family/carers if they have further questions prior to subsequent meetings	

6. Evaluation

Open disclosure survey forms provided to clinical staff	
Open disclosure process evaluated	

11. Appendix 3 *Open disclosure checklist*

Patient name: _____ Patient Number: _____ Date of incident / adverse event: _____		**Tick if completed or enter N/A / comment**
1. Incident detection & notification	☐ Prompt clinical care to the patient to prevent further harm	
	☐ Adverse event assessed for severity and level of response - RiskClear Incident entered	
	☐ Support for staff provided / offered	
	☐ Appropriate personnel and authorities notified	
	☐ Patient record updated	
2. Signalling open disclosure	☐ Adverse event acknowledged to the patient	
	☐ Apology or expression of regret, including saying sorry, provided	
	Lower-level open disclosure responses may conclude at this point and be evaluated.	
	☐ Negotiation with the patient on: ☐ the formality of open disclosure required ☐ the time and place for open disclosure ☐ who will participate in the open disclosure	
	☐ A health service contact provided to the patient	
	☐ Designated patient contact person(s) or appropriate patient support person identified	
	☐ Written confirmation provided to the patient	
	☐ All relevant documentation filed in the appropriate place / RiskClear updated	
3. Preparing for open disclosure	☐ Interprofessional team prepare for open disclosure	
	☐ Open disclosure participants agreed	

	☐ Individual identified to lead the open disclosure	
	☐ Necessary meeting information gathered	
	☐ Patient health service contact identified (if not already done at step 2)	
4. Open disclosure discussion	☐ Patient provided with the names and roles of all attendees	
	☐ A sincere and unprompted apology or expression of regret is provided	
	☐ Adverse event is clearly explained	
	☐ Future care is agreed	
	☐ Patient is given an opportunity to tell their story, exchange views and observations and ask questions	
	☐ Patient is encouraged to describe the personal effects of the adverse event	
	☐ Open disclosure plan is agreed, recorded and signed	
	☐ Patient is assured that they will be informed of further findings and recommendations for system improvement	
	☐ Practical and emotional support are offered to the patient	
	☐ Staff members are supported	
	☐ Agreement to hold follow-up meeting(s) if required	
	☐ Meetings documented and filed and patient record / RiskClear updated	
	☐ Documentation provided to patient	
5. Follow-up	☐ Senior clinicians or management (where appropriate) involved in follow up discussion	
	☐ Future care agreed	

	☐ Outcomes of investigations and the resulting practice changes shared with patient	
	☐ Patient offered the opportunity to discuss the process with another clinician (e.g. a general practitioner)	
	☐ Patient record / RiskClear updated and relevant documentation provided to patient	
6. Completing the process	☐ Agreement reached between the patient and the clinician, or alternative course of action provided	
	☐ Patient provided with final written and verbal communication, including investigation findings	
	☐ Details communicated to the patient's primary care provider	
	☐ Evaluation surveys offered to patient (or face to face if more appropriate)	
	☐ Staff evaluation surveys completed	
	☐ Patient record / RiskClear updated including appending completed checklist	

Signature: _____

Print name: _____

Title/position: _____

Date: _____

12. Supporting External Documentation / Legislation

Doc No.	Name of Document	Version No.	Source
	Aust Open Disclosure Framework	2013	Aust Comm on Safety & Quality in Healthcare
	National Safety & Quality Health Service Standards – Standard 1.12 Incident Management & Open Disclosure		https://www.safetyandquality.gov.au/our-work/open-disclosure/the-open-disclosure-framework
	Department of Health Victoria: Open disclosure following adverse events in health services		https://www.health.vic.gov.au/quality-safety-service/open-disclosure-following-adverse-events-in-health-services
	Victorian Charter of Human Rights and Responsibilities Act 2006	V 15	https://www.legislation.vic.gov.au/in-force/acts/charter-human-rights-and-responsibilities-act-2006/015
	NSW Government: Open Disclosure		https://www.cec.health.nsw.gov.au/Review-incidents/open-disclosure
	WA Department of Health: Open Disclosure		https://ww2.health.wa.gov.au/Articles/N_R/Open-disclosure
	RTAC COP: Critical Criterion 3. Stakeholder Feedback	V 8	https://www.fertilitysociety.com.au/rtac-australia-new-zealand/

13. Related Policies & Procedures

Related Policies & Procedures		
Document Code	**Name**	**Division**
GOV CORP 005	Adora Consumer Feedback Policy and Procedure	QRC

14. Version Control & Authorisation

Document Owner.	Quality, Risk and Compliance

Version	Author	Approver	Date Approved	Change History
1	Marje Rauhala	QRC Manager / NLT (via email)	26/09/2022	New Adora template