

## TITLE

**ONGOING MANAGEMENT OF CLINICAL ADVERSE EVENTS**SCOPE

Provincial

## DOCUMENT #

PS-95-03

## APPROVAL AUTHORITY

Quality Safety and Outcomes Improvement Executive  
Committee

## INITIAL EFFECTIVE DATE

November 1, 2017

## SPONSOR

Quality and Healthcare Improvement

## REVISION EFFECTIVE DATE

Not applicable

## PARENT DOCUMENT TITLE, TYPE AND NUMBER

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.

If you have any questions or comments regarding the information in this document, please contact the Policy & Forms Department at [policy@ahs.ca](mailto:policy@ahs.ca). The Policy & Forms website is the official source of current approved policies, procedures, directives, standards, protocols and guidelines.

**OBJECTIVES**

- To describe the steps which must be taken within Alberta Health Services (AHS) when a serious **clinical adverse event** (CAE) occurs. This procedure may be used in less clinically serious circumstances at the discretion of any **accountable leader**.
- To ensure that the ongoing 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 procedure for the ongoing management of CAEs follows and is in conjunction with the *AHS Immediate Management of Clinical Adverse Events Procedure*.

**PRINCIPLES**

Serious CAEs require appropriate response and investigation, coordinated by an AHS accountable leader. The organizational response to this type of event should be consistent, compassionate and fair.

- Everyone will be able to trust that AHS will use effective processes to evaluate what occurred in context, and respond to the individuals involved.
- Actions will be evaluated in consideration of the context of what occurred, rather than results and outcomes.

- Individuals will not be held accountable for system and/or organizational errors over which they have no control.
- Individuals will be treated with care, compassion, support, respect and dignity.
- AHS leaders are accountable to identify system changes / improvements that can be made based on what is learned during the evaluation of a CAE and make recommendations to improve patient safety. Those who work within or are impacted by the organization will engage in the improvement process.
- Individuals will be held appropriately accountable for reckless behaviour or intent to **harm**.

## 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 Ongoing management of CAEs will occur:
  - a) for all events where the outcome of the CAE on the patient is serious (i.e., severe harm or death);
  - b) at the discretion of the accountable leader in less clinically serious circumstances, including hazards, harms and close calls; or
  - c) for CAEs that have not been resolved to the satisfaction of the patient during the immediate management of the CAE.
- 1.2 This procedure is in addition to and in coordination with the steps taken in the *AHS Immediate Management of Clinical Adverse Events* Procedure.
- 1.3 A single accountable leader is responsible for coordinating all aspects of the ongoing management of a CAE.
- 1.4 The accountable leader may be a department leader, program director or other administrative leader as determined by the circumstances.
  - a) In deciding who the accountable leader shall be, consider an individual who:
    - (i) has accountability for the operational area that the CAE occurred; and

- (ii) has the authority to make decisions and take actions as outlined in this procedure.
  - b) In complex CAEs that affect multiple areas, the accountable leader will be determined collaboratively by the leadership teams of the affected areas.
  - c) If unable to determine an appropriate accountable leader, responsibility for determination of an accountable leader shall be made by the Senior Operating Officer, Senior Program Officer or Senior Medical Officer or designate.
    - (i) Leaders may consult with provincial or zone Patient Safety departments for assistance.
- 1.5 The Patient Safety page on Insite has resources to assist with this procedure.
- 1.6 The accountable leader may request support from the following AHS resources:
  - a) Patient Safety (for support regarding this procedure);
  - b) Patient Relations department;
  - c) Legal & Privacy department;
  - d) Employee and Family Assistance Program (EFAP);
  - e) Physician and Family Support Program (PFSP);
  - f) Workplace Health and Safety;
  - g) Medical Affairs and/or Human Resources;
  - h) Disclosure of Harm consultants; and
  - i) Provincial AHS clinical departments (e.g., Provincial Midwifery Services, Pharmacy Services, Diagnostic Imaging, Laboratory Services, Emergency Medical Services [EMS]).
- 1.7 The patient may request that family member(s) be included in any discussions.
- 1.8 Some CAEs may affect multiple patients. All affected patients involved shall be supported using this procedure as appropriate.
- 1.9 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.

## 2. Handover/Notification

- 2.1 After being notified about a CAE, the accountable leader will receive a handover report from the **clinical leader** who handled the immediate management as per the AHS *Immediate Management of Clinical Adverse Events* Procedure.
- a) The accountable leader will review the work to date regarding the AHS *Immediate Management of Clinical Adverse Events* Procedure and ensure that all steps have been completed or continue as appropriate.
  - b) If there was no clinical leader initiating the immediate management of the CAE, the accountable leader will ensure that all steps of the AHS *Immediate Management of Clinical Adverse Events* Procedure are completed.
- 2.2 The accountable leader shall provide notification of the CAE and how it is being managed to the following as soon as possible:
- a) the AHS executive via the AHS *Urgent Notification to an Emerging Issue Report* or an update if this report has already been done;
  - b) the **most responsible health practitioner** of the patient;
  - c) the clinical leader and manager of the location where the CAE occurred; and
  - d) local **Patient Safety staff**.
- 2.3 As appropriate, the accountable leader shall ensure mandatory reporting to external bodies in a manner keeping with applicable privacy policy and legislation. This will include but not be limited to:
- a) Health Canada;
  - b) Alberta Health;
  - c) regulatory bodies (e.g., College & Association of Registered Nurses of Alberta [CARNA], College of Physicians & Surgeons of Alberta [CPSA]); and/or
  - d) regulated reporting to organizations such as Protection for Persons in Care, Child and Family Services, and the local Police agency.
    - (i) AHS Legal and Privacy may be contacted to provide advice regarding appropriateness of these types of reports.
- 2.4 The accountable leader will contact the Communications department if there is a need to inform or respond to the public regarding a CAE.

### 3. Patient Support

- 3.1 The accountable leader shall 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.
- 3.2 As appropriate, the accountable leader shall ensure continuation or initiation of the AHS *Disclosure of Harm* Procedure.
- a) AHS Disclosure Consultants are available to assist with disclosure as listed on the AHS external website.
- 3.3 It is the responsibility of the accountable leader to ensure that there is regular communication with the patient via a single point of contact who:
- a) will provide ongoing regular support and communication primarily to the patient (or a patient spokesperson if the patient identifies one) related to management of the CAE until resolution; and
- b) will provide information about follow-up processes that may occur and associated timelines.
- 3.4 The accountable leader, in partnership with the patient, shall assess any practical and emotional supports the patient may need.
- a) Every effort shall be made to secure these supports through existing AHS resources.
- b) Practical supports may include, but are not limited to:
- (i) parking;
  - (ii) food;
  - (iii) transportation;
  - (iv) accommodation;
  - (v) community support;
  - (vi) additional medical care; and/or
  - (vii) other considerations as determined by specific circumstances.
- c) If practical support needs exceed the accountable leader's spending authority as per the AHS *Delegation of Authority for Financial Commitments "Financial Authorization" Matrix* for one (1) year operating expenditures, approval from more senior leadership is required in accordance with the matrix.

- d) If the patient requests a copy of their health care record, the accountable leader shall work with Finance and Access and Disclosure to assure that it is provided promptly without expense to the patient.
  - e) Hold any bills from AHS for any related uninsured services until resolution has been reached and the appropriateness of billing has been considered.
- 3.5 The accountable leader may at any time, provide the patient and the family with contact information for the Patient Relations department. See the AHS *Patient Concerns Resolution Policy* and AHS *Patient Concerns Resolution Process Procedure*.
- a) The Patient Relations Department may be contacted by the accountable leader for advice on how:
    - (i) the accountable leader may best facilitate the concern review process; or
    - (ii) the Patient Relations department may assist in facilitating the concern review process.
  - b) Initiation of the **Patient Concerns Resolution Process** does not replace the ongoing management of the CAE by the accountable leader.

#### 4. Staff Support

- 4.1 The accountable leader shall support and communicate with the staff and medical staff by (See the AHS *Tips for Supporting Staff Involved in Clinically Serious Adverse Events* on Patient Safety page on Insite):
- a) reviewing immediate supports that have been offered and determining whether additional support is required;
  - b) providing information regarding the process and next steps of managing the CAE, including informing the staff and medical staff that they:
    - (i) may be contacted for purposes of review or analysis;
    - (ii) may be asked to participate in a meeting with the patient; and
    - (iii) should be informed of any resulting review findings and recommendations; and
  - c) consider the need to bring functional teams (e.g., programs) together to share general information. This may include that a serious CAE has occurred and that a process is underway to understand what happened and how to make patient care safer.

- (i) This information is provided by the local leader and is intended to open dialogue, avoid secrecy, isolation and shame.
  - 4.2 The accountable leader may contact the following groups to coordinate support for all directly and indirectly impacted staff and medical staff, including but not limited to:
    - (i) the Employee and Family Assistance Program (EFAP); and
    - (ii) the Physician and Family Support Program (PFSP).
  - 4.3 If staff are unable to continue to provide safe patient care, the accountable leader will coordinate with Workplace Health and Safety and/or Ability Management to determine appropriate management of time off work.
  - 4.4 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*.
- 5. Environmental Safety**
- 5.1 If medical devices are involved in or suspected of contributing to a CAE, the accountable leader shall ensure the *PLEASE Quarantine* process is followed as summarized in the *AHS Immediate Management of Clinical Adverse Events Procedure*.
    - a) The accountable leader shall ensure that suspect medical devices remain in quarantine until deemed safe to return to use by Clinical Engineering.
  - 5.2 In the case of a suspected medication administration related CAE, in addition to the steps outlined in the *AHS Immediate Management of Clinical Adverse Events Procedure*, the accountable leader shall notify:
    - a) the local Pharmacy Department Manager for awareness and to implement possible corrective action; and
    - b) the Medication Quality and Safety Team, Pharmacy Services.
- 6. Documentation of Clinical Adverse Event (CAE) Management**
- 6.1 The accountable leader will document all steps taken related to the *AHS Immediate Management of Clinical Adverse Events Procedure* and the *AHS Ongoing Management of Clinical Adverse Events Procedure*.
    - a) Copies of the documentation of CAE management should be provided to departments providing support including but not limited to Patient Safety and Patient Relations.

6.2 Documentation related to CAE management will be separate from the health record of the patient as per the AHS *Clinical Documentation Directive* and AHS *Clinical Documentation Process Directive*.

- a) Only portions of the CAE management that relate to or impact the patient's care or safety shall be documented on the patient's health record.

## 7. Evaluation of the Clinical Adverse Event (CAE)

7.1 The accountable leader shall conduct an initial evaluation of the CAE to identify potential issues related to quality of patient care and services provided.

- a) The purpose of the initial evaluation is to determine whether additional review or investigation is required to learn from the CAE and to make improvements to the health care system.
- b) Dimensions of quality to consider include acceptability, accessibility, appropriateness, effectiveness, efficiency and safety (see the *Alberta Quality Matrix for Health*).
- c) The accountable leader will review the facts of the CAE, confirm factual information with others (e.g., supervisors, staff and medical staff involved) and determine appropriate follow-up processes.
  - (i) An initial evaluation is conducted by accessing data sources (e.g., patient health records, health information systems, **Reporting and Learning System for Patient Safety [RLS]**, MySafetyNet, recordings, existing documentation regarding management of the CAE) to understand available facts leading up to the CAE.
  - (ii) The accountable leader will determine if a written chronology outlining the available facts is necessary to determine if there are system issues. As appropriate, the chronology shall be created within five (5) business days of the accountable leader becoming aware of the CAE.
- d) For CAEs, where the patient received patient care in multiple areas, the initial evaluation and decision regarding follow-up processes should be done in consultation with other impacted AHS leaders.
- e) A Patient Safety staff representative can assist with determining the scope of the potential issues and identify current work underway related to these issues (e.g., **Quality Assurance Review [QAR]** recommendations in progress).

7.2 The accountable leader can move to inform and improve (see section 8 of this document) without investigation if the initial evaluation of factual information provides an understanding of how and why a CAE occurred and:



- a) hazards are already well-known and shall be addressed through quality improvement; and/or
  - b) another method of learning from the CAE has been selected that is related to improving **health care professionals'** practices rather than system improvements (e.g., simulation, **educational case rounds**).
- 7.3 There are specific timelines for the completion of steps of QAR and Patient Safety Review (see the AHS *Quality Assurance Review [QAR] Handbook*), which shall be followed, as applicable.
- 7.4 If the accountable leader determines that additional investigation is required to learn about the CAE, so that improvements to patient safety can be made, one (1) or more of the following evaluation methods may be initiated:
- a) Quality Assurance Review (QAR):
    - (i) Used for CAE where it is suspected that system issues contributed to the CAE or where facts that led to the CAE are unclear, and staff and medical staff will feel most safe sharing their opinions under the protection of Section 9 of the *Alberta Evidence Act*.
      - Protection under Section 9 of the *Alberta Evidence Act* means that speculative discussions and opinions shared in the context of a QAR are not producible or compellable at any legal or administrative proceeding.
    - (ii) See the AHS *Quality Assurance Review (QAR) Handbook* regarding processes for initiating and conducting a QAR.
      - See the AHS *Systems Analysis Methodology (SAM) Handbook* for additional information regarding conducting system reviews.
    - (iii) Contact the appropriate Patient Safety staff (zone, provincial or program-based) for support with this process.
  - b) Patient Safety Review (PSR):
    - (i) Used for events where the facts that led to the CAE are clear and undisputed, and it is determined that staff and medical staff are comfortable discussing the event and system issues without the protection of Section 9 of the *Alberta Evidence Act*.
    - (ii) See the AHS *Systems Analysis Methodology (SAM) Handbook*.
    - (iii) Contact your local Patient Safety staff (zone, provincial or program-based) for support with this process.

- c) **Human Factors evaluation:**
- (i) Used in situations where the interface between users and equipment (or work environment) contributed to human error.
  - (ii) Contact the provincial Patient Safety department Human Factors team for support with this process.
- d) **Administrative Review** (also known as performance review):
- (i) The accountable leader will determine if an Administrative Review is appropriate (see the *Accountability Decision Support Tool* on the Just Culture page of Insite).
  - (ii) Support for the Administrative Review can be provided by:
    - Human Resources, if the actions of an AHS staff person require evaluation;
    - Medical Affairs, if the actions of a medical staff person require evaluation; or
    - the Provincial Midwifery department, if the actions of a midwifery staff person require evaluation.
- e) **Patient Concerns Resolution Process (PCRP):**
- (i) Used to address specific patient questions about the CAE or other concerns related to their patient care.
  - (ii) See the AHS *Patient Concerns Resolution Policy* and *Patient Concerns Resolution Process Procedure*.
  - (iii) The Patient Relations department may be consulted regarding this process.

## 8. Inform and Improve

- 8.1 After the required evaluation(s) have been completed, the accountable leader shall ensure that:
- a) the results of the evaluation(s) are shared as appropriate in accordance with the AHS *Disclosure of Harm Procedure*, AHS *Patient Safety Learning Summary Procedure* and/or AHS *Patient Safety Alerts and Safer Practice Notices Procedure*; and
  - b) steps are taken to improve health care services, at the individual or organizational level as appropriate.

- 8.2 The accountable leader shall ensure that the patient has been provided with the most accurate understanding possible about the CAE that has been obtained. Steps that will be taken to improve the health care system will be shared with the patient as per the AHS *Disclosure of Harm* Procedure.
- 8.3 To address any patient safety issues identified through the ongoing management of a CAE, the accountable leader may initiate one (1) or more of the following processes:
- a) **Patient Safety Learning Summary (PSLS):**
    - (i) To share the results and recommendations of reviews or initiatives.
    - (ii) See the AHS *Patient Safety Learning Summary* Procedure.
  - b) **Patient Safety Alerts (PSA):**
    - (i) Issued when an identified patient safety issue requires urgent attention and action.
    - (ii) Requires feedback to the Patient Safety department that appropriate corrective action was taken.
    - (iii) See the AHS *Patient Safety Alerts and Safer Practice Notices* Procedure.
  - c) **Safer Practice Notice (SPN):**
    - (i) Used to inform staff and medical staff of changes to, or reminders of, best practice.
    - (ii) See the AHS *Patient Safety Alerts and Safer Practice Notices* Procedure.
  - d) Educational Case Rounds:
    - (i) Educational presentation and discussion allowing a group of health care professionals to engage in learning from case studies within a just culture.
    - (ii) See the AHS *Education Case Rounds* document on the AHS external website.
  - e) Quality Improvement Initiative:
    - (i) Implemented when the issue(s) that led to the CAE are understood and recommendations for system improvement require development, testing, evaluation and implementation.

- (ii) See the *Alberta Health Services Improvement Way (AIW)* methodology.
  - (iii) Contact Clinical Quality Improvement staff (zone, provincial or program-based) for assistance.
- f) Simulation:
- (i) Allows staff and medical staff to practice critical skills in a simulated setting for the purpose of improving individual and team performance. System issues identified in a CAE can be used to create simulation scenarios to allow health care teams to practice managing difficult or unusual situations in a realistic setting.
  - (ii) The provincial eSIM team can be contacted for support with developing simulations.

## 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 *Ongoing 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 accountability remains at the senior level.

**Administrative Review** means a process that examines the actions and behaviours of individuals during a patient safety event. Any review examining the actions and behaviours of medical staff shall be managed in accordance with the Alberta Health Services *Medical Staff Bylaws* and *Rules*.

**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.

**Educational Case Round** means an inter-professional activity designed for the purpose of providing education for health care providers. These Rounds engage a number of individuals to focus on learning from case studies within a Just Culture. Cases may be chosen from various sources that relate to medical management, clinical processes/pathways or recurring system issues. Unlike Quality Assurance Reviews, Educational Case Rounds are not protected under Section 9 of the Alberta Evidence Act (Alberta) and formal recommendations for system improvements are not generated.

**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.

**Harm** means an unexpected outcome for the patient, resulting from the care and/or services provided, that negatively affects the patient's health and/or quality of life.

**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.

**Human Factors evaluation** means a study by the Human Factors Department of how health care providers work, that result in a report of processes and equipment that contribute to a high quality, safe, efficient health care system.

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

**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.

**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.

**Patient Concerns Resolution Process (PCRP)** means the process of review and resolution of concern(s) raised by complainants within Alberta Health Services.

**Patient Safety Alert (PSA)** means the standard document and process used when an issue requires urgent attention and action. These alerts are rare and require feedback to the Provincial Patient Safety Department that appropriate action was taken.

**Patient Safety Learning Summary (PSLS)** means the standard document and collaborative process to ensure that patients, families and health care providers can see the linkage between reporting, managing and analyzing clinical adverse events and other types of initiatives, culminating in the sharing of transparent, respectful, and non-identifying recommendations for improvement and organizational learning.

**Patient Safety staff** means staff employed to promote quality patient care and patient safety at a site, program, business area, zone or provincial level.

**Quality Assurance Review (QAR)** means a quality assurance activity conducted under the terms of section 9 of the *Alberta Evidence Act* (Alberta).

**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.

**Safer Practice Notice (SPN)** means the standard document and process used to inform staff, medical staff and midwifery staff of changes to or reminders of leading practice.

**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)
  - *Immediate Management of Clinical Adverse Events Procedure* (#PS-95-02)
  - *Medical Staff Bylaws*
  - *Medical Staff Rules*
  - *Patient Concerns Resolution Policy* (#PRR-02)
  - *Patient Concerns Resolution Process Procedure* (#PRR-02-01)
  - *Patient Safety Alerts and Safer Practice Notices Procedure* (#PS-95-05)
  - *Patient Safety Learning Summary Procedure* (#PS-95-06)
- Alberta Health Services Resources:
  - *Accountability Decision Support Tool*
  - *Alberta Health Services Improvement Way (AIW)*
  - *Delegation of Human Resources Authority Matrix*
  - *Education Case Rounds*
  - *PLEASE Quarantine Process* (Contracting, Procurement, and Supply Management)
  - *Quality Assurance Review (QAR) Handbook*
  - *Systems Analysis Methodology (SAM) Handbook*
  - *Tips for Supporting Staff involved in Serious Clinical Adverse Events* (Patient Safety)
  - *Urgent Notification to an Emerging Issue*
- Non-Alberta Health Services Documents:
  - *Alberta Evidence Act* (Alberta)
  - *Alberta Quality Matrix for Health* (Health Quality Council of Alberta)

## VERSION HISTORY

Date	Action Taken
November 01, 2017	Non-substantive change
<a href="#">Click here to enter a date</a>	Optional: Choose an item