

TITLE

IMMEDIATE AND ONGOING MANAGEMENT OF CLINICAL ADVERSE EVENTS

SCOPE

Provincial

DOCUMENT

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

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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 describe the immediate management steps which the **clinical leader** must take when a **clinical adverse event (CAE)** is recognized, and the ongoing management process, if required.
- To ensure that the immediate and ongoing needs of the **patient** and **health care provider(s)** involved in a CAE are managed appropriately according to evidence-based principles and practices.
 - In this Procedure, references to the patient will include the patient's **family**, if the patient wishes.
- To ensure CAEs are managed in a way that advances patient- and family-centered care and fosters quality patient and family experiences.
- To support organizational shared learning and patient safety improvement following a CAE.

PRINCIPLES

An effective and compassionate approach requires leaders to follow AHS just culture principles (Refer to *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 The immediate management of a CAE includes the following steps (for detailed information refer to Section 2 below).
 - a) Respond to the patient's immediate needs.
 - b) Ensure the environment is safe for other patients and health care providers.
 - c) Secure and remove medical devices and medications that may have contributed to the CAE.
 - d) Notify the **most responsible health practitioner (MRHP)** and **accountable leader within 24 hours of the CAE**.
 - e) Offer support to the patient(s) and health care providers involved in the CAE.
 - f) Initiate a **disclosure of harm** conversation with patient in accordance with the AHS *Disclosure of Harm* Procedure.
 - g) Document the CAE in the patient's medical record.
 - h) Report the CAE in the Reporting and Learning System (RLS) for Patient Safety.
 - i) Complete other mandatory reporting if required.
- 1.2 The ongoing management of a CAE process includes the following steps (for detailed information refer to Section 3 below).
 - a) Handover management of the CAE to an accountable leader.
 - b) Ensure that applicable steps in the immediate management as per Section 1.1 above are complete.
 - c) Complete internal and external notifications as required:
 - (i) AHS *Urgent Notification to an Emerging Issue* Form; and/or

- (ii) other notifications as required (e.g., legislative or regulatory bodies).
 - d) Determine if further investigation is required.
 - e) Select an appropriate review method.
 - f) Share lessons learned.
- 1.3 The AHS *Immediate and Ongoing Management Checklist for Management of CAEs* is available on the Patient Safety webpage on Insite.

2. Immediate Management of a CAE

- 2.1 Respond to the patient's immediate needs. When a CAE has occurred, the health care provider shall respond to the patient's immediate medical needs and report the CAE to a clinical leader who will initiate the immediate management of the CAE.
- 2.2 Immediate management of CAEs shall be coordinated by a single clinical leader who will ensure a fair and consistent response. The clinical leader shall:
- a) determine whether any additional patients may be harmed by the hazard(s) or impacted by the CAE, and ensure necessary steps are taken to prevent further harm;
 - b) continue to address the patient(s) needs;
 - c) maintain or create a safe environment for patients and health care providers;
 - d) communicate the facts of the CAE to all directly involved health care providers, so that they can ensure that the patient's care plan is updated to include necessary changes in patient care and monitoring; and
 - e) handover management of the CAE to a subsequent clinical leader if needed (e.g., at shift change) and/or to an accountable leader if required for ongoing management.
- 2.3 If **medical devices** are involved in, or suspected of contributing to, a CAE, refer to the AHS *Medical Device Safety* Policy Suite. The clinical leader shall ensure the following occurs as appropriate:
- a) retain all medical devices involved in or suspected of contributing to the CAE, regardless of the level of harm or contamination;
 - (i) Refer to the AHS *Medical Device Safety - Preparing and Shipping for Investigation* Procedure.

- b) follow the AHS *PLEASE Quarantine Checklist* if harm to any person occurred;
 - c) complete reporting;
 - (i) Any **medical device incident** and/or **medical device problem** that occurred at an **AHS setting**, or a medical incident that a health care provider is made aware of that occurred elsewhere, shall be reported to the AHS Medical Device Safety team, through the AHS Sharepoint or RLS *Medical Device Incident or Problem (MDIP) Report Form* links on Insite or Connect Care Hyperspace.
 - (ii) Refer to the *AHS Medical Device Incident or Problem Reporting Procedure*.
 - d) ensure the suspect medical devices remain in quarantine until Medical Device Safety advises next steps; and
 - e) 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 (refer to the *Fatality Inquiries Act [Alberta]*).
- 2.4 If a **medication** or **medication management** process is suspected to have contributed to the CAE, the clinical leader shall ensure the following occurs as appropriate:
- a) secure and remove medications that may have contributed;
 - b) for a suspected medication **dispensing** CAE:
 - (i) notify the local Pharmacy Manager immediately and provide information;
 - lot number or batch numbers of any quarantined medication(s);
 - (ii) do not return medication(s) into circulation until advised by Pharmacy that it is safe to do so;
 - c) for a suspected medication administration CAE:
 - (i) notify the MRHP;
 - (ii) notify the local Pharmacy Manager;
 - (iii) Pharmacy shall support the clinical leader;

- (iv) if needed, clinical Pharmacists shall provide assistance to the MRHP with the clinical management of the patient.
- d) include Pharmacy in the RLS report for all medication-related CAEs.
- e) report adverse drug reaction that meets the criteria of **Serious Adverse Drug Reaction (SADR)**, as defined in the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law), via:
 - (i) the AHS *Serious Adverse Drug Reaction* Form within Connect Care; or
 - (ii) the AHS *Medication or Other Substances Reporting* Form on the RLS Insite page for sites that are not using Connect Care.
- 2.5 The clinical leader shall notify the MRHP and immediate supervisor or Manager for the area within 24 hours of being aware of the CAE.
- 2.6 The clinical leader and/or accountable leader shall ensure that the disclosure of harm conversation is initiated, that includes an apology and acknowledgment of any harm that has occurred to the patient, in accordance with the AHS *Disclosure of Harm Procedure*.
- 2.7 Patient Support
 - a) The clinical leader and/or accountable leader shall offer support to patient(s) involved in the CAE including if appropriate:
 - (i) discuss with the patient if they wish to have their care transferred to other health care providers. If so, facilitate as soon as feasible;
 - (ii) address the emotional needs of the patient (e.g., private space, reassurance);
 - (iii) address the spiritual needs of the patient (e.g., assisting with finding a spiritual leader or member of a faith or cultural community);
 - (iv) address the information needs of the patient (e.g., provide an AHS single point of contact for communication with the patient);
 - (v) AHS resources, such as telephone, parking, food, transportation , accommodation, community support, additional medical care, and/or other considerations as determined by specific circumstances;
 - If the needs of the patient exceed the clinical or 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.

- If the patient requests a copy of their health care record, the clinical and/or accountable leader shall work with Finance and the Access and Disclosure department to assure that it is provided promptly without expense to the patient.
 - Hold any bills from AHS for any related uninsured services until resolution has been reached and the appropriateness of billing has been considered.
- (vi) provide the patient and the family with contact information for the Patient Relations department. Refer to the AHS *Patient Concerns Resolution* Policy and AHS *Patient Concerns Resolution Process* Procedure; and
- initiation of the patient concerns resolution process does not replace the immediate and ongoing management of the CAE by the clinical leader and/or accountable leader.

2.8 Health Care Provider Support

- a) The clinical leader and/or accountable leader shall ensure the following support for health care providers involved in a CAE as appropriate:
- (i) attend to the immediate medical and emotional needs of all healthcare providers involved in the CAE;
 - Consider a team debrief of the event to support the team and learn of any additional immediate needs.
 - (ii) determine if the health care providers are able to continue to provide safe patient care;
 - The accountable leader shall coordinate with Workplace Health and Safety and/or Ability Management to determine appropriate management of time off work if applicable.
 - (iii) if medical staff are unable to continue to provide safe patient care, they shall 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*;
 - (iv) if midwifery staff are unable to continue to provide safe patient care, they shall work with the accountable leader to determine appropriate coverage as soon as it is safe and feasible to do so,

as per the processes outlined in the *AHS Midwifery Staff Bylaws* and *AHS Midwifery Staff Rules*;

- (v) arrange support for health care providers who were directly and indirectly involved in the CAE (refer to the *AHS Tips for Supporting Staff Involved in Clinically Serious Adverse Events*). Provide if necessary:
- a quiet and private place for all communication and documentation to occur;
 - information for health care providers to report work related hazards, illnesses, and injuries into MySafetyNet system on onsite;
 - information about and referral to support programs and encourage healthcare providers to seek assistance, including but not limited to:
 - health care providers may call the AHS Employee Family Assistance Program (EFAP) intake line 24/7/365 at 1-877-273-3134.
 - Physicians may contact the Alberta Medical Association Physician and Family Support Program, also a confidential 24/7 support line, at 1-877-SOS-4MDS for options and support.
 - Midwives may contact Alberta Association of Midwives Association (AAM on-Call) 24/7 by calling 1-866-418-3773 (ext. 2262 for non-urgent and ext. 2265 for urgent). Additional supports are available for clinical leaders and accountable leaders to for the management of the CAE (refer to Section 3.1 c) below).

2.9 Document the CAE in the patient's **health record**. For all CAEs, the clinical or accountable leader shall ensure the following occurs:

- a) Documentation of the CAE in the health record should include only portions of the CAE management that relate to or impact the patient's care or safety and meet the *AHS Clinical Documentation Directive* and *AHS Clinical Documentation Process Directive* requirements. Include at minimum the following:
- (ii) known facts (no opinions or speculation);
 - (iii) the patient care plan as a result of the CAE;

- (iv) notification(s) of others of a CAE (e.g., MRHP, Manager); and
 - (v) the facts of disclosure conversations that have occurred (refer to the AHS *Disclosure of Harm* Procedure).
- b) Documentation related to CAE management (not related to patient clinical care) will be separate from the health record.
- 2.10 The clinical leader and/or accountable leader should ensure that the CAE is reported in the RLS (refer to the AHS *Reporting of Clinical Adverse Events, Close Calls, and Hazards* Procedure)
- a) Users with permissions to log in and review RLS reports (Advanced User, Designate, and Participant Reviewer) should document the event follow-up within RLS.
- 2.11 Health care providers shall support meeting AHS mandatory reporting requirements (refer to Section 2.12 below) as required.
- 2.12 The clinical leader and/or accountable leader shall complete additional mandatory notification of certain events required by legislation and/or policy including but not limited to the following:
- a) *Protection for Persons in Care Act* (Alberta);
 - b) *Medical Examiner as per Fatality Inquiries Act* (Alberta);
 - c) *Fatality Inquiries Act* (Alberta);
 - d) *AHS Keeping Patients Safe From Abuse Policy*;
 - e) *Continuing Care Health Service Standards* (Alberta Health);
 - f) *Child, Youth and Family Enhancement Act* (Alberta);
 - g) *Protecting Canadians from Unsafe Drugs & Devices Act* (Vanessa's Law) [Canada];
 - h) *AHS Transfusion of Blood Components and Blood Products Policy*; and
 - i) *Mental Health Services Protection Act* (Alberta).
- 2.13 The clinical leader shall notify the accountable leader if ongoing management of the CAE is needed. Handover to an accountable leader for ongoing management of CAEs is required but not limited to the following circumstances:
- a) when the outcome of the CAE for the patient is severe harm or death;
 - b) when the CAE is considered a potential **never event**;

- c) when the CAE involves multiple patients;
- d) when the immediate management of the CAE does not resolve the hazard and related issues;
- e) when the CAE has not been resolved to the satisfaction of the patient; and/or
- f) at the discretion of the accountable leader in less clinically serious circumstances, including **hazards**, **close calls**, no apparent harm, minimal or moderate **harm**.

2.14 If the immediate management of the CAE addresses and resolves the hazard and related issues and fulfills the needs of the patient and health care providers, then resolution has been achieved and the management of the CAE is complete.

3. Ongoing Management of a CAE

- 3.1 Ongoing management of CAE shall be coordinated by a single accountable leader who shall continue to ensure a fair and consistent response (e.g., apply a system versus an individual approach).
- a) 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, Senior Medical Officer, or a designate.
 - b) If CAEs affect multiple patient care areas or programs, the leadership teams of the affected areas shall collaboratively determine the accountable leader.
 - c) Clinical leaders and accountable leaders may access additional support to manage the CAE, including:
 - (i) Manager/Administrator on-call;
 - (ii) MRHP;
 - (iii) Patient Safety Representative;
 - (iv) Patient Relations;
 - (v) Health Law and/or Legal and Privacy;
 - (vi) Employee and Family Assistance Program;
 - (vii) Physician and Family Support Program;
 - (viii) Workplace Health and Safety;

- (ix) Medical Affairs;
 - (x) Human Resources;
 - (xi) Media Relations and Proactive Issues Management;
 - (xii) Disclosure of Harm consultants;
 - (xiii) Health Professions Strategy & Practice; and/or
 - (xiv) Provincial AHS clinical departments (e.g., Provincial Midwifery Services, Pharmacy Services, Diagnostic Imaging, Laboratory Services, Emergency Medical Services).
- 3.2 The accountable leader shall review the work to date regarding the immediate management of CAE during the handover from the clinical leader to ensure that all steps have been completed or continue as appropriate.
- 3.3 The accountable leader shall provide ongoing support and communication with the patient related to management of the CAE and the disclosure of harm process until resolution as per AHS *Disclosure of Harm* Procedure. This includes providing information about follow-up processes that may occur and associated timelines.
- 3.4 When a CAE is not immediately recognized (e.g., retained foreign object discovered post-surgery) and immediate management of the CAE did not occur, the accountable leader shall ensure that all steps of the immediate management of CAE are completed.
- 3.5 In addition to reporting completed in the immediate management of the CAE, the accountable leader should provide notification of the CAE and how it is being managed to the following as appropriate:
- a) AHS executive via the AHS *Urgent Notification to an Emerging Issue Report* or an update if this report has already been done;
 - b) MRHP of the patient;
 - c) clinical leader/Manager of the location where the CAE occurred;
 - d) appropriate Patient Safety Representative(s); and
 - e) regulatory bodies (e.g., College of Registered Nurses of Alberta, College of Physicians & Surgeons of Alberta) in consultation with Human Resources.
- 3.6 An initial investigation of the facts supports the accountable leader to determine if there is a need for further review of a CAE and the appropriate review method(s).

- a) For CAEs, where the patient received patient care in multiple patient care areas or programs, the initial investigation and decision regarding further review should be done in consultation with other AHS leaders impacted by the CAE.
 - b) All CAEs requiring ongoing management are subject to an initial investigation by the accountable leader which should be completed within five (5) business days and involves:
 - (i) collecting information from the patient health record;
 - (ii) clarifying the facts through conversations with involved health care providers; and/or
 - (iii) creating a chronology of the events leading up to the CAE (timeline).
 - c) A Patient Safety Representative may assist with the following:
 - (i) highlighting areas where more information is needed to understand the event and identify system related issues;
 - (ii) completing the AHS *Job Aid To Evaluate Clinical Adverse Events*; and
 - (iii) providing consultation on just culture and system thinking.
 - d) When the accountable leader has requested Patient Safety support with a timeline, the decision to further review the CAE should be made within ten (10) business days in consultation with the Patient Safety Representative.
 - e) Further review is not required when the initial investigation provides sufficient understanding of the CAE and there were no system issues or hazards identified.
 - f) A workplace investigation is required when there are potential issues with performance or professional conduct of individuals involved in the CAE. Consult Human Resources.
- 3.7 The accountable leader, in consultation with a Patient Safety Representative, determines whether further review of the CAE is required. One (1) or more review method(s) may be considered (refer to Table 1 below).

Type of Review Method	Purpose	Department
Quality Assurance Review (QAR)	Used for a 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 <i>Alberta Evidence Act</i> . <i>Target completion for a QAR is 90 business days for concise/comprehensive reviews and 180 business days for aggregate reviews.</i>	Provincial or Zone Patient Safety Department
Patient Safety Review (PSR)	Used for a CAE 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 <i>Alberta Evidence Act</i> . <i>Target completion for a PSR is 90 business days for concise/comprehensive reviews and 180 business days for aggregate reviews.</i>	Provincial or Zone Patient Safety Department
Human Factors Evaluation	Used in situations where the interface between users and equipment (or work environment) contributed to human error	Human Factors (Provincial Patient Safety Department)
Quality Improvement Initiative	Used when the issue(s) that led to the CAE are understood and recommendations for system improvement require identifying improvement opportunities, collecting information and data, identifying issues, generating potential solutions, and implementing and evaluating results.	Provincial or Zone Clinical Quality Department
Educational Case Round	Used when a group of health care providers engage in learning from case studies within a just culture	Appropriate Clinical Department
Simulation	Used when system issues identified in a CAE are used to create simulation scenarios to allow health care teams to practice managing difficult or unusual situations in a realistic setting	Provincial eSIM Team

Table 1: Review Methods

- 3.8 After the appropriate review(s) have been completed, the accountable leader shall ensure that steps are taken to share lessons learned and improve health care services, at the local or organizational level as appropriate.
- a) The accountable leader shall ensure that the patient has been provided with information on the facts related to the CAE, as appropriate. Actions that will be taken to improve the health care system shall be shared with the patient as per the AHS *Disclosure of Harm Procedure*.
 - b) The accountable leader shall ensure that the health care providers working in the program area where the CAE occurred are provided with information related to the CAE. The accountable leader will share de-identified information about the event, lessons learned, and how the organization plans to improve.
 - c) The accountable leader may request support from their Patient safety Representative to develop one (1) or more of the following tools to communicate the organization's response to a CAE:
 - (i) **Patient Safety Learning Summary (PSLS)**: Used to share the results and recommendations of reviews or initiatives. Refer to the AHS *Patient Safety Learning Summary Procedure*.
 - (ii) **Patient Safety Alert (PSA), Safer Practice Notice (SPN), or Patient Safety Memo (PSM)**: Used to communicate timely patient safety information. Refer the AHS *Patient Safety Alerts, Safer Practice Notices, and Patient Safety Memos 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 and 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 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 (as determined by the circumstances and/or mutually agreed upon).

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

Dispense(-ing) means to provide a medication pursuant to a prescription for a person but does not include the administration of a medication to a person. Dispensing is a restricted activity under law (*Government Organization Act* [Alberta]).

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 something that has the potential to contribute to harm.

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.

Health record means the collection of all records documenting individually identifying health information in relation to a single person.

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.

Note: At AHS and related entities, "Medical Devices" are generally referred to as either "Equipment" or "Product" to correspond with the associated functional work streams (acquisition, maintenance, and risk management processes) associated with equipment (maintained medical devices) and product (consumable medical devices and surgical instruments).

Medical device incident means a medical device problem that has led to the death or a serious deterioration in the state of health of a patient, user, or other person, or could do so were it to recur. This includes circumstances requiring unexpected testing or care to prevent or mitigate the risk of harm to a patient or other person, and incidents that occurred as a result of off-label/abnormal use. This is equivalent to a Serious Clinical Adverse Event (CAE) or Near-Miss Serious CAE, or a worker device incident with harm, at AHS.

Medical device problem means an actual or potential deficiency that may affect performance or safety; an unexpected quality issue or a safety hazard; a failure of a medical device to perform in accordance with its intended purpose when used in accordance with the Manufacturer's Instructions for Use (MIFU), or a deterioration in its effectiveness; any

inadequacy in its labelling or in its directions for use, or in its design. This includes any medical device safety hazard, close call, or adverse event, whether or not the medical device affected a patient or other person.

Medication means any substance or mixture of substances manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings, and restoring, correcting or modifying organic functions in human beings.

Medication administration means the activity of supplying a dose of a medication for the purpose of immediate ingestion, application, inhalation, insertion, instillation, or injection. The administration of medications is more than just a psychomotor task of giving a medication to a patient. It also includes a cognitive and interactive aspect of care involving assessing the patient, making clinical decisions, and planning care based on this assessment. Medication administration requires the knowledge and skills of a competent health care professional.

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).

Medication management means a team-based approach to prevent and reduce patient safety incidents related to medications by addressing all areas of the medication management process from the medication order to preparation and dispensing to administration of the medication and ongoing monitoring of the patient.

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 AHS to perform the duties required to fulfill the delivery of such a treatment/procedure(s) within the scope of their practice.

Never event means a unique group of clinical adverse events, considered 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 all persons, inclusive of residents and clients, who receive or have requested health care or services from Alberta Health Services and its health care providers. Patient also means, where applicable:

- a) a co-decision-maker with the person; or
- b) an alternate decision-maker on behalf of the person

Patient Safety Alert (PSA) means the notification used by clinical leaders to bring attention to a significant patient safety hazard and requires health care providers to take immediate action. The risk is usually applicable across multiple zones.

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 Memo (PSM) means the notification used by clinical leaders to bring attention to a patient safety hazard and advise health care providers to take recommended action. The risk is usually limited to a targeted audience within a unit, site, or program within a single zone.

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

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

Recommendation tracker means the database that serves as an organizational memory of the assessment, review, and outcome of health care system investigations resulting from clinical adverse events, close calls, and hazards.

Safer Practice Notice (SPN) means the notification used by clinical leaders to bring attention to a patient safety hazard and informs health care providers to take action based on recommended patient care practices. The risk is usually applicable across multiple zones.

Serious Adverse Drug Reaction (SADR) means an adverse drug reaction (excluding immunizations and blood products, which have alternative reporting procedures) that has resulted in:

- Hospitalization or prolongation of existing hospitalization;
- Congenital malformation;
- Persistent or significant disability or incapacity;
- Life threatening situation or death; or
- Medical intervention to prevent any of the above.

REFERENCES

- Alberta Health Services Governance Documents:
 - *Clinical Documentation Directive (#1173)*
 - *Clinical Documentation Process Directive (#1173-01)*
 - *Delegation of Approval Policy Suite (#1168)*
 - *Disclosure of Harm Procedure (#PS-95-01)*
 - *Job Aid to Evaluate CAE*
 - *Keeping Patients Safe from Abuse Policy (#1153)*
 - *Medical Staff Bylaws*
 - *Medical Staff Rules*
 - *Medical Device Safety Policy Suite (#PS -103)*
 - *Midwifery Staff Bylaws*
 - *Midwifery Staff Rules*
 - *Medical Device Incident or Problem Reporting Procedure (#PS-103-03)*

- *Patient Concerns Resolution Policy (#PRR-02)*
- *Patient Concerns Resolution Process Procedure #(PRR-02-01)*
- *Patient Safety Alerts, Safer Practice Notices, and Patient Safety Memos Procedure (#PS-95-05)*
- *Patient Safety Learning Summary Procedure (#PS-95-06)*
- *Recognizing, Responding To, and Learning From Hazards, Close Calls, and Clinical Adverse Events Policy (#PS-95)*
- *Reporting of Clinical Adverse Events, Close Calls, and Hazards Procedure (#PS-95-04)*
- *Transfusion of Blood Components and Blood Products Policy (#PS-59)*
- **Alberta Health Services Resources:**
 - *Delegation of Approval Authority Resources*
 - *Employee and Family Assistance Program (EFAP)*
 - *Job Aid To Evaluate Clinical Adverse Events*
 - *Just Culture Guiding Principles*
 - *Medical Device Incident or Problem PLEASE Quarantine Checklist*
 - *System Analysis Method (SAM)*
 - *Tips for Supporting Staff Involved in Clinically Serious Adverse Events*
 - *Urgent Notification to an Emerging Issue Report*
- **Alberta Health Services Forms:**
 - *Serious Adverse Drug Reaction Form*
 - *Medication or Other Substances Reporting Form*
 - *Medical Device Incident or Problem Report (MDIP) Form*
- **Non-Alberta Health Services Documents:**
 - *Alberta Evidence Act*
 - *Child, Youth and Family Enhancement Act Children's Services (Alberta)*
 - *Continuing Care Health Service Standards (Alberta Health)*
 - *Fatality Inquiries Act (Alberta)*
 - *Mental Health Services Protection Act (Alberta)*
 - *Physician and Family Support Program (PFSP)*
 - *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) (Canada)*
 - *Protection for Persons in Care Act (Alberta)*

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