Thunder Bay Regional Health Sciences Centre

Policies, Procedures, Standard Operating Practices

No. QM-70

Title: Mandatory Disclosure of Harm/Critical Incidents	☒ **Policy** ☒ **Procedure** ☐ **SOP**
Category: General **Sub-category:** Quality and Risk Management	**Distribution:** Patient care areas
Endorsed: Vice President, Clinical Services, Quality and Corporate Affairs **Signature:** **Endorsed:** Chief of Staff **Signature:**	**Approval Date:** Sept. 7, 2004 **Reviewed/Revised Date:** Jan. 20, 2025 **Next Review Date:** Jan. 20, 2028

CROSS REFERENCES: (QM-60) Incident Learning System (ILS): Reporting, Investigation and Trending of Incidents and Near Misses; (QM-80) Quality of Care Reviews

1. PURPOSE

Provide an overview of managing harm/critical incidents at Thunder Bay Regional Health Sciences Centre (the Hospital), as required by legislation.

2. POLICY STATEMENT

Patients at the Hospital have a right to relevant information about all aspects of their care and the Hospital will provide a full and frank disclosure of harm to patients and their families/substitute decision-makers as soon as possible. This includes an obligation on the part of all healthcare professionals to:

- Inform patients about events that do not result in clinical consequences but about which a reasonable person would want information because it might assist them in planning future care.
- Provide patients and families with a voice in the process and keep them informed throughout the process.
- For critical incidents, hospitals are also required to disclose to the patient any systemic steps being taken, or that have been taken, to avoid the risk of similar incidents occurring in the future.

3. SCOPE

Disclosure is required for all levels of harm, whether mild, moderate, severe or critical incident. This policy applies to all staff, professional staff, and learners.

4. DEFINITIONS

Clinical Debrief (aka "Hot Debrief"): Following a critical incident, a meeting to summarize the case, determine what went well and opportunities for improvement, and highlight where actions are required.

Critical Incident*:* Defined in Regulation 965 of the *Public Hospitals Act*, 1990, as:
Any unintended event that occurs when a patient receives treatment in a hospital:
a) that results in death, or serious disability, injury or harm to the patient; and
b) does not result primarily from the patient's underlying medical condition or from a known risk inherent in providing treatment.

Disclosure: The acknowledgment and discussion of harm/critical incident with a patient or the authorized substitute decision-maker.

Harm: Any injury, complication, or adverse event sustained by a patient in the course of healthcare treatment.

Levels of Harm:

- **Mild** - Patient outcome was symptomatic, symptoms were mild, loss of function or harm was either minimal or intermediate but short-term, and no intervention or only a minimal intervention was required (e.g. extra observation or minor treatment).

- **Moderate** - Patient outcome was symptomatic, required more than a minimal intervention (e.g. additional operative procedure or additional therapeutic treatment), and/or an increased length of stay and/or caused permanent or long-term harm or loss of function.
- **Severe** - Patient outcome was symptomatic, required a life-saving or other major medical/surgical intervention, shortened life expectancy and/or caused major permanent or long-term harm or loss of function.
- **Death** - On balance of probabilities, death was caused or brought forward in the short-term by the incident.

Patient Safety Incident: An event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. There are three types of patient safety incidents:

- **Harmful incident:** A patient safety incident that resulted in harm to the patient.
- **Near miss:** A patient safety incident that did not reach the patient and, therefore, no harm resulted.
- **No-harm incident:** A patient safety incident that reached the patient but no discernible harm resulted.

Substitute Decision-Maker (SDM): A third party identified to participate in the decision-making on behalf of a person who lacks decision-making capacity as defined in the *Health Care Consent Act*, 1996.

5. PROCEDURE

5.1. Upon the discovery of harm (any level), the healthcare team should meet as soon as possible to discuss. This may just be a conversation with the Department Manager, or for more serious events/critical incidents, a clinical debriefing (aka “hot debrief”) should occur. Members of this debrief team may include involved Staff, Professional Staff, Managers, Directors, Section Chiefs, Quality and Risk Management, and the Executive Vice President(s) and Chief of Staff. For a detailed outline of clinical debriefing, please refer to QM-80 *Quality of Care Reviews*.

5.2. The team will determine who the most appropriate healthcare professional(s) is to disclose the event. If required, further consultation with members of the Senior Leadership Team may be sought.

5.3. Disclosure should be made to the patient, SDM as appropriate, or if the patient is deceased, the personal representative or estate trustee. Family members may be invited to participate with patient consent.

5.4. Disclosure should occur as soon as possible after the event. Timing of the disclosure may be affected by the patient’s ability to comprehend the information.

5.5. A full and sincere apology may contribute to a successful disclosure discussion. An apology is not an admission of legal liability, nor does it absolve healthcare professionals of harm that has occurred, or shield them from a finding of liability in the future.

5.6. The team will initiate steps to develop and implement a plan of care to rectify the harm and prevent a reoccurrence.

5.7. Any learner who has disclosed to the supervisor and/or the most responsible healthcare professional that a patient has sustained harm through the care provided, has fulfilled their individual obligation. If the learner is not satisfied with the response of the supervisor and/or healthcare professional to the disclosure of harm/critical incident, the learner may discuss the issue with the appropriate next level of leadership. This may include the Department Manager and/or Program Director, Manager of Academic Affairs, Director of Medical Affairs and/or Chief of Staff (for medical learners), or Director of Quality and Risk Management.

5.8. Following the disclosure of a critical incident, there is a further obligation on the Hospital to advise the individual of the systemic steps, if any, the Hospital is taking or has taken in order to avoid or reduce the risk of further similar critical incidents. The content and date of this further disclosure must be documented.

5.9. Disclosure of critical incidents to the Medical Advisory Committee (MAC) is compulsory. The MAC is responsible for identifying systemic or recurring quality issues and making recommendations to

the Board related to the quality of care provided in the Hospital by Professional Staff. The MAC is required to make recommendations directly to the Quality of Care Committee (QOCC). The QOCC is required to consider these recommendations in making its own recommendations to the Board.

5.10. The President and CEO must provide aggregate critical incident data to the Board Quality Committee at least two times per year. This report is shared with the entire Board at least two times a year as well. This will ensure compliance with Regulation 965 of the *Public Hospitals Act*, 1990, and the *Excellent Care for All Act*, 2010.

5.11. When there is uncertainty regarding the obligation for disclosure, consultation with the appropriate Manager, the Director of Quality and Risk Management, the Bioethicist, or the legal retainer program is recommended. Disclosure of critical incidents should not be provided by a healthcare professional in isolation of Hospital administration.

6. REPORTING

Reporting for all harm/critical incidents will follow the processes outlined in policy QM-60 *Incident Learning System (ILS): Reporting, Investigation and Trending of Incidents and Near Misses*.

7. DOCUMENTATION

7.1. Patients have the right to decline receiving disclosure of information. This should be documented in the patient's chart.

7.2. All disclosure discussions with the patient, SDM and family, should be documented factually in the patient's chart.

7.3. Reports of any critical incidents with respect to the patient, including the required information noted in section 5.10 of the Procedure, must be documented in the patient's chart (including information relating to when disclosure was made).

8. GUIDELINES FOR DISCLOSURE

8.1. When patient harm/critical incident has been identified, the patient, SDM as appropriate, and family (with patient consent) should be offered a face-to-face meeting with the healthcare professional(s) identified by the team.

8.2. Hospitals are also required to disclose to the patient any systemic steps being taken or that have been taken to avoid the risk of similar critical incidents occurring in the future. In the event where the critical incident is being reviewed under the *Quality of Care Information Protection Act*, 2016, the Hospital is still required to disclose the above facts, consequences, actions, and the systemic steps actually taken.

8.3. The healthcare professional(s) involved in disclosing an event should:

- Provide a private, quiet and comfortable setting
- Ensure all relevant documentation is available
- Communicate that an unintended event has occurred
- Acknowledge the event with empathy
- Provide a short, objective factual summary of the event
- Describe how the event affected the patient's health status and treatment plan
- Outline a recommended care/treatment plan
- Elicit questions and concerns
- Respond objectively to questions
- Note unanswered questions and ensure prompt, thorough responses
- Avoid speculation, attribution of blame
- Indicate that there will be follow up meetings to examine the event and make appropriate changes to prevent re-occurrences
- Explain any steps taken to correct the event
- Have a non-involved member of the staff be present to document the discussion
- Establish arrangement for follow up meeting if it is a critical incident

8.4. Support should be provided for the patient, SDM and family at the time of disclosure (e.g. Social Work, Spiritual – Religious Care, Bioethicist, Patient Advocate, etc.).

8.5. Support should also be provided for involved staff and professional staff (e.g. Bioethicist, Leadership, etc.).

9. RELATED PRACTICES AND/OR LEGISLATIONS

Excellent Care for All Act, 2010

Health Care Consent Act, 1996

Quality of Care Information Protection Act, 2016

Regulation 965 of the Public Hospitals Act, 1990

10. REFERENCES

College of Nurses of Ontario. Code of Conduct. 2019.

College of Physicians and Surgeons of Ontario. Disclosure of Harm Policy. 2003.

College of Physicians and Surgeons of Manitoba. Physician Disclosure of Harm that Occurs in the Course of Patient Care. 2003.

Ontario Ministry of Health, Ministry of Health and Long Term Care. Critical Incident Reporting. 2013.

Quality of Care Information Protection Act. Review Committee Recommendations. 2014.