MSP – 36 – Open Disclosure

Part 1: Why do we have this procedure?

Open Disclosure is the process of open communication with the patient, and or their family/support person, following an adverse or unexpected event that may or may not result in harm to the patient.

Open disclosure can:

- Improve patient safety through improved understanding of how things go wrong
- Learn from what caused things to go wrong and to prevent them in the future
- Increase trust between patients and healthcare providers
- Assist patients to become more active partners in their care.

The Ballarat Surgicentre encourages staff, as well as patients and their family or carers, to identify and report when things go wrong or when patients are harmed to prevent them in the future.

Open Disclosure is enacted when:

- When health care does not go to plan, evidence suggests that patients want to know and understand what happened and why. They want to feel there is genuine regret that the event occurred, and they want to know that steps will be taken to minimize the risk of similar events occurring again.
- In the event of a data breach that may have the potential to cause harm.

Part 2: Who is involved in the procedure?

This is assigned to:

- BOM
- CEO
- DON
- VMO's
- All staff, as applicable
- Patients/Carers
- Regulators
- External Contractors

Part 3: What are the steps in the process?

The Open Disclosure Process will commence after the **detection of a clinical incident** by:

- A member of staff at the time of the incident.
- When an unexpected outcome is first detected sometime after the incident.
- A patient who expresses concern or dissatisfaction with their health care at the time of the incident, or sometime after the incident,
- Incident discovered at audit, such as clinical audit or medical records review.

The Open Disclosure Process will commence after **detection of a data breach** when:

- A customer's personal information is lost or stolen.
- A database containing personal information is hacked.
- Personal information is mistakenly provided to the wrong person.

- Employees accessing or disclosing personal information outside the requirements or authorization of their employment.
- Paper records stolen from insecure recycling or garbage bins.

PRINCIPLES OF OPEN DISCLOSURE

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.

   Patients, their family and carers involved in an open disclosure process will be provided with a copy of the 'Open disclosure of things that don't go to plan in health care – a booklet for patients beginning an open disclosure process' handout, saved on the k:drive/complaints records/open disclosure/consumer handbook.

2. **Acknowledgement**
   All adverse events should be acknowledged to the patient, their family and carers as soon as practicable. Health service organizations 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 carer(s)**
   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.
   - Supported in a manner appropriate to their needs.

5. **Supporting, and meeting the needs and expectations of those providing health care**
   Health service organizations should create an environment in which all staff are:
   - Encouraged and able to recognize 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 and 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. Outcomes 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 analyzed to prevent them recurring. Good governance involves a system of accountability through a health service organization'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 should be developed by health service organizations with full consideration for patient and clinician privacy and confidentiality, in compliance with relevant law (including federal, state and territory privacy and health records legislation). However, this principle needs to be considered in the context of *Principle 1: Open and timely communication.*

KEY ELEMENTS OF 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
  - 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 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 organization, 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.

KEY COMPONENTS OF OPEN DISCLOSURE DISCUSSIONS

1. Introductions

The patient, their family and carers is told the name and role of everyone attending the meeting, and this information is also provided in writing.

2. Saying sorry

A sincere and unprompted apology or expression of regret is given on behalf of the healthcare service and clinicians, including the words 'I am' or 'we are sorry'. Examples of suitable and unsuitable phrasing of an apology are provided in the resource titled Saying Sorry: a guide to apologizing and expressing regret in open disclosure available at www.safetyandquality.gov.au/opendisclosure

3. Factual explanation: providers

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. **Factual explanation: patient, family and carer(s)**
   The patient, family and carers have the opportunity 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. **Personal effect of the adverse event**
   The patient, family and carers is/are encouraged to talk about the personal effect of the adverse event on their life.

6. **Plan agreed and recorded**
   An open disclosure plan is agreed on and recorded, in which the patient, their family and carer(s) outline what they hope to achieve from the process and any questions they would like answered. This is to be documented and filed in the appropriate place and a copy provided to the patient, their family and carers.

7. **Pledge to feed back**
   The patient, their family and carers is assured that they will be informed of any further reviews or investigations to determine why the adverse event occurred, the nature of the proposed process and the expected time frame. The patient, their family and carers are given information about how feedback will be provided on the investigation findings, by whom and in what timeframe, including any changes made to minimize the risk of recurrence.

8. **Offer of support**
   An offer of support to the patient, their family and carers should include:
   - Ongoing support including reimbursement of out-of-pocket expenses incurred as a result of the adverse event.
   - Assurance that any necessary follow-up care or investigation will be provided promptly and efficiently.
   - In the relevant settings, clarity on who will be responsible for providing ongoing care resulting from the adverse event
   - Contact details for any relevant service they wish to access information about how to take the matter further, including any complaint processes available to them

9. **Support for patients and staff**
   The patient, their family and carers engages in open disclosure with staff. Staff are supported by their colleagues, managers, and health service organization, both personally (emotionally) and professionally, including through appropriate training, preparation and debrief.

10. **Other health service organizations**

    In cases where the adverse event spans more than one location or service, relevant clinicians and staff will ensure, where possible, that all relevant staff from these additional institutions are involved in the open disclosure process.

Refer:

- MSP 00 – Records Managing Including Patient Files
- MSP 38 – Complaints Procedure

OTHER CONSIDERATIONS:

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 associated investigations are completed, and the causative factors are known.
A written account of the open disclosure meeting should be provided to the patient, their family and carers and a copy filed in the patient record.

Any incident leading to an open disclosure event is documented by exception on a **IIIR form** and sent to the DON for logging. All open disclosure events are reported to BOM.

Part 4: Monitoring and Compliance

Open Disclosure policy and procedures is regularly assessed in order to maintain, compliance with relevant regulatory authorities and best practice standards.
A risk assessment was undertaken initially to establish facility standards. Compliance with the policy standard is monitored through the IIIR system and any issues are addressed in accordance with the IIIR procedure.

Part 5: Documents and records needed for this procedure, and how they are stored.

Document Title/Form Number	Paper or Electronic	Where are they kept	How long for (years)	Access restrictions	Comments
BOM Minutes	P/E	Forms/Management Executive Office	7 years	DON/CEO/MAC	
IIIR Register & Action Plan	P/E	Server/Master Index IIIR Folder – Executive Office	7 years	DON/All staff	
F-22-01 IIIR Form	P/E	DON/IIIR File	7 years	All staff	
Risk Matrix	P/E	Server/Forms DON/IIIR FILE	7 years	DON/All staff	
Website	E	Server		Anyone	

Part 6: References

National Safety and Quality Health Service Standards 2nd edition 2017
National Safety and Quality Open Disclosure Framework. Australian Commission on Safety and Quality in Health Care: www.safetyandquality.gov.au/opendisclosure
Health Services (Health Service Establishment) Regulations 2013 incorporating amendments 1 July 2018
Australian Commission on Safety and Quality in Health Care, Open disclosure of things that do not go to plan in health care – A booklet for patients beginning an open disclosure process, www.safetyandquality.gov.au/opendisclosure