Policy:	**Serious Reportable Events Reporting Policy**
Originating Branch:	**Systems, Performance and Partnerships (Quality & Patient Safety)**
Original Approval Date:	12/13/2012
Effective Date:	12/22/2013 Revised 02/01/2021 Revised 05/02/2024 Revised 09/24/2024 Revised 01/23/2025
Approved By:	 **Deputy Minister Health and Wellness**
Version: 3	

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 the Nova Scotia Health Authority (NSHA), the IWK Health Centre (IWK) and the Emergency Health Services (EHS) system operator to report Serious Reportable Events (SREs) (as defined in this policy) in a timely and standardized manner.

1.2 This policy is made under the authority of the *Health Authorities Act*, the *Emergency Health Services Act,* and the *Quality-improvement Information Protection Act* (QIIPA).

- Under section 6 of the *Health Authorities Act,* the Minister has the authority and responsibility to set the strategic direction of the health system, establish policies, standards and guidelines for the provision and administration of health services and establish informational requirements and standards for health-information systems. Under sections 5 and 8, the Minister has the authority to ensure accountability for monitoring, measuring, and evaluating the quality, efficiency, accessibility, and comprehensiveness of health services delivered by the health authorities.
- Under section 4 of the *Emergency Health Services Act*, the Minister has the authority to monitor, inspect and evaluate ambulance services, emergency health services and communications-centre services. Under section 5, the

Minister has the authority to establish standards for the management, operation and use of ground and air ambulances providing emergency or non-emergency services, for emergency health services and for communications-centre services.

- Under section 4 of the *Quality-improvement Information Protection Act*, the Minister may direct a quality-improvement committee (of the EHS system operator, the NSHA and/or IWK) to provide to the Minister such quality-improvement information that does not include personal health information or personal information and recommendations that do not include personal health information or personal information, as the Minister directs, in any form the Minister directs, for the purposes only of planning and managing the health system or conducting Province-wide quality-improvement activities.

2. DEFINITIONS

In this policy:

2.1 Emergency Health Services (EHS) system operator means an organization contracted by the Minister to provide emergency health services throughout the province.
2.2 Healthcare Organization means the Nova Scotia Health Authority, the IWK Health Centre, or the EHS system operator.
2.3 Patient means an individual who receives services or support from a health authority, the EHS system operator, or from healthcare providers who are employed by or privileged to a health authority or the EHS system operator.
2.4 Patient Safety Improvement Plan means a written description of how the organization intends to respond to SREs that are most pertinent to their organization, including the rationale and methods to be applied.
2.5 Patient Safety Improvement Report means a written summary of the patient safety improvement initiatives that were implemented during the previous year, including which initiatives have been expanded to other areas and/or have been implemented province wide.
2.6 Quality Improvement Activity means an activity of a quality improvement committee or any other activity that is part of a program or plan

(i) approved by a health authority, the Minister or an entity referred to in clause 3(1)(c) of the Quality Improvement Information Protection Act, and
(ii) implemented for the purpose of assessing, investigating, evaluating or making recommendations respecting the provision of health services by a health authority, the Minister or an entity referred to in clause 3(1)(c) of the Quality Improvement Information Protection Act, with a view to maintaining or improving the quality of health services.

2.7 Quality Improvement Committee means a committee established to carry out quality improvement activities.
2.8 Quality Improvement Information means information in any form that is communicated for the purpose of, or created in the course of, carrying out a quality improvement activity.
2.9 Quarterly Reporting means reporting on fiscal year quarters (Q1: April-June, Q2: July-September, Q3: October- December and Q4: January-March).
2.10 Serious Harm means a significant change in the ability of patients to function as they did before the event.

2.11 Serious Reportable Event or **SRE** means an unintended event that occurred while receiving a health service that results in death or serious harm to the patient and does not result primarily from the patients' underlying medical condition or from a known risk inherent in providing the service. Also included are events that fall within the Regulatory and Potential Criminal Events category. Some of these types of events may not be unintentional or result in harm but are serious and require tracking and reporting. All serious reportable events are listed in Appendix A and Appendix B, and are reportable to the Department of Health and Wellness in accordance with this policy.

3. POLICY OBJECTIVES

The objectives of this policy are to:

3.1 Provide a standardized reporting process for SREs and quality improvement planning and results from the Healthcare Organizations to DHW.
3.2 Enhance communication between the Healthcare Organizations and DHW regarding SREs, including the response to these events in a timely and consistent manner.
3.3 Allow the Healthcare Organizations and DHW to collaboratively monitor, measure and evaluate SRE data.
3.4 Enhance collaboration between the Healthcare Organizations and DHW for the purpose of identifying opportunities for coordinated province-wide, preventative and proactive improvements to the healthcare system through the analysis of SRE data.
3.5 Improve Healthcare Organization and DHW accountability and transparency of SRE reporting in the Nova Scotia healthcare system.
3.6 Ensure DHW oversight of SREs and maintain public trust in the healthcare system.

4. APPLICATION

4.1 This policy applies to DHW, NSHA, IWK and the EHS system operator.
4.2 This policy does not apply to continuing care service providers including licensed nursing homes, resident care facilities, funded and approved Home Care Agencies or Home Oxygen Vendors, or community hospices. These facilities will continue their current reporting practices to the Department of Seniors and Long-term Care (DSLTC) or the NSHA, as the case may be. Any events that fall under the jurisdiction of the *Protection for Persons in Care Act* will continue to be reported as per established processes.
4.3 This policy does not affect the obligation of the Healthcare Organizations to follow existing processes to notify the Chief Medical Officer of Health pursuant to the requirements of the *Health Protection Act*, to report disaster management events through the Emergency Response System, to report incidents pursuant to the requirements under the *Protection for Persons in Care Act*.
4.4 This policy does not replace any other legislation, policy, contractual or other requirement for reporting to DHW.

5. POLICY DIRECTIVES

5.1 This policy will require two streams of reporting of SREs to DHW.

5.1.1. E-mail notification of a specific subset of SREs (as outlined in sections 5.2 to 5.5 below) and
5.1.2. Aggregate quarterly reporting of SREs (as outlined in sections 5.6 to 5.9 below).

Notification of Specific Subset of SREs

5.2 A Healthcare Organization shall notify DHW by e-mail (SREreporting@novascotia.ca), as soon as reasonably practical, of all SREs which meet any one or more of the following criteria:

- Involve multi-person disclosure that may have significant system-wide or cross jurisdictional implications;
- Are or would be reasonably perceived as a threat to the safety of the public;
- Have the potential to undermine public confidence in the health system.

5.3 In making a notification under section 5.2, a Healthcare Organization shall communicate only factual details of the SRE, without disclosing personal identifying information of patients or providers.

The following information shall be provided by the Healthcare Organization and will be documented by DHW:

5.3.1 Name of person contacting DHW
5.3.2 Name of Healthcare Organization and Zone (if applicable)
5.3.3 Location of the event (geographic)
5.3.4 Applicable Service / Care Area (such as EHS, Emergency Room, Surgical Unit etc)
5.3.5 Date of the event
5.3.6 Time of the event
5.3.7 The type of incident from the list of SREs in Appendix A and Appendix B
5.3.8 Type of persons involved in the incident (staff, patient, others)
5.3.9 Who has been notified within the Healthcare Organization
5.3.10 Whether the requirements of the Healthcare Organization's policy(s) in relation to disclosure of the event have been met, including whether the information has been shared with the patient and/or family
5.3.11 Contact information for follow-up if needed.

5.4 The assigned Quality and Patient Safety (QPS) team member with DHW will document all incoming e-mails pursuant to section 5.2 and inform, in writing, the following:

- Deputy Minister
- Chief, Strategy, Performance and Partnerships
- Senior Executive Director, Planning, Performance and Digital
- Senior Executive Director/Executive Director for impacted Branch
- Director, Performance and Accountability

5.5 DHW shall provide support (as necessary) to the Healthcare Organization throughout the investigation of the event. DHW and the Healthcare Organization shall work collaboratively to coordinate their respective communications in relation to responding to the SRE, as necessary.

Aggregate Quarterly Reporting of SREs

5.6 A Healthcare Organization shall report quarterly, to DHW, the aggregate number of events for each category and type of incident from the list of SREs in Appendix A and Appendix B.

5.7 A Healthcare Organization shall submit the validated quarterly reports of SREs pursuant to section 5.1 to DHW via Secure File Transfer no later than 20 business days after the end of each fiscal quarter.

5.8 A Healthcare Organization shall include an SRE in the quarterly report for the quarter in which the SRE is discovered. SREs newly discovered from past reporting quarters shall be reported in the quarter they are discovered but will be identified or noted separately as having occurred in an earlier quarter.

5.9 DHW shall publicly report SREs on DHW website no later than 35 business days after the end of a fiscal quarter.

Submission of Patient Safety Improvement Plan and Report

5.10 Pursuant to Section 4 of the *Quality-improvement Information Protection Act*, a Healthcare Organization shall submit to DHW an annual Patient Safety Improvement (PSI) Plan describing how they intend to respond to SREs that are most pertinent to their organization and a PSI Report summarizing the patient safety improvement initiatives that were implemented during the previous year, that do not include personal health information or personal information, arising out of the review of any SRE by a Quality Improvement Committee of the Healthcare Organization.

5.11 The Healthcare Organization shall submit the PSI Plan and PSI Report to the Senior Strategist, Quality and Patient Safety, within 40 business days after the start of each fiscal year.

Analysis and Sharing Lessons Learned

5.13 A Healthcare Organization shall collate, analyse, and provide to DHW information regarding trends in the SRE data and patient safety improvement initiatives to:

- Identify any areas of high risk to patient safety which may extend beyond the Healthcare Organization which experienced the event(s).
- Explore opportunities for greater implementation of preventative practices on a province-wide basis; and
- Subject to applicable legislation and policies, share lessons learned and aggregate data with other health systems stakeholders.

6. POLICY GUIDELINES

6.1 The Healthcare Organizations will continue to manage SREs according to their own policies and procedures.
6.2 The Healthcare Organizations and DHW shall ensure that their staff are trained and knowledgeable about this policy.

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 Director or delegate, Performance and Accountability has responsibility for ongoing monitoring and enforcement of this policy.

8. MONITORING / OUTCOME MEASUREMENT

8.1 The Director or Delegate, Performance and Accountability will monitor the implementation, performance, and effectiveness of this policy.

9. REPORTS

9.1 The Healthcare Organizations will submit aggregate quarterly reports and annual Patient Safety Improvement Plans and Reports as required by Section 5 of this policy.

10. REFERENCES

10.1 Canadian Patient Safety Institute (2015) *Never Events for Hospital Care in Canada*
10.2 Canadian Patient Safety Institute (2012) *Critical Incident Analysis Framework*
10.3 Canadian Patient Safety Institute (2011) *Patient Safety in Emergency Medical Service*
10.4 National Quality Forum (2011) *Serious Reportable Events in Healthcare*
10.5 Saskatchewan Health Critical Incident Reporting Guidelines (2023)
10.6 Ground and Air Medical Quality in Transport (2023) *Quality Improvement Consensus Metrics*
10.7 Identifying a List of 'Never Events' to Effect System Change: A Systematic Review and Narrative Synthesis, *British Medical Journal* (2023)
10.8 National Health Services' *Patient Safety Incident Response Framework* (2022)
10.9 *Protection for Persons in Care Act*, *2018*
10.10 *Health Authorities Act, 2019*
10.11 *Quality Improvement Information Protection Act*, *2022*
10.12 *Emergency Health Services Act, 2017*
10.13 *Health Protection Act, 2021*

11. APPENDICES

11.1 *Appendix* A: DHW / NSHA / IWK List of Serious Reportable Events / IWK LIST OF SERIOUS REPORTABLE

11.2 *Appendix B:* EHS system operator List of Serious Reportable Events / IWK LIST OF SERIOUS REPORTABLE

12. VERSION CONTROL

Version: 5	Department of Health and Wellness Serious Reportable Event Reporting Policy Version 1.0, Dec. 13, 2013 Version 2.0, Feb. 1, 2021 Version 3.0, May 2, 2024 Version 4.0, Sept. 24, 2024 REVISED JAN. 23, 2025

13. INQUIRIES

13.1 Inquiries regarding this policy should be directed to:

Director or Delegate
Performance and Accountability
Nova Scotia Department of Health & Wellness
Email: Duncan.Stewart@novascotia.ca

APPENDIX A

DHW / NSHA / IWK List of Serious Reportable Events

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

1. SURGICAL EVENTS

Surgery includes endoscopies and other major invasive procedures.

a. **Surgery performed on the wrong body part or the wrong patient or conducting the wrong procedure.**
Defined as any surgery performed on a body part or patient or procedure conducted 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. **Unintended retention of a foreign object in a patient after surgery or other procedure**
Excludes objects intentionally implanted as part of a planned intervention, objects present prior to surgery that were intentionally retained and objects not present prior to the procedure that are intentionally left in when the risk of removal exceeds the risk of retention (such as micro-needles, broken screws).
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c. **Death during or immediately after surgery of an ASA Class I or II patient**[1]
Includes procedures where anesthesia was administered; the planned surgical procedures 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.

2. PRODUCT OR DEVICE EVENTS

a. **Patient death or serious harm associated with the use of improperly sterilized instruments or equipment, or contaminated drugs, devices, or biologics provided by NSHA/IWK.**
Includes 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 harm 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.

[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.

c. **Patient death or serious harm associated with intravascular air embolism that occurs while being cared for by NSHA/IWK.**
Excludes deaths associated with neurosurgical procedures known to present a high risk of intravenous air embolism.

d. **The wrong tissue, biological implant or blood product was given to a patient.**

3. PATIENT PROTECTION EVENTS

a. **Discharge or release of a patient of any age, who does not have decision-making capacity in regard to decisions about the patient's personal care, to the care of someone who does not have custody of the patient, or decision-making authority in regard to medical or personal care of the patient.**

b. **Patient under the highest level of observation leaves a secured facility without the knowledge of staff.**
This event pertains only to patients whose condition (e.g., dementia, psychosis, at risk of suicide) requires them to be cared for in a secure facility or unit. It can involve a patient deliberately leaving the ward or facility, or accidentally wandering away.

c. **Patient suicide, or attempted suicide that resulted in death or serious harm, in instances where suicide-prevention protocols were to be applied to patients under the highest level of observation while being cared for by NSHA/IWK.**
Defined as events that result from patient actions after admission to a facility or program of the NSHA/IWK. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to a hospital.

4. CARE MANAGEMENT EVENTS

a. **Patient death or serious harm associated with a medication or fluid error including but not limited to errors involving the wrong drug, wrong dose, 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 harm associated with the delay or improper administration of blood or blood products.**

c. **Maternal death or serious harm while being cared for by NSHA/IWK.**
Includes events that occur within 42 days post-delivery.

d. **Full-term fetal or neonatal death or serious harm associated with labour or delivery while being cared for by NSHA/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 of illness related to phenylketonuria.

e. **Patient death or serious harm as a result of failure to identify and treat metabolic disturbances.**

This event will focus only on hypoglycaemia in an admitted patient and hyperbilirubinemia in neonates (defined as bilirubin levels>500 mol/L). Neonate refers to the first 28 days of life.

f. Stage 3 or 4 pressure ulcers or unstageable pressure injuries acquired after admission to a facility of NSHA/IWK.
Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.

Includes, but is not limited to, events where:

- *The pressure ulcer was reasonably preventable considering the patient's underlying condition(s), the care plan, circumstances and context, and clinical judgment,*
- *There was equipment malfunction, breakdown, misuse or a failure to provide necessary equipment that could have contributed to the development or progression of the pressure ulcer,*
- *The use or misuse of restraints was a contributing factor in the development or progression of the pressure ulcer,*
- *There was a breach of policy that could have contributed to the development or progression of the pressure ulcer,*
- *There were modifiable environmental factors involved that contributed to the development or progression of the pressure ulcer.*

g. Patient death or serious harm, related to diagnosis, as a result of the treatment provided or not provided.

h. Patient death or serious harm due to a failure to inquire whether a patient has a known allergy to medication, or due to administration of a medication where a patient's allergy had been identified.

5. ENVIRONMENTAL EVENTS

a. Patient death or serious harm associated with electric shock while being cared for by NSHA/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 harm associated with a burn incurred from any source while being cared for by NSHA/IWK.

d. Patient death associated with a fall while being cared for by NSHA/IWK.
Excludes those events where patient and/or family member have chosen to live with known fall risk with mobilization.

Includes, but is not limited to, events where:

- *The fall was reasonably preventable considering the patient's underlying condition(s), the care plan, circumstances and context, and clinical judgment,*
- *There was equipment malfunction/failure, breakdown, misuse or a failure to provide necessary equipment that could have contributed to the fall,*
- *The use or misuse of restraints was a contributing factor in the fall,*
- *There was a breach of policy that could have contributed to the fall,*
- *There were modifiable environmental factors involved that contributed to the fall.*

e. Patient death or serious harm associated with the use or lack of restraints or bedrails while being cared for in a facility.

f. Patient death or serious harm due to uncontrolled movement of a ferromagnetic object in an MRI area.

6. REGULATORY AND POTENTIAL CRIMINAL EVENTS

a. Any instance of care ordered by or provided by someone impersonating a licensed healthcare provider.
b. Abduction of a patient of any age.

c. Sexual abuse or assault of a patient that occurs on or in the property owned or controlled by the NSHA/IWK.

d. Patient death or serious harm from a physical assault that occurs on or in the property of NSHA/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 NSHA/IWK.
This includes, but is not limited to, assaults perpetrated at a patient's home while receiving home care or mental health services.

APPENDIX B

DHW / EHS Pre-hospital Care List of Serious Reportable Events

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

7. EHS PRE-HOSPITAL CARE EVENTS

a. Medication administration error
Includes wrong patient, drug, dose, route, time, technique or documentation.

b. Adverse drug event during transport resulting from medication use

c. Unplanned dislodgement of therapeutic device
Includes endotracheal tube, tracheostomy tube, supraglottic airway, IVs, central venous lines, arterial lines, umbilical artery or venous catheter, and intraosseous access.

d. Hypoxia during transport
Pulse oximetry drops below 90% and excludes those with chronic oxygen saturations lower than 90%.

e. Medical equipment failure
Examples include IV pumps and ventilators that malfunction during transport, broken monitor leads, empty medical gas tanks, etc.

f. Decision making and clinical judgment error
Not following treatment protocols, inappropriately discharging patient from care, basic life support paramedics unable to determine need for advanced care paramedics.

g. Transport-related patient injury
Includes a patient fall, a loose piece of transport equipment that falls and strikes the patient, injury suffered in a transport vehicle accident, etc.

h. Undue delay in response or treatment for any reason, resulting in death or serious harm
This event focuses on those in cardiac arrest, having an ST elevated myocardial infarction (STEMI), stroke or have sustained major trauma.

i. Patient death or serious harm during the offload period.