

TITLE

RECOGNIZING AND RESPONDING TO HAZARDS, CLOSE CALLS AND CLINICAL ADVERSE EVENTSSCOPE

Provincial

DOCUMENT

PS-95

APPROVAL AUTHORITY

Quality Safety and Outcomes Improvement Executive Committee

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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 provide Alberta Health Services (AHS) **staff** and **medical staff** with a standard approach to managing patient safety **hazards, close calls** and **clinical adverse events** (CAE).
- To ensure that the needs of the **patient**, AHS staff and medical staff are managed appropriately.
 - In this policy and its procedures, references to the patient will include the **family** if the patient wishes.

PRINCIPLES

- Patients: We believe in a collaborative approach to improvement that includes engagement with patients and those who have been involved in CAEs. We will work to help support them and to rebuild trust in AHS.
- Our People: We recognize that **health care providers** may also be harmed when a CAE occurs. When their patients are harmed, health care providers may suffer from professional and personal anguish. We will support and treat our people with care, compassion, respect and dignity.
- Patient Safety: Health care providers aim to minimize risks to patients' physical and psychological well-being. Patients, 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 they provide to patients.

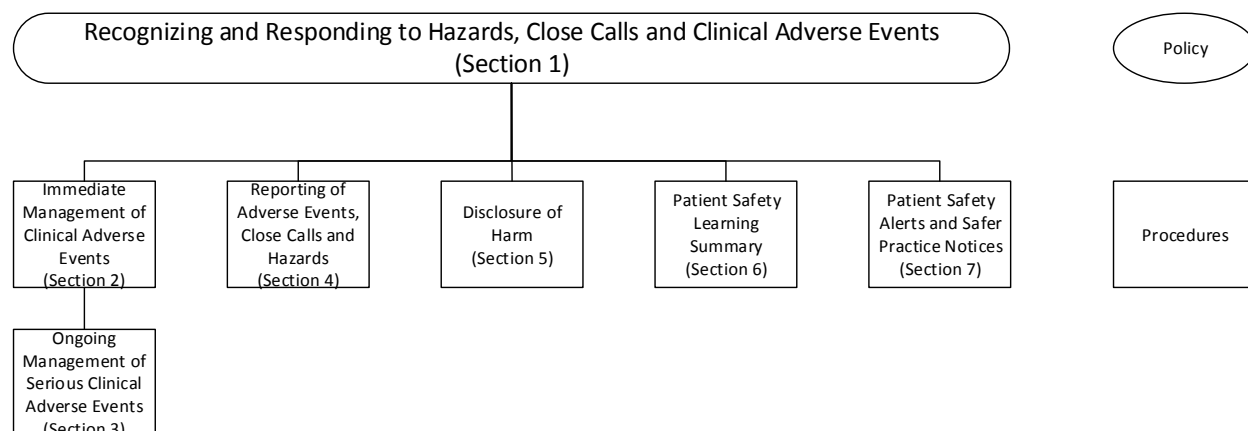
- **Just Culture:** We support all stakeholders with empathy and thoughtfulness following a CAE. We strive to create an environment where everyone feels safe, encouraged, and enabled to discuss safety concerns. When a CAE occurs, actions are evaluated impartially in consideration of the circumstances and context of what occurred, rather than results and outcomes. We avoid the temptation to reduce complex issues to simple individual human error.
- **Learning:** We recognize that understanding and learning from CAEs is essential to improving patient safety. This is accomplished respectfully with the utmost sensitivity, empathy and compassion for all involved.

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. Overview of Clinical Adverse Event Management



- 1.1 AHS leaders become aware of patient safety hazards, close calls and CAEs through a number of different ways, including:
- verbal notification from staff;
 - the **Reporting and Learning System for Patient Safety (RLS)**;
 - notification from Patient Relations; and
 - the AHS *Urgent Notification to an Emerging Issue Report*.

2. Immediate Management of Clinical Adverse Events

- 2.1 Immediate management of CAEs will be coordinated by a single **clinical leader** who will ensure a fair and consistent response in accordance with the AHS *Immediate Management of Clinical Adverse Events* Procedure.
- 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.
- 2.2 Immediate management of a CAE should be started as soon as it is identified and completed as soon as feasible, ideally within 24 to 48 hours of the event, as per the AHS *Immediate Management of Clinical Adverse Events* Procedure.
- 2.3 During immediate management, the clinical leader must consider the following elements:
- a) patient support (and family members as appropriate);
 - b) staff and medical staff support;
 - c) environmental safety for patients, staff and medical staff;
 - d) documentation of CAE management; and
 - e) notification to directly involved health care professionals, the most responsible practitioner and AHS leaders.
- 2.4 Management of a CAE can be concluded after the immediate management of the CAE stage if:
- a) the outcome of the CAE on the patient is not serious;
 - b) there is no need for further investigation; and
 - c) the CAE has been resolved to the satisfaction of the patient.

2.5 If the criteria outlined in section 2.4 of this document are not met, the clinical leader will hand over the management of the CAE to an **accountable leader** as per the AHS *Ongoing Management of Clinical Adverse Events* Procedure.

3. Ongoing Management of Clinical Adverse Events

3.1 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.

3.2 A fair and consistent process shall be utilized by the accountable leader in accordance with the AHS *Ongoing Management of Clinical Adverse Events* Procedure.

3.3 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 the AHS *Ongoing Management of Clinical Adverse Events* 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.

3.4 Ongoing management of a CAE starts when the clinical leader completes handover to the accountable leader, ideally within 24 to 48 hours of the CAE being identified. Ongoing management of a CAE may take months to complete, but should be prioritized by AHS stakeholders to minimize any delays.

- 3.5 Ongoing management follows the immediate management process and the accountable leader has the additional responsibilities related to the following elements:
- a) receiving of handover from clinical leader;
 - b) notification both internally and as appropriate externally;
 - c) patient support (and family members as appropriate);
 - d) staff and medical staff support;
 - e) environmental safety for patients, staff and medical staff;
 - f) documentation of CAE management;
 - g) evaluation of the CAE;
 - h) consideration of any opportunities to improve patient safety and selection of one (1) or more established methods for learning from CAEs; and
 - i) sharing of review outcomes to improve patient safety.
- 3.6 In order for patient safety to be realized, the accountable leader shall take steps to share what was learned from the review of a CAE with relevant stakeholders within AHS, and ensure that effective actions are taken to improve quality and safety.

4. Reporting of Clinical Adverse Events, Close Calls and Hazards

- 4.1 The Reporting and Learning System for Patient Safety (RLS) is the appropriate method for reporting CAEs, close calls and hazards related to patient safety.
- 4.2 The RLS is a system of reporting that spans the continuum of patient care in AHS and plays an important role in supporting patient safety by ensuring that CAEs, close calls and hazards are reviewed individually and in aggregate.
- a) The primary function of the RLS is to identify health system risks to patient safety so that action can be taken to mitigate these risks for patients.
 - b) RLS reports are trended, analyzed and shared for the purpose of organizational learning.
 - c) Feedback of organizational learning is provided to reporters and also to those who would benefit from such learning.

- 4.3 All staff and medical staff have a responsibility to voluntarily report CAEs, close calls and hazards for the purpose of learning about and improving the safety of patients and the health care system.
- a) AHS is committed to fostering a just culture that includes reporting and learning as a key element (see the *AHS Just Culture Guiding Principles*). This means that reporting is conducted within a psychologically safe environment where human fallibility is acknowledged.
 - b) Reporting to RLS does not replace staff and medical staff requirements to:
 - (i) notify clinical leaders of CAEs as per immediate management (see section 2 of this document); and
 - (ii) document the known facts about the event in the patient's health record.

5. Disclosure of Harm

- 5.1 AHS expects **disclosure** conversations to be conducted with patients if there has been any harm, if there is any risk of potential future harm, or if there is any change in patient care or monitoring as a result of patient care provided, in accordance with the *AHS Disclosure of Harm Procedure*. These conversations should be supported by leaders, when required.
- 5.2 When an event has occurred and none of the criteria in section 5.1 of this document are met, disclosure is discretionary, but shall be done if it is felt the patient would benefit from knowing or would want to know.
- a) If it is unclear whether the patient would benefit from disclosure or would want to know, disclosure shall occur.
- 5.3 As part of the disclosure, patients should receive:
- a) acknowledgement and an apology, including a commitment to determine the facts without speculation, and share them with the patient in an appropriate and timely manner;
 - b) the most accurate understanding possible about what has occurred, and its significance for the patient;
 - c) an understanding of how the organization will respond; and
 - d) AHS lessons learned and what will be done to prevent similar harm from occurring in the future.

- 5.4 Sharing of information with the patient:
- a) Information shall be shared in a manner demonstrating compassion and empathy and shall be supportive of the patient's needs.
 - b) Disclosure of Harm is a process and may require a series of conversations to reach resolution.
 - c) All information sharing shall be done in a manner that is respectful of the privacy of all individuals involved in accordance with all appropriate applicable legislation.

6. Patient Safety Learning Summaries

- 6.1 When learning arises from the CAE that should be shared broadly, there will be consideration for completion and distribution of a **Patient Safety Learning Summary (PSLS)**, as per the AHS *Patient Safety Learning Summary Procedure*.
- 6.2 A PSLS shall not include any information that identifies the patient, health care providers, or site of the event in accordance with AHS *Collection, Access, Use, and Disclosure of Information Policy*, the *Alberta Evidence Act (Alberta)* and the *AHS Just Culture Guiding Principles*.

7. Patient Safety Alerts / Safer Practice Notices

- 7.1 As appropriate, when a patient safety hazard (a set of circumstances that if left unchanged could harm or contribute to the harm of a patient) is identified, a **Patient Safety Alert (PSA)** or **Safer Practice Notice (SPN)** as per the AHS *Patient Safety Alerts and Safer Practice Notices Procedure* shall be completed and distributed.
- 7.2 **Patient Safety staff** shall facilitate the distribution of timely, targeted and user-friendly information, including known facts and risk mitigation strategies, to stakeholders in order to support patient safety and promote just culture.

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 *Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events* Policy and procedures. 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.

Close call means an event that has potential for harm and is intercepted or corrected prior to reaching the patient.

Disclosure means the formal process involving an open discussion between a patient and staff of Alberta Health Services about the events leading to a serious clinical adverse event, hazard or harm.

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.

Hazard means a situation that has potential for harm and does not involve a patient.

Health care provider means any person who provides goods or services to a patient, inclusive of health care professionals, staff, students, volunteers and other persons acting on behalf of or in conjunction with Alberta Health Services.

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 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.

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

- Appendix A: *Management of Clinical Adverse Events Process*
- Alberta Health Services Governance Documents:
 - *Collection, Access, Use, and Disclosure of Information Policy* (#1112)
 - *Disclosure of Harm Procedure* (#PS-95-01)
 - *Immediate Management of Clinical Adverse Events Procedure* (#PS-95-02)
 - *Ongoing Management of Clinical Adverse Events Procedure* (#PS-95-03)
 - *Reporting of Clinical Adverse Events, Close Calls and Hazards Procedure* (#PS-95-04)
 - *Patient Safety Alerts and Safer Practice Notices Procedure* (#PS-95-05)
 - *Patient Safety Learning Summary Procedure* (#PS-95-06)
- Alberta Health Services Resources:
 - *Just Culture Guiding Principles*
 - *Urgent Notification to an Emerging Issue Report*
- Non-Alberta Health Services Documents:
 - *Alberta Evidence Act* (Alberta)

VERSION HISTORY

Date	Action Taken
November 1, 2017	Non-substantive change
Click here to enter a date	Optional: Choose an item

APPENDIX A

Management of Clinical Adverse Events Process

