Bluewater Health Corporate Policy Manual

Category	**Professional Staff**		**Policy**
Section			
Title:	**Disclosure of Patient Safety and Critical Incidents**		
Issuing Body	Chief of Staff		**COR-PS-A-10.10**
Approved by	Medical Advisory Committee		
Effective Date: January 2004	Revised Date: July 2004 November 2009 November 2011 January 2012 February 2015 October 2017 September 2018 January 2019		Reviewed Date: January 2019
Controlled document. Any documents appearing in paper form must be used for reference purposes only. The on-line copy on the file server above must be considered the current documentation.			

Policy Objectives

The purpose of this policy is to assist providers and to affirm that patients are entitled to be informed of all aspects of their health care. This includes the right to disclosure of harm that may have occurred to him or her in the course of receiving health care (College of Physicians and Surgeons of Ontario [CPSO], 2010). It is the policy of Bluewater Health to provide disclosure of critical incidents/patient safety incidents/outcomes to patients and/or their substitute decision makers (SDMs). In addition, health care providers have ethical, professional, and legal obligations to disclose adverse events (Canadian Medical Protective Association [CMPA], 2008). Requirements related specifically to critical incident disclosure are also detailed within this policy.

Ontario Ministry of Health: Critical Incident Acts and Regulations

On July 1, 2010, new amendments to Regulation 965 under the *Public Hospitals Act* came into effect in Ontario. These amendments expand the disclosure requirements to include mandatory disclosure of critical incidents to the Medical Advisory Committee (MAC) and the hospital administrator, in addition to the affected patient/Substitute Decision Maker (SDM).

Beginning January 1, 2011, the Board is required to ensure that the administrator provides aggregated critical incident data to the Quality Committee established under the *Excellent Care for All Act* at least two times per year. In addition, where the MAC identifies systemic or recurring quality of care issues in making recommendations to the Board related to the quality of care provided in the hospital by the medical staff, dental staff, extended class nursing (appointed) and midwifery staff, the MAC is now required to make recommendations about those issues directly to the Quality Committee, and the Quality Committee is required to consider these recommendations in making its own recommendations to the board.

The Hospital Management Regulation made under the *Public Hospitals Act* with Ontario regulation 484/16 requires that a designated patient relations person must participate in each critical incident review and a person acting on behalf of the hospital must offer to interview the affected patient's estate or the person who has authority to make decisions if

the patient is incapable as part of the critical incident review. Under this same regulation, hospitals must disclose the *material facts* of what occurred with respect to the critical incident, the *consequences for the patient* of the critical incident, and the *actions taken and recommended to be taken* to address the consequences to the patient of the critical incident, including any health care or treatment that is advisable. Hospitals will also be required to disclose a description of the *cause(s)* of the critical incident.

Terms of Reference

Patient Safety Incident:
"An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient. Includes: Harmful incident, No harm incident, Near Miss" (Canadian Patient Safety Institute [CPSI], 2011)

Harmful Incident:
A patient safety incident that resulted in harm to the patient (replaces "adverse event" and "sentinel event" (Canadian Patient Safety Institute [CPSI], 2011)

No Harm Incident:
"A patient safety incident which reached a patient but no discernible harm resulted" (Canadian Patient Safety Institute [CPSI], 2011)

Near Miss:
"A patient safety incident that did not reach the patient." Replaces "close call." (CPSI, 2011)

Critical Incident:
For the purposes of this policy is defined as "any unintended event that occurs when a patient receives treatment in the 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 (Ontario Hospital Association [OHA], nd)

Harm:
"Impairment of structure or function of the body and/or any deleterious effect arising therefrom. Harm includes disease, injury, suffering, disability and death." (CPSI, 2011)

Initial Disclosure:
"The initial discussion with the patient that should occur as soon as reasonably possible after an event" (CPSI, 2011)

Post-analysis Disclosure:
"Subsequent communications with a patient about known facts related to the reasons for the harm after an analysis of the adverse event" (CPSI, 2011)

Threshold for Disclosure

The Canadian Disclosure Guidelines (2008) state, "whenever a patient suffers harm, for whatever reason, the healthcare provider or organization has an obligation to communicate to the patient about that harm and, if applicable, the event that led to the harm. Harm that has resulted from the inherent risks of an investigation or treatment should always be communicated to the patient. Such harm should not be prematurely attributed to simply 'a complication' of the investigation or procedure." The CMPA advises that if an inherent risk of an investigation or procedure has occurred, the most responsible physician should talk to the patient about the nature and likely implications for the patient's immediate and future health, including what might be done to improve the situation (CMPA, 2008). The Canadian Disclosure Guidelines (2008) diagram provides an overview determining the type of event and the requirements for disclosure (Appendix A).

Procedure

A breakdown of the disclosure process would closely resemble the following 5 steps:

1) Attend to clinical care. This could include:
    - Addressing clinical needs
    - Dealing with emergences
    - Considering next steps in clinical care
    - Providing emotional support
2) Planning the initial disclosure:
    - What are the facts?
    - What will you say?
    - Who will be present? Who will lead?
    - When will the meeting take place?
    - Where will the meeting take place?
3) The initial disclosure meeting
    - Provide the known facts
    - Express regret as appropriate
    - Avoid blame and speculation
    - Confirm plan for further clinical care
    - Arrange follow-up, identify contact process, and outline expectations for further information
    - Document the disclosure
4) Analysis
5) Post-analysis disclosure
    - Provide further facts and information on steps taken
    - Express regret again, consider apology if appropriate
    - Document the discussions

Disclosing a Critical Incident

The responsibility for disclosing a critical incident or other patient safety incidents to a patient generally rests with the most responsible physician. The MRP should consider bringing a second person, such as the Medical Director, to the disclosure meeting. In situations where the attending physician is not the appropriate person to participate in the discussions, the designation of an alternate physician will be made by the Medical Director of the Program. As per the Hospital Management Regulation made under the *Public Hospitals Act* with Ontario regulation 484/16 requires that a designated patient relations person must participate in each critical incident review and a person acting on behalf of the hospital must offer to interview the affected patient's estate or the person who has authority to make decisions if the patient is incapable as part of the critical incident review.

The initial disclosure will:

- Occur as soon as it is reasonably possible after the harmful incident or outcome has become apparent
- Be documented in the health record, along with any and all outcomes of the critical incident
- Always take place in a location that promotes privacy and confidentiality

In the case of catastrophic harmful incidents or critical incidents, **the Chief of Professional Staff, Medical Director, and/or Chief Nursing Executive and the Executive on call shall be contacted** as soon as it is reasonably possible after gaining knowledge of the harmful incident or critical incident and before disclosure has taken place. The Chief Nursing Executive/Chief of Professional Staff or delegate will coordinate the incident analysis process, follow-up and review.

Whenever possible, the Chief of Professional Staff or other member of the Executive Council will coordinate the disclosure process and be present for the disclosure.

If the critical incident/patient safety incident is not related to care provided by credentialed staff, but is related to care provided by another health professional, then the responsibility for disclosure will rest with that health professional who will consult with the Chief Nursing Executive, Program Director/ Program Manager/Medical Program Director, and Program VP, in partnership with the most responsible physician.

Residents or Medical Students are required to disclose to their supervising physician any patient safety incidents. The supervising physician must bring the matter to the attention of the attending physician who is responsible for disclosing to the patient/family/SDM.

Critical Incident Disclosure Requirements

Disclosure of critical incidents must be made to the Medical Advisory Committee (MAC), the hospital administrator and the affected patient. If the patient is incapable, disclosure can occur to a person lawfully authorized to make decisions on behalf of the patient. If the patient has died, the disclosure shall occur (in this order):

a) To the patient's estate trustee;
b) To the person who has assumed responsibility for the administration of the estate, if the estate does not have an estate trustee; or
c) To a person lawfully authorized to make treatment decisions on behalf of the patient immediately prior to the patient's death.

Disclosure to the Medical Advisory Committee (MAC) and the administrator must include:

- The material facts of what occurred with respect to the critical incident;
- Consequences for the patient of the critical incident, as they become known; and,
- The actions taken and recommended to be taken to address the consequences to the patient of the critical incident, including any health care or treatment that is advisable.*

Disclosure to the patient/SDM must include:

- The material facts of what occurred with respect to the critical incident;
- Consequences for the patient of the critical incident, as they become known;
- The actions taken and recommended to be taken to address the consequences to the patient of the critical incident, including any health care or treatment that is advisable;
- Any systemic steps being taken or that have been taken to avoid the risk of a similar critical incident occurring in the future.

In the event that a health care practitioner discovers that a critical incident, harmful incident or outcome, which occurred at Bluewater Health, has not been disclosed to a patient/family/SDM, then the practitioner has the responsibility to inform their Department/Division Head. The responsible Department/Division Head will investigate the matter in conjunction with the Chief of Professional Staff and Chief Nursing Executive, as appropriate and in reference to the above policy.

Documentation of the Disclosure

Documentation of the disclosure must be entered into the patient's hospital record and include the following:

- Date, time and place of disclosure meetings;
- Names of all individuals present at the meeting, including staff, medical staff, patient, family members and SDM, and their relationship to the patient;
- Discussion points including:
    - Reaction/questions of participants
    - Any proposed treatment
    - Any offers of assistance made and response of patient/family/SDM
    - Notation if the patient/family/SDM refuses to receive the disclosure information
    - The patient/family/SDM request to view the health record

Please view Appendix B for a disclosure documentation form.

Provision for Patient Support

In addition to any medical treatments needed, consideration should also include the need for spiritual care, social work, etc.

Provision for Health Care Provider Support and Education

Critical Incident Stress Management diffusing/debriefing services are available to any person/team/unit who requires emotional support to cope with the event. The individual requesting support should contact the Program Director/Manager/Shift Manager to request this service. The Director/Manager/Shift Manager will contact the Senior Social Worker or delegate to arrange the session within 72 hours of the event. Individual counseling support can be arranged by contacting EFAP.

Provision for: near miss events, events with the potential to harm and no harm events

The Canadian Disclosure Guidelines (2008) state that we should consider whether an ongoing safety issue exists for the patient or whether the patient is aware of the event. It may be prudent to discuss an event with the patient to be sure that he or she is aware of the potential for an ongoing or repeat safety issue. If the patient is aware, a discussion may alleviate concerns and maintain trust. If there is no immediate harm but the potential for future harm exists, we need to evaluate the consequences, severity, and potential for future harm in considering disclosure. When uncertain, disclosure should occur.

Patient and Family Feedback

Patients and families must be offered a consultation with the Patient Experience Specialist should they wish to provide feedback on the disclosure process.

References

1. Canadian Disclosure Guidelines Being Open with Patients and Families (2011). Canadian Patient Safety Institute.

2. College of Physicians and Surgeons of Ontario (CPSO) – “Disclosure of Harm Policy Statement” May 2010

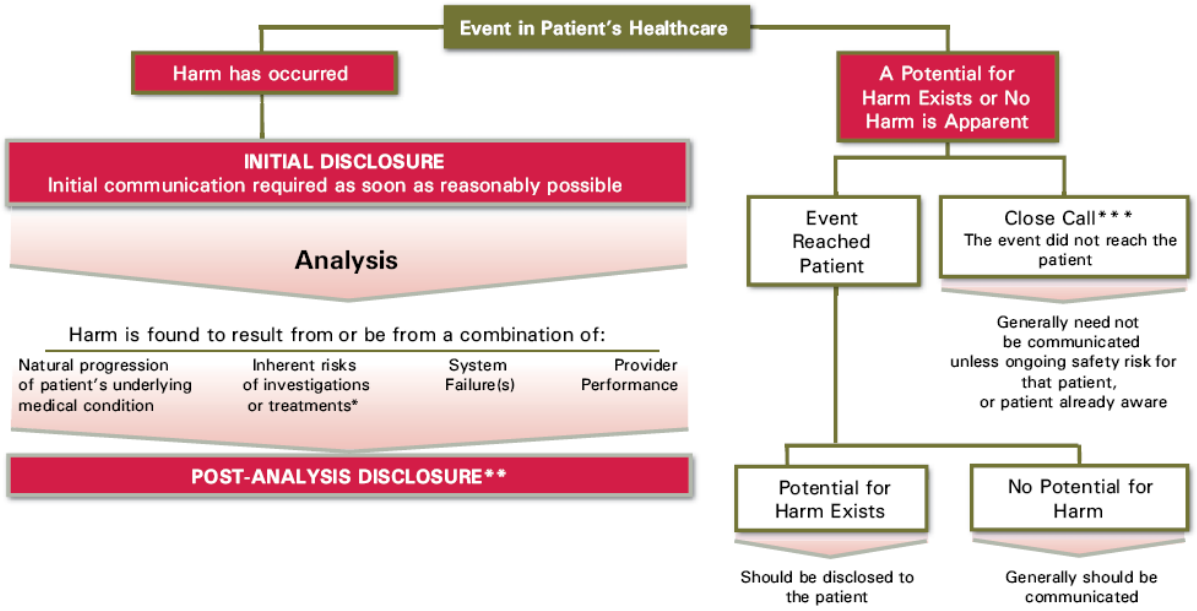
3. Communication with your patient about harm (2008). Canadian Medical Protective Association.

4. Ontario Hospital Association: An Ontario Guide to Disclosure

5. Canadian Disclosure Guidelines (2008). Canadian Patient Safety Institute.

APPENDIX A

Illustration B: Determining the Type of Event and the Requirements for Disclosure



* Refers to harm known to be associated with the investigation or treatment

** Management in consultation with providers to determine what further information is to be disclosed.

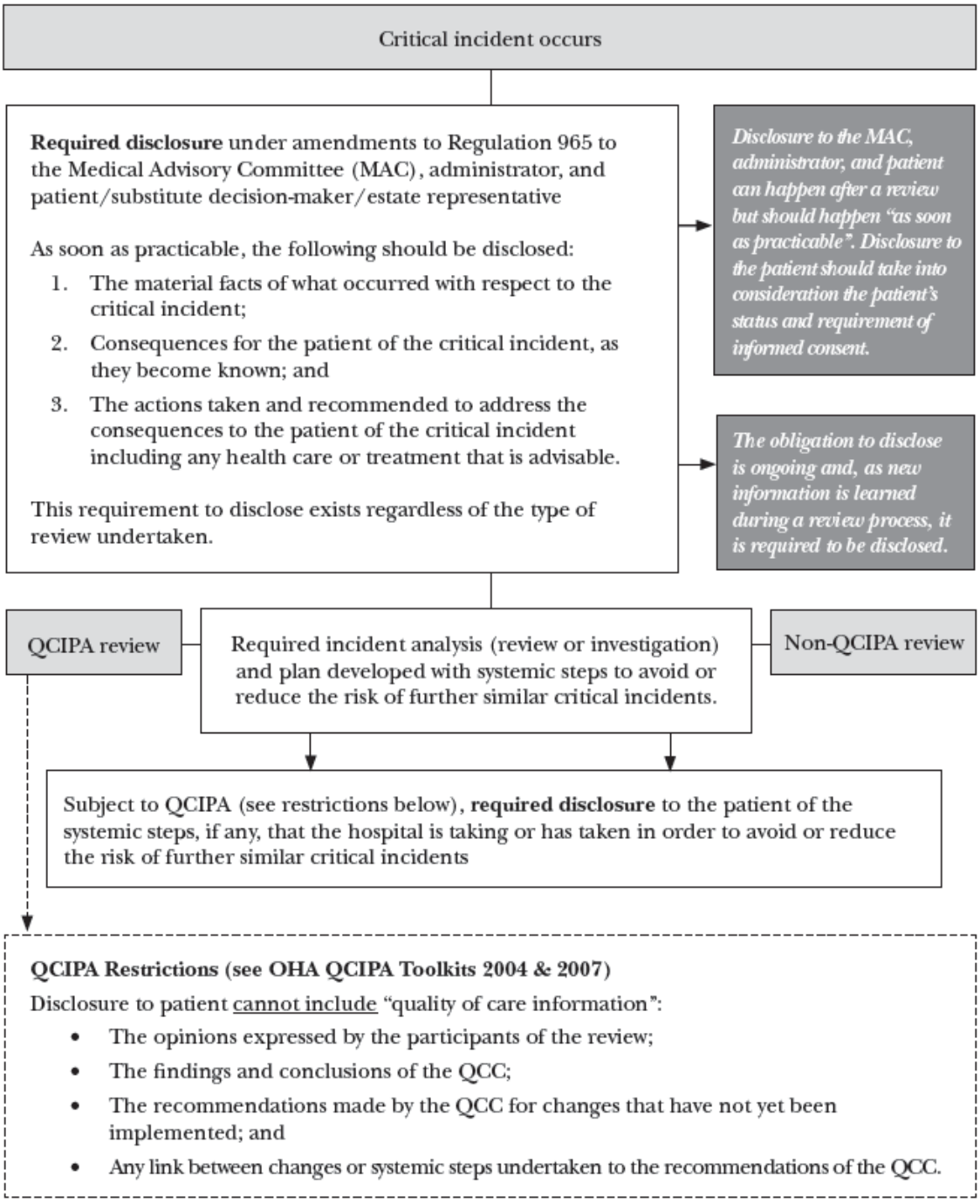
*** It is strongly encouraged that close calls be reported to healthcare organizations

APPENDIX B

Documentation of Disclosure Meeting

Date		
Time		
Place		
Hospital Attendees	Patient/Family Attendees	Relationship to Patient
Brief Factual Description of Preventable Adverse Event/Critical Incident		
Responses & Questions of Attendees		
Request by patient/Substitute Decision Maker/Power of Attorney to Review Chart ☐yes ☐ no		
Clinical Management Options (eg) Transfer of Care to Another Physician		
Services Offered (Social Work, Spiritual Care)		
Responses of Relatives to above offers		
Name of Staff Contact	Date of Contact	Person to be Contacted
Risk Management Signature Date:		

APPENDIX C


Critical incident occurs
Required disclosure under amendments to Regulation 965 to the Medical Advisory Committee (MAC), administrator, and patient/substitute decision-maker/estate representative
As soon as practicable, the following should be disclosed:
1. The material facts of what occurred with respect to the critical incident;
2. Consequences for the patient of the critical incident, as they become known; and
3. The actions taken and recommended to address the consequences to the patient of the critical incident including any health care or treatment that is advisable.
This requirement to disclose exists regardless of the type of review undertaken.
Disclosure to the MAC, administrator, and patient can happen after a review but should happen "as soon as practicable". Disclosure to the patient should take into consideration the patient's status and requirement of informed consent.
The obligation to disclose is ongoing and, as new information is learned during a review process, it is required to be disclosed.
QCIPA review
Required incident analysis (review or investigation) and plan developed with systemic steps to avoid or reduce the risk of further similar critical incidents.
Non-QCIPA review
Subject to QCIPA (see restrictions below), required disclosure to the patient of the systemic steps, if any, that the hospital is taking or has taken in order to avoid or reduce the risk of further similar critical incidents
QCIPA Restrictions (see OHA QCIPA Toolkits 2004 & 2007)
Disclosure to patient cannot include "quality of care information":
• The opinions expressed by the participants of the review;
• The findings and conclusions of the QCC;
• The recommendations made by the QCC for changes that have not yet been implemented; and
• Any link between changes or systemic steps undertaken to the recommendations of the QCC.