Disclosure of Serious Patient Safety Incidents

1. Introduction

Providence Health Care ("PHC") seeks to create a culture of safety for our patients, residents, and Assisted Living tenants. In this culture, health care providers are encouraged to share their concerns about patient safety and to disclose patient safety incidents (also called "adverse events") or medical errors as they occur.

PHC also seeks to create a just culture that recognizes patient safety incidents as symptoms of potential underlying systems failures that could manifest through any clinician. Enhanced safety for our patients and residents requires open acknowledgement of these incidents so that root causes can be identified and actions taken to prevent a recurrence.

Central to this policy is respect for the rights of patients, residents and their families to be informed about a serious incident as soon after the event as possible. Full and timely disclosure is critical since feelings of distress or harm are likely to be experienced by patients or residents if information is withheld. Effective communication of events, expression of regret, and appropriate care can influence these feelings and the sense of trust patients have in the care team.

1.1. Purpose

This policy provides information to PHC healthcare providers in the disclosure of serious patient safety incidents to patients, residents, and their families and contributes to a standardized process for identifying, reporting, and investigating serious patient safety incidents; and provides a process for improvement of patient care following patient safety incidents.

1.2. Scope

This policy applies to all PHC facilities. For ease of language, assisted living tenants are not specifically named but are implied in any reference to patient/resident.

2. Policy

It is the goal of PHC to provide quality care to our patients and residents. Despite constant and committed efforts to provide quality patient care, on occasion patients and residents are harmed rather than helped by health care. Sometimes these poor outcomes are unavoidable. At other times they result from preventable mistakes or medical errors.

Any adverse event where there is harm, injury or complication due to health care delivery should be disclosed to the patient or resident and their family.

The disclosure must include:

- The material facts of what occurred with respect to the serious patient safety incident;

- Consequences for the patient of the serious patient safety incident as they become known; and
- The actions taken to address the consequences to the patient of the serious patient safety incident, including any health care or treatment that is advisable.

Disclosure must *not* include:

- Discussions that took place during quality improvement activities in keeping with the BC Evidence Act;
- The identity of other patients or information that could potentially lead to the identification of other patients; or
- And disciplinary actions taken involving staff or physicians.

Risk Management must be contacted prior to disclosure of any adverse event likely to result in a request for compensation or litigation.

Serious patient safety incidents are subject to the Patient Safety Incident Reporting process.

2.1. Disagreement

Where there is disagreement about whether or how to disclose a patient safety incident, team members may consult with PHC Ethics Services, Risk Management or Patient Relations. If an individual or individuals are believed to be withholding disclosure of a serious patient safety incident, the concerned care provider(s) should consult with their team, relevant leader or Risk Management.

2.2. Exceptions to Disclosure

Exceptions to disclosure *may* exist where there is serious risk of significant harm to the patient, resident, or their family as a result of disclosure, but a decision not to disclose will only be made after consultation with Risk Management or Ethics.

Disclosure of near misses and minor patient safety incidents is a matter of clinical and professional judgment. If information about the incident could assist the patient, resident, or their family in the future, it should be disclosed.

2.3. Disclosure in Connection with Research

Serious patient safety incidents that occur during the course of a clinical trial are subject to this policy and to the reporting procedures outlined by the UBC-PHC Research Ethics Board.

Disclosure of a serious patient safety incident should take place as soon as possible after ensuring that the patient or resident's care needs are met. The standard for disclosure is based on the "Disclosure of Unanticipated Outcomes" framework from the Institute for Healthcare Communication.

2.4. Meeting Attendance

The person taking the lead at the meeting should be the most responsible care provider or most senior relevant leader.

The person taking the lead should be accompanied by at least one other member of staff, such as the Risk Manager, Program Director or Physician Program Director. The additional person provides support for the discussion and bears witness that disclosure has taken place.

Other members of the healthcare team treating the patient may also be required to assist with support of the patient or resident and their family or provide factual content.

If possible, hold a pre-meeting amongst the healthcare professionals so that everyone knows the facts and understands the goals of the meeting.

Ask the patient, resident, or their family who they would like to attend the meeting. If the patient is not capable of making health care decisions, ensure that the Substitute Decision Maker will be present (see PHC Consent Policy for Substitute Decision Maker procedures)

Determine in advance of the meeting sources of support and counseling which can be offered to the patient or resident and their family.

If subsequent meetings with the patient or resident and their family are required, it is preferable that those who led the first meeting also attend to ensure continuity.

2.5. Meeting Timelines

The first disclosure meeting should take place as soon as possible after the event, with consideration given to the patient or resident, and their family availability and circumstances. Depending on the severity of the incident, multiple meetings may be required.

Offer the patient or resident and their family a choice of times for the meeting to be held.

The meeting should not be cancelled unless absolutely necessary or unless requested by the patient, resident, or their family.

2.6. Meeting Place

The meeting should be held in a quiet room with a minimum of disruptions or distractions.

Consider whether the meeting can be held outside of the unit or place that the incident occurred, as this may add to the difficulty for the patient, resident, or their family.

Consider also, in some circumstances, travelling to meet the patient, resident, or their family for their convenience.

2.7. Meeting Approach

Speak to the patient or resident and their family in a clear and straightforward manner. Avoid jargon, acronyms or overly technical medical language. Be as sympathetic and understanding as possible.

Consider the needs of the patient/family with special circumstances, such as disabilities or cultural needs. Obtain an independent interpreter if there is a language barrier (see PHC Consent Policy for interpreter resources).

2.8. Discussion

Introduce and explain the role of everyone present to the patient or resident or their family. Determine who is the Substitute Decision Maker (if needed) and if a family spokesperson needs to be chosen.

Acknowledge what happened. Apologize &/or express regret on behalf of the team and the organization. Expression of regret is not an admission of liability.

Avoid speculating or attributing blame. Stick to the facts that are known at the time and assure the patient or resident and their family that as more facts about the event become available, they will be shared with them. However, it is the policy of Providence Health Care not to provide the names of individuals responsible for a medical error or serious adverse event.

Check that they have understood what you have told them and offer to answer any questions.

Provide contact information for a member of the team who can be reached for further information, and provide information on available support and counselling. Contact information for PHC Patient Relations may also be provided.

2.9. Follow-up

Maintain a dialogue with the patient or resident and their family by addressing any new concerns, sharing new information once available and providing information on counseling as appropriate.

Consider if a subsequent meeting(s) is indicated.

The most responsible care provider (or delegate) must record in the medical record a factual account of the event *and* of the disclosure meeting including:

- the time and date
- where the meeting was held
- who was present
- the factual information that was presented
- key questions raised by the patient or resident and their family
- the plans for follow-up.

Facts of the event, as well as information about any investigation or recommendations, should also be recorded in the Patient Safety Learning System.

3. Responsibilities

It is the responsibility of all healthcare providers to ensure familiarity with this policy, and ensure that disclosure occurs whenever there is a patient safety incident. If any individual health care provider does not feel confident in their ability to manage this conversation, they are encouraged to seek the advice of their leader, and/or participate in the training in Disclosure of Unanticipated Outcomes ("DUMO") offered to all PHC physicians and employees.

The following responsibilities are pertinent to disclosure of Critical Incidents

3.1. Program Directors and Physician Program Directors

Be knowledgeable about all aspects of PHC's disclosure policy, process and resources.

3.2. Most Responsible Provider

Determine the most appropriate individual(s) to disclose the incident to the patient/resident/family.

Participate in the disclosure conversation as appropriate, and be knowledgeable about the consequences of the harm and resulting changes in the care plan.

Ensure ongoing communication with the patient or resident and their family regarding the patient safety incident.

3.3. Nursing and Allied Health

Participate in the disclosure conversation as required.

3.4. Risk Management

Provide regular DUMO training.

Provide real time support for disclosure conversations as required/requested.

4. Compliance

Disciplinary action will not follow for incidents arising from a medical error or adverse event where disclosure and reporting follows promptly. Disciplinary action may follow where there has been a cover-up and/or refusal to disclose, or where the event was the result of negligence or other unacceptable behaviour.

5. Supporting Documents

5.1. Related Policies

Patient Safety Incident Management

Consent to Health Care

6. Definitions

"Critical Incident" is an incident resulting in serious harm (loss of life, limb or vital organ) to the patient, or the significant risk thereof. Critical Incidents will be assigned a severity rating of 4 or 5.

"Disclosure" is the imparting, by health care workers to patients or their families, of information pertaining to any health care incident affecting (or liable to affect) the patient's interests. The obligation to disclose is proportional to the degree of harm to the patient arising from an incident.

"Health care management" includes the actions of individual care providers as well as the broader systems and care processes, and includes both doing the wrong thing (commission) or failing to do the right thing (omission).

"Incident (patient safety incident)" is an event or circumstance which could have resulted, or did result, in **unnecessary** harm to a patient.

"Medical Error" is the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. (Note: A medical error may or may not cause harm. A medical error that does not cause harm does not result in an adverse event.)

"Minor Incident" is an incident or error that does not cause lasting harm and does not create a risk of harm in the future.

"Must report" incidents are incidents that the PHC Senior Leadership Team have agreed must be reported whenever they occur, regardless of severity.

"Near Miss" is an event that would have been an incident (i.e. actual harm) but was not because of luck or timely intervention. This can also be called a "good catch".

"Reporting" is the providing of information to an appropriate public authority, internal or external, regarding a patient safety incident.

7. References

1. Disclosure of Unanticipated Medical Outcomes, February 2016, Fraser Health Authority
2. Canadian Patient Safety Institute, "*Draft National Guidelines for the Disclosure of Adverse Events*". May 2, 2007.
3. Health Quality Council of Alberta, "*Disclosure of Harm to Patients and Families*". Provincial Framework, July 2006.
4. Massachusetts Coalition for the Prevention of Medical Errors, "*When Things Go Wrong: responding to adverse events*". A Consensus Statement of the Harvard Hospitals, March 2006.