# Learning from Clinical Adverse Events

# A GUIDE FOR LEADERS

### 2024

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## Introduction

The essence of healthcare leaders lies in their commitment to ensuring quality care while maintaining patient safety. We work in complex healthcare systems; therefore, it is essential to recognize all contributing factors to identify system vulnerabilities when a clinical adverse event (CAE) occurs.

Alberta Health Services (AHS) provides tools and resources like the AHS Patient Safety Policy Suite and Procedures to empower accountable leaders to respond, manage, and learn from a CAE, transforming such events into positive experiences for all involved. The AHS Clinical Adverse Events Toolkit and the Quality Assurance Commitee (QAC) Handbook, for example, were designed to support clinical safety leads, patient safety representatives, and operational leaders in navigating the internal processes of a system review. These resources are all posted on Insite, the AHS internal webpage.

This guide provides an overview of the different methods (including QARs) that leaders can use to review CAEs (and the outputs generated from such reviews), which aims to support leaders in making decisions about the most appropriate review method for a CAE.

Accountable leader refers to individuals who enable the completion of the listed steps in managing the AHS Immediate and Ongoing Management of Clinical Adverse Events Procedure with the support of patients, families, care and support staff, and other key partners. Responsibility for some or all of the management components may be delegated to the appropriate level of responsible administrative leader, but the accountability remains at the senior level.

Understanding how and when to use these resources is crucial in meeting the unique needs of patients, families, staff, and leaders and reducing the risk of future adverse events through learning.

Nevertheless, "first do no harm" remains a sacred obligation for all in health care, and success requires "constancy of purpose for improvement." Without renewed board and executive leadership and accountability for safety and without concerted, persistent investment in and monitoring of change, a summary study 34 years from now may again look all too familiar, with millions upon millions of patients, families, and health care staff paying the price for inaction. (N Engl J Med 2023).

Donald M. Berwick, M.D., M.P.P.



### **Process Overview**

When clinical adverse events occur, it is crucial to **provide immediate care to the patient and those providing care.** It is also vital to ensure environmental safety and remove any unsafe equipment. All devices involved in harm and near-harm CAEs must be retained for investigation by following the **PLEASE Quarantine** steps. Finally, disclose, document, and report.

The accountable leader is notified of the adverse event, ensures immediate care is provided, and then conducts an initial assessment. The initial assessment includes understanding the event's chronology and key facts to decide which processes need to occur. The diagram below illustrates the pathway to responding and choosing methods to review the event and how to share lessons learned.



The AHS Provincial Patient Safety Team developed a **Job Aid to Evaluate Clinical Adverse Events (CAE)**, which helps accountable leaders decide which review method is appropriate for a specific adverse event. Leaders need to understand the differences between various resources and processes, as they have different objectives and outcomes that cater to the unique needs of everyone involved. <u>Table 1</u> provides information on the potential review methods, the output from these methods, and available supports which can be helpful when deciding on the most appropriate review method.

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### Review Methods, Outputs & Supports

Table 1

POTENTIAL REVIEW METHOD	OUTPUTS	SUPPORTS
Quality Assurance Review (QAR) or a Patient Safety Review (PSR)	Description of the event, system related issues, and recommendations. If appropriate, a Patient Safety Learning Summary.	Provincial, Zone, or Program Patient Safety Representatives
Educational Case Rounds	These rounds promote learning from case studies and not intended to produce system-level recommendations or assess individual provider performance but may uncover events that require further review. (Previously known as M&M)	Appropriate Clinical Department
Administrative Review	An evaluation of whether a staff member or medical staff member's actions in a specific event were appropriate or inappropriate; performance management plan may result.	Human Resources Any review involving a physician is managed by Medical Affairs
Quality Improvement Initiative	For a particular problem or issue, a project team will define the opportunity, build understanding of the situation, implement an improvement, and sustain results. Projects range from small to large. If appropriate, a Patient Safety Learning Summary.	Zone Clinical Quality Department
Human Factors Evaluation	AHS has integrated Human Factors principles and evaluative methodologies into Workspace Design, Device Evaluation, Medication Safety, Information Design, Human Error Management, and eSafety to reduce the possibility of unexpected outcomes for patients while improving efficiency.	Human Factors
Simulation	Simulation can be applied to learn what happened after an adverse event and/or to identify latent patient safety hazards that may not otherwise be detected.	eSim <sup>™</sup>
Patient Concerns Resolution Process	Responses to patients/families specific questions and concerns about their care in compliance with the Alberta Patient Concerns Resolution Process Regulation 28/2016.	Patient Relations Department



Understanding each method is important in knowing who to consult, what to prepare, what kind of follow-up is required, and how to share learnings. The following is a brief overview for each of the methods:

#### 1. Quality Assurance Review (QAR)

- Protected by section 9 of the Alberta Evidence Act
- Planned or systematic evaluations of the healthcare components
- The goal is to identify system issues and make recommendations for improvement to continually improve the quality of healthcare services provided
- Conducted by an AHS approved Quality Assurance Committee (QAC) or a QAC Subcommittee with a standardized Terms of Reference (TOR); meets regularly with defined membership
- Uses Systematic Systems Analysis (SSA) or another recognized systems review methodology
- Reviews and implementation of resulting recommendations are tracked in a provincial database by Patient Safety
- Requested by the accountable leader and involves stakeholders to develop recommendations. An operational owner is accountable for the implementation of recommendations
- Reviews may be aggregated to understand patient safety risks impacted by practice trends and improvement strategies developed in a protected manner. Individual performance issues are not addressed. If data reveals a trend or common contributing factors, the responsible leader is informed for review and next steps
- Target completion is 90 business days for concise/comprehensive reviews and 180 business days for aggregate reviews

Note: Factual information, such as documentation in the patient health record is not protected under section 9. Contact a clinical safety lead for further information.

**QAR Scenario:** A patient certified under the Mental Health Act elopes from a secured inpatient mental health unit and attempts self-harm.

**QAR Scenario:** Analysis of Code Blue calls within a site.





#### 2. Patient Safety Review

- NOT protected by section 9 of the Alberta Evidence Act
- Requested when the available facts (e.g., clinical records, dispatch recordings) are sufficient to understand what happened and identify opportunities for system improvements
- Conducted by a Clinical Safety lead or a Patient Safety Representative at the request of an accountable leader
- Uses Systematic Systems Analysis (SSA) or another recognized systems review methodology
- All documents arising from this review are producible in subsequent proceedings and witnesses can be questioned on the contents of the review
- Reviews and the implementation of resulting recommendations for improvement are tracked in a provincial database
- Target completion is 90 business days for concise/comprehensive reviews and 180 business days for aggregate reviews

**Patient Safety Review Scenario:** Morphine is ordered, instead hydromorphone is drawn up but the error is recognized prior to the medication being given.

#### 3. Educational Case Rounds

- NOT protected by section 9 of the Alberta Evidence Act
- Formerly termed Morbidity & Mortality Rounds
- Designed to engage a number of individuals to focus on learning from case studies
- Formal recommendations for system improvements are not generated. However, these rounds can identify events that do require additional review processes
- Conducted as an inter-professional educational activity and details of cases being reviewed are deidentified

**Educational Case Rounds Scenario:** A peripartum patient presents to the emergency department with signs and symptoms of heart failure requiring an emergency c-section. A review of such case was presented to increase awareness of peripartum cardiomyopathy.



#### 4. Administrative Reviews

- Not protected under section 9 of the Alberta Evidence Act
- Conducted in collaboration with Human Resources or Medical Affairs for Physicians
- Information may be protected from disclosure pursuant to privacy legislation; however, this is assessed on a case-by-case basis

Administrative Review Scenario: Aggregated data in the context of peer group comparison reveals a trend related to performance that is outside of accepted limits, as determined by the clinical group. For example, a physician commits an error in managing infection control. Upon a review by the physician's Medical Leader and Medical Affairs; determination will be made on how to proceed with the investigation. i.e. informal or pursuant to the Medical Staff Bylaws/Rules.

### 5. Quality Improvement (QI) Initiative

- Is a planned activity to address a defined problem, collect and measure baseline data, design solutions using improvement tools and methodologies, to continuously improve and sustain services, products, or processes
- Recommended when the reasons for an adverse event are understood and improvements can be made without a formal investigation
- Uses QI tools such as Process Maps, Fishbone Diagram, Driver Diagrams, Graphs & Charts) and QI Methodologies (The Model for Improvement/PDSA, Lean, Six Sigma, and our own AHS Improvement Way (AIW)
- Use of more than one QI methodology is recommended as each methodology has strengths and weaknesses and often, there is more than one way to solve problems.
- AIW is a common organization-wide approach for solving problems, implementing improvements, and managing change based on Lean and Six Sigma principles. The QI project lead identifies /clarifies the issue with the healthcare team as a starting point in the AIW process
- Some examples of the focus of work are: Improving access to an outpatient / specialty clinical service, streamlining processes for patient care, and service redesign to enhance service efficiency among the others
- · Zone/Local Clinical QI teams are available to consult regarding QI initiatives

**Quality Improvement Initiative Scenario:** A wrong site surgery in a high-volume surgical environment occurs the week after an aggregate review of all wrong site surgeries and one week prior to the implementation of an AIW pilot to reduce wrong site surgeries.



#### 6. Simulation

- Not protected under section 9 of the Alberta Evidence Act
- Prospectively identifies potential preventable hazards in the system that may be contributing to an adverse event either in situ on a unit, in a simulation lab, or when commissioning a new space or testing a new process
- Can also be used to recreate an adverse event within a safe environment, without risking patient harm, incorporating the environment, equipment, health-care team behaviors and system processes that may have contributed to the complexities of an adverse event.

**Simulation Scenario:** Discovering the batteries are dead for the defibrillator on a care unit when running a simulation around resuscitation/acute deterioration. If this was not found proactively by the simulation team, the same may have occurred when resuscitating a patient.

#### 7. Human Factors Evaluation

- Not protected under section 9 of the Alberta Evidence Act
- Studies how health-care providers work and then designs workspaces, equipment, tools, and information that is easy to use and contributes to a high-quality and safe healthcare system
- Have two goals: (1) to reduce the possibility of unexpected outcomes for patients and (2) improve efficiency through human factors evaluation and design.
- AHS has integrated human factors design principles and evaluative methodologies in various projects at local, zonal and provincial levels.

**Human Factors Evaluation Scenario:** A patient is given the wrong medication because two medication vials looked the same. Human factors would recommend ways to differentiate the medication vials to minimize the potential for error.



#### 8. Patient Concerns Resolution Process

- A fair, consistent, transparent, and timely process for patients to raise concerns about their healthcare experience or that of someone they are concerned about
- Initiated at the request of the patient / complainant and is conducted in compliance with legislation (<u>Patient Concerns Resolution Process Regulation 28/2016</u>) and the AHS Patient Concerns Resolution Process Policy Suite.
- Patients are encouraged to speak with their care team first when they have questions or concerns. If needed, they can contact the manager or supervisor for help, or contact the <u>Patient Relations Department</u> via phone, mail or complete an <u>online patient</u> <u>feedback form</u> to submit feedback.
- The Patient Relations Department uses the Feedback and Tracking (FACT) database to document all interactions with patients and complainants. The database only includes quantitative data to protect privacy and serves as an indicator for leaders to follow-up with further reports as well as a measure of patient satisfaction and experience. The database is updated quarterly, and narratives can be requested from Clinical Quality Metrics (CQM).

**Patient Concerns Resolution Process Scenario:** A patient's family member believes a caregiver to be unprofessional when she witnesses the caregiver ignoring a call for patient assistance in favour of finishing a text message.



## Summary

Accountable leaders have the responsibility to uphold a safety culture. A safe culture is one that prioritizes learning, accountability, and error prevention. Leaders and care providers are held accountable for unprofessional conduct, but not punished for human mistakes. Errors are identified and mitigated before harm reaches the patient, and feedback loops allow frontline staff to learn from previous errors and prevent recurrences.

### Highlight 1

- AHS has tools & resources to help accountable leaders respond, manage & learn from adverse events.
- Leaders responsible for the area where a CAE occurs are accountable for the appropriate handling and response to the event.
- Understanding the correct review method is essential to meet the needs of stakeholders and promote learning.

### Highlight 2

- Accountable leaders have a responsibility to understand and support the process involved with the management of CAEs using the different review methods: learning process, products, and available supports.
- Accountable leaders can utilize the Job Aid to Evaluate Clinical Adverse Events (CAE) to decide which review method is the most appropriate.
- Each review method is supported by different departments which possess the expertise to ensure that the chosen review method is appropriate for the CAE in question.

### Highlight 3

- The Alberta Evidence Act's section 9 offers protection to healthcare professionals to have confidential and protected discussions without fear of legal or administrative consequences.
- Section 9 protection is only provided in Quality Assurance Reviews.
- All CAE follow up and review methods aim to promote a safety culture using a non-punitive approach by considering all contributing factors and circumstances in the context of which they occurred.

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#### A GUIDE FOR LEADERS

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