National Patient Safety Policies

Disclosure of Patient Safety Events

2022

المركز السعودي لسلامة المرضى
SAUDI PATIENT SAFETY CENTER

Introduction

SPSC recognizes the necessity to address the national need to standardize the disclosure of patient safety events process and emphasize that disclosure is a process of several steps, not a single event.

When a patient safety incident occurs, patients need to have timely and full disclosure of the event that includes an apology, acknowledgment of responsibility, what happened, expressions of sympathy, and a discussion of what is being done to prevent recurrence of the event.

Barriers that may hinder the disclosure process include lack of training, a culture of blame, and fear of lawsuits. To reduce these concerns, it is recommended that health care facilities establish a just culture that encourages staff to report events.

SPSC encourages all Healthcare institutions to have policies and procedures that address patient safety events, including the disclosure process.

Acknowledgement

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1. POLICY STATEMENT

The policy is intended to recommend a national Open Disclosure framework to encourage healthcare organizations develop "Open Disclosure" policies and procedures tailored to their needs and resources.

2. SCOPE

- The policy directive is to set out the best practices and minimum requirements for the Open Disclosure process to ensure that patients, their families, and healthcare providers communicate effectively about patient safety events.
- Legal and Disciplinary processes are outside the scope of the framework.
- This framework applies to all healthcare settings.

3. DEFINITIONS/ABBREVIATIONS

Open Disclosure
The open discussion of an incident that results in harm (or might result in future harm) to a patient while receiving health care. The elements of Open Disclosure are an expression of regret, a factual explanation of what happened, the potential consequences and the steps being taken to manage the event and prevent recurrence. (Australian Commission on Safety and Quality in Health Care definition)

No-harm incidents
An error or system failure that reaches the patient but does not result in patient harm. (Australian Commission on Safety and Quality in Health Care definition)

Near misses
An incident that did not cause harm but had the potential to do so. (Australian Commission on Safety and Quality in Health Care definition)

Apology
An apology in relation to an Open Disclosure of a patient safety incident means an expression of sympathy or regret. (Australian Commission on Safety and Quality in Health Care definition)

Multidisciplinary team
A healthcare team comprising individuals from various professions (nursing, medical, allied health, administrative, management) and disciplines within these professions. (Australian Commission on Safety and Quality in Health Care definition)

4. POLICY FRAMEWORK

1-SPSC encourages that Open Disclosure is considered a routine part of an episode of care and a critical element of continuous effective communication with patients.

2- The healthcare organization shall have a standardized mechanism for Open Disclosure that include the following stages:

- Identify when things go wrong
- Address immediate needs and provide support
- Acknowledge and apologize or express regret
- Find out and explain what happened
- Learn from the experience and make improvements
- Documentation of the process

3-All healthcare organizations need to initiate an Open Disclosure of all incidents that trigger Open Disclosure (table 1) to the patient and/or their families as soon as possible and as is practicable.

Open Disclosure is ideally conducted within 24 - 48 hours after the incident occurs or becomes known to the healthcare provider or as soon as the patient is physically and emotionally available to participate in the discussion and if deemed necessary, to have a support person present.

4-The staff member who detected the patient safety incident will consult responsible leaders/ committee or team, as appropriate, to assess and determine the required level of response.

5- The Open Disclosure process shall occur in 2 stages initial disclosure and post-event analysis.

6- For every case that needs disclosure, healthcare institutions need to appoint a trained individual to lead the Open Disclosure based on the previous discussion with the patients their families.

7-The disclosure process shall be documented in the patient's medical record.

8-Open Disclosure for sentinel events that impacted the patients must be recorded on the Saudi Patient Safety Center's sentinel event portal, indicating if Open Disclosure has occurred or not. (Effective September 2022).

9-Cases of Deferral of Open Disclosure need to be identified and decided only in rare and exceptional circumstances.

5. PROCEDURES

<u>The general principle of Open Disclosure:</u>

All Healthcare facilities need to identify and educate healthcare providers and other hospital staff regarding patient safety incidents that need Open Disclosure.

After detecting a patient safety incident, a multidisciplinary team (e.g., healthcare providers, head of relevant department/managers, or any other relevant structure or department) must ensure that steps are taken to prevent or reduce further harm to the patient immediately.

After identifying the type of the incident, the following measures should be implemented by the hospital:

1. All the incidents need to be reported through the hospital reporting system
2. If the incident is identified as a sentinel event, the hospital needs to report the event through the SPSC portal and any other relevant authorities
3. Notify the patient of the incident and the facts that are known up to that point in time
4. Investigate the clinical incident
5. Provide feedback to the patient
6. Develop an agreed plan for the ongoing care of the patient

When healthcare organizations identify an incident that triggers Open Disclosure (table1), the process may take place in two steps, including: initial and post analysis

In preparation for the initial disclosure meeting, consider the following:

- Decide who will be involved in the meeting depending on the nature of the event or the anticipated reaction of the patient (e.g., family members, healthcare translator, those required to meet any special needs of the patient).
- It is recommended that Most Responsible Physician (MRP) should usually take the lead of the meeting. In situations where (MRP) is unable to attend the meeting, a suitable delegate can be in charge and clearly explains the reasons for MRP absence.
- The leader of the meeting should be well trained on how to provide the required information appropriately to the patient and well-oriented about the case to provide answers for any clinical questions the patient may have.

<u>Apologizing:</u>

It is very important to ensure that expressing sincere and genuine apologies by the healthcare team is important in each step of the disclosure process.

The initial disclosure process: (before investigation and analysis)

- During the initial meeting, information addressed to the patient or families should focus on the known facts with special attention to the emotional and information needs of the patient.
- Information regarding the second step of disclosure after investigation needs to be given to the patient and/or their families.

The post-analysis disclosure:

(An assigned team) in the hospital shall review the incident and plan for the next step of disclosure (The team review the incident may not be the same who plan for disclosure).
During post-analysis disclosure, the healthcare facility needs to focus on the reason for harm, apology and implement corrective actions to avoid reoccurrence of the event.

The team shall assess the need for additional meeting/meetings based on the situation and outcome of the first meeting.

Assessing the level of response:

The assigned team/staff shall assess the patient safety incident that triggers Open Disclosure and determine the following:

- The level of response needed based on the degree of harm the patient experienced.
- The required interventions (e.g., psychological, clinical) needed as a result of this harm.

According to HSE Ireland the following level of responses are suggested:
A low-level response is usually initiated for patient safety incidents where there has been no harm to the patient or the harm to the patient is minimal – this level of response may involve just one meeting with the patient.
A high-level response involves the full Open Disclosure process and will be initiated for patient safety incidents where the patient has suffered a moderate or higher level of harm.

Communicating risks to patients and media:

Complications, risks, and side effects associated with medical conditions, care, and treatment must be communicated to patients in a timely manner and fully understood.

A relevant structure/ department in the organization shall provide patients with information about whom to contact if they have further concerned or questions.

The information provided, apology, and any agreed actions must be documented in the patient's healthcare record.

The hospital shall prepare media-sharing content to be shared with media if needed.

Documentation of Open Disclosure:

The hospital needs to document the major points discussed with patients and/or their families during Open Disclosure meetings, including the following details:

- Date, time, and location of the meeting
- Name and roles of those present
- Facts presented in the discussion
- Agreed on care/treatment plan and actions
- Apology provided
- Participants' reactions and responses
- Agreed-upon next steps
- Any plan for providing follow-up and further information to the patient and family, if appropriate
- Name and details of the patient's contact person

Recommendations during Recording:

- The disclosure meeting should end with proper documentation process.
- It is recommended to review key decisions to make sure that everyone has a shared understanding of what was discussed and agreed upon facts to be documented in the disclosure Form as well as Medical Record.
- All brief, fact-based notes from the meeting should then be documented and shared with all those present, providing an opportunity for review by all involved before they are inserted into the medical record.
- The disclosure process needs to be documented in the patient's medical record this could be in progress notes or any other suitable place based on each hospital policy.

Deferral of Open Disclosure

Prompt Open Disclosure may not be indicated in every situation. For example, if the physical or mental health of the patient prevents them from participating in the meeting.

If the assigned team, consider that deferral is the best option for the patient the rationale for deferral and plans for when Open Disclosure will take place must be clearly documented in the patient's medical record.

Where possible, the deferral decision should be independently verified by a practitioner or colleague who was not involved in the incident. This verification must also be documented in the patient's medical record.

There are rare situations when Open Disclosure may not be appropriate, including some instances of self-harm, suicide, or criminal acts. It is recommended that advice be sought from a relevant structure in the hospital, including psychiatric consultation. In these circumstances, the relevant structure in the hospital may give consideration that Open Disclosure may be waived.

Any consideration of waiving must be briefed to the hospital CEO and include a description of the incident and subsequent investigation and rationale for waiving the Open Disclosure process.

Management of stress after patient safety incident:

Patient safety incidents are stressful for patients and families, as well as for physicians and other healthcare providers. In some circumstances, if the emotional distress is significant, it may be prudent to transfer the patient's care to another physician.
At all times, it is important for physicians to look after their own emotional and physical health.

- Seek emotional support from colleagues, trusted friends, family, or your own physician.
- In the course of these discussions, do not discuss clinical details and continue to safeguard patient health information.

You should consider transferring the care of the patient in the event of any of the following:

- The patient requests or prefers it
- The patient's condition requires care you cannot provide
- You feel your emotional state may interfere with the provision of care now required

Staff support and training members of the clinical team should receive appropriate support from the hospital when a clinical incident occurs. The clinical team should also receive appropriate training in communication and the principles of Open Disclosure.

6. MONITORING PERFORMANCE MEASUREMENT

The hospital may consider the following suggested indicators to measure and monitor performance:

- Proportion of all incidents openly disclosed (The hospital needs to set a target).
- Number of Open Disclosure processes that commenced and concluded in a reporting period (The hospital needs to set a time frame).

7. ATTACHMENTS

Type of Event	Disclose Yes/No
Harm event	Always disclose
Suspected harm event (harm is suspected but not confirmed)	Always disclose
No Harm event*	Generally, disclose – It is important to be sure that harm has not occurred as a result of an incident and the best way to ensure this is to discuss the incident with the patient. This approach is recommended for most no-harm events.
Near Miss event*	Near Miss events generally do not require Open Disclosure but must be assessed on a case-by-case basis, depending on the potential impact the event could have had on the patient. If, after consideration of the near miss event, it is determined that (i) there is a risk of/potential for future harm i.e., there is potential for the "near miss" event to become a "harm" event in the future and/or (ii) that informing the patient would assist in the prevention of future harm this must be discussed with the patient.
Table 1: Events that trigger Open Disclosure ***Source- HSE Open Disclosure Policy- Reference Number NATOD-POL-001***	

8. REFERENCES

-CMPA. 2021. Physician-patient | Disclosure | CMPA Good practices. [online] Available at: < https://www.cmpa-acpm.ca/en/education-events/good-practices/physician-patient/disclosure-of-patientsafety-incidents> [Accessed 17 November 2021].

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