

TITLE

REPORTING OF CLINICAL ADVERSE EVENTS, CLOSE CALLS AND HAZARDSSCOPE

Provincial

DOCUMENT

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

SCHEDULED REVIEW DATE

November 01, 2020

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

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OBJECTIVES

- To describe the Alberta Health Services (AHS) processes for reviewing and responding to **clinical adverse events (CAE)**, **close calls** and **hazards** submitted to the **Reporting and Learning System for Patient Safety (RLS)**.
- To describe roles and accountabilities of **staff** and **medical staff** with respect to RLS reports.
- To establish accountabilities for reporting, reviewing, sharing, trending and analyzing clinical adverse events, close calls and hazards submitted to the RLS.
- To ensure timely and consistent processes for the review of close calls and hazards submitted to the RLS.

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 RLS is a system for AHS internal reporting, which is focused on a system approach where patient safety is advanced by learning from clinical adverse events, close calls and hazards for the purpose of improving health care.
- 1.2 Reporting of clinical adverse events, close calls and hazards is most effective within a just culture, whereby staff and medical staff feel safe to report without fear of reprisal. Staff and medical staff participation in the identification and reporting of clinical adverse events, close calls and hazards is key in achieving a just culture (see the AHS *Just Culture Guiding Principles*).
- 1.3 All submitted RLS reports of clinical adverse events, close calls and hazards are reviewed individually and in aggregate, trended and shared for the purpose of organizational learning.
- 1.4 RLS reports are shared widely within AHS for quality improvement purposes.
 - a) Free-text, narrative fields shall not have any identifiers regarding staff, medical staff, the **patient** or location.

Note: This does not preclude providing patient identifiers in the patient-affected fields of the RLS.
 - b) All reporter and reviewer narrative fields must contain strictly factual, relevant information. No opinions, speculation or accusations are to be included.
- 1.5 The RLS is not to be used for:
 - a) performance management;
 - b) reporting performance issues;
 - c) notification of workplace health and safety issues;
 - d) reporting narcotic count discrepancies when no patient is involved;
 - e) reporting lost property, security or privacy breaches;
 - f) reporting family or visitor behaviour without a patient safety component; and
 - g) reporting criminal activity.
 - (i) If a report describing criminal activity or deliberate **harm** of a patient is received, it shall be forwarded immediately to the appropriate **clinical leader** for follow-up.

2. Clinical Adverse Event Management

- 2.1 When a clinical adverse event occurs, the AHS *Immediate Management of Clinical Adverse Events* Procedure and AHS *Ongoing Management of Clinical Adverse Events* Procedure shall be followed.

3. Disclosure of Harm

- 3.1 If a clinical adverse event results in any harm to a patient, 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, then the AHS *Disclosure of Harm* Procedure shall be followed.

- a) In cases where a close call has occurred, disclosure is discretionary based on whether it is felt the patient would benefit from knowing or would want to know. If unsure of the patient's preference, the Disclosure of Harm process shall occur.

- 3.2 Disclosure status shall be recorded on the RLS report.

4. Confidentiality

- 4.1 Information submitted to the RLS will be managed in accordance with the AHS *Code of Conduct* and legislation, including the *Health Information Act* (Alberta) and the *Freedom of Information and Protection of Privacy Act* (Alberta).

5. RLS Exact Location

- 5.1 The RLS **Exact Location** is the location where the patient was when the problem was discovered.
- 5.2 When an RLS report is submitted, the **Advanced User** and **Designate(s)** for the Exact Location are notified via email.
- 5.3 Each RLS Exact Location shall have an assigned Advanced User. Facility and program leaders are responsible for ensuring Advanced Users are assigned within their area of accountability.
- 5.4 If a **Reporter** has selected the wrong Exact Location, a reviewer can submit a request to change this through the Support/Requests/Issues form on the RLS Education & Training Resources page on Insite.

6. Roles and Responsibilities in Reporting of Clinical Adverse Events, Close Calls and Hazards

- 6.1 Reporters:
- a) Before submitting a RLS report, a Reporter is required to:

- (i) notify the clinical leader of all serious clinical adverse events, including **never events** (see the AHS *Immediate Management of Clinical Adverse Events* Procedure); and
 - (ii) document the facts of the clinical adverse event in the patient's **health record** as per the AHS *Clinical Documentation* Directive and AHS *Clinical Documentation Process* Directive. The fact that a RLS report was submitted shall not be documented in the health record.
- b) All Reporters have a responsibility to voluntarily submit RLS reports regarding clinical adverse events, hazards or close calls that they are aware of, either as an involved party or discoverer.
 - (i) RLS reports can be submitted on-line or by telephone.
 - (ii) RLS reports shall be submitted as soon as possible, ideally within 72 hours of discovering an event.
 - (iii) More than one (1) person may submit an RLS report regarding the same event.
 - (iv) A Reporter does not need to be directly involved in an event in order to submit an RLS report.
- c) Reporters shall provide their contact information.
 - (i) Reporters may submit confidentially by choosing to not share their contact information with Advanced Users and other operations reviewers.
 - (ii) Clinical Quality Metrics and Patient Safety shall still receive contact information for necessary follow-up.
 - (iii) When a valid email address is provided, Reporters shall receive an automated acknowledgment and unique RLS report number for reference and follow-up purposes.
- d) Reporters shall include as many patient identifiers as possible in a RLS report to facilitate necessary follow-up.
 - (i) If there are multiple patients involved in the event, all patients may be included in a single RLS report.
- e) Reporters shall report the degree of harm for the event based on the information available to the Reporter at the time of the reporting (see Appendix A: *RLS Severity Definitions*).

- (i) If multiple patients are reported in a single event, the patient with the greatest level of harm shall be used to determine the degree of harm for the events.
 - f) Reporters may suggest additional Exact Locations that might benefit from reviewing the event.
 - g) Reporters may request feedback from the Advanced User about the outcome of the RLS report.
 - h) Reporters may request a de-identified summary of RLS information for learning and quality improvement purposes from the Advanced User.
- 6.2 Users with permissions to log in and review RLS reports (Advanced User, Designate, **Participant Reviewer**) should:
- a) provide feedback to staff and medical staff regarding the use of RLS reports to make system improvements;
 - b) document the event review and follow-up within RLS;
 - c) use RLS' Communications, Actions and Other Reader functions to share RLS reports with other service and program users to ensure all relevant departments are informed of the event for the purpose of organizational learning and system improvement; and
 - d) conduct RLS trending and analysis of RLS reports to identify system issues for the purpose of making system improvements.
- 6.3 The Advanced User:
- a) is the primary contact for an Exact Location. There can be only one Advanced User for each Exact Location;
 - b) shall receive email notification for each report submitted for their Exact Location;
 - c) shall review RLS reports;
 - (i) All 'New' reported events for their assigned Exact Location(s) should be reviewed within three (3) working days of notification.
 - (ii) The RLS Report Status Update field status shall be updated at the time of review to reflect the review status of 'Being Reviewed' or 'Review Completed.'
 - d) shall have a Designate assigned who will also assume Advanced User responsibilities in their absence;
 - e) is the only user type that can be selected to receive RLS action requests;

- f) shall revise the appropriate RLS fields if there are status updates to the event disclosure or severity status after it has been submitted; and
 - g) shall close RLS reports once the review is complete.
 - (i) Within 20 working days from the date the report was submitted, RLS reports should be closed by updating the 'RLS Report Status Update' field to 'Review Completed.'
 - (ii) If at 20 working days the review is still in progress, this should be documented in the RLS. Once the review is completed, the RLS report shall be closed.
- 6.4 The Designate:
- a) can have multiple Designates for each Exact Location;
 - b) shall receive email notifications for their Exact Location; and
 - c) shall assume the duties of the Advanced User as required.
- 6.5 The Participant Reviewer:
- a) can have multiple Participant Reviewers for each Exact Location;
 - b) shall not receive email notifications for RLS records submitted to their Exact Location(s); and
 - c) shall log into the RLS to review RLS reports that have been made accessible to them.
- 6.6 **Patient Safety staff:**
- a) shall review all RLS reports for their assigned geographic, facility or program responsibility;
 - b) shall identify individual RLS reports that require follow-up with the appropriate **accountable leader** to inform activities aimed to improve the safety of patient care; and
 - (i) If a serious clinical adverse event is identified, they shall follow up with the accountable leader to ensure, if appropriate, initiation of the AHS *Immediate Management of Clinical Adverse Events* Procedure and AHS *Ongoing Management of Clinical Adverse Events* Procedure.
 - c) provide skills development and support at the request of RLS users.
- 6.7 Clinical Quality Metrics Staff:

- a) manage and maintain the RLS;
- b) review and classify clinical adverse events, close calls and hazards to support aggregate trending and analysis, and organizational learning;
- c) shall manage any required changes to status that other users cannot directly make themselves. Requests for changes will be made via the RLS Education & Training Resources page on Insite. Some examples of changes they may make include:
 - (i) de-identification of reporter narratives;
 - (ii) rejection of RLS reports; and
 - (iii) updating Exact Locations;
- d) develop and publish RLS communication, education and training resources;
- e) respond to requests for education and support submitted through the automated Support/Requests/Issues form on the RLS Education & Training Resources page on Insite; and
- f) analyze RLS reports for the purpose of supporting the development of recommendations for system improvements to patient safety.

7. Trending and Analysis of Individual and Aggregate RLS Reports

7.1 RLS reports shall be used to:

- a) educate staff and medical staff of patient safety hazards;
- b) solicit ideas on how to reduce further safety risks;
- c) provide information on actions taken to reduce patient harm;
- d) provide context for patient safety risks;
- e) assist in identifying potential solutions; and
- f) review the results of system improvements.

8. Rejecting RLS Reports

8.1 Clinical Quality Metrics staff shall move the following types of reports to 'Rejected' status:

- a) Workplace Health and Safety reports (Reporters should submit to Workplace Health and Safety via MySafetyNet);
- b) lost property (Reporters should contact their local Protective Services);

- c) narcotic count discrepancies with no patient involved (Reporters should submit to Pharmacy);
 - d) performance complaints (Reporters should submit to an appropriate supervisor);
 - e) privacy breaches without a patient safety component (Reporters should submit to Privacy); and
 - f) family or visitor behaviour without a patient safety component (Reporters should refer to an appropriate supervisor).
- 8.2 Reporters who have provided a valid email address are notified of RLS reports that have been moved to 'Rejected' status and requested to redirect the report to the appropriate recipient as specified in section 8.1 of this document.
- 8.3 Rejected reports remain in RLS in the 'Rejected' folder in the RLS 'Report Status Update' field.

9. Releasing RLS records External to Alberta Health Services

- 9.1 AHS has discretion to release RLS reports externally for certain purposes.
- 9.2 All requests for release of RLS reports external to AHS, including patient requests, shall be submitted to the Support/Requests/Issues form on the RLS Education & Training Resources page on Insite.
- a) Clinical Quality Metrics will vet all external requests for RLS records through the Legal & Privacy Division.
- 9.3 RLS reports shall not be provided to professional regulatory bodies (e.g., College and Association of Registered Nurses of Alberta [CARNA], College of Physicians and Surgeons of Alberta [CPSA]).

10. RLS Education

- 10.1 Managers are responsible to ensure their staff are educated on the AHS *Reporting of Clinical Adverse Events, Close Calls and Hazards* Procedure as part of their orientation.
- 10.2 Additional training may be requested via the RLS Education & Training Resources page on Insite.

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

Advanced user means the person who is responsible for reading all reported events in RLS for their assigned Exact Location and is the single point of contact for that location. This person will receive email notification for each report upon submission and for Other Reader or Action Communication assigned to that Exact Location. There can only be one Advanced User for each Exact Location.

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.

Designate means the person will have full access to all reports for assigned Exact Locations and will receive email notifications for each report upon submission. There can be multiple Designates for each Exact Location.

Exact Location means the location where the patient was when the problem was discovered. This location is also responsible for investigating the event as necessary and sharing with other involved locations.

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

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

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

Participant Reviewer means the person will have full access to all reports for assigned Exact Locations but will not receive email notification for event reports upon submission. There can be multiple Participant Reviewers for each Exact Location.

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

Reporter means an Alberta Health Services staff, medical or midwifery staff, student, volunteer or other person acting on behalf of Alberta Health Services who reports a clinical adverse event, close call or hazard to the Reporting & Learning System for Patient Safety (RLS).

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

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

REFERENCES

- Appendix A: *RLS Severity Definitions*
- Alberta Health Services Governance Documents:
 - *Clinical Documentation Directive* (#1173)
 - *Clinical Documentation Process Directive* (#1173-01)
 - *Code of Conduct*
 - *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)
- Alberta Health Service Resources
 - *Just Culture Guiding Principles*
- Non-Alberta Health Services Documents:
 - *Alberta Evidence Act* (Alberta)
 - *Health Information Act* (Alberta)
 - *Freedom of Information and Protection of Privacy Act* (Alberta)

VERSION HISTORY

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

APPENDIX A

RLS Severity Definitions

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

Close Call - An incident that has potential for harm and is intercepted or corrected prior to reaching the patient.

Minimal Harm - Outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short-term and no or minimal intervention (for example, extra observation, investigation, review or minor treatment) is required.

No Apparent Harm - Outcome is not symptomatic or no symptoms are detected and no treatment is required.

Moderate Harm - Outcome is symptomatic, requiring intervention (for example, additional operative procedure, additional therapeutic treatment) or an increased length of stay, or causing minor permanent, long-term harm or loss of function.

Severe Harm - Outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, or shortening life expectancy or causing major permanent, long-term harm or loss of function.

Death - On balance of probabilities, the incident was considered to have played a role in the patient's death.

Reference: Canadian Institute for Health Information, National System for Incident Reporting, Minimum Data Set, 2012