Policy Name: Open Disclosure Policy

Originating Department: VH- QAL

Scope:

This document describes Virtus Health's policy with regard to Open Disclosure.

This process is part of the risk management program

The procedure applies to all clinical departments and locations of the Virtus Health Group

Responsibility:

Responsibility to ensure compliance with this procedure rests with:

a. CEO - lead the organisation's Open Disclosure policy and practice
b. Managing Director – is responsible to manage the Open Disclosure process within their jurisdiction.
c. Medical Director - is responsible for the Open Disclosure process with regard to the fertility specialists and clinicians within their local sites.
d. Senior Managers – ensure compliance with policy and training of Staff
e. Quality Compliance and Risk Manager – audit compliance to the procedure.

Policy

It is Virtus Health's Policy to comply with the Australian Open Disclosure Framework. The points below describe how the framework is implemented within our organisation to ensure a consistent approach to Open Disclosure.

The principles of Open Disclosure include being transparent, truthful, open and honest, respecting patient autonomy and putting the welfare of the patient first. Openness and honesty is the basis for the relationship of trust that patients have with their fertility specialist, clinician, their clinical team and the health service organisation in which they are being treated.

Adverse events: Are described as any harm experienced by patients, partners, family or carers during the course of their treatment. This can include physical and psychological harm.

All adverse events must be managed as per the Virtus Adverse Event and Feedback Reporting and Management Policy. The adverse event policy also describes the process of notification and referral to relevant regulatory bodies and Insurers, this must be followed to ensure all legal and insurance obligations are met.
For any incidents which require open disclosure of an adverse event the Managing or Medical Director must be involved in the process of Open Disclosure.
All adverse events must be documented in RiskMan.

Open disclosure describes the way the organisation communicates with and supports, patients, partners and their family and carers, who have experienced harm or an adverse event during health care. Open disclosure is a patient right, is anchored in professional ethics, considered good clinical practice and is part of the care continuum.

The elements of open disclosure are:

- an apology or expression of regret including the words 'I am/we are sorry'
- a factual explanation of what happened
- an opportunity for the patient to relate their experience
- a discussion of the potential consequences of the adverse event
- An explanation of the steps being taken to manage the event and prevent recurrence.

The Australian Open Disclosure Framework's eight guiding principles are:

1. Open and timely communication

If things go wrong, the patient, partner, 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.

All Open Disclosure communication must be documented in the patient file and should include:

- Patient, family and support person contact details
- All discussions
- All information provided
- Logistical details, plans proposed
- The time, date and place of the disclosure discussion and the names and relationships of those present
- The plan for providing further information to the patient and their support persons
- Agreements and commitments made
- Offers of support and the responses received
- Questions posed by the patient and their support persons and the answers given
- Plans for follow-up as discussed with the patient and their support persons
- Progress notes relating to the clinical situation and accurate summaries of all points explained to the patient and their support persons
- Copies of letters sent to the patient and their support persons and relevant clinicians.

2. Acknowledgement

All adverse events should be acknowledged to the patients, partners, family or carers as soon as practicable. The Virtus Health group involved should acknowledge when an adverse event has occurred and initiate open disclosure.

3. Apology or expression of regret

As early as possible, the patients, partners, family or 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. An example of potential wording could be:
I am/we are sincerely sorry that this has occurred. It is clear that something went wrong and we are in the process of investigating it. We will give you information as it comes to hand. It is very

important for us to understand your version of what happened. We can go through this now if you like, or we can wait until you are ready to talk about it.

4. Supporting and meeting the needs and expectations of patients, partners, family and carers

The patients, partners, family or carers 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.

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

Equally important is the support of staff who were involved in the adverse event. Staff, especially clinicians, can often be strongly affected in these circumstances and should be monitored and offered professional counselling or other forms of support.

The organisation's culture will have a strong bearing on how staff are supported and able to cope following an adverse event (in turn, the level of support provided to staff in these circumstances can be a strong determinant of organisational culture).

Virtus Health 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.
- Supported through the open disclosure process.

It is part of the responsibility of management and executive to foster a culture that avoids any blaming of individuals.

6. Integrated clinical risk management and systems improvement

Thorough clinical review and investigation of adverse events and adverse outcomes must be conducted as per the Virtus Adverse Event and Feedback Reporting and Management Policy. The information obtained about incidents from the open disclosure process should be incorporated into quality improvement activities.

7. Good governance

Open disclosure requires good governance frameworks and clinical risk and quality improvement processes. Through the Incident reporting system, presented at the highest level of governance, adverse events are investigated and analysed to prevent them recurring. Incident Reports are subject to review through Internal Audit.

Measuring and evaluating open disclosure is a key aspect of fostering the right culture for open disclosure. Reporting outcomes is a strong signal that the organisation takes openness and transparency seriously.

8. Confidentiality

In addition to the Privacy Policies concerning patient information, consideration must be given to protecting the privacy and confidentiality of staff and clinicians involved. Staff and Managers involved in the investigation and resolution of Incidents should only disclose information relating to the event as required to perform those actions.

The open disclosure process and key considerations.

This section provides a summary of the open disclosure process and outlines some key considerations of the process for the management team responsible for the process.

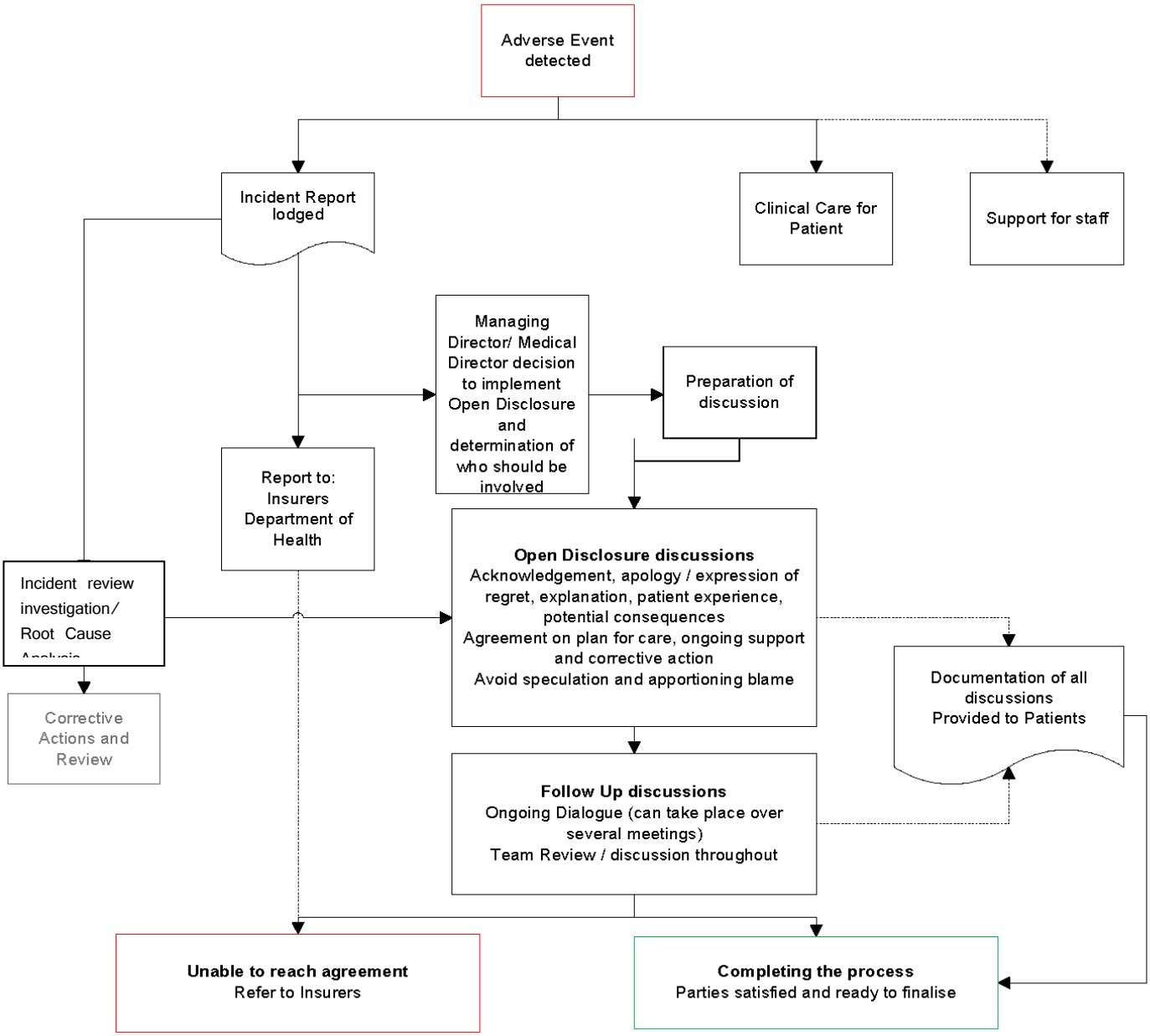
1. Detecting and assessing incidents	• Detect adverse event through a variety of mechanisms • Provide prompt clinical care to the patient to prevent further harm • Assess the incident for severity of harm and level of response • Provide support for staff • Initiate a response, ranging from lower to higher levels • Notify relevant personnel and authorities • Ensure privacy and confidentiality of patients, staff and clinicians are observed

2. Signalling the need for open disclosure	• Acknowledge the adverse event to the patient, their family and carers including an apology or expression of regret.
	• Signal the need for open disclosure
	• Negotiate with the patient, their family and carers or nominated contact person;
	  ○ the formality of open disclosure required
	  ○ the time and place for open disclosure
	  ○ who should be there during open disclosure
	• Provide written confirmation
	• Provide a direct 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 nominated contact person 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

	• 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 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
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

Open Disclosure as part of Incident Accident Reporting Process at Virtus Health



If a fertility specialist or clinician refuses to disclose information to a patient for whatever reason they should be counselled by the Territory Medical Director and Managing Director and the ethical obligation and Virtus open disclosure policy explained.

There may be circumstances where staff may identify that they do not feel prepared to participate in open disclosure and these should be acknowledged, respected and addressed in the appropriate manner.

Clinicians and staff have rights that should be considered during the open disclosure process. The most relevant rights are:

- The right to seek appropriate legal advice and to disclose information to legal advisers in a manner that ensures that it attracts legal professional privilege
- The right to be treated fairly by the institution and to receive natural justice and procedural fairness
- The right – and on some occasions, the contractual obligation – to seek appropriate advice and guidance from their indemnity insurers or medical defence organisations.

Related Documents:

Virtus Health Adverse Event and Feedback Reporting and Management Policy
Local Territory reporting Procedures
Australian Open Disclosure Framework