University Health Network
Policy & Procedure Manual
Clinical: Patient Safety Event Reporting & Review

Policy

University Health Network (UHN) is committed to creating a culture where leaders, physicians, staff, learners, volunteers, patients, and families speak up for safety. Safety and eliminating preventable harm to patients and visitors are everyone's responsibility. UHN will maintain a framework for identification, analysis, management, and monitoring of patient safety events and near miss events.

All staff and physicians must:

- report safety events and near miss events using the UHN Safety Event Reporting & Review eForm as soon as possible following an actual or potential occurrence
- disclose to patients/substitute decision makers (SDMs) in accordance with Disclosure of Safety Events to Patients policy 3.20.007

The following types of safety events must be reported:

- issues involving patient care (e.g. medications, falls, infection control-related events, diagnostics, adverse events related to implantable devices or medical equipment, treatment)
- events related to visitors (e.g. falls)
- privacy incidents
- workplace violence events where a patient is harmed or has the potential for harm

All safety events resulting in an injury/illness or potential injury/illness to staff, physicians, learners, volunteers, or agency/contract staff, including workplace violence incidents, must be reported through the online Safety Event Portal under the Workplace Safety Event link. (Refer to Accident/Incident Reporting & Investigation policy 6.60.001, Reporting a Critical Injury or Fatality policy 6.60.002, and Violence & Domestic Violence in the Workplace policy 6.30.004 for further details.) Events can also be reported within the health information system (HIS) by selecting the **Safety Event eForm** tab.

Note: Reviews of safety events are done for quality assurance purposes only. They are done on a confidential basis to ensure full participation of all physicians and staff in the process. Safety event reports contain confidential information and should not be printed and/or distributed; however, factual information contained in a

safety event report may be provided to the patient to whom the incident relates upon request. (Refer to Privacy policy 1.40.007.)

All safety events will be reviewed using the UHN Safety Event Cause Analysis process to ensure a consistent and coordinated approach. This consists of the following phases:

- initiation
- screening
- analysis
- development
- implementation
- sharing
- monitoring

Each procedure is further outlined in the Safety Event Review Procedures. This document contains policies and procedures for:

- Patient Safety Events
- Expectations for Reviewing a Patient Safety Event:
  a. Staff and Physicians
  b. Managers, Delegates, MRPh
  c. Clinical Director or Medical Lead
  d. Vice-Presidents
  e. Quality of Care Committees (QCC)
  f. Quality Improvement and Patient Safety Specialist
  g. Quality Assurance and Compliance Specialist
  h. Recommendation Owners
- Procedures:
  a. Workplace Violence Events
  b. Privacy Incidents:
     i. Staff Member or Physician
     ii. Researchers and Patient Notification
     iii. Manager of Affected Unit/Department
     iv. Privacy Office

Patient Safety Events

All patient safety events are reviewed using one of the following four review approaches (described further in the Safety Event Review Procedures):

- Local Review
- Debrief
- Root Cause Analysis (RCA)

- Multi-Incident Review

The following general review timelines must be followed, regardless of the review type:

Table 1: Timeline of Patient Safety Event Procedures

Phases	Timeline		Phase Description
Initiate	0 to 24 hours		When a potential safety event is identified
Screen	24 to 48 hours		Determine the appropriate safety event review required
Analyze	2 to 4 weeks		Conduct a safety event review, and identify and report incidents that meet the criteria for Vanessa's Law to Health Canada
Develop	2 to 4 weeks		Develop recommendations to address causes
Implement	2 to 3 months	Or in parallel	Implement proposed recommendations
Share	2 to 3 months		Share the root causes and recommendations
Monitor	6 to 12 months		Completion and evaluation of recommendations

Notes:

- Listed timelines are for the current phase only. Each time period starts from the end of the previous phase.
- The Implement, Share, and Monitor phases can be done in parallel once the event is reviewed at the site Quality of Care Committee (QCC).
- For Debriefs and Multi-Incident Reviews, the Develop and Analyze phases are done **simultaneously** within a 2-week timeframe from the Screen phase.
- For RCA's, the Develop and Analyze phases are done as **two distinct phases**, each with a 2 to 4-week timeframe.
- For additional information regarding the Quality of Care Information Act and Vanessa's Law, see:
  a. Appendix E: Quality of Care Information Protection Act (QCIPA)
  b. Appendix F: Vanessa's Law

Expectations for Reviewing a Patient Safety Event

Staff and Physicians

All staff and physicians who identify potential patient safety events must ensure the appropriate steps are followed. This includes any immediate measures to ensure the patient's or visitor's safety, securing of event related items and safety event reporting within 24 hours. They are also responsible for notifying the appropriate manager, most responsible physician (MRPh), and/or the most responsible practitioner (MRPr). The MRPh/MRPr must be informed in accordance with Paging Protocols, Response Times & Escalation of Emergent, Urgent & Non-urgent Clinical Care Concerns policy 3.10.039. Physicians must also complete initial disclosure to patients/SDMs in accordance with Disclosure of Safety Events to Patients policy 3.20.007. Physicians must also complete initial disclosure to patients/SDMs in accordance with Disclosure of Safety Events to Patients policy 3.20.007.

Staff and physicians involved in the safety event must participate in the Initiate to Analyze phases of **local reviews** for events that are not potential serious safety events (SSEs) 1 to 4 (i.e. near-miss events, precursor safety events) and **debriefs**. Physicians and staff who are directly involved in a safety event undergoing a RCA will be asked to participate in RCA 1:1 interviews led by quality improvement and patient safety specialists.

Further guidance on these specific roles are outlined in the Safety Event Review Procedures.

Manager/Delegate/MRPh

Immediately following a safety event, managers/delegates/MRPhs must support individuals involved in the safety event, ensure that immediate risk is mitigated, and assist those involved with adhering to the steps outlined in the Safety Event Review Procedures. These steps are to be followed within 24 hours of event occurrence. In addition, managers/delegates/MRPhs must take remedial action, if needed, to ensure safety is established, and inform their leader/supervisor of the event (e.g. via the huddle structure), as appropriate.

Unit managers are responsible for leading and completing **local reviews** with unit staff, as well as collaborating with the quality assurance and compliance specialist to determine eligibility for Vanessa's Law reporting (refer to Appendix F: Vanessa's Law). This must be completed within 2 to 4 weeks each for review and developing local recommendations. The unit manager must also complete the Manager's Report section in the UHN Safety Event Reporting & Review eForm with the findings.

For **debriefs**, managers are responsible for compiling a sequence of events and attending the debrief meetings, in addition to completing the Manager's Report section in the UHN Safety Event Reporting & Review eForm.

Where a **RCA** is performed, managers must facilitate and support completion of the RCA, which is to be completed in a 2 to 4-week timeframe for each of the Analyze and Develop phases, by providing the leading quality improvement and patient safety specialist with names of individuals directly involved in the safety event, and communicating priority of participating staff/physicians.

The MRPh or Patient Relations specialist must ensure that final disclosure to the patient/family/SDM is completed in accordance with Disclosure of Safety Events to Patients policy 3.20.007 within 2 to 3 months of recommendation implementation.

Clinical Director (CD) or Medical Lead

CDs/medical leads are responsible for initiating and leading the **SSE screen call/meeting** for potential SSEs 1 to 4 within 24 to 48 hours of event occurrence. They are also responsible for ensuring completion of initial mitigations in accordance with Disclosure of Safety Events to Patients policy 3.20.007. When appropriate, the CD is responsible for invoking the Quality of Care information Protection Act (QCIPA) at the start of the SSE screen call/meeting. (Refer to Appendix E: Quality of Care Information Protection Act (QCIPA).)

CDs/medical leads are responsible for leading the safety event **debrief** for potential SSEs 1 to 4, ensuring attendance by appropriate stakeholders and appropriate disclosure to the patient/SDM as per Disclosure of Safety Events to Patients policy 3.20.007. They are responsible for confirming the Safety Event Classification (SEC) within 14 days of event reporting.

It is also the CD/medical lead's role to invoke the QCIPA at the beginning of the debrief.

For potential SSEs 1 to 4, the quality improvement and patient safety specialist must be notified of the event and invited to attend the debrief.

The Incident Review section in the UHN Safety Event Reporting & Review eForm must be completed by the CD/medical lead with the findings from the debrief.

For potential SSEs 1 to 4 which also meet the criteria outlined in the Safety Event Review Procedures and that may pose organizational risk or delay in debrief, CDs/medical leads must ensure appropriate escalation to their aligned vice-presidents (VPs).

During the debrief, the CD/medical lead is responsible for leading the development of recommendations for causes identified during the debrief and ensuring recommendation

owners and due dates are identified. After the debrief, CDs/medical leads must review recommendations at appropriate quality committees for approval within 2 to 4 weeks and complete the Recommendation section in the UHN Safety Event Reporting & Review eForm.

For all event review types, the CD/medical lead are responsible for sharing recommendations with their respective teams within 2 to 3 months from review completion.

Note: Multi-incident reviews follow the review phases and timelines; however, multiple events with commonalities are grouped together for analysis. The specified turnaround time may not apply in the case of a multi-event review and will be determined on a case-by-case basis.

For a **RCA**, the CD/medical lead may be identified as **root cause sponsors**. Root cause sponsors are responsible for:

- working with the leading quality improvement and patient safety specialist to identify RCA team members
- ensuring initial disclosure to the patient/SDM has occurred (in accordance with Disclosure of Safety Events to Patients policy 3.20.007)
- scheduling and prioritizing all RCA team meetings in alignment with the review phase timelines
- acting as a primary liaison on the RCA team for the aligned patient safety specialist to help ensure that the RCA is completed in the 2 to 4 week timeframe for each of the Analyze and Develop phases

The CD/medical lead is also responsible for managing the overall quality of RCA outcomes. Specific guidelines of tasks to be followed for CDs/medical leads can be found in the Safety Event Review Procedures.

Vice-Presidents (VPs)

VPs will receive escalation from CDs/medical leads when a potential SSE 1 to 4 meets criteria for organizational risk as outlined in the Safety Event Review Procedures, or when an event encounters delay to debrief.

For RCAs, VPs of the impacted area(s) may be asked to participate as an executive sponsor, and are responsible for participating in the Analyze and Develop phases and for ensuring escalation to senior leadership as required.

Quality of Care Committees (QCCs)

The appropriate **quality committees** (UHN QCC or UHN QCC delegate committee) are responsible for auditing completion of recommendations, reviewing SSE 1 to 4 audit

results, and evaluating the findings within a 2 to 3 month timeframe. The aligned QCC must notify recommendation owners and request that new strategies are developed when strategies are found to be ineffective in addressing the cause.

Note: Site and/or UHN QCCs **may both** be responsible for evaluating effectiveness of recommendations.

Quality Improvement and Patient Safety Specialist (PSS)

The quality improvement and PSS must review all new potential SSEs 1 to 4 reported through the UHN Incident Reporting & Review eForm (Monday to Friday) and follow up with the manager/CD/medical leads where the safety event occurred within 24 hours (on business days) of being reported.

Quality improvement and PSSs must support CDs/medical leads in initiating the appropriate safety event review process for potential SSEs 1 to 4. This includes collaborating with the quality assurance and compliance specialist to ensure reporting of events that meet Vanessa's Law criteria (refer to Appendix F: Vanessa's Law) are completed within a 2 to 4 week timeframe.

The quality improvement and PSS should provide adequate support for **debriefs of potential SSEs 1 to 4**. For events reviewed under the QCIPA (refer to Appendix E: Quality of Care Information Protection Act (QCIPA)), the quality improvement and PSS must ensure addition of the review to the appropriate QCC agenda. If a debrief has not occurred within 14 days of reporting, the quality improvement and PSS must escalate to the director of Quality, Safety & Clinical Adoption. All confirmed SSEs 1 to 4 must be incorporated into the site and UHN Serious Safety Event Rate (SSER).

The quality improvement and PSS is responsible for leading and completing a RCA within a 2 to 4-week timeframe each for the Develop and Analyze phases. The quality improvement and PSS is responsible for working in partnership with key collaborators, RCA team members, RCA executive sponsors and RCA co-sponsors, as well as the quality assurance and compliance specialist, to draft potential recommendations and for leading recommendation meetings within the 2 to 4-week timeframe. With the co-sponsors and executive sponsor, they must also share the RCA findings and recommendations at the appropriate quality committees for approval.

Note: The list of UHN QCC delegate committees can be found in the UHN QCC Terms of Reference, and details of the analysis process are described in the Safety Event Review Procedures.

Note: Where learners are involved in a safety event, the quality improvement and PSS must work with the director of Post-Graduate Medical Education, Wightman-Berris Academy, director of Medical Education, or senior director of Clinical Education to

invite the learner to participate. For RCAs, the learner's medical learner education lead (or a delegate) must be present during learner interviews.

Quality Assurance and Compliance Specialist

The quality assurance and compliance specialist must engage with Quality and Safety team members to verify eligibility of incidents meeting Vanessa's Law criteria (refer to Appendix F: Vanessa's Law) for reporting to Health Canada within the required timeframe. This includes the following activities:

- Weekly review of safety events via the incident reporting system, and follow-up with appropriate stakeholders upon initial assessment.
- Collaboration with the quality improvement and PSS in the review of SSEs, including participation in the debrief process.
- Report incidents that meet the criteria for Vanessa's Law to Health Canada within 30 days.

Recommendation Owners

Recommendation owners are responsible for ensuring completion of corrective actions for long-term recommendations within 2 to 3 months after the recommendation development. Recommendation owners may be asked to share recommendation updates at program, portfolio, or UHN QCCs, and to provide status updates in the Recommendation section of the UHN Incident Reporting & Review eForm.

Recommendation owners should be assigned recommendations which align with the **most proximal deviation** to the patient, as determined by the quality improvement and PSS during analysis. This may not be clear or known until after the review is conducted. If any changes arise, including a change in ownership, the recommendation owners must inform the safety event review team and the aligned quality improvement and PSS of the changes.

Note: Specific guidelines of tasks for recommendation owners can be found in the Safety Event Review Procedures.

Definitions

Cause/root cause: Identified on a potential, rather than conclusive, basis.

Near miss: An unexpected, unusual, or unplanned event where there was a deviation to generally accepted practice standards, but where no harm reached the patient/visitor/

staff because the initiating error was caught before it reached the patient by either a detection barrier built into the process or, sometimes, by chance.

Quality of Care Committee (QCC): A body of one or more individuals that performs quality of care functions designated under the purposes of the Quality of Care Information Protection Act (QCIPA). The activities of a QCC are to study, assess, or evaluate the provision of healthcare with a view to improving or maintaining the quality of healthcare, including critical safety event reviews.

The quality of care information (hereinafter '**information**') collected and/or discussed by the QCC is protected under the Quality of Care Information Protection Act (QCIPA).

Recommendation owner: The person most responsible for overseeing a recommendation. If a committee is responsible, a committee member must be identified to champion the project. If this individual is unknown at the time or not present at the safety event review, a member of the review team will connect with the review team's proposed person most responsible for overseeing the recommendation and be the interim recommendation owner.

Safety event: (Formerly known as "incident.") Any unexpected, unusual, or unplanned event and/or near miss, causing harm or potential harm to:

- patients
- visitors
- staff
- UHN operations

Safety Event Classification System: A coding system which identifies the degree of harm to the patient caused by deviations from generally accepted performance standards (GAPS). The five levels of Serious Safety Events (SSEs) are:

- SSE 1 – Death
- SSE 2 – Severe Permanent Harm
- SSE 3 – Moderate Permanent Harm
- SSE 4 – Severe Temporary Harm
- SSE 5 – Moderate Temporary Harm

Serious safety event (SSE): An unexpected, unusual, or unplanned event where there was a deviation to generally accepted practice standards, resulting in moderate to severe patient/visitor harm or death. (**Note:** Worker safety events are not classified using the SSE classification.)

Severity categories: Ratings used by the Safety Event Report writer and manager signing off. See Appendix B: Safety Event Classification for categories and descriptions.

UHN Safety Event Cause Analysis: The review and analysis process used for SSEs to:

- Learn from safety issues to identify the appropriate system improvements to prevent recurrence.
- Create a culture of continuous quality improvement.
- Collect and manage data to understand trends that will identify organizational risks.

UHN Serious Safety Event Rate (SSER): An indicator that measure the aggregate preventable harm across UHN. The SSER is a volume-adjusted measure of SSEs, those events occurring from a deviation from generally accepted performance standards and resulting in moderate to severe patient harm or death. The SSER is calculated monthly as the number of SSEs for the previous 12 months per 10,000 adjusted patient days for the same time period.

Procedures

Workplace Violence Events

For workplace violence events that do not involve harm or potential harm to patients, see Violence & Domestic Violence in the Workplace policy 6.30.004.

Privacy Incidents

Note: A privacy incident occurs when an agent knows, or has reason to believe, personal health information (PHI) was collected, used (including viewing), or disclosed without proper authorization, and when PHI is lost or stolen.

Staff Member or Physician

1. Identify scope and contain the incident as much and as quickly as possible.
    - Determine if the incident would allow unauthorized access to any additional PHI (e.g. an electronic information system) and take necessary steps to prevent this from recurring (e.g. change passwords and/or ID numbers, and/or temporarily shut down a system).
    - Take steps to contain the incident by stopping the flow of information or retrieving the information.

- Retrieve hard and/or electronic copies of any PHI that has been disclosed.
- Ensure that no copies of the PHI have been made and/or retained by the individual who was not authorized to receive the information.
- Obtain the recipient's contact information for potential follow-up, if required.
- **If the incident involves a fax:**

    a. Cancel the fax as soon as possible.

    b. If a fax was successfully sent to the wrong healthcare provider (e.g. doctor, nurse, or other healthcare provider), ask the provider to confirm shredding of the pages.

    c. If a fax was sent to a recipient who is not a healthcare provider (e.g. member of the public), retrieve the pages by sending a courier or picking up the paper.

- **If the incident involves an email:**

    a. Delete the email if still in the outbox.

    b. Recall the email and opt for notification of recall success.

        Note: To do this, open the email from the 'Sent Items' folder, select 'Actions', select 'Recall This Message', and check box 'Tell me if recall succeeds or fails for each recipient'. Emails sent to non-UHN email addresses cannot be recalled.

    c. If an email cannot be recalled successfully, request that the recipient confirm deletion of the email from all folders (i.e. both Inbox and Deleted Items folders).

- **If the incident involves other types of media (e.g. electronic devices, papers, etc.):**

    a. Search for papers and devices, and request help (from Housekeeping, Security, and/or report lost or stolen media to police, etc.) if necessary.

    b. Lock up remaining papers and devices at risk.

2. Notify the area manager.

3. For moderate, severe, or critical incidents, notify the Privacy Office.

   - After hours, for critical/severe/moderate incidents, contact the site AOC.

4. Submit an incident report via the UHN Safety Event Reporting & Review eForm, classify the incident as 'Privacy,' and classify the type of privacy incident based on the following criteria:

   - **Near miss:** Incident identified, patient(s) not impacted.

   - **Minor:** Involves identifiable PHI and/or corporate confidential information (CCI), and at least one of the following:

     a. 1 to 10 individuals have been impacted
     b. no risk of intentional harm to individual(s)

   - **Moderate:** Involves identifiable PHI and/or CCI, and at least one of the following:

     a. 11 to 50 individuals have been impacted
     b. minimal risk of intentional harm to individual(s)

   - **Severe:** Involves identifiable PHI and/or CCI, and at least one of the following:

     a. 51 to 100 individuals have been impacted
     b. suspected risk of intentional harm to individual(s)

   - **Critical:** Involves identifiable PHI and/or CCI, and at least one of the following:

     a. more than 100 individuals have been impacted
     b. proven risk and/or confirmed case of intentional harm to individual(s)

   Notes:

   - For incidents that could fit under more than one classification, select the more serious classification (e.g. if an incident affects 5 patients but there is a suspected risk of intentional harm, classify the incident as severe, not minor).

   - "Intentional harm" means PHI will be deliberately be used in an inappropriate manner (e.g. to publicize information, embarrass a patient, or to sell the information).

   - Do not delay submitting a report because of uncertainty about the severity level. The level can be changed at manager sign-off

5. For moderate, severe, or critical incidents, use the Incident Management Checklist found in Appendix A of the UHN Protocol for Managing Privacy Incidents for guidance.

6. Consult with the Privacy Office regarding patient notification.

   Note: Only send patient notifications in an event of a breach if the Privacy Office has recommended a notification and has vetted the content and method of the notification.

7. Engage in investigation and remediation activities, as instructed by the Privacy Office and area manager/AOS.

Researchers and Patient Notification

1. **Researchers:** Contact the Research Ethics Board (REB) and Privacy Office for next steps prior to notifying patients in an event of a suspected or confirmed privacy breach.

Manager of Affected Unit/Department

1. Notify relevant UHN departments (e.g. People and Culture, Patient Relations, Legal Affairs).

2. Complete incident reporting and review processes.

3. Oversee and ensure containment and remediation.

4. Support personnel involved in the incident.

5. Work through tasks in the Incident Management Checklist found in Appendix A of the UHN Protocol for Managing Privacy Incidents.

6. Where the manager and/or Privacy Office deems appropriate, conduct additional review or investigation, such as:

   - review the circumstances surrounding the incident
   - review the adequacy of existing policies and procedures in protecting PHI
   - organizational/departmental training, education review
   - an audit of access to patient records

7. Consult with the Privacy Office regarding patient notification.

   Note: Only send patient notifications in an event of a breach if the Privacy Office has recommended a notification and has vetted the content and method of the notification.

Privacy Office

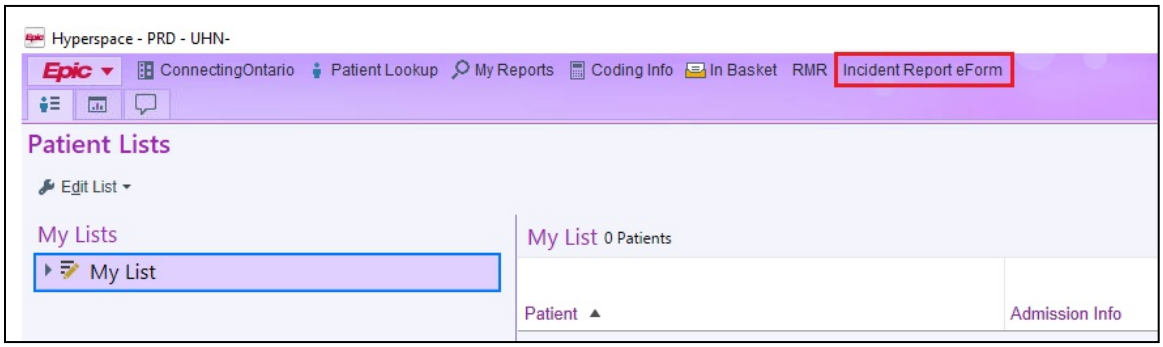
1. Provide guidance in managing containment and remediation.

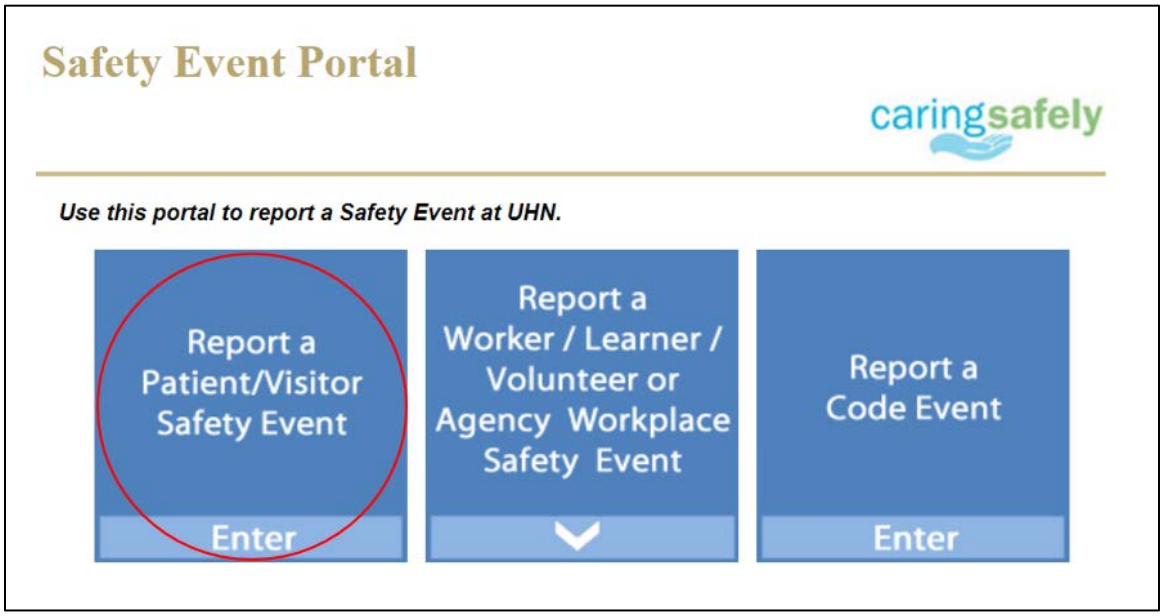
2. Provide guidance on notification plan and materials.

3. Notify the chief legal officer and/or the Office of the Information and Privacy Commissioner (IPC) of new incidents, and provide updates about active incidents.

4. Notify police in appropriate circumstances.

Appendix A: UHN Safety Event Workflow





Safety Event Portal link.

UHN Safety Event Workflow

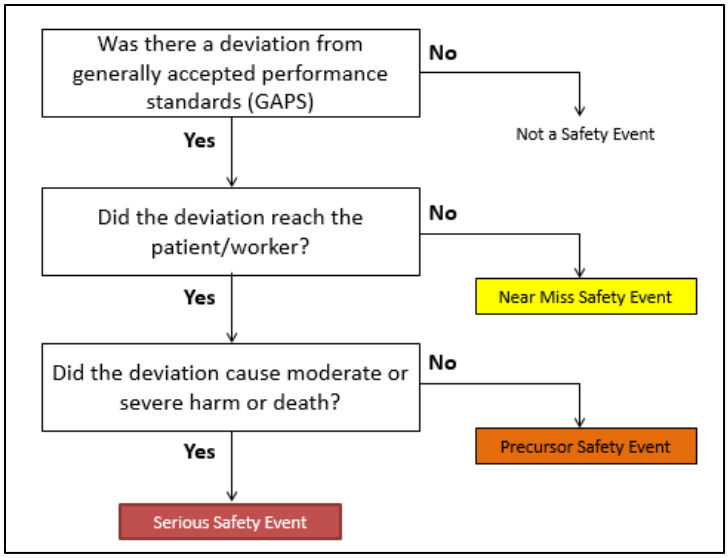
Appendix B: Safety Event Classification

Impact of Safety Event

* Impact of Safety Event:

- ○ **Critical:** Safety event occurred that resulted in, or contributed to, death, near death or permanent harm.
- ○ **Severe:** Safety event occurred that required a medical or surgical intervention necessary to sustain life, or may have contributed to permanent harm and/or prolonged hospitalization, or required admission to acute care from rehab/CCC.
- ○ **Moderate:** Safety event occurred that resulted in temporary loss of function or temporary harm requiring medical intervention. Safety event did not result in prolonged hospitalization.
- ○ **Minor:** Safety event occurred, reached the person(s), caused minor harm or no harm.
- ○ **Near Miss/Potentially Severe:** Safety event occurred but did not reach any person(s). Reaching the person(s) would have resulted in a severe or critical Safety event.
- ○ **Near Miss:** Safety event occurred but did not reach any person(s).
- ○ **Not A Safety Event:** This is not a preventable Safety Event as there was no deviation from generally accepted performance standards.

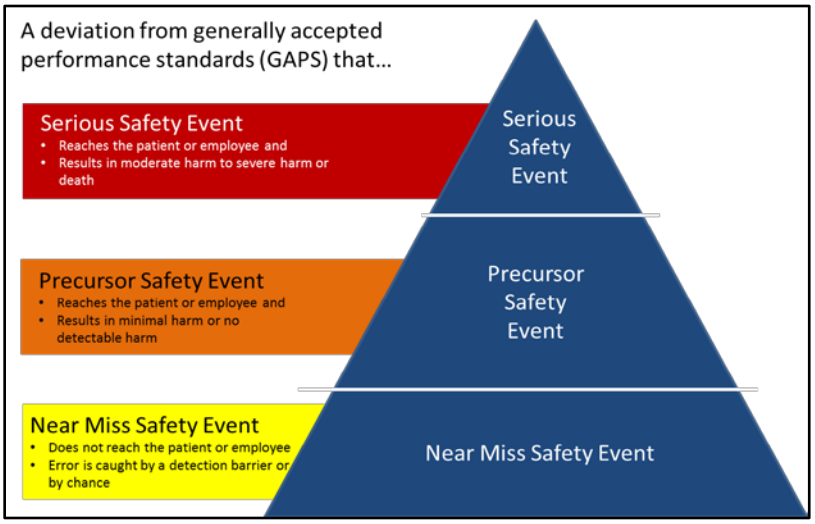
Safety Event Classification Algorithm



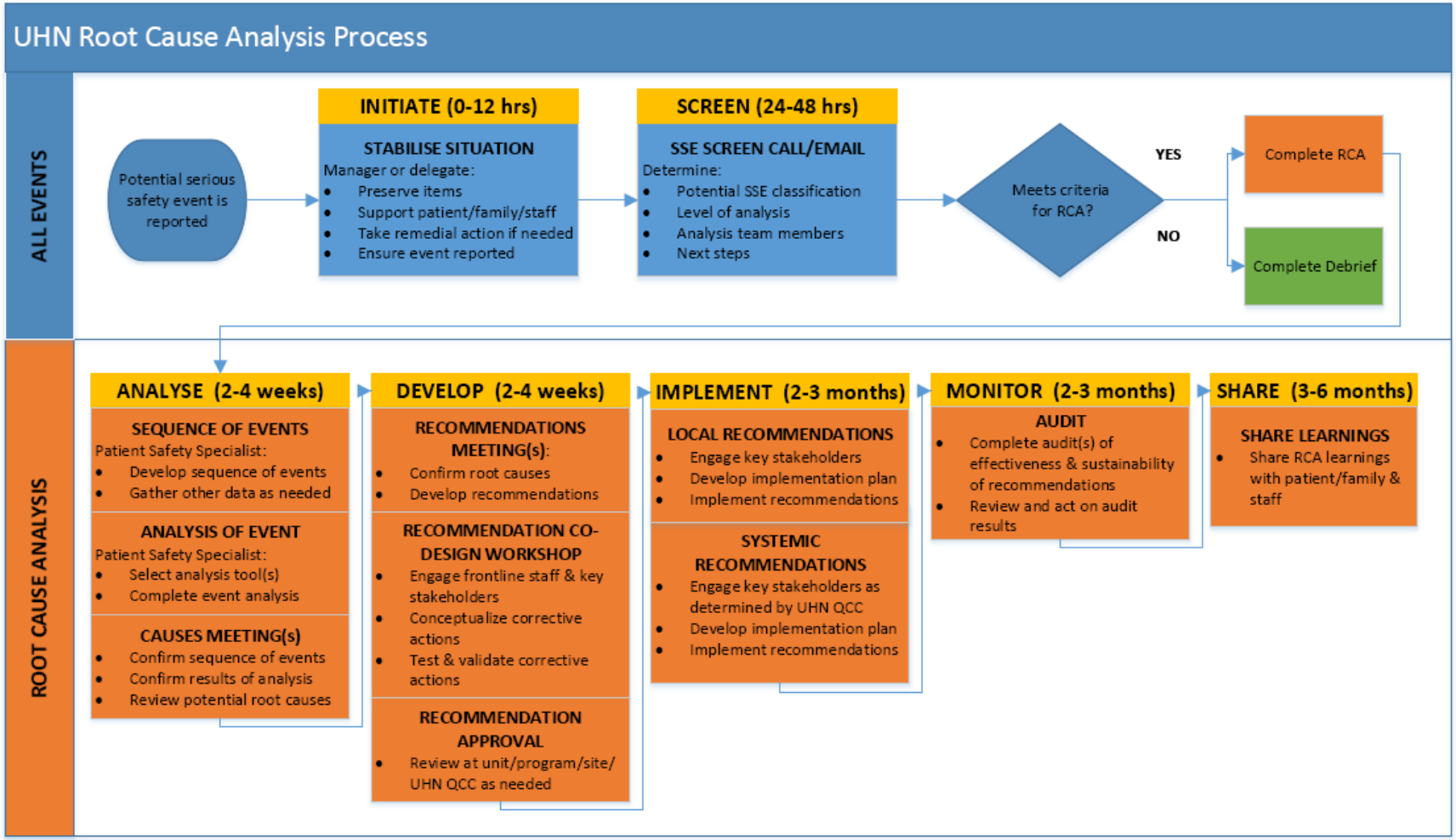
Safety Event Classification Levels of Harm

	Code	Level of Harm	Patient Harm Descriptions
Serious Safety Event	**SSE 1**	**Death**	A deviation in GAPS resulting in death.
	SSE 2	**Severe Permanent Harm**	A deviation in GAPS resulting in critical, life-changing harm with no expected change in clinical status; includes events resulting in permanent loss of organ, limb, or vital physiological or neurologic function.
	SSE 3	**Moderate Permanent Harm**	A deviation in GAPS resulting in significant harm with no expected change in clinical condition yet not sufficiently severe to impact activities of daily living or business functioning; includes events that result in permanent reduction in physiologic reserve, disfigurement, and impaired or aided sense of function.
	SSE 4	**Severe Temporary Harm**	A deviation in GAPS resulting in critical, potentially life-threatening harm yet lasting for a limited time with no permanent residual; requires prolonged transfer to a higher level of care/monitoring, transfer to a higher level of care for a life-threatening condition, or an additional major surgery, procedure, or treatment to resolve the condition.
	SSE 5	**Moderate Temporary Harm**	A deviation in GAPS resulting in significant harm lasting for a limited time; requires a higher level of care/monitoring or an additional minor procedure or treatment to resolve the condition.

Safety Event Classification Pyramid

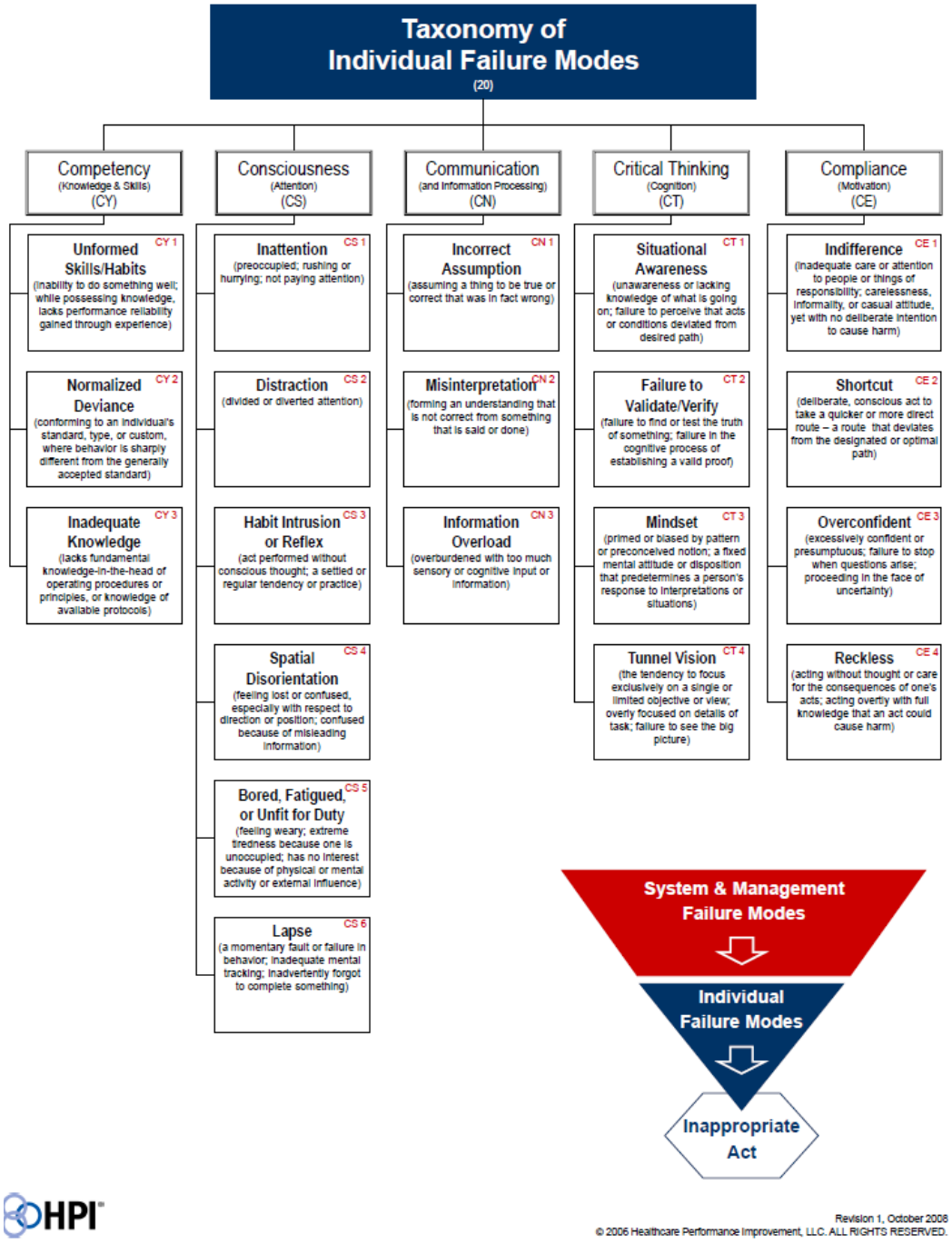


Appendix C: Root Cause Analysis Process

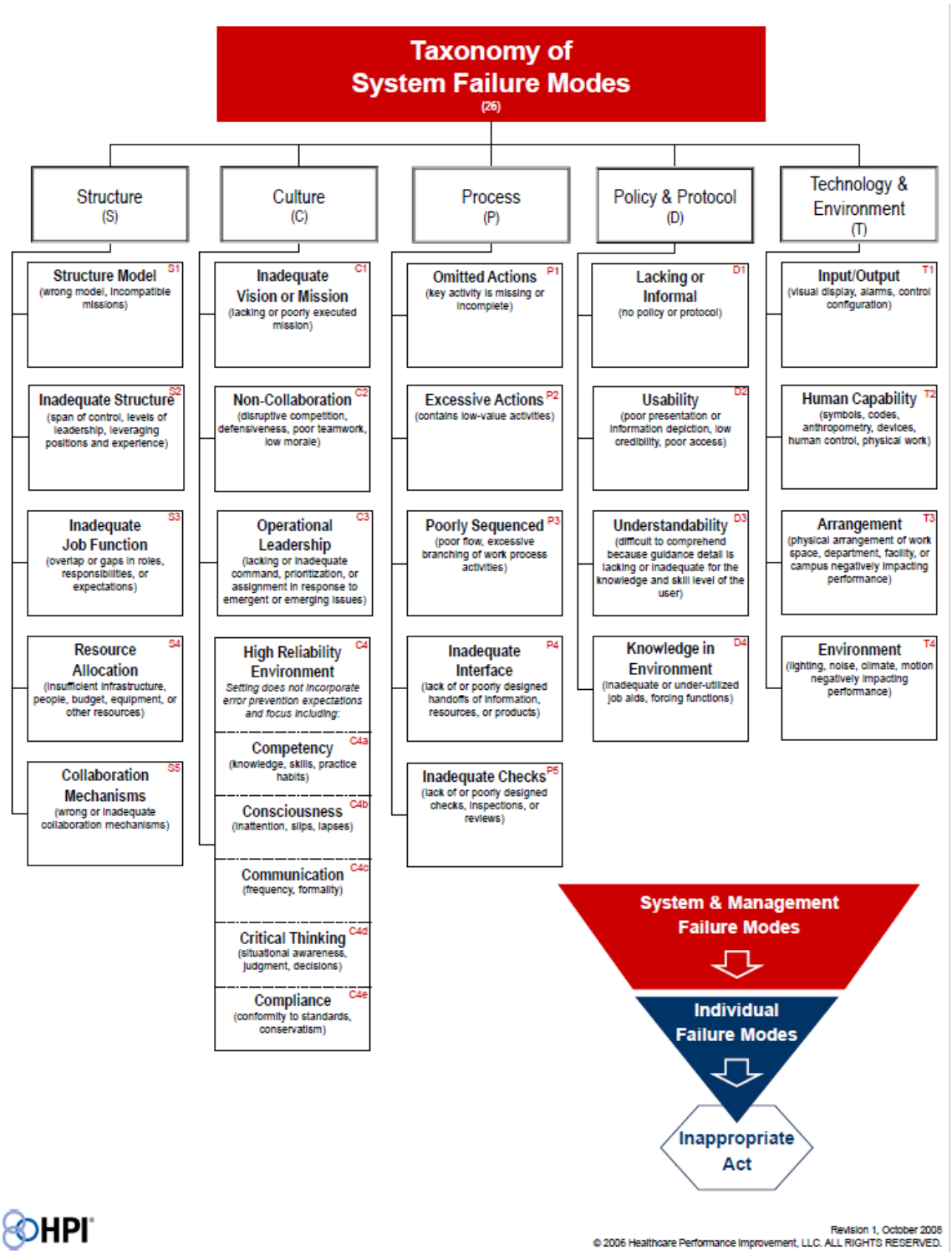


Appendix D: Taxonomy of Failure Modes

Taxonomy of Individual Failure Modes



Taxonomy of System Failure Modes



Appendix E: Quality of Care Information Protection Act (QCIPA)

QCIPA Overview

The QCIPA recognizes "that healthcare providers and other staff in health facilities sometimes need to hold confidential discussions to identify and analyze errors affecting patients, systemic problems and opportunities for quality improvement in patient healthcare." The Act further outlines that "protections are needed to encourage and enable healthcare providers and other staff of health facilities to share all available information, provide honest assessment and opinions and participate in discussions to improve patient healthcare without fear of retaliation." (*QCIPA, Preamble*)

Therefore, the QCIPA provides broad statutory protections to those who participate in the mechanism of a quality review process under the legislation. Under the QCIPA, there is assurance that protected discussions may not be used in collateral proceedings, professional regulatory complaints, and/or civil suits.

What is Protected?

The QCIPA provides the following protections with respect to quality of care information that is provided to a Quality of Care Committee:

- Quality of care information is inadmissible as evidence in a civil proceeding or a matter before a tribunal or regulatory health college. (QCIPA, s. 10)
- No person may be dismissed, demoted, disciplined, or otherwise disadvantaged by reason that they have disclosed information to a quality of care committee. Every person or corporation who contravenes this section is guilty of an offence and subject to a fine. (QCIPA, ss. 11 and 12)
- No action or other proceeding may be instituted against a person who, in good faith, discloses information to a quality of care committee at the request of the committee or for the purposes of assisting the committee to carry out its quality of care functions. (QCIPA, s. 13)
- Persons who disclose quality of care information in contravention of the Act are guilty of an offence and subject to fines. (QCIPA, s. 12)

What is Quality of Care Information?

"Quality of care information" means information that:

- is collected or prepared by or for a quality of care committee for the sole or primary purpose of assisting the committee in carrying out its quality of care

functions,

- relates to the discussions and deliberations of a quality of care committee in carrying out its quality of care functions, or
- relates solely or primarily to any activity that a quality of care committee carries on as part of its quality of care functions, including information contained in records that a quality of care committee creates or maintains related to its quality of care functions. (QCIPA, s. 2(2))

What is not Included?

"Quality of care information" does not include:

- Information contained in a patient record.
- Information contained in a record that is required by law to be created or to be maintained.
- Information relating to a patient in respect of a critical safety event that describes:

  a. facts of what occurred with respect to the safety event,
  b. what the quality of care committee or health facility has identified, if anything, as the cause or causes of the safety event,
  c. the consequences of the critical safety event for the patient, as they become known,
  d. the actions taken and recommended to be taken to address the consequences of the critical safety event for the patient, including any healthcare or treatment that is advisable, or
  e. the systemic steps, if any, that a health facility is taking or has taken in order to avoid or reduce the risk of further similar safety event.

- Information that consists of facts contained in a record of a safety event involving the provision of healthcare to a patient. (QCIPA, s. 2(3))

Appendix F: Vanessa's Law

Vanessa's Law is the mandatory reporting of all documented serious adverse drug reactions, as well as all documented medical device incidents, by healthcare institutions to Health Canada. The process is coordinated by the quality assurance and compliance specialist from the Biomedical Engineering team, in collaboration with the Quality, Safety & Clinical Adoption team.

Criteria

The reporting requirements for hospitals apply to therapeutic products, including:

- pharmaceuticals (prescription and non-prescription)
- biologic drugs (excluding vaccines administered under a routine immunization program of a province or territory)
- radiopharmaceutical drugs (Schedule C to the Food and Drugs Act)
- disinfectants
- medical devices (Section 1 of the Medical Devices Regulations); examples of medical devices, by class, can include:
  a. Class I – hospital beds
  b. Class II – infusion sets
  c. Class III – infusion pumps
  d. Class IV – certain pacemakers/defibrillators

Incidents are categorized as:

- **Adverse drug reaction (ADR):** A noxious and unintended response to a drug that occurs at any dose and that:

  a. requires inpatient hospitalization or prolongation of existing hospitalization, **or**
  b. causes congenital malformation, **or**
  c. results in persistent or significant disability or incapacity, **or**
  d. is life-threatening or results in death

- **Medical device incident (MDI):** An incident related to a failure of a medical device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use that has led to the death or a serious deterioration in the state of health of a patient, user, or other person, or could do so were it to recur

Process

The quality assurance and compliance specialist will review all reported near miss, minor, and moderate safety events through the Safety Event Portal, along with severe and critical safety events forwarded by the Quality, Safety & Clinical Adoption team, to identify if the Vanessa's Law criteria is met for reporting to Health Canada.

Reporting

The quality assurance and compliance specialist will coordinate with appropriate stakeholders within UHN and report all safety events that meet Vanessa's Law criteria, to Health Canada **within 30 calendar days** from first documentation of the incident.