REPORTING OF CLINICAL ADVERSE EVENTS, CLOSE CALLS, AND HAZARDS

OBJECTIVES

• To describe the Alberta Health Services (AHS) processes for reviewing and responding to clinical adverse events (CAEs), close calls, and hazards submitted to the Reporting and Learning System (RLS) for Patient Safety.

• To describe roles and accountabilities of health care providers’ use of the RLS.

• To establish accountabilities for reporting, reviewing, sharing, trending, and analyzing CAEs, close calls, and hazards submitted to the RLS.

• To ensure timely and consistent processes for the review of clinical adverse events, 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 an AHS managed resource, which is focused on a systems approach where patient safety is advanced by identifying and learning from CAEs, close calls, and hazards for the purpose of improving health care.
1.2 Reporting of CAEs, close calls, and hazards is most effective when health care providers feel safe to report without fear of reprisal. **Reporter** participation in the identification and reporting of clinical adverse events, close calls, and hazards is key element to achieving a **just culture** (refer to AHS Just Culture Guiding Principles).

1.3 All RLS submissions of CAEs, close calls, and hazards are reviewed individually and in aggregate, trended, and shared for the purpose of organizational learning.

1.4 RLS information is shared widely within AHS for improvement purposes.
   a) Free-text, narrative fields shall not have any personal identifiers, including but not limited to provider, patient, and/or family names.

   **Note:** Identifiers should be provided when requested as part of follow-up to a RLS report.

   b) The most effective reporter and reviewer narratives contain only factual information. Opinions, blame, and speculation should not be included.

1.5 The RLS is **not** to be used for:
   a) performance management;
   b) investigations unrelated to a patient safety hazard or event;
   c) reporting performance issues related to others;
   d) notification of workplace health and safety issues;
   e) reporting narcotic count discrepancies when no patient is involved;
   f) reporting lost property;
   g) privacy breaches; and/or
   h) reporting any person’s behaviour without a patient safety component.

2. **Clinical Adverse Event Management**

2.1 When a CAE occurs, the AHS **Immediate and 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.
4. Confidentiality

4.1 Information submitted to the RLS shall 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).

4.2 Reporters may request additional confidentiality when reporting by choosing to not share their contact information with the advanced user who receives the report.

   a) A health care provider’s request for confidentiality shall be respected with all due care by all potential users of a report up to the point patient safety is compromised (e.g., a reporter could be contacted by a 3rd party for additional information about a report to support change).

4.3 All contents of a report may be made available following review by AHS Legal when required by any relevant legislation (e.g., Freedom of Information and Protection of Privacy Act [Alberta], Alberta Rules of Court).

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 RLS exact location are notified via email.

5.3 Each RLS exact location requires an assigned advanced user. Operational leaders are responsible for ensuring advanced users are assigned within their area of accountability.

5.4 When the RLS exact location is incorrect, a request can be submitted to change this through the RLS contact page on Insite.

6. Roles and Responsibilities in Reporting of CAEs, Close Calls, and Hazards

6.1 Health care providers (i.e., reporters) reporting an event:

   a) are first required to:

      (i) notify the appropriate clinical leader of all CAEs (refer to the AHS Immediate and Ongoing Management of Clinical Adverse Events Procedure); and

      (ii) document the facts of the CAE in the patient’s health record as per the AHS Clinical Documentation Directive and AHS Clinical Documentation Process Directive. The fact that an RLS report was submitted is not required in the health record.
b) can contribute to improving patient care when they voluntarily submit RLS reports regarding CAEs, close calls, or hazards that they are aware of. Each submission to RLS is an opportunity for local and system learning;

c) are asked to submit a report as soon as possible;

d) may submit a report in addition to anyone else submitting a report for the same event;

e) do not need to be directly involved in an event in order to submit an RLS report;

f) shall provide their contact information;

g) will receive an automated acknowledgment and unique RLS report number for reference when a valid email address is provided;

h) should try to include as many patient identifiers as possible in the appropriate section of an RLS report. Patent identifiers increase the report’s relevance, facilitates use of additional information, and improve the learning opportunity;

(i) If there are multiple patients involved in the event, all patients may be included in a single RLS report.

i) shall report the degree of harm for the event based on the facts available at the time of reporting (see Appendix A: RLS Severity Definitions);

(ii) In an RLS report including multiple patients, the patient with the greatest level of harm shall be used to determine the degree of harm for the report.

j) may suggest additional exact locations to increase awareness of the event;

k) may request feedback about the status of the RLS report; and

l) may request a de-identified summary of RLS information for learning and quality improvement purposes.

6.2 Users with permissions to log in and review RLS reports (i.e., advanced user, designate, participant reviewer) are accountable for:

a) providing feedback to reporters regarding report submissions;

b) documenting the event’s review and follow-up within RLS for future learning opportunities;
c) sharing RLS reports with other RLS users to ensure all relevant stakeholders are aware of an event and are given the opportunity to contribute to improvements; and

d) reviewing RLS reports for trends and hot spots for potential improvement.

6.3 The advanced user:

a) is the primary contact for an exact location. There can be only one (1) advanced user for each exact location;

b) shall receive an automatically generated notification for each report submitted for their exact location;

c) should initiate review of new RLS reports within three (3) working days of the report submission date;

d) shall include all relevant health care providers in the review process as appropriate and feasible;

e) shall update the ‘Report Status Update’ field to reflect the review status as appropriate;

f) shall have one (1) or more assigned Designate(s) who shall assume advanced user responsibilities in their absence and support timely review of RLS reports;

g) shall revise the appropriate RLS fields if there are status updates to the event disclosure or severity status after it has been submitted; and

h) shall close RLS reports once the review is complete within 20 working days from the date the report was submitted.

(i) 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) shall receive automatically generated notifications for their exact location; and

b) shall assume the duties of and support the advanced user as required.

6.5 The participant reviewer:

a) shall not receive automatically generated notifications for RLS reports submitted to their exact location(s); and
6.6 **Quality and safety stakeholders:**

a) shall review all RLS reports for their assigned geographic, facility or program responsibility; and

b) shall identify RLS reports that require follow-up with the appropriate accountable leader to inform activities undertaken to improve the safety of patient care.

6.7 Clinical Quality Metrics (CQM) staff shall:

a) manage and maintain the RLS;

b) review and classify CAEs, close calls, and hazards that are not classified upon submission to support aggregate trending and analysis, and organizational learning;

c) manage any required changes to RLS reports that other users cannot directly make themselves. Some examples of changes are:

   (i) de-identification of health care provider narratives;

   (ii) rejection of RLS reports; and

   (iii) updating exact locations;

d) develop and publish RLS communication, education, and training resources;

e) follow-up with health care providers when it is unclear if a submitted report fits the criteria for a RLS report;

f) respond to requests for access, education, support, and reporting; and

g) analyze RLS reports in support of organizational learning and 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) engage the organization on patient safety events;

b) solicit ideas on how to reduce further safety risks;

c) provide information 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 CQM staff shall move the following types of reports to ‘Rejected’ status:

   a) performance or behavior concerns about AHS employees, members of the medical and midwifery staffs, students, volunteers, other persons acting on behalf of Alberta Health services (including contracted service providers as necessary), and any other user or contributor to RLS (health care providers should notify their manager);

   b) any person’s behaviour without a patient safety component (health care providers should notify their Manager);

   c) Workplace Health and Safety reports (health care providers should submit to Workplace Health and Safety via MySafetyNet);

   d) lost property (health care providers should contact their local Protective Services);

   e) narcotic count discrepancies with no patient involved (health care providers should submit to Pharmacy);

   f) privacy breaches without a patient safety component (health care providers should submit to Privacy);

   g) where information was intended for a different system; and

   h) other concerns where no patient safety component is identified.

8.2 Health care providers (i.e., reporters) who have provided a valid email address will be notified of RLS reports that have been ‘Rejected’ and requested to redirect the report to the appropriate recipient as specified in Section 8.1 (above).

8.3 Rejected reports remain in the RLS system, are identified as ‘Rejected’, and are excluded from reporting and analysis.

8.4 Users may request review of an RLS report’s rejection status.

9. Releasing RLS reports External to Alberta Health Services

9.1 All requests for release of RLS reports external to AHS, including patient requests, shall be submitted to Clinical Quality Metrics.
9.2 AHS shall comply with any legal or contractual requirements in the provision of RLS reports to named parties.

9.3 Research requests require Ethics approval and an AHS Data Disclosure agreement.

10. RLS Education

10.1 Managers are responsible to ensure health care providers 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 Contact page on Insite. CQM is responsible for RLS education standards. Additional content creators are encouraged to consult with CQM to ensure content consistency.

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 AHS 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 monitoring and responding to all reported events in RLS for their assigned exact location and is the primary 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 who will have full access to all reports for assigned exact locations and will receive email notifications for each report upon submission and for ‘Other Reader’ or ‘Action’ communications assigned to that exact location. This person has the delegated RLS authority of the advanced user. There can be multiple designates for each exact location.
Exact location means the location where the patient was when the problem was discovered.

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.

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.

Participant reviewer means the person who will have 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 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

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

Reporter means all Alberta Health Services employees, members of the medical and midwifery staffs, students, volunteers, other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary), and any other user or contributor to the RLS.

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.

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 and Ongoing Management of Clinical Adverse Events Procedure (#PS-95-02)
- Recognizing, Responding To, and Learning From Hazards, Close Calls, and Clinical Adverse Events Procedure (#PS-95)
- Alberta Health Service Resources
  - Just Culture Guiding Principles
- Non-Alberta Health Services Documents:
  - Alberta Rules of Court
  - Health Information Act (Alberta)
  - Freedom of Information and Protection of Privacy Act (Alberta)

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RLS Severity Definitions

**Hazard** - A situation that has potential for harm, has not yet occurred, and has not yet reached 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*