AK0400 GUIDELINE 1.2 ONGOING MANAGEMENT OF ADVERSE EVENTS
ENDORSEMENT DATE: FEBRUARY 2022

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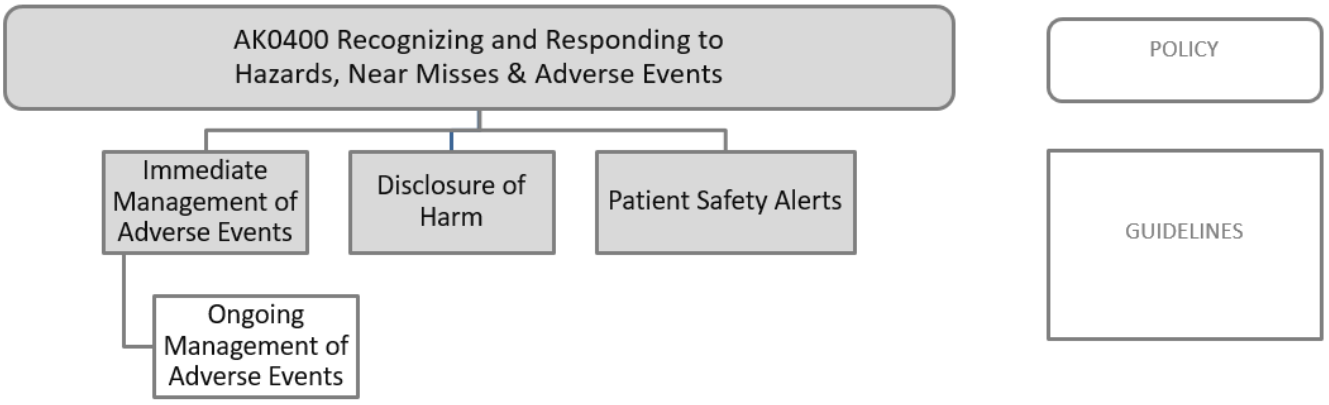
The ***OFFICIAL*** version is available on the InsideNet.

DEFINITIONS

Accountable leader	The individual who has ultimate accountability to ensure the consideration and completion of the listed steps in the AK0400 Guideline 1.2 Ongoing Management of Adverse Events. The accountable leader may delegate responsibility for some or all of the components of management to others, but the accountability remains with the accountable leader.
Adverse event (AE)	An unexpected and undesired event which results in an unintended consequence and is directly associated with the care or services provided to the patient rather than the patient's underlying condition.
Apology	An expression of sympathy or regret, preferably using the words "I'm/we're sorry". An apology is not necessarily an admission of error.
Circle of Care	A group of internal and external healthcare providers supporting a specific person, with whom personal information is shared based on an implied consent model, for the purpose of contributing to their health care plan and meeting the service needs for them and their family.
Clinical leader	The most senior leader immediately available to manage an adverse event. This may be a charge nurse, on-duty supervisor, administrator on call, most responsible practitioner, unit manager, Quality Review Coordinator or other leader as appropriate.
Critical incident	An adverse event that results in severe physical or psychological harm or death.
Decision Review Team	Brought together by the accountable leader with support from Patient Safety and Risk Management, a Decision Review Team includes operational leaders, medical staff and network leaders who review a serious adverse event and collectively make decisions regarding next steps and the need for further review.
Disclosure	The imparting of information to a patient and/or family pertaining to harm.
Family	One or more individuals identified by the patient as an important support, and who the patient wishes to be included in any encounters with the health care system, including, but not limited to, family members, legal guardians, friends and informal caregivers. For patients unable to express their wishes, family would include those we can share health information with as per established consent processes.
Handler	The Handler designated in the PSLS report is responsible for ensuring the event is investigated appropriately and that necessary actions are taken. During the Immediate Management phase of an adverse event, the Handler would be the clinical leader. During the Ongoing Management phase of an adverse event, the Handler would be the accountable leader.
Harm	An unexpected and undesired outcome for the patient that negatively affects the patient's physical, psychological (mental or emotional) health and/or quality of life. The PSLS defines degrees of harm as: 1 – No harm 2 – Minor harm 3 – Moderate harm 4 – Severe harm 5 – Death
Hazard	A circumstance, agent or action with the potential to cause harm.
Most Responsible Practitioner (MRP)	The Most Responsible Practitioner is the Physician, Nurse Practitioner, Oral Surgeon or Midwife whose name appears in the patient's chart designated as

	the MRP and who has overall responsibility for directing and coordinating the medical care and management of an individual patient, resident or client.
Near miss	An event with the potential for harm that did not result in harm because it did not reach the patient due to timely intervention or good fortune (sometimes called a close call or good catch).
Never Event	Adverse events that may result in serious patient harm or death and that are preventable using organizational checks and balances.
Patient	Includes all clients, residents, service users and persons in care in Interior Health facilities and programs. In this policy and associated guidelines, references to the patient will include the family if the patient wishes.
Patient Safety Learning System (PSLS)	BC Patient Safety Learning System (PSLS) is a web-based tool used by health-care professionals across B.C. to report and learn from adverse events, near misses and hazards that occur in health care settings.
Person & Family Centered Care	A Person & Family Centered Care approach puts patients at the forefront of their health and care, ensures they retain control over their own choices, helps them make informed decisions and supports a partnership between individuals, families and health care service providers.
Second harm	Negative effects on health and well-being resulting from the impact of being involved, witnessing or affected by an adverse event. Family members of patients, care providers and others may be affected.
Trauma-Informed Practice	A strengths-based framework grounded in an understanding of and responsiveness to the impact of trauma. It emphasizes physical, psychological and emotional safety for everyone, and creates opportunities for survivors to rebuild a sense of control and empowerment.

Overview of AK0400 Recognizing and Responding to Hazards, Near Misses & Adverse Events



PRINCIPLES

Person & Family Centered Care: We believe in a collaborative approach to safety that includes engagement with patients, their families (if family involvement is aligned with patient wishes), and others who have been involved or affected by Adverse Events (AEs). We will work to ensure they are treated with dignity, respect, compassion and empathy using a trauma-informed and culturally safe approach to support healing and rebuild trust with Interior Health. Information sharing, participation and collaboration with patients and families will occur to the greatest extent possible throughout this process in keeping with applicable privacy and legislation. Patients are entitled to the facts about the care they receive.

Just Culture: Interior Health promotes a 'just culture' in which transparency, fairness, accountability and a focus on learning and improvement from AEs are key elements. We support all people with empathy

and support following an AE. We avoid speculation or making assumptions that a poor clinical outcome is the result of error or poor judgment – a review needs to take place before any assignment of accountability might occur.

Our People: We recognize that health-care providers may also be harmed when an AE occurs. When patients in their care are harmed, health-care providers may suffer from professional and personal anguish. We will support and treat employees and medical staff with care, dignity, respect, compassion and empathy in keeping with the principles of a Just Culture.

Patient Safety: Health-care providers aim to minimize risks to patient's physical and psychological well-being. Patients, employees, medical staff and the public should not be exposed to harm where it is reasonably avoidable. Health-care providers, to the extent they have control, and health systems are accountable for the quality of patient care provided.

We strive to create an environment where everyone feels safe, encouraged and enabled to report and discuss safety concerns. We recognize the potential for hindsight bias (the perception following an event that it was more predictable than it actually was) and outcome bias (we evaluate actions impartially in consideration of the circumstances and context of what occurred, rather than based on results and outcomes). We avoid the temptation to reduce complex issues to simple individual human error.

Learning: We recognize that understanding and learning from AEs is essential to improving patient safety. This is accomplished respectfully with the utmost sensitivity, empathy and compassion for all involved.

1.0 GUIDELINE

1.10 Key Points

1.11 Ongoing management of AEs will occur for any of the following criteria:

- For all events where the outcome of the AE for the patient and/or providers causes serious physical/psychological harm or death,
- For all AEs considered to be Never Events,
- Where the clinical leader determines further investigation is needed, and/or
- At the discretion of the accountable leader based on extenuating circumstances.

Unresolved concerns from the patient/family may also require ongoing management (e.g. additional disclosure conversations, complaints escalation process).

1.12 These steps are in addition to and in coordination with the steps taken by the clinical leader in the AK0400 Guideline 1.1 Immediate Management of Adverse Events.

1.13 A single accountable leader is responsible for coordinating all aspects of the ongoing management of an AE.

1.14 The accountable leader may be a department leader, clinical operations director, program director or other administrative leader as determined by the circumstances.

In deciding who the accountable leader shall be, consider an individual who:

- Has accountability for the operational area that the AE occurred, and
- Has the authority to make decisions and take actions as outlined in this guideline.

In complex AEs that affect multiple areas/programs, the accountable leader will be determined

collaboratively by the leadership teams of the affected areas/programs.

If unable to determine an accountable leader, responsibility for determining an accountable leader shall be made by the executive director.

1.15 Accountable leaders may consult with IH Patient Safety for assistance. Additional support is available as needed from IH Risk Management and IH Communications.

Note: The order of the steps below is recommended; however, the actual order of the steps shall reflect the needs of each situation and may be done concurrently.

1.20 Receiving Handover from the Clinical Leader

1.21 After being notified about an AE, the accountable leader will receive a handover report from the clinical leader who handled the immediate management as per the AK0400 Guideline 1.1 Immediate Management of Adverse Events.

The accountable leader will review the steps taken by the clinical leader and ensure that all steps have been completed or continue them as needed.

1.30 Physical and Psychological Support for Patients

Using a trauma-informed approach, the accountable leader shall ensure the physical and psychological needs of all affected patients and/or families will continue to be met.

1.31 As appropriate, the accountable leader shall ensure continuation or initiation of the AK0400 Guideline 1.3 Disclosure of Harm. Disclosure coaches are available to support the process as necessary.

1.32 It is the responsibility of the accountable leader to ensure that there is regular communication with the patient and/or family via a single point of contact who:

- Will provide ongoing regular support and communication with the patient and/or family related to management of the AE until resolution, and
- Will provide information about follow-up processes that may occur and associated timelines.

Any change in point of contact needs to be clearly communicated to the patient and/or family so they do not feel abandoned.

1.33 The accountable leader, in partnership with the patient and/or family, shall assess the need for any practical supports. Funding, if applicable, is coordinated through the British Columbia Health Care Protection Program (contact IH Risk Management for support). Practical supports may include, but are not limited, to:

- Parking,
- Food,
- Transportation,
- Accommodation,
- A quiet space for family communication to occur,
- Community support,
- Additional medical care, and/or
- Other considerations as determined by specific circumstances.

Consider following up with affected family members 24 to 48 hours after the event to express

concern for their well-being and assess further needs.

1.34 If the patient and/or family requests a copy of the health care record, the accountable leader shall support them to complete a Request for Access to Personal Health Records or access to My Health Portal.

1.35 If the patient is uninsured, consult with Accounts Receivable to consider holding bills for uninsured services until resolution has been reached and the appropriateness of billing has been considered.

1.36 The accountable leader works closely with the patient and/or family after an AE to resolve their concerns. Despite best efforts, if the patient and/or family still has unresolved concerns, the accountable leader shall provide the patient and family with contact information for the Patient Care Quality Office (PCQO). There is no deadline for opening a complaint. The PCQO process can run concurrently with or subsequent to the ongoing management of an AE and does not replace the steps described in this guideline.

1.40 Physical and Psychological Support for Employees and Medical Staff

1.41 Being involved or present when harm occurs can be very traumatic for health-care providers. The emotional distress that occurs is referred to as 'second harm' and can have a negative effect on health and wellness. Providers may suffer in silence, change their role, leave the profession or even self-harm.

After an event occurs, it is important to be compassionate and supportive of those involved, utilizing a trauma-informed approach. Avoid making an assumption that a poor clinical outcome is the result of an error or poor judgment – a review needs to take place before any assignment of accountability. Avoid making any premature, unsubstantiated or inappropriate remarks about the professional competency of other providers. Recognize and avoid hindsight bias (the perception following an event that it was more predictable than it actually was).

The accountable leader shall continue to provide emotional support and referral as needed for affected employees, students, volunteers and medical staff. This may include considering the need for a team debrief after the event.

1.42 For those directly involved in the event, the accountable leader shall provide information regarding the process and next steps in management of the AE, including:

- That they may be invited to contribute their understanding of an event during an AE review,
- That they may be invited to lead or participate in a disclosure meeting with the patient and/or family,
- That they may be invited to participate in a critical incident debriefing with the team if they feel it would be of benefit, and
- The privacy and confidentiality of the event review process.

1.50 Environmental Safety for Patients, Visitors, Volunteers, Employees and Medical Staff

1.51 In the case of a medical device incident, the accountable leader shall ensure equipment involved in the event remains in quarantine until deemed safe to return to use by Biomedical Engineering, and that the AE is reported in PSLS as a Medical Device Incident to facilitate the process of mandatory reporting for hospitals under Vanessa's Law.

1.60 Documentation

1.61 The accountable leader will document all steps taken related to this guideline, separate from the patient health record. These steps can be documented in PSLS.

1.62 Portions of the AE management that relate to or impact the patient's care should be included in the patient health record. All facts surrounding an event can be documented in a patient's chart. For example, this might include documenting that an incorrect dose of a medication was given, that a piece of equipment was incorrectly applied, or that orders were not carried out. Do not include speculation or opinion in the health record. Health records should not be altered or changed.

1.70 Notification Internally and Externally

The accountable leader shall confirm who has been notified and consider who else needs to be notified of the event and how it is being managed. This may include:

- Chief of Staff,
- Medical Staff Department Head,
- Clinical Network Director,
- Clinical Operations Leaders,
- the relevant Vice President and/or Executive Medical Director,
- IH Patient Safety,
- IH Risk Management, and/or
- IH Communications.

1.71 For some AEs, additional reporting to external bodies may be required. The accountable leader may ask for support from the executive director or IH Patient Safety for this process. Reporting may include but is not limited to:

- Reporting may be required to relevant regulatory bodies if applicable (BC Colleges, Boards and Commissions for Regulated Health Professions).
- Anyone with reason to believe there has been abuse against a patient shall follow the AH0100 Abuse-Free Environment for Clients policy.
- Any reportable incident within long-term care must be documented and reported by the licensee in accordance with the process and guidelines set out in Division 6 of the Residential Care Regulations.
- Operators of Assisted Living facilities must take immediate and appropriate action in response to a reportable (serious) incident in accordance with Schedule E of the Assisted Living Regulation.
- Anyone who has reason to believe a child needs protection must promptly report the matter to the Director/designate as per section 14 of the *Child, Family and Community Service Act*.
- Facts and circumstances relating to the death of an adult or child where the person has reason to believe meets the criteria outlined in Part 2 of the *B.C. Coroners Act* must be reported to the coroner.
- All hospitals in Canada are required to report serious adverse drug reactions and medical device incidents to Health Canada within 30 days of the event being documented within the hospital, as per Vanessa's Law. In IH, employees and medical staff shall use PSLS to continue to report any adverse drug reaction and medical device incident, no matter how serious. Reporting to Health Canada in B.C. will be facilitated through Central PSLS.
- Some events must be reported to the Ministry of Health if they meet the threshold outlined in the Protocol for Health System Response to Adverse Events and Service

Issues.
- If an adverse reaction to a transfusion of blood components or products occurs, then the Transfusion Medicine Services/Lab must be made aware and the transfusion reaction reported to the authorized prescriber as per IH Transfusion Practices Practice Standard TP31500.

1.80 Review of the AE

1.81 The purpose of the initial review is to learn more in order to develop the most accurate understanding of the event. This review may be led by the accountable leader, with support from IH Patient Safety. An accurate understanding of the event is needed to:

- Inform the disclosure process,
- Communicate lessons learned to the providers involved,
- Identify system issues related to the quality of patient care and services provided, and
- Identify local actions for improvement (if applicable).

1.82 Various sources of information will be consulted for the initial review, including but not limited to:
- Patient health record,
- Conversations with involved providers and patients and/or family members or other witnesses,
- MEDITECH,
- PSLS, and/or
- Documentation on the initial management process by the clinical leader.

1.83 The accountable leader will ensure a clinical timeline of the event has been created, with support from IH Patient Safety as needed.

1.84 For AEs where the patient received care in multiple facilities or areas, the initial review and decision regarding follow-up processes will be done in consultation with those leaders.

1.85 The accountable leader will consider the following criteria after the initial review has been completed:

- Have the facts of the AE been determined?
- Is there enough information about what occurred in order to conclude the disclosure process as per AK0400 Guideline 1.3 Disclosure of Harm?
- If systems issues have been identified, are they already known and being addressed through current mechanisms for improvement?

1.86 If the accountable leader can answer yes to all of the questions above, they can conclude the initial review. Any actions to be taken should be assigned through the PSLS for tracking. Follow-up shall be completed with the patient and providers as per section 1.90 below.

1.87 If the accountable leader determines that the answer to any of the above questions is no, additional review may be required. The accountable leader can convene a Decision Review Team to help determine the most appropriate course of action.

With support from IH Patient Safety, the accountable leader will identify the relevant participants to attend a Decision Review Team, and ensure a meeting is arranged. In addition to the accountable leader, invited participants will include, but are not limited, to:

- Clinical leader (if appropriate),
- Administrative and medical leadership from IH Patient Safety,

- Chief(s) of Staff from site(s) involved,
- Executive Medical Director(s) from site(s) involved,
- Administrative and medical leadership from applicable Clinical Network,
- Risk Management, and
- Others as pertinent.

The Decision Review Team will collectively decide whether further review is warranted, the type of review required, who will lead it and next steps. Further review may take the following forms:

- **Critical Incident Review:** Used for AEs where harm has occurred to develop the best understanding of the event through a systemic, non-linear perspective, using appropriate methods and tools from a variety of data sources. This may include, but is not limited to, interviews with the patient and/or family, interviews with providers involved, review of applicable policies and guidelines, review of evidence or best clinical practices and consultation with internal or external clinical or technical experts.

  Critical Incident Reviews will be conducted under section 51 of the *Evidence Act* where applicable to ensure all individuals involved in the review can have open and honest conversations about the quality of care provided without fear that the information can be used in civil legal proceedings.

- **Quality Review:** Used for AEs where there was no harm but opportunities to improve the system have been identified.

- **Accountability Review:** Used for events where the actions or decisions of a specific provider need a closer look. If the staff member is an employee, the accountable leader will consult with their Employee Relations Advisor for support. If it is a member of the Medical Staff, the accountable leader will reach out to the appropriate Chief of Staff for support.

1.90 Follow-Up After AE Review

1.91 After a Critical Incident Review, Quality Review or Accountability Review have been completed, the accountable leader shall ensure that:

- The patient and/or family has been provided with the most accurate understanding of the AE as per AK0400 Guideline 1.3 Disclosure of Harm,
- Actions taken as a result of the critical incident or quality review are shared with the patient and/or family and health-care providers involved in the event, and
- Learning from the review is shared with applicable stakeholders (consult with IH Patient Safety or IH Risk Management regarding prohibitions on sharing information from reviews protected under section 51 of the *Evidence Act*).

2.0 REFERENCES

N/A

3.0 DEVELOPED BY

Director, Patient Safety

4.0 REVISED BY

N/A

5.0 REVIEWED BY

N/A

6.0 ENDORSED BY

Health Authority Medical Advisory Committee October 2021
Quality Management Committee December 2021
Senior Executive Team February 2022

Please provide a list of keywords to aid in searching for this tool:

Harm; Safety; Disclosure; Incident; Critical; Adverse Event; Hazard; Near Miss; Ongoing

Appendix A Never Events

Never events are AEs that may result in serious patient harm or death and that are preventable using organizational checks and balances. Never events are not intended to reflect judgment, blame or provide a guarantee; rather, they represent a call-to-action to prevent their occurrence. While the PSLS is a voluntary reporting system, staff and physicians are strongly encouraged to report any never events they may become aware of in the PSLS.

Additional explanation to help determine whether an AE is considered a Never Event is available in the Never Events for Hospital Care in Canada document.

1. Surgery on the wrong body part or the wrong patient, or conducting the wrong procedure.
2. Wrong tissue, biological implant or blood product given to a patient.
3. Unintended foreign object left in a patient following a procedure.
4. Patient death or serious harm arising from the use of improperly sterilized instruments or equipment provided by the health-care facility.
5. 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.
6. Patient death or serious harm due to the administration of the wrong inhalation or insufflation gas.
7. Patient death or serious harm as a result of one of five pharmaceutical events.
   The following five pharmaceutical events represent errors that can result in serious consequences for patients:
   - Wrong-route administration of chemotherapy agents, such as vincristine administered intrathecally (injected into the spinal canal).
   - Intravenous administration of a concentrated potassium solution.
   - Inadvertent injection of epinephrine intended for topical use.
   - Overdose of Hydromorphone by administration of a higher-concentration solution than intended (e.g. 10 times the dosage by drawing from a 10 mg/mL solution instead of a 1 mg/mL solution, or not accounting for needed dilution/ dosage adjustment).
   - Neuromuscular blockade without sedation, airway control and ventilation capability.
8. Patient death or serious harm as a result of failure to identify and treat metabolic disturbances.
9. Any stage III or stage IV pressure ulcer acquired after admission to hospital.
10. Patient death or serious harm due to uncontrolled movement of a ferromagnetic object in an MRI area.
11. Patient death or serious harm due to an accidental burn.
12. Patient under the highest level of observation leaves a secured facility or ward without the knowledge of staff.
13. Patient suicide, or attempted suicide that resulted in serious harm, in instances where suicide prevention protocols were to be applied to patients under the highest level of observation.
14. Infant abducted, or discharged to the wrong person.
15. Patient death or serious harm as a result of transport of a frail patient, or patient with dementia, where protocols were not followed to ensure the patient was left in a safe environment.