




Health and Wellness

Policy: Serious Reportable Event Interim Reporting Policy

Originating Branch: Healthcare Quality, Patient Safety & Wait Time Improvement

Original Approval Date: 2012/12/13 **Effective Date:** 2013/12/22

Approved By: 
Frances Martin, A/Deputy Minister Health and Wellness

Version #:1.0

1. POLICY STATEMENT

1.1. This policy aims to inform the Department of Health and Wellness (DHW) of current risks to patient safety and quality issues facing the health system by requiring District Health Authorities (DHAs) and the IWK Health Centre (IWK) to report serious reportable events (as outlined in the policy) in a timely and standardized manner.

2. DEFINITIONS

In this policy:

2.1. **Adverse Event:** means collectively:

- 2.1.1. a patient safety incident which is an event or circumstance which could have resulted in or did result in unnecessary harm to a patient; and
- 2.1.2. a harmful incident which is a patient safety incident that resulted in harm to the patient.

2.2. **Disability:** means a physical or mental impairment that substantially limits one or more of the major life activities of an individual.

2.3. **Patient:** means an individual who receives services or support from health care providers who are employed by or privileged to DHAs/IWK. For the purposes of this policy, the term also includes those referred to as clients and/or residents.

2.4. **Serious Reportable Events:** a subset of adverse events adopted from Saskatchewan's Critical Incident Reporting Guidelines (2004); and adapted as necessary for the Nova Scotia context. A serious reportable event is an adverse health event which results in serious disability or death and includes but is not limited to the actual or potential loss of life, limb or function related to a health care service provided by a DHA or the IWK (see Appendix A).

3. POLICY OBJECTIVES

The objectives of the policy are to:

- 3.1. Provide a standardized reporting process for serious reportable events from DHAs/IWK to the DHW.
- 3.2. Enhance communication between the DHAs/IWK and the DHW regarding serious reportable events including the response to these events in a timely and consistent manner.
- 3.3. Allow the DHAs/IWK and DHW to collaboratively monitor, measure and evaluate serious reportable event data.
- 3.4. Enhance collaboration between the DHAs/IWK and the DHW for the purpose of identifying opportunities for coordinated, province-wide preventative and proactive improvements to the healthcare system through the analysis of serious reportable event data.
- 3.5. Improve DHA/IWK/DHW accountability and transparency of serious reportable event reporting in the Nova Scotia healthcare system.
- 3.6. Maintain public trust in the health care system.

4. APPLICATION

- 4.1. This policy applies to all DHAs listed under the *Health Authorities Act* and to the IWK.
- 4.2. This policy does not apply to continuing care service providers, including licensed nursing homes, resident care facilities, or funded and approved Home Care Agencies or Home Oxygen Vendors. These facilities will continue their current reporting practices to the Continuing Care Branch of DHW. Any events that fall under the jurisdiction of the *Protection for Persons in Care Act* will continue to be reported as per established processes.

5. POLICY DIRECTIVES

- 5.1. This policy will require two streams of reporting of serious reportable events to the DHW:
 - telephone notification of specified serious reportable events (as outlined in sections 5.2 to 5.5 below) and
 - aggregate quarterly reporting of Serious Reportable Events (as outlined in sections 5.6 to 5.8 below).

Telephone Notification:

- 5.2. The DHA/ IWK shall notify the DHW by telephone as soon as reasonably practical of serious reportable events which meet any one or more of the following criteria:

- involve multi-person disclosure that may have significant system-wide or cross jurisdictional implications; or
- are perceived as a threat to the health of the public; or
- have the potential to undermine public confidence in the health system.

5.2.1. The DHA/IWK shall continue to follow existing processes to notify the provincial Medical Officer of Health pursuant to the requirements of the Health Protection Act.

5.2.2. The DHA/IWK shall continue to follow existing processes to report disaster management events through the Emergency Response System.

5.2.3. This Policy does not replace any other DHW Policy which may require specific reporting to the DHW Duty Officer/administration.

5.3. The DHA/IWK shall communicate only factual details of the serious reportable event, however, personal identifying information of patients or providers **must not** be provided. The following information shall be provided and will be documented by DHW staff:

- Name of caller;
- District/Organization;
- Date of the event;
- Time of the event;
- Location of the event;
- Nature of the event, limited to the provision of the category of the incident from the DHW/DHA/IWK list of Serious Reportable Events (see Appendix A).
- Type of persons involved in the incident (staff, patient, others);
- Who has been notified within the District/Organization; and
- Whether the requirements of the DHA/IWK's policy(s) in relation to disclosure of the event have been met (has the information been shared with the patient/family).

5.4. The DHW will document all incoming calls and use the information received to:

- inform/update the Minister as necessary;
- communicate information to the most appropriate DHW branch; and
- provide support (as necessary) to the DHA/IWK throughout the district's investigation of the event.

5.5. The DHW and the DHA/IWK shall work collaboratively to coordinate their respective communications in relation to responding to the serious reportable event as necessary.

Aggregate Quarterly Reporting:

5.6. The DHA/IWK shall report quarterly, to the DHW, the aggregate number of events for each event type as defined in the *DHW/DHA/IWK List of Serious Reportable Events* (See Appendix A).

5.7. The quarterly reports of Serious Reportable Events as detailed in section 5.6 above shall be

submitted via email to the DHW no later than 20 business days after the end of each fiscal quarter.

5.8. The DHW will collate, analyse and trend the aggregate data received to:

- identify any areas of high risk to patient safety which may extend beyond the DHA/IWK which has experienced the event(s);
- explore opportunities for greater implementation of preventive practices on a province-wide basis; and
- share, subject to the any applicable legislation or policies, lessons learned and aggregate data with other health systems stakeholders.

6. POLICY GUIDELINES

6.1. The DHA/IWK will continue to manage adverse events according to their own policies and procedures.

7. ACCOUNTABILITY

7.1. For the purpose of the administration of this policy, accountability is delegated to the Deputy Minister of Health and Wellness.

7.2. The Executive Director of Health System Quality has responsibility for on-going monitoring and enforcement of this policy.

8. MONITORING / OUTCOME MEASUREMENT

8.1. The Executive Director of Health System Quality will monitor the implementation, performance and effectiveness of this policy.

9. REPORTS

n/a

10. REFERENCES

- 10.1. *Disclosure of Adverse Events Policy, 2005*
- 10.2. *Health Protection Act, 2004 (amended 2010)*
- 10.3. *Protection for Persons in Care Act (2007)*
- 10.4. *Saskatchewan Health Critical Incident Reporting Guideline, 2004*

11. APPENDICES

- 11.1. Appendix A: DHW/DHA/IWK List of Serious Reportable Events
- 11.2. Appendix B: Telephone Notification Algorithm

12. INQUIRIES

12.1. Inquiries regarding this policy should be directed to:

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13. VERSION CONTROL

Version Control:	Department of Health and Wellness Serious Reportable Event Interim Reporting Policy
	Draft 0.1, Nov 01, 2013 (Original)
	Draft 0.2, Nov 22, 2013 (Revised Appendix B)
	Draft 0.3, Nov 29, 2013 (Revisions from Provincial Quality Directors Group)
	Draft 0.4, Dec 3, 2013 (Revised with Final feedback from Provincial Quality Directors Group)
	Draft 0.5, Dec 11, 2013 (Revised with feedback from CDHA and IWK)
	Version 1.0, Dec 13, 2013 (Revised with feedback from IWK)

APPENDIX A: DHW/DHA/IWK List of Serious Reportable Events

Serious Reportable Event refers to an adverse health event as defined in the Nova Scotia Department of Health and Wellness Serious Reportable Event Interim Reporting Policy which results in serious disability or death and includes but is not limited to the actual or potential loss of life, limb or function related to a health care service provided by a DHA or the IWK.

The following is a list of events that must be reported to the Nova Scotia Department of Health & Wellness pursuant to the Nova Scotia Department of Health and Wellness Serious Reportable Event Interim Reporting Policy.

The final item in each category allows for the possibility of adverse health events that fit the description given above, but were not anticipated when the list was created. Such events are also reportable.

1. SURGICAL EVENTS

Surgery includes endoscopies and other major invasive procedures

- a. Surgery performed on a wrong body part
Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.
- b. Surgery performed on the wrong patient
Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.
- c. The wrong surgical procedure performed on a patient
Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.
- d. Retention of a foreign object in a patient after surgery or other procedure
Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.
- e. Death during or immediately after surgery of an ASA classification I-II¹ patient
Includes procedures where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately after surgery means within 24 hours of surgery or other invasive procedure, or, if surgery was not completed, within 24 hours of induction of anesthesia.

¹ ASA Classification I - Normal healthy patient, II - A patient with mild systemic disease. Canadian Anesthesiologists' Society. *Appendix II: American Society of Anesthesiologists' Classification of Physical Status.*

- f. An adverse health event leading to death or serious disability associated with any other surgical event while a patient is receiving a health care service provided by a DHA or the IWK

2. PRODUCT OR DEVICE EVENTS

- a. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by a DHA or the IWK
Includes generally detectable contaminants such as infectious matter or foreign substances in drugs, devices, or biologics regardless of the source of contamination and/or product.
- b. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended
Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, ventilators, and mechanical devices used to lift, bathe, or shower patients.
- c. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for by a DHA or IWK
Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
- d. An adverse health event leading to death or serious disability associated with any other product or device while a patient is receiving a health care service provided by a DHA or IWK

3. PATIENT PROTECTION EVENTS

- a. An infant discharged to the wrong person
- b. Patient death or serious disability associated with patient disappearance
Excludes events involving competent adults.
- c. Patient suicide or attempted suicide resulting in serious disability while being cared for by a DHA or the IWK
Defined as events that result from patient actions after admission to a facility or program of the DHA or IWK. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to a hospital.
- d. An adverse health event leading to death or serious disability associated with any other patient protection event while a patient is receiving a health care service provided by a DHA or the IWK

4. CARE MANAGEMENT EVENTS

- a. Patient death or serious disability associated with a medication or fluid error including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration
Excludes reasonable differences in clinical judgment on drug selection and dose.
- b. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products
- c. Maternal death or serious disability while being cared for by a DHA or the IWK
Includes events that occur within 42 days post-delivery.
- d. Full-term fetal or neo-natal death or serious disability associated with labour or delivery while being cared for by a DHA or the IWK
Full-term fetus is >37 completed weeks gestation. Neonate refers to the first 28 days of life. Includes failure to screen for and prevent neonatal post-discharge dehydration or illness related to phenylketonuria.
- e. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for by a DHA or the IWK
- f. Neonatal death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia
Hyperbilirubinemia is defined as bilirubin levels >500 μ mol/L. Neonate refers to the first 28 days of life.
- g. Stage 3 or 4 pressure ulcers acquired after admission to a facility of a DHA or the IWK
Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
- h. Patient safety incident, related to diagnosis, where the treatment provided or not provided leads to patient death or serious disability.
- i. An adverse health event leading to death or serious disability associated with any other care management event while a patient is receiving a health care service provided by a DHA or the IWK

5. ENVIRONMENTAL EVENTS

- a. Patient death or serious disability associated with electric shock while being cared for by a DHA or the IWK
Excludes events involving planned treatments such as electric countershock.
- b. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- c. Patient death or serious disability associated with a burn incurred from any source while being cared for by a DHA or the IWK
- d. Patient death associated with a fall while being cared for by a DHA or the IWK
- e. Patient death or serious disability associated with the use or lack of restraints or bedrails while being cared for in a facility
- f. An adverse health event leading to death or serious disability associated with any other environmental event while a patient is receiving a health care service provided by a DHA or the IWK

6. CRIMINAL EVENTS

- a. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other health care provider
- b. Abduction of a patient of any age
- c. Sexual assault of a patient that occurs on grounds owned or controlled by a DHA or the IWK
- d. Patient death or serious disability from a physical assault that occurs on grounds owned or controlled by a DHA or the IWK
- e. Any sexual or physical assault of a patient perpetrated by an employee, member of the medical staff, volunteer, student or an individual under contract with a DHA or the IWK
Includes, but is not limited to, assaults perpetrated at a patient's home while receiving home care or mental health services.
- f. An adverse health event leading to death or serious disability associated with any other criminal event while a patient is receiving a health care service provided by a DHA or the IWK

APPENDIX B: Telephone Notification Algorithm

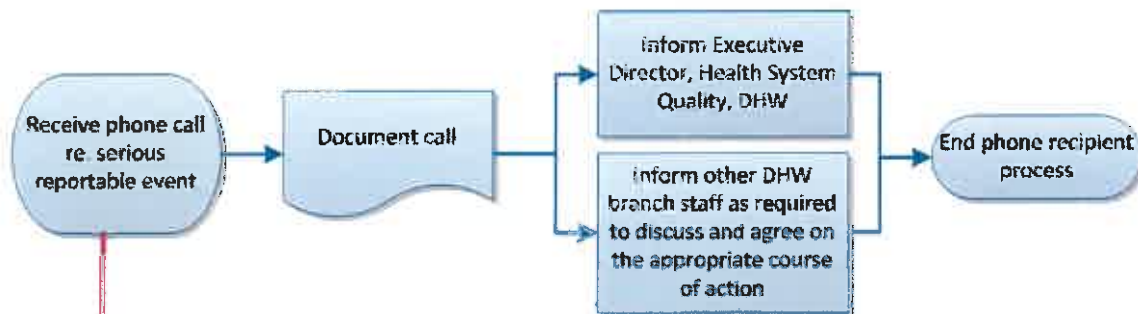
The DHA/IWK will adhere to the following process:



Be prepared to provide the following:

- Name of caller;
- District/Organization;
- Date of the event;
- Time of the event;
- Location of the event;
- Nature of the event, limited to the provision of the category of the incident from the DHW/DHA/IWK list of Serious Reportable Events.
- Type of persons involved in the incident (staff, patient, others);
- Who has been notified within the District/Organization; and
- Whether the requirements of the DHA/IWK's policy(s) in relation to disclosure of the event have been met (has the patient/family been informed).

The 'telephone notification recipient' will adhere to the following process:



- Health System Quality staff will receive calls on business days (0800-1600)
- DHW Duty Officer will receive calls during non-business hours; Duty Officer will follow existing processes in response to the call