

TITLE

IMMEDIATE MANAGEMENT OF CLINICAL ADVERSE EVENTSSCOPE

Provincial

DOCUMENT

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APPROVAL AUTHORITY

Quality Safety and Outcomes Improvement Executive
Committee

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Not applicable

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Recognizing and Responding to Hazards, Close Calls and
Clinical Adverse Events Policy (#PS-95)

SCHEDULED REVIEW DATE

November 01, 2020

NOTE: The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definitions section.

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OBJECTIVES

- To describe the steps which must be taken within Alberta Health Services (AHS), when a **clinical adverse event (CAE)** occurs.
- To ensure that the immediate needs of the **patient, staff** and **medical staff** involved in a CAE are managed appropriately according to evidence-based principles and practices.
 - In this procedure, references to the patient will include the **family** if the patient wishes.
- The immediate management of CAEs precedes and is in conjunction with the AHS *Ongoing Management of Clinical Adverse Events Procedure*.

PRINCIPLES

Clinical adverse events require immediate response, assessment, and if needed, handover.

An effective and compassionate approach requires leaders to follow AHS **just culture** principles (see *AHS cares* and *AHS Just Culture Guiding Principles*).

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, Students, Volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

ELEMENTS

1. Points of Emphasis

- 1.1 When any AHS staff or medical staff member recognizes a possible CAE has occurred, they shall report it to a **clinical leader**.
- 1.2 Immediate management of CAEs will be coordinated by a single clinical leader who will ensure a fair and consistent response.
 - a) The clinical leader may be a charge nurse, on-duty supervisor, administrator on call, **most responsible health practitioner**, unit manager or other leader as determined by the circumstances.
 - b) The clinical leader will be mutually agreed upon by those immediately available to assume the responsibilities of the role.
 - c) In deciding who the clinical leader shall be, consider an individual who:
 - (i) is immediately available at the location of the CAE;
 - (ii) is the most senior/experienced leader available; and
 - (iii) if possible, has a pre-existing relationship with the patient.
- 1.3 The clinical leader will assess the facts to determine the required next steps.
 - a) While fact collection is vital, it is important to evaluate the CAE through a systems lens in the context of the situation and circumstances in which it occurred and the reasoning for individuals' actions at the time.
- 1.4 The duties of the clinical leader may be turned over to subsequent clinical leaders, as needed (e.g., at shift changes). Appropriate briefing of a new clinical leader shall occur.
- 1.5 Immediate management of a CAE should be started as soon as it is identified and be completed as soon as feasible, ideally within 24 to 48 hours.
- 1.6 If a CAE occurs, the clinical leader may consider requesting support from AHS resources including but not limited to:
 - a) Disclosure of Harm consultants;
 - b) the Administrator on call (who shall be made aware in the cases of serious CAEs and may be able to provide guidance on immediate management); and/or
 - c) the Employee and Family Assistance Program.
- 1.7 The Patient Safety page on Insite has resources to assist with this procedure.

- 1.8 Some CAEs may directly affect multiple patients. All affected patients shall be supported using this procedure.
- 1.9 A serious CAE requires ongoing management. The clinical leader shall ensure the immediate steps are initiated and a handover occurs to an **accountable leader** for ongoing management. See the AHS *Ongoing Management of Clinical Adverse Events* Procedure.

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

2. Patient Support

The clinical leader will ensure the following occurs as appropriate:

- 2.1 The medical needs of the patient are being attended to.
- 2.2 Determine whether any additional patients have been or have the potential to be affected by the CAE and ensure all possible steps are taken to prevent further harm.
- 2.3 If there has been harm, begin the apology and acknowledgement portion of the disclosure process in accordance with the AHS *Disclosure of Harm* Procedure.
- 2.4 Discuss with the patient if they wish to have their care transferred to other **health care professionals** and/or medical staff. If so, facilitate as soon as feasible.
- 2.5 Emotional needs/support for the patient (e.g., private space, reassurance).
- 2.6 Immediate practical support (e.g., access to a telephone, snacks, quiet space).
- 2.7 Spiritual support such as assisting with finding a spiritual leader or member of a faith or cultural community.
- 2.8 Provide contact information for an AHS accountable leader.
 - a) Ensure that the AHS accountable leader is aware.
 - b) If appropriate, arrange in consultation with the patient for an AHS single point of contact.

3. Staff Support

The clinical leader shall ensure the following occurs as appropriate:

- 3.1 Immediate first aid and/or medical aid is offered to any staff and/or medical staff if required under the circumstances.
- 3.2 Determine the needs of the staff and medical staff and transfer patient care to alternate providers if necessary.

- a) If staff are temporarily unable to continue to provide safe patient care, they will be supported to stop working and alternate staffing will be identified.
 - b) Support all impacted staff, not just those who were directly providing patient care to the affected patient(s), including but not limited to:
 - (i) other staff who may have interacted with the patient including non-health care professionals;
 - (ii) staff from other units who have been involved directly or indirectly with the patient; and
 - (iii) any leaders of affected areas.
 - c) If medical staff are unable to continue to provide safe patient care, they will work with their medical administrative leader and/or colleagues to determine appropriate coverage as soon as it is safe and feasible to do so, as per the processes outlined in the *AHS Medical Staff Bylaws* and *AHS Medical Staff Rules*.
- 3.3 Offer support to the staff and medical staff.
- a) When possible, arrange a quiet and private place for all communication and documentation to occur.
 - b) Provide emotional support to assist in coping with the CAE.
 - c) Provide information about and referral to support programs and encourage staff and medical staff to seek assistance, including but not limited to:
 - (i) the Employee and Family Assistance Program (EFAP); and
 - (ii) the Physician and Family Support Program (PFSP).

4. Environmental Safety

The clinical leader shall ensure the following occurs as appropriate:

- 4.1 Maintain or create a safe environment. Ensure the area is safe for patients, visitors, staff and medical staff before allowing anyone to return.
- 4.2 If the patient is deceased, leave all **medical devices**, medications, clothing, and/or invasive items with the deceased until removal is approved or directed by the Medical Examiner (see *Fatality Inquiries Act* [Alberta]).
- 4.3 If medical devices are involved in, or suspected of contributing to a CAE, follow the *PLEASE Quarantine* process:

- a) Preserve evidence by not changing settings or disconnecting parts unless needed to do so. In the case of a serious CAE, consider photographing **equipment** in place prior to quarantining.
 - b) Label the involved devices for quarantine and leave together.
 - c) Ensure reporting of medical device problems through e-Facilities (for equipment) or Product Feedback (for **products**). Contact local Clinical Engineering or the Medical Device Safety Information Line for assistance.
 - d) Apply surface disinfection and biohazard containment.
 - e) Send for quarantine and hold:
 - (i) equipment and attached products go to local Clinical Engineering; and
 - (ii) stand-alone clinical products go to the local clinical manager,and ensure that suspect medical devices remain in quarantine until deemed safe to return to use by Clinical Engineering.
 - f) Establish a secure chain of evidence by maintaining product under quarantine until next steps have been determined. If there was harm, do not release items or information to the vendor until authorized by the appropriate department.
- 4.4 For a suspected medication-related CAE:
- a) **Medication dispensing errors:**
 - (i) Notify the local Pharmacy Manager immediately.
 - (ii) If applicable, secure, quarantine and remove from circulation the medication(s) involved.
 - Record lot number or batch numbers of any quarantined medication(s).
 - (iii) Do not return medication(s) into circulation until advised by Pharmacy that it is safe to do so.
 - b) **Medication administration errors:**
 - (i) Notify the local Pharmacy Manager.
 - (ii) Pharmacy will provide collaborative support to the clinical leader.

(iii) If needed, clinical pharmacists will provide assistance to the most responsible health care practitioner with the clinical management of the patient.

c) Include pharmacy in the **Reporting and Learning System for Patient Safety (RLS)** report for all medication-related CAEs.

5. Documentation of Clinical Adverse Event Management

For all CAEs, the clinical leader shall ensure the following occurs:

5.1 The CAE is documented in the **health record** as per the AHS *Clinical Documentation Directive* and AHS *Clinical Documentation Process Directive*, and shall include:

- a) known facts;
- b) the patient care plan as a result of the CAE;
- c) notification(s) of others of a CAE (e.g., most responsible health practitioner, manager); and
- d) the facts of disclosure conversations that have occurred. (See AHS *Disclosure of Harm Procedure*).

Note: Only objective data shall be documented on the health record. Thoughts and opinions should not be included.

5.2 The AHS *Immediate Management Checklist* for clinical adverse events is available on the Patient Safety page on Insite for clinical leaders to use as a documentation tool.

5.3 How the CAE is managed shall be documented separately from the health record of the patient.

5.4 CAEs, including close calls, should be reported in the RLS (see the AHS *Reporting of Clinical Adverse Events, Close Calls and Hazards Procedure*).

a) Documenting in the RLS does not replace the obligation for staff and medical staff to document information relating to patient care in the health record.

5.5 In addition to reporting to the RLS, there is additional mandatory notification of certain events. These include but are not limited to the following.

a) Anyone with reasonable and probable grounds to believe there is or has been abuse against a patient shall follow the AHS *Keeping Patients Safe from Abuse Policy*.

- b) Any incident within the supportive living or long-term care accommodation in which the safety or security of a resident is breached must be documented and reported in accordance with the process and guidelines set out in the *Continuing Care Health Service Standards* (Alberta Health).
 - c) Anyone with reasonable or probable grounds to believe that a child has been or there is substantial risk that they will be abused, neglected or emotionally injured, has a legal responsibility to contact the nearest office of Child and Family Services or Delegated First Nations Agencies.
 - d) If a **serious adverse drug reaction** occurs, the reporter is encouraged to report the event as per the *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)* (Canada).
 - e) If an adverse reaction to transfusion of blood components or products occurs, then the AHS *Transfusion of Blood Components and Products* Policy shall be followed.
- 5.6 If staff injury has occurred, report in the MySafetyNet system.
- 5.7 In addition to the above, when there has been a serious CAE, the clinical leader shall:
- a) record the names and contact information of all:
 - (i) staff and medical staff:
 - involved with the serious CAE; and
 - working on the unit;
 - (ii) visitors present at the scene; and
 - (iii) anyone else who may have relevant information about the serious CAE.

6. Notify/Handover

- 6.1 The clinical leader shall communicate the CAE to all directly involved health care professionals, so that appropriate patient care and monitoring will occur.
- 6.2 The clinical leader will notify the following individuals (as soon as possible, within 24 hours of being aware of the CAE):
- a) most responsible health practitioner; and
 - b) immediate supervisor or manager for the area.
- 6.3 In the event of a serious CAE, including AHS **never events**, the clinical leader shall ensure that handover of CAE management is done with the accountable

leader who will be handling ongoing management of the serious CAE (see the *AHS Ongoing Management of Clinical Adverse Events Procedure*).

DEFINITIONS

Accountable leader means the individual who has ultimate accountability to ensure the consideration and completion of the listed steps in the management of the Alberta Health Services *Immediate Management of Clinical Adverse Events Procedure*. Responsibility for some or all of the components of management may be delegated to the appropriate level responsible administrative leader, but the accountability remains at the senior level.

Clinical adverse event (CAE) means an event that reasonably could or does result in an unintended injury or complications arising from health care management, with outcomes that may range from (but are not limited to) death or disability to dissatisfaction with health care management, or require a change in patient care.

Clinical leader means the senior leader immediately available to provide immediate management of a clinical adverse event. This may be a charge nurse, on-duty supervisor, administrator on call, most responsible health practitioner, unit manager or other leader as appropriate.

Equipment means medical devices that are supported by a designated Alberta Health Services Department or contracted service provider(s).

Family (-ies) means 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.

Health care professional means an individual who is a member of a regulated health discipline, as defined by the *Health Disciplines Act* (Alberta) or the *Health Professions Act* (Alberta), and who practices within scope and role.

Health record means the Alberta Health Services legal record of the patient's diagnostic, treatment and care information.

Just culture means an environment where everyone feels safe, encouraged, and enabled to discuss quality and safety issues, where reporting and learning are key elements.

Medical device means an item, whether used alone or in combination, including software, intended by the manufacturer for use on patients, for any of the following purposes:

- a) diagnosis, prevention, monitoring, treatment, or alleviation of, or compensation for of a disease, an injury or handicap;
- b) investigation, replacement, or modification of the anatomy or of a physiologic process; and/or
- c) control of conception.

Medical staff means physicians, dentists, oral and maxillofacial surgeons, podiatrists, or scientist leaders who have an Alberta Health Services Medical Staff appointment.

Medication administration error means an error in providing the medication to the patient (i.e., primary source clinical area).

Medication dispensing error means an error in the preparation or distribution (i.e., primary source Pharmacy department).

Most responsible health practitioner means the health practitioner who has responsibility and accountability for the specific treatment/procedure(s) provided to a patient and who is authorized by Alberta Health Services to perform the duties required to fulfill the delivery of such a treatment/procedure(s) within the scope of his/her practice.

Never event means a unique group of clinically serious adverse events, considered clinically serious regardless of patient outcome. Named because there are known mitigation strategies available and if appropriately implemented would prevent occurrence of the event.

Patient means an adult or child who receives or has requested health care or services from Alberta Health Services and its health care providers or individuals authorized to act on behalf of Alberta Health Services. This term is inclusive of residents, clients and outpatients.

Product means medical devices that are not maintained, such as clinical consumables or reusable surgical instruments.

Reporting and Learning System for Patient Safety (RLS) means the electronic software program designated by Alberta Health Services to report patient related events resulting in adverse events, close calls or hazards.

Staff means all Alberta Health Services employees, midwifery staff, students, and other persons acting on behalf of or in conjunction with Alberta Health Services.

REFERENCES

- Alberta Health Services Governance Documents:
 - *Clinical Documentation Directive* (#1173)
 - *Clinical Documentation Process Directive* (#1173-01)
 - *Disclosure of Harm Procedure* (#PS-95-01)
 - *Keeping Patients Safe from Abuse Policy* (#1153)
 - *Medical Staff Bylaws*
 - *Medical Staff Rules*
 - *Ongoing Management of Clinical Adverse Events Procedure* (#PS-95-03)
 - *Reporting of Clinical Adverse Events, Close Calls and Hazards Procedure* (#PS-95-04)
 - *Transfusion of Blood Components and Products Policy and Procedure* (#PS-59 and #PS-59-03)
- Alberta Health Services Resources:
 - *AHS cares*
 - *Just Culture Guiding Principles*
- Non-Alberta Health Services Documents
 - *Continuing Care Health Service Standards* (Alberta Health)

- *Fatality Inquiries Act* (Alberta)
- *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)* (Canada)

VERSION HISTORY

Date	Action Taken
November 01, 2017	Non-substantive change
Click here to enter a date	Optional: Choose an item