February 2014, Revised January 2021
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REPORTING PATIENT SAFETY EVENTS

What are the different types or classifications of patient safety events?

- > The patient safety events are divided into different types in the <u>BC Patient Safety and</u> Learning System (PSLS).
 - <u>Level 1 No Harm:</u> An event that could cause harm but is caught before it reaches the patient (an almost event).
 - <u>Level 2 Minor Harm:</u> An unexpected, undesired event directly associated with care or services reaches the patient resulting in minor harm / injury.
 - <u>Level 3 Moderate Harm:</u> An unexpected, undesired event directly associated with care or services reaches the patient resulting in moderate harm / injury.
 - Level 4 Severe Harm: An unexpected, undesired event directly associated with care or services reaches the patient resulting in severe harm / injury.
 - <u>Level 5 Death:</u> An unexpected, undesired event directly associated with care or services resulting in or significantly contributing to the patient's death.
- Levels 4 and 5 are considered critical events and involve the loss of life, limb or organ.
- > Please refer to the examples from PSLS outlined at the end of this document.

When should a patient safety event be reported?

- > All patient safety events should be reported
- When a patient is involved in an event or almost involved in an event.
- > An event is something outside of the scope of, or not consistent with, the routine care of a patient.

Who is responsible for reporting a patient safety event?

- Anyone with access to the NH network is responsible for reporting a patient safety event including NH hospital and facility staff, Medical Staff, etc.
- > Event reports are to be completed on PSLS by the staff involved or those that discovered the event.



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> Staff should immediately notify their supervisors, managers and/or administration-on-call for critical events and follow the critical events checklist.

What are the reporting requirements in PSLS?

- > Certain fields must be completed by the individual reporting an event depending on whether the event actually happened or if it was an 'almost event' (could have happened).
- Those individuals reporting events must indicate: the degree of harm; for almost events only, how the event was caught before it happened and the potential for harm; a category to describe the event, details of the event and ideas for improvement. They also select the place, facility and department/program area most related to the event.
- > Drop-down lists are automatically generated for subsequent fields depending on how previous fields have been completed, including a list of appropriate 'handlers' i.e. someone responsible for following-up on the event.
- > It is important to complete the PSLS form accurately in order to select an appropriate 'handler'.

What is a 'handler' and why have I been identified as one?

- > The term 'handler' is used to describe individuals assigned by their organizations to manage safety event follow-up activities after a reporter submits an event in BC PSLS.
- As a Medical Staff Leader, you play a key role in responding to and following up on safety event reports.
- Responding to patient safety events is a learning opportunity. You can help to foster a culture of safety and learning by actively promoting open, trusting communication among Medical Staff members and the broader health care team.

What else should be considered when reporting a patient safety event in PSLS?

- > NH Co-Leaders should ensure their Medical Staff know to report only the facts related to an event.
- Avoid assigning blame and giving opinions about the event when reporting regardless of severity.



Who will receive notification regarding patient safety events?

- The Chief of Staff and the NH Risk Management Office automatically receive a notice from the PSLS system (BCPSLS <u>noreply@bcpsls.ca</u>) when a level 4 or 5 critical event (severe harm or death) occurs in their facility for their information.
- If a Medical Staff Leader (or a Medical Staff Member) is identified by the person reporting the event in PSLS as a 'handler' they will receive an email from the same address (BCPSLS noreply@bcpsls.ca).

What are the responsibilities of NH Co-Leaders regarding patient safety events?

- Generally, NH Co-Leaders should work with the PSLS Coordinator and/or Quality Leads to generate, monitor and review PSLS reports for quality improvement processes and staff education.
- > If they are named as a 'handler', they are responsible:
 - To review the PSLS report for accuracy
 - o To investigate and understand the causes that underlie the event reported to them
 - To close the event on PSLS when resolved, and
 - To recommend changes to the organization's systems and processes to reduce the probability of such an event in the future.

Related Legislation, Policies and Guidelines

➤ BC Patient Safety and Learning System (PSLS). (Accessed November 2020) Patient Safety and Learning System Website: https://bcpslscentral.ca/

References

Northern Health. (Accessed November 2020). *Patient Safety Incident and Adverse Event Reporting*. https://ournh.northernhealth.ca/PoliciesProcedures/DST%20Published%20Policies/2-1-3-030.pdf

BCPSLS Central. (Accessed December 2020). *Self-Learning Modules*. https://bcpslscentral.ca/elearning-modules/





Examples Related to PSLS Degree of Harm (from PSLS)

No Harm:

- Patient receiving codeine post op physician discontinues order order is not flagged for processing - nurse gives codeine instead of switching to Tylenol - extra dose - no harm to patient.
- Oximeter malfunctioning reading is 65% patient looks pink, in no distress new machine applied stats 100% no harm to patient.
- Patient slipped on wet floor while ambulating without assistance regained balance without falling but jarred back causing temporary increase in soreness. Recovered quickly without any additional pain medication or intervention. No harm to patient.
- Blood ordered due to low counts. Delay in getting blood from lab due as no porters available. Delay in giving blood but no adverse effects noted. No harm to patient.

Minor Harm:

- Patient's IV goes interstitial, red, swollen, sore. Requires warm compresses and Tylenol.
 OK after a few hours, results in bruise.
- Patient receives total enteral feed in 1 hour instead of 4 hours. Agitated, moaning, vomits. Needs extra bloodwork to check lytes.
- Patient up to bathroom without assistance after epidural wears off. Falls, red area on knee, some bleeding from episiotomy incision. Physician examines, ice applied.

Moderate Harm:

- Patient's IV goes interstitial on infusion 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.
- Injury or drug variance/reaction that has the potential to: a) significantly alter hospital stay
 or treatment plan or b) result in admission to hospital or a higher level of care.

Severe Harm:

Patient's IV goes interstitial during surgical procedure - on infusion pump - leg is grossly swollen, white, hard, pulseless - compartment syndrome diagnosed - requires emergency fasciotomy to release pressure - suffers severe pain, needs IV antibiotics, skin grafts – spends significant extra time in hospital - is left with limp and severe scarring.



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- Patient falls out of bed, fractures c-spine, requires surgery to fuse and repair, spends time
 in halo traction, in hospital for long period of time as a result, left with some permanent
 neurological deficits.
- Wrong side surgery results in patient's healthy kidney being removed instead of cancerous one. Cancerous kidney subsequently removed, patient on dialysis awaiting transplant.
- Patient receives 10-fold dose of IV morphine, has respiratory arrest, requires resuscitation, is transferred to ICU and ventilated x 1 day, recovers but spends extra 2 days in hospital, family very upset.

Death

- 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 seeking treatment for 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.

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INVESTIGATING PATIENT SAFETY EVENTS

Why are patient safety events investigated?

Events are investigated to identify contributing factors and to implement improvements/changes to reduce the likelihood that such an event would reoccur.

Are all patient safety events investigated?

- > Ideally, yes. Events should be reviewed and the level of investigation and degree of intervention depends on the severity of the event.
- As an example, no harm events may not all require individual review. Rather, it would instead be beneficial for NH Co-Leaders to generate monthly PSLS reports for no harm events and examine them as a whole for trends.
 - The Northern Health PSLS Coordinator and/or the Quality Leads can assist with generating and reviewing PSLS data for review and quality improvement processes.
- Generating and reviewing monthly PSLS reports is a recommended best practice for NH Co-Leaders for all levels of events, regardless whether a specific, individual investigation or quality review has been or is being conducted.
- > For the purposes of this summary we are focusing on the processes and considerations for investigating critical events.

What are the responsibilities of NH Co-Leaders regarding investigating patient safety events?

- If they are named as a 'handler':
 - To review the PSLS report for accuracy,
 - To investigate and understand the causes that underlie the event reported to them,
 - To close the event on PSLS when resolved, and
 - To recommend changes to the organization's systems and processes to reduce the probability of such an event in the future.
- The Patient Safety Learning System guides the handler through the information that they need to provide as part of an investigation.



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A general guideline when investigating an event is to keep in mind: what happened to the patient?

What should be secured and documented for the investigation of an serious or critical adverse event?

- ❖ As the handler, you may delegate this task if needed, but are required to provide oversight
- ❖ Be sure to communicate with Co-Leads to ensure that the appropriate documentation and necessary items have been secured.
- > The scene should be secured immediately.
- > All items relevant to the event must be secured and saved (i.e. medication vials, solutions, syringes, equipment, etc.).
- All documentation relevant to the event should be gathered, secured and saved. This includes assignment sheets, rotations, incident and follow-up reports completed by staff, written standards related to the incident, health records (check for completeness) and any other related materials (notes, etc.).
- > Depending on the timing and severity of an event, a patient's health records/chart should be secured. If the patient is deceased, instruct Health Records to secure the chart. If the patient is still admitted, instruct Health Record to create a certified copy of the chart at the time of the event for investigation and review processes.

Related Legislation, Policies and Guidelines

Health Care Protection Program. (2011, January). Section 51 of the Evidence Act: Toolkit for Health Care Agencies.

References

Government of BC. (Accessed December 2020). *Health Care Evidence, S.51*. https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/96124 01#section51

Northern Health. (Accessed November 2020). *Patient Safety Incident and Adverse Event Reporting*. https://ournh.northernhealth.ca/PoliciesProcedures/DST%20Published%20Policies/2-1-3-030.pdf

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Northern Health. (Accessed December 2020). Health Care Protection Program (HCPP): Reportable Incidents.

 $\underline{https://ournh.northernhealth.ca/PoliciesProcedures/DST\%20Published\%20Policies/4-2-1-\underline{030.pdf}$



REVIEWING ADVERSE EVENTS

What should be reviewed?

- > Individual events and trends should be reviewed.
- Critical events involving the loss of life, limb or organ (typically level 4 and 5 events) should be reviewed.
- If a trend regarding patient safety events is identified, it could be examined further through a quality review.

What are the different types of reviews?

- Administrative Review
 - Examples include reviews to improve housekeeping services or practices.
- Accountability Review
 - This type of review focuses on the conduct or performance of an individual health care provider. This can typically be characterized as a human resources (HR) review.
 - System failures and areas for improvement may be identified through an accountability review.

Quality Review

- Quality reviews focus on systems issues. They are designed to identify the causes of adverse events or close calls by looking at the system within which the care was provided.
- Events and issues that arise in hospitals can be protected by Section 51 of the Evidence Act.
- The Patient Care Quality Office may bring forward a patient complaint that will require physician leadership.

When should reviews be conducted?

- Ideally within days of an event.
- As soon as reasonably practical.

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How do I choose the best type of review?

- Work with the NH Risk Management office, your co-lead, and quality committees to determine an appropriate review type for each event.
- > Generally, two types of reviews are available at the hospital/institutional level: Accountability Reviews and Quality Reviews.
- > Refer to Figure 1 below for step by-step considerations to determine which type of review is most appropriate.

Can there be more than one review of an event?

- > One case or event can undergo multiple reviews, even at the same time.
- As an example, one event could involve an accountability (HR) review, be moving through a complaints process (outside of Section 51) and also be subject to a quality review.

How does Section 51 of the *Evidence Act* apply to a quality review?

- Section 51 is legislation that prohibits the release of and admissibility of evidence or information prepared by a properly constituted quality committee.
- Refer to <u>Section 51 Protection for Quality Reviews</u> summary.

When should Section 51 be initiated?

> Reliance on Section 51 protection of a quality review must be determined at the outset.

Related Legislation, Policies and Guidelines

- ➤ Government of BC. (2020, December). BC Evidence Act, S. 51.
 - o http://www.bclaws.ca/Recon/document/ID/freeside/00 96124 01
- Canadian Patient Safety Institute. (2011, November). Canadian Disclosure Guidelines.
 - http://www.patientsafetyinstitute.ca/english/toolsresources/disclosure/pages/default.
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- Northern Health Medical Affairs. (2016, February). Medical Staff Complaints, Discipline and Appeal Process Toolkit.
 - https://ournh.northernhealth.ca/oursites/NHCommittees/vpmedicine/OurNH%20Doc uments/Toolkit-NH-Medical-Staff-Complaints-Discipline-and-Appeal-Processes-2016.pdf

References

Government of BC. (Accessed December 2020). *Health Care Evidence*, *S.51*. https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/96124 01#section51

Canadian Medical Protective Association (CMPA). (2009). Learning From Adverse Events: Fostering a just culture of safety in Canadian hospitals and health care institutions. Ottawa, ON: CMPA. https://www.cmpa-acpm.ca/en/advice-publications/browse-articles/2010/just-culture-of-safety-why-protecting-quality-improvement-reviews-is-important-for-everyone

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Figure 1: Choosing the best type of review in hospitals/healthcare institutions (CMPA

website)

Unexpected clinical outcome, adverse event, or close call

Triage of an event

Step 1 - Preliminary collection of facts

o Triage is done by clinically knowledgeable leadership

Step 2 – Determine if further analysis is required

- Determined by objective criteria (may be determined by law in certain provinces)
- Not all adverse events require further analysis (will still require disclosure to patients)

Step 3 – If further analysis is required, choose the appropriate type of event review by using the following triage questions:

- a) Is it alleged there is a deliberate violation of sound policy by an individual provider?
- b) Is there a concern about health of the provider?
- c) Is the dominant concern in this case about the clear lack of knowledge or skills, or significant unprofessional conduct by an individual provider?

INFORMATION FIREWALL

NO to all questions

YES to any questions

Quality Improvement Review by the quality improvement committee or subcommittees:

Focuses on system (context of care) failures

Do provider accountability issues surface?

If significant concerns about the competency of an individual provider are identified, then the review is halted and redirected without details to the accountability route

Expected outcome:

Possible recommendations for system changes to provide better patient care; education for all providers

Accountability Review of individual provider by leadership/management

Focuses on individual provider's performance. Required when there are concerns about an individual provider's performance based on the triage questions above

Do system issues surface?

If system issue(s) are identified, consider also referring case for quality improvement review

Expected outcome for provider:

Graded response of support, possible targeted education, sometimes sanctions

Source: Canadian Medical Protective Association (CMPA). (2009). Learning from Adverse Events: Fostering a just culture of safety in Canadian hospitals and health care institutions. Ottawa, ON: CMPA

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SECTION 51 PROTECTION FOR QUALITY REVIEWS

What is Section 51 of the BC Evidence Act?

Legislation that prohibits the release of and admissibility into evidence of information and documents generated by a properly constituted quality committee during the review of care provided in a hospital.

What is the purpose of Section 51?

- > Conducting quality reviews under Section 51 allows for frank and open discussion with the care team, creating a safe environment for an honest appraisal of adverse events.
 - Creating this safe environment supports the team to identify quality improvement opportunities for the organization to prevent similar events from happening in the future
- Section 51 reviews are not for the purpose of "hiding" adverse events and health care providers are still obligated to disclose adverse events to patients. For more information on how to disclose adverse events to patients, see the CMPA website.

What is protected under a Section 51 review?

- > Any "information, records, summaries, reports or other documentation made or compiled for the purpose of submission to or made at the request of a Section 51 Committee or which arose out of the study, investigation, evaluation or program carried on by a Section 51 Committee" are all prohibited from disclosure.
 - o This includes the opinions voiced during the review, as well as conclusions drawn

Are there any exceptions?

- Actions taken as a result of a Section 51 quality review may be discussed with patients and families. However, we generally avoid making a direct link between those actions and a quality review.
- Information from a Section 51 review may also be disclosed in limited circumstances, for example research or regulatory bodies. However, this information cannot be released in medical malpractice litigation.

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> If you are being asked for information, it is important that you talk to your Medical Director, VP Medicine or Regional Director of Risk Management for confirmation about release of the protected information.

What is not protected under a Section 51 review?

- > Any factual information that is or should be included in the patient's chart.
- Reviews conducted for a purpose other than improving or maintaining quality of care such as a complaint with the intent to disclose to a patient or family or reviews related to care provided in the community (i.e. that cannot be tied to hospital-based care).

What are you allowed to discuss or share?

- All activities, information and discussions relating to a Section 51 review are considered confidential. Details of the review should not be discussed outside of the committee as per the non-disclosure requirements.
- However, originals or copies of medical or hospital records and all clinically factual information that is or should have been included in the patient's chart can be shared under usual patient confidentiality, including facts in an incident report not included in the patient chart and medical facts that were learned during the review2
- > As well, that a quality of care review was conducted and when it occurred can be shared.

How do you conduct a section 51 quality review?

- > Properly constituted quality committees must conduct these types of reviews. These can be existing committees or committees convened for a specific review.
 - The NH Board has delegated the authority to the NHMAC to conduct quality reviews under Section 51. As such, the NHMAC will delegate this responsibility to the HSDA MAC or Local MAC. Any MAC member may initiate a Section 51.
 - Other than MAC, Morbidity and Mortality Rounds (M&M Rounds) can also rely on Section 51 if the M&M Committee has a formal Terms of Reference that have been approved by and report to a MAC.
- Any committee that has been delegated the authority to conduct Section 51 Reviews must have Terms of Reference that includes the purpose to be related to quality, a reporting structure that flows back to MAC, scope of activities and a list of membership.



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- o If the Committee does not have a reporting relationship to MAC, it cannot conduct quality reviews under Section 51.
- > Effective quality reviews are multi-disciplinary, patient-centered and need to include your co-leader.
 - Key stakeholders in reviews can include the interdisciplinary care team, expert witnesses, Risk Management, Quality Leads.

Who do you contact if you aren't sure about the process, need advice, or more information?

- Medical Director
- VP Medicine
- Regional Manager of Risk Management

Role of NHMAC in Section 51

The NHMAC is named by the board as the committee responsible for conducting care quality reviews under section 51 of the *Evidence Act*.

Through developed terms of reference, including a reporting structure that leads back to NHMAC, other medical staff committees can be delegated to initiate and receive quality review reports. This includes HSDA and local MACs.

Steps in the process:

- 1. For a quality review to fall within section 51 privilege, it must be conducted for a qualified committee.
 - a. This means any level MAC, or any other sub-committee delegated, through proper terms of reference, can request a review be completed.
 - b. Medical leaders (Chief of Staff, Department Head, etc.) through their roles in the MAC can commission and receive the reports from reviews.
 - c. A medical leader participates in the review, which should also include the appropriate co-leader, and any other physicians and staff that are pertinent to the review.
- 2. Once the review is conducted, the committee may make recommendations.
 - Information on conducting quality reviews can be found in the <u>Northern Health</u> Adverse Events Toolkit
 - b. The summary report and recommendations are completed by the committee conducting the review using this <u>template</u>.
 - c. The summary report with recommendations are sent to the committee with oversight

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3. Review by MAC

- a. The MAC reviews the summary and recommendations and either accepts the report, or provides feedback to the reviewing committee. This is where there is opportunity for rebuttal or further deliberation.
- b. The MAC may provide feedback to the committee, requesting further consideration of identified issues or changes to the recommendations.
- c. The committee will reconsider, if necessary, and provide a final report back to the MAC.
- d. Once the report is accepted and approved by MAC, the summary and recommendations are submitted through minutes to NHMAC, and ultimately the NH Board.

4. Opportunities

- a. At each level of MAC, minutes containing report summaries and recommendations are reviewed.
- b. When applicable, recommendations should be considered for relevance beyond the site/program of review.
 - This may include communication beyond the MAC structure, and could include communicating the recommendations and actions to a program medical lead and executive lead, for program implementation across NH.

For example, there is a birth event at UHNBC:

- 1. UHNBC Perinatal Review Committee conducts a quality review of care provided
- Quality review findings are minuted, and reported to UMAC
- 3. UMAC reviews and approves findings; any discussion is minuted.
- 4. UMAC minutes are submitted to NIMAC
- NIMAC minutes are submitted to NHMAC
- 6. NHMAC minutes are submitted to the NH Board (via 3P Committee).

Related Legislation, Policies and Guidelines

- ➤ Government of BC. (December 2020). BC Evidence Act, S. 51.
 - https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/00 96124 01#section
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- Government of BC. (2020 December). Medical Research (BC Cancer Agency) and Health Status Registry Act.
 - https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/18001
- ➤ Government of BC. (2020 December). BC Health Professions Act.
 - http://www.bclaws.ca/Recon/document/ID/freeside/00 96183 01
- ➤ Government of BC. (2020 December). BC Emergency Health Services Act.



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- > Canadian Patient Safety Institute. (2011 November). Canadian Disclosure Guidelines.
 - http://www.patientsafetyinstitute.ca/english/toolsresources/disclosure/pages/default. aspx

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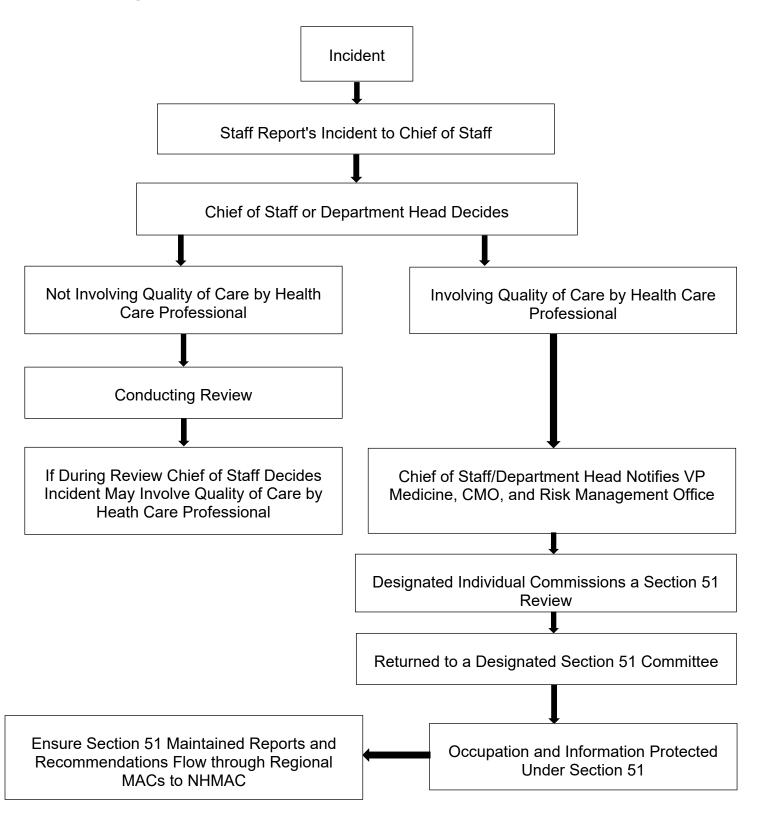
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Northern Health. (Accessed November 2020). *Patient Safety Incident and Adverse Event Reporting*. https://ournh.northernhealth.ca/PoliciesProcedures/DST%20Published%20Policies/2-1-3-030.pdf



Figure 1.0: Section 51 Process for NH Medical Staff





DISCLOSURE OF PATIENT SAFETY EVENTS

Northern Health has a policy that outlines the requirements and processes for disclosure of adverse events: <u>Disclosure of Adverse Events Policy.</u>

Which patient safety events need to be disclosed?

- Any adverse event where there is harm, injury or complication due to health care service delivery should be disclosed to the client.
- Exceptions can occur, but a decision not to disclose must be made within a structured process and by more than one individual (for example, the disclosure team or an ethics review process).

Should 'no harm' events be disclosed?

- ➢ If disclosing a 'no harm' or 'almost event' could assist a client in the future, it should be disclosed. This is a matter of clinical and professional judgement.
- > Broader Northern Health care teams should be made aware of 'almost events' in order to learn from and prevent future adverse events.

Who is the client?

The client is someone who receives care or services from a health care agency within Northern Health. These individuals can be patients, residents or clients in acute (hospital facilities), residential or community settings. They may also be their families or, where appropriate, substitute decision makers.

What is disclosure?

Health care workers sharing information with a patient about a health care event that does or may affect that patient's interest.

Why do we disclose?

Northern Health Clients are entitled to know about the care and treatment they are provided.



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Physicians, managers and other medical staff and health care providers are professionally and ethically obligated to be transparent, open and honest with their patients. Disclosure is one component of this.

What do we disclose?

A description of the agreed upon known facts (avoiding speculation, opinion and blame)

A description of the potential consequences of the adverse event to the client, how they are to be managed, and any additional ongoing care requirements.

When do we disclose?

Disclosure of adverse events should take place as close to the event as possible, after ensuring the client's safety and that the client's care needs are met.

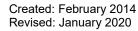
Timing should take into consideration the client's clinical condition, the availability of key staff and support person(s), the availability of the client's support person(s), the client's/family's preference, the privacy and comfort of the client, and the emotional and psychological state of the client.

How do we disclose?

Several steps, what to consider at each step and a checklist is outlined in the Northern Health's <u>Disclosure of Adverse Events Policy</u>. The <u>Canadian Disclosure Guidelines</u> is also a helpful resource.

Recommended Disclosure Steps:

- 1. Ensure patient safety
- 2. Identify key individuals
 - Health care professionals involved in the adverse event
 - Person(s) responsible for initial disclosure conversation
 - Support person(s) who are available for the patient
- 3. Initial disclosure conversation
 - Should include: an apology, known facts, patient/family questions and concerns, consequences of event and any side effects to look for, discussion of ongoing care, what happens next, arrangement for future meeting(s), contact details.





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- Should be documented (date, time, location; names and roles of those present; facts presented, questions raised and answers given, and reactions in the discussion).
- 4. Offer emotional support
 - To: patient and family members, disclosing health professional, health care professionals involved in the adverse event.
- 5. Follow-up discussions/dialogue

Related Legislation, Policies and Guidelines

- Canadian Patient Safety Institute. (2011 November). Canadian Disclosure Guidelines: Being Open with Patients and Families.
 - o https://www.patientsafetyinstitute.ca/en/toolsResources/disclosure/Pages/default.aspx

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