Patient Safety Incident Management

1. Introduction

To support staff, Providence Health Care (PHC) promotes a fair, open and consistent environment that does not seek to assign blame when incidents occur. This will encourage a culture and willingness to be open and honest to report any situation where things have, or could, go wrong so learning can occur and future harm can be prevented.

1.1. Purpose

This policy establishes the reporting and management expectations for patient safety incidents at PHC that are intended to encourage a healthy reporting culture that supports continuous learning in order to optimize patient outcomes.

1.2. Scope

This policy applies to all PHC sites and Staff.

2. Policy

PHC requires that Staff report any incident resulting in serious harm or death. PHC encourages and supports Staff to report any other incidents which involve real or potential impact ("good catches/near misses") on the safety of patients.

Reporting of incidents is through the Patient Safety Learning System (PSLS).

Staff who report patient safety incidents, whether or not an error was involved, shall not be retaliated against in any manner and are protected from such acts. Staff will not be held accountable for system flaws over which they have no control.

At the same time, PHC has a responsibility to address the actions of individual(s) should they fail to meet professional, patient care and/or service standards. These situations include:

- Intentional acts meant to harm or deceive
- Physical or mental impairment of Staff
- Substance abuse by Staff
- Insufficient skill, knowledge or expertise of Staff.

If it becomes clear that a Staff member cannot practice in a reliably safe manner, in spite of education and counselling, this situation will be treated as a competency issue in accordance with professional standards and Human Resources principles.

Note: Incidents involving employee injuries are addressed by Occupational Health and Safety policies and guidelines.

Effective management of patient safety incidents helps identify areas that need improvement, brings understanding of influencing factors and circumstances, minimizes distress for patients and ensures attention to issues of risk and liability. PHC is committed to the implementation of a comprehensive incident management system that includes:

- Reporting
- Investigation
- Analysis
- Implementation of recommendations, and
- Follow-up.

3. Responsibilities

3.1. All Staff

All Staff are responsible for conducting themselves within the spirit of this policy and for contributing towards enhanced patient safety and a culture of safety in the workplace.

3.2. Leaders

All Leaders are responsible for promoting a culture of safety in which Staff can readily report incidents in order to learn and work to improve the safety of patient care.

3.3. Program / Site Directors

It is the responsibility of the Program Directors and Leader(s) of a given Patient or Resident Care Area, Department, Program or Service to ensure that adequate reporting and follow-up of incidents is completed, emphasizing a non-punitive quality improvement approach.

3.4. Risk Management

The responsibility for overseeing this policy is delegated to the Risk Manager. See also Appendix C for a list of roles and individual accountabilities.

4. Compliance

Failure by Staff to comply with this policy may result in disciplinary action, up to and including the loss of privileges or termination of employment.

5. Procedure

5.1. Reporting

If an incident occurs:

- Provide the necessary care and services required to treat the patient, resident, and their family.

- Report the incident to the immediate supervisor/leader. Notify the MRP, depending on severity (mandatory for critical incidents and "must report" incidents).
- Complete the Patient Safety Event Report form in PSLS and assign a handler. All incidents should be reported within 24 hours of occurrence. The reporter should include their name in the report unless there is a concern about possible repercussions as a result of the report, in which case anonymous reporting is supported.

All "must report" critical incidents will be assigned a severity level of at least 4, even if the apparent severity is less.

Record the facts only of the incident on the patient's chart, including the results of any examinations or tests; what injuries, if any, were sustained; and any treatments which may have been administered. Completing a PSLS report is an administrative process, and this does not need to be recorded in the chart.

If the incident is thought to be related to the use/failure of an electronic device, medical supplies, devices or medications, please manage as directed in Appendix F.

5.2. Handling

5.2.1 For all Incidents

Managers, leaders and directors are all responsible for reviewing details on the PSLS report, including a review to ensure that the information entered on the form is complete and accurate. PSLS reviews are to be initiated within 5 days of the report being completed.

Confirm that any device/equipment involved is secured according to the direction in Appendix F.

Confirm that appropriate individuals have been notified about the incident, including the patient/resident/family and providers. Contact the Risk Manager if there is any question about whether disclosure is required.

Determine if any follow-up is required. Record the results of any investigation/case review in the "Follow-up" section of the PSLS report. If follow-up is required by someone other than the handler, you can create a new "Action" or simply email from within PSLS in order to assign the work to the appropriate individual.

Ensure that the follow-up Actions are completed. No harm events (severity level 1) should be moved into final approval within 20 days of reporting and actions are not required in these cases. Minor and moderate harm events (severity level 2 & 3) should be moved into final approval within 30 days of reporting.

5.2.2 For Critical Incidents

PSLS will provide automatic email notification to the Risk Manager and appropriate leaders of all incidents that lead to severe harm or death (severity level 4 or 5).

Patient Care Managers or their delegate, in consultation with Risk Management if required, will:

1. Determine whether further notification to any of the following is required:
    - The Medical Director/Physician Director of the program affected (probably appropriate in most cases)
    - The coroner (604-660-7708), in the event of reportable death
    - The RCMP/VPD (e.g. foul play is suspected)
    - Patient Care Quality Office (local 68284) if a complaint is likely
    - Employee and Family Assistance Program for staff support
    - The Ministry (in consultation with Risk Management, using the decision support tool in Appendix D)

2. Ensure that all Staff involved with the patient or assigned to the patient at the time of the event document their observations/understanding of the event as soon as possible. Documentation of the facts of the event should be in the patient chart. Documentation of opinions/suggestions for improvement should be on the PSLS form.

3. Work with Risk Manager to assist with investigation and coordination of reviews.

Severe harm events (severity level 4 & 5) should be moved into approval in PSLS within 60 days of reporting. Critical incident reviews should be completed within 90 days of the event.

6. Supporting Documents

6.1. Related Policies

Incident Reporting Policy for Employees

Safe Reporting

7. Definitions

"Critical Incident": 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 in PSLS.

"Culture of safety": A culture that acknowledges the high-risk nature of an organization's activities, a blame-free environment where individuals are able to report errors or near misses without fear of reprimand or punishment, encourages collaboration across ranks and disciplines to see solutions to patient safety problems and commits resources to address safety concerns.

"Error": An error is a failure to carry out a planned action as intended or application of an incorrect plan. Errors may manifest by doing the wrong thing (commission) or by failing to do the right thing (omission), at either the planning or execution phase

"Handler": The person identified to take the lead role on following up an incident.

"Incident (patient safety incident)": An event or circumstance that could have resulted, or did result, in unnecessary harm to a patient.

"Most Responsible Provider ("MRP")": Medical staff member, Nurse practitioner or Midwife

"Must Report Incidents": Incidents that the PHC Senior Leadership Team have agreed must be reported whenever they occur, regardless of severity. Please see Appendix A for a list of "must report" critical incidents.

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

"Patient": Intended to encompass everyone who receives health services across the continuum of care (e.g. patient, client, resident, tenant).

"PSLS": The Patient Safety Learning System – a web-based tool used by healthcare providers across BC to report patient safety concerns such as adverse events, good catches and hazards. Available on PHC Connect.

"Reporter": The person who completes a Patient Safety Event Report form in PSLS. Reports are to be completed for incidents, critical incidents and near misses. At Providence Health Care, every Staff member is a potential Reporter.

"Staff" for the purposes of this policy means all employees (including management and leadership), Medical Staff Members (including physicians, midwives, dentists and Nurse Practitioners), residents, fellows and trainees, health care professionals, students, volunteers, contractors and other service providers.

8. References

1. Protocol for Health System Response to Adverse Events and Service Issues: BC Ministry of Health, March 22, 2012
2. PHSA Board Policy AS 120: Hazards, Injuries, Harm, Adverse Events and Near Misses: Non-Punitive Reporting June 24, 2010
3. Patient Safety Event Management August 2009 (FHA policy)
4. Management of Incidents Involving Patients/Clients January 2007 (VCH policy)
5. Incident Management April 2011 (Island Health policy)
6. Sunnybrook & Women's Policy I-P-2800: Accountability for Patient Safety March 2005

7. National Quality Forum Serious Reportable Events

Questions

Contact: Risk Management and/or Patient Safety

9. Appendices

Appendix A: Must report" critical incidents
Appendix B: Severity level/degree of harm
Appendix C: Roles and accountabilities
Appendix D: Risk assessment & situation response
Appendix E: Individual and system accountabilities
Appendix F: Management of equipment involved in an incident

Appendix A: Must Report Critical Incidents[1]

In addition to the "Must Report Critical Incidents" listed below, Program areas may define their own list of Must Report Critical Incidents, which will be communicated throughout the Program by Program leaders.

Surgical/Interventional Events

1. Surgery performed on the wrong site
2. Surgery performed on the wrong patient
3. Wrong surgical or other invasive procedure performed on a patient
4. Unintended retention of a foreign object after surgery or another procedure. (Incorrect counts in and of themselves warrant investigation, but are not necessarily considered a Must Report Critical Incident)
5. Intraoperative or immediate postoperative death in an ASA Class I patient

Product or device events

6. Patient death or serious injury associated with the use of contaminated drugs, devices or biologics provided by PHC
7. Patient death or serious disability associated with the use or function of a device in patient care, in which the device is being used for a function other than as intended (i.e. "off-label" use)
8. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in PHC

Patient protection events

9. Discharge or release of a patient/resident of any age, who is unable to make decision, to other than an authorised person
10. Patient death or serious injury associated with patient elopement (disappearance)
11. Patient suicide, attempted suicide or self-harm that results in serious injury while an inpatient, or within 72 hours of being discharged

Care management events

12. Patient death or serious injury associated with a medication error (e.g. errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)
13. Patient death or serious injury associated with unsafe administration of blood products
14. Maternal death or serious injury associated with labour or delivery in a low-risk pregnancy
15. Death or serious injury of a neonate associated with labour or delivery in a low-risk pregnancy
16. Patient death or serious injury associated with a fall while being cared for in any PHC site
17. Any Stage 3, Stage 4 or unstageable pressure ulcer acquired after admission/presentation to a PHC site
18. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen

19. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology or radiology test results.

Environmental events

20. Patient or staff death or serious injury associated with an electric shock
21. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas or is contaminated by toxic substances
22. Patient or staff death or serious injury associated with a burn incurred from any source
23. Patient death or serious injury associated with the use of physical restraints or bedrails

Radiologic Events

24. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area

Potential Criminal events

25. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist or other licensed health care provider
26. Abduction of a patient/resident of any age
27. Sexual abuse/assault on a patient or staff member within or on the grounds of a PHC facility
28. Death or serious injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a PHC facility

NOTE: An adverse outcome that is directly related to the natural course of the individual's illness or underlying condition, for example, terminal illness present at the time of presentation, is not reportable except for suicide in, or following elopement from, an in-patient stay.

Appendix B: Severity level/Degree of harm

Degree of Harm	Description
1 No Harm	An unexpected, undesired event directly associated with care or services reaches the patient but no harm/ injury occurs. **Examples:** Patient receiving codeine post op - physician discontinues order - nurse gives codeine instead of switching to Tylenol - extra dose - no harm. Patient slipped on wet floor while ambulating without assistance - regained balance without falling.
2 Minor Harm	An unexpected, undesired event directly associated with care or services reaches the patient resulting in temporary injury or minor harm, perhaps requiring minor intervention. **Examples:** Patient's IV goes interstitial, red, swollen, sore. OK after a few hours, results in bruise. Patient receives total enteral feed in 1 hour instead of 4 hours. Needs extra bloodwork to check lytes. Patient up to bathroom without assistance after epidural wears off. Falls, red area on knee, some bleeding from incision. Physician examines, ice applied.
3 Moderate Harm	An unexpected, undesired event directly associated with care or services reaches the patient resulting in significant temporary or mild permanent harm, requiring intervention. **Examples:** Patient's IV goes interstitial on pump - limb is hard, site looks burned, plastic surgery consulted, ointment and dressings applied, some scarring occurs. Patient falls out of bed, complains of pain in arm, x-rays reveal fracture, patient spends several additional days in hospital due to pain and mobility issues, needs home care set up before discharge can occur.
4 Severe Harm	An unexpected, undesired event directly associated with care or services reaches the patient resulting in permanent harm with substantial impairment of a person's functional abilities or quality of life and/or requiring major medical/surgical treatment and/or emergency medical treatment to prevent death. **Examples:** Patient falls out of bed, fractures c-spine, requires surgery, extended hospital stay, left with some permanent neurological deficits. Wrong side surgery results in patient's healthy kidney being removed instead of cancerous one. Patient receives x10 dose of IV morphine, has respiratory arrest, requires resuscitation and transfer to ICU but ultimately recovers.
5 Death	An unexpected, undesired event directly associated with care or services reaches the patient resulting in or significantly contributing to the patient's death. **Examples:** Patient is inadvertently given hydromorphone instead of morphine resulting in a massive overdose, respiratory depression and death. Patient's bowel is nicked during abdominal surgery, patient succumbs to massive infection. Patient comes to ED with chest pain, but does not speak English. No interpreter is available and patient, who also has flu-like symptoms, is triaged as low priority by ED staff. Several hours later, while sitting in the waiting area, collapses and dies due to massive cardiac event.

Appendix C: Roles and Accountabilities

Role	Accountability in response to an incident[2]
Staff	• Take necessary steps to mitigate harm to the patient • Report immediately to supervisor/manager/ medical director as appropriate • Disclose to patient and family if appropriate • Report incidents, critical incidents and near misses into PSLS • Secure devices, equipment or clinical supplies that may be needed for investigation of the incident • Participate in system review • Participate in quality improvement activities to reduce or eliminate hazards and reduce injuries, harm and future incidents • Make use of staff support services when needed
Managers/Leaders	• Perform initial review of all PSLS reports • Ensure appropriate level of review of non-critical incidents • Provide feedback to reporters on the reporting process and review outcomes • Collaborate with staff to identify area-specific opportunities for improvement • Identify, convene and participate in critical incident investigations • Ensure appropriate disclosure has occurred • Forward action items to other programs or departments for further follow-up as necessary • Ensure action on recommendations • Report out on the findings and actions to the program Quality & Patient Safety Committee
Directors	• Review initial investigation, analysis and follow-up actions of severity level 4 & 5 events to ensure appropriateness and comprehensiveness • Identify and support quality improvement activities • Report to responsible SLT member
Program Quality & Patient Safety Committees	• Review cumulative incident data in order to identify trends and opportunities for improvement activities • Review all incidents with severity level 4 & 5 and determine appropriate forum for review – see Appendix E • Designate committee members to facilitate critical incident reviews • Receive and endorse recommendations from review committees

[2] Descriptions assume that the situation has been stabilized and the patient/family/visitor's immediate needs have been met

	• Support quality improvement initiatives • Monitor implementation of recommendations • Report on recommendations to the PHC Quality, Patient Safety & Clinical Risk Committee
Risk Management	• Receive and ensure completion of all incident reports and follow-up records. Determine whether a critical incident review is required • Notify SLT when a critical incident has occurred • Ensure appropriate disclosure has occurred, and facilitate if required. In cases where large scale disclosure is required, and/or where population health and safety is at risk, the Ministry may be involved in or lead the disclosure process. • Ensure that the appropriate individuals (Medical Director/Leader, Program Director, Operations Leader, appropriate Program VP, Site Leader, Risk Manager) meet as soon as possible to review the completeness of the initial reports and determine the nature of any actions required (including whether or not a Critical Incident Review is required) • Notify HCPP as required • Determine the required level of organisational response, utilising the risk assessment/heat map provided by the BC Ministry of Health and facilitate investigation as required • Report to BC Ministry of Health as required • Respond to requests from HCPP, Coroner and legal representatives. • Receive and compile all reports for quality and legal purposes. • Assist with/facilitate incident investigation as necessary • Maintain PSLS database to facilitate trending and reporting • Identify trends across sites, populations and programs as possible • Link with other departments and programs regarding indicator data for trending, reporting, and improving outcomes • Communicate trend information by providing reports to programs, departments and administrators • Provide education in event follow-up and analysis • Establish structured processes for incident review, including critical incident review and analysis • Work with the Healthcare Protection Program to address liability issues arising from incidents • Report to the Senior Leadership Team and the Quality & Performance Improvement Committee of the Board on a regular basis • Participate in provincial learning opportunities

Quality, Patient Safety & Clinical Risk Committee	• High level PSLS review • Receive Program Q&PS Committee reports • Forum for dissemination and discussion (and possibly broader adoption) of recommendations generated by critical incident reviews
Communications	• Responsible for leading and coordinating communications regarding large scale disclosure in collaboration with Government Communications and Public Engagement.
SLT	• Receive Risk Management reports • Approve recommendations and allocate resources as required • Remove barriers to implementation of approved recommendations • Monitor performance and outcome of risk prevention, mitigation or management strategies • Advocate for external support – Health Authorities, MOH, etc. • Provide Support and guidance to Medical Teams • Provide leadership for adherence to this policy
MAC	• Receive Risk Management reports • Receive summary of Department/Division M&M reviews • Approve recommendations which are within the authority of MAC • Make recommendations for resource allocations to SLT • Make recommendations regarding quality to Board as appropriate • Monitor performance and outcome of risk prevention, mitigation or management strategies through Quality and Safety initiatives • Make recommendations to Department Heads and Medical Staff members regarding appropriate actions and follow-up • Provide recommendations to MAC CfE as appropriate • Provide assistance to PHC and the PHC Board regarding aspect of medical staff related issues and concerns regarding follow-up • Help address cross Medical Department issues
Board	• Receive Risk Management and MAC reports • Authorize resource allocation decisions as required • Provide direction to SLT and MAC as required on recommended actions and follow-up

Appendix D: Risk Assessment and Situation Response

The Ministry of Health ("Ministry") requires that the following risk assessment be used to determine the required level of response. It is recognised that the assessment may need to be revised in the short or medium term given changes to escalation and/or impact risks as the situation unfolds.

Risk Assessment/Heat Map

Escalation						
	5 Large numbers of patients or staff, or impact across provinces; high current or anticipated external interest	Moderate	Moderate	High	Extreme	Extreme
	4 Several patients or staff in each of several HAs; significant current or anticipated external interest	Low	Moderate	High	High	Extreme
	3 Several patients or staff, or could involve other HAs; moderate current or anticipated external interest	Low	Moderate	Moderate	Moderate	High
	2 One patient or staff member, may affect others locally; some current or anticipated external interest	Low	Low	Moderate	Moderate	High
	1 One patient or staff member, isolated event; no external interest or none anticipated	Low	Low	Low	Moderate	Moderate
		1	**2**	**3**	**4**	**5**
		Insignificant; no harm event; hazard identified. No service issue identified.	Minor; actual, perceived or near miss of minor harm to patient or staff; minor disruption to single facility or program. Service issue may be identified.	Moderate; actual perceived or near miss of moderate harm to patient or staff; moderate disruption to single facility/ program. Service issue identified.	Major; actual or near miss of severe harm to patient or staff; significant disruption/impact to single facility or program. Health system compromised.	Catastrophic; actual or near miss of death of multiple patients or staff; multiple people suffer permanent harm and/or death; permanent disruption or loss of facilities or programs. Health system compromised.
		Impact				

Utilising the risk assessment rating, the Risk Manager will use the following chart to determine the level and type of Ministry involvement required:

Low	Informing Ministry of the event is optional.
Moderate	Ministry must be informed of the event, initial impacts and actions as soon as possible; Ministry will advise what information is required for reporting and may provide ad hoc direction on the management of the event.
High	Ministry must be informed of the event, initial impacts and actions immediately; Ministry and health authority may jointly manage the event.
Extreme	Ministry must be informed of the event, initial impacts and actions immediately; Ministry may direct the management of the event.

In events assessed as Moderate, High and Extreme, the Ministry and PHC Risk will jointly determine whether the involvement of other health authorities is necessary in management of the event.

The Board Chair will be notified by a member of the Senior Leadership Team in advance of any event where the Ministry is being informed. Risk Management will use their discretion in providing notification of any other critical incident to the Board Chair.

Appendix E: Individual and System Accountabilities

The flow chart on the following page is intended to be used in collaboration with this grid to help identify the type of review required.

	Individual[3]	System
Honest mistake	• Report incident • Participate in systems review • Suggest remedial actions • Assist in development and testing of remedial actions	• Consider preparing a safety alert for local dissemination and/or beyond organization when appropriate • Systems review • Develop improvements • Implement improvements
Honest mistake but fails substitution test	As above, plus • Additional training • Mentoring program when available	As above, plus • Search for mitigating factors such as training, supervision, workload
Deliberate violation of protocol	As above, plus • Consult with professional organization	As above, plus • Internal investigation • Modification of duties when appropriate
Possible ill health of staff, including substance abuse	As above, plus • Assessment and treatment based on human resources and occupational health policies and procedures	• Internal investigation • Notify occupational health • Notify professional colleges when appropriate
Intentional harm or criminal act	Seek counsel (Legal counsel, Risk Manager, HR advisor)	• Internal investigation • Notify VP Medical Affairs and VP Professional Practice • Notify police when appropriate • Notify professional colleges when appropriate • Suspension if patients or staff are perceived to be at immediate risk

[3] Adapted from Sunnybrook & Women's accountability framework

Appendix F: Management of equipment involved in an incident

Category	Example	Immediate action	Disposition
Electronic device	Infusion pump, ventilator	Remove from service and label **DO NOT USE.** Document the serial number or any identifying inventory number in PSLS	Arrange for device to be sent to Biomedical Engineering
Rolling stock or equipment	Commode chair, bed brakes	Remove from service and label DO NOT USE. Document the serial number or any identifying inventory number in PSLS	Arrange for the equipment to be sent to Facilities Maintenance and Operations for the appropriate service for repairs.
Medication or IV fluid	Unlabelled syringe, IV bag	Preserve rather than discard.	Await instruction from Pharmacy or Risk Management.
Clinical equipment or supply	IV tubing, gloves, cleaning solutions	Preserve rather than discard. Complete the Clinical Product / Supplies & Equipment Complaint Form and fax to HSSBC.	Place product in an appropriate biohazard bag / container and await further instruction from clinical supplies & equipment.

Effective Date:	November 9, 2022			
First Released:	01-May-2000			
Last Revised:	November 9, 2022			
Last Reviewed:	November 9, 2022			
Approved By:	PHC			
	Senior Leadership Team / Executive Sponsor: Norm Peters			
Owners:	PHC			
	Patient Safety & Risk Management			
Revision History:	**Version**	**Date**	**Description/ Key Changes**	**Revised By**
	3	9-Nov-2022	Minor updates	Camille Ciarniello