

Corporate Policy & Procedures
Manual

Number: III-45.PROC.1

Date Approved

July 9, 2019

Approved by: Chief Operating Officer and Chief Medical Officer

Policy Lead: Clinical Quality Consultant

Date Effective

September 9, 2019

Next Review (3 years from Effective Date)
September 2022

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.

Purpose To describe steps which must be taken to ensure that the immediate needs of the

patient/resident, family, staff and medical staff involved in a clinical adverse event (CAE), close call or hazard are addressed appropriately according to evidence-based

principles and practices.

Parent Policy Covenant Health Corporate Policy # III-45, Clinical Adverse Events, Close Calls and

Hazards

Applicability This procedure applies to all Covenant Health facilities, staff, medical staff, volunteers,

learners and any other persons acting on behalf of Covenant Health.

Responsibility All Covenant Health staff, physicians, volunteers, learners and any other persons acting

on behalf of Covenant Health will demonstrate commitment to the safety of all

patients/residents by adhering to this procedure.

Procedure

When any <u>staff or medical staff member</u> recognizes the occurrence of a possible Clinical Adverse Event (CAE), close call or hazard, they shall:

- · provide necessary immediate interventions within their scope, and
- report it as soon as possible to the immediate clinical leader/supervisor of the patient/resident care unit/service (e.g. charge nurse, assistant head nurse, allied health team leader, etc.).

Immediate management should begin as soon as the event is identified and be completed as soon as feasible. The immediate clinical leader/supervisor shall ensure the applicable steps of this procedure are followed:

- The order of the steps may be adjusted to meet the needs of each situation;
- The duties of the clinical leader may be turned over to subsequent clinical leaders, as needed (e.g. atshift changes). Appropriate briefing of a new clinical leader shall occur;
- The immediate clinical leader may, at any time, request the assistance of a higher level of leadership (e.g. Manager on Call, Unit Manager, Program/Site Manager, etc.); and
- Clinical leadership for the Immediate Management of the CAE may be transferred to a higher level of leadership when appropriate and when accepted by that leader. Appropriate briefing of the new clinical leader shall occur.

For **clinically serious adverse events** (CSAE's), use of the voluntary job aids, *CSAE Guide: Immediate Management* (<u>Acute</u> or <u>Continuing Care</u>) and <u>CSAE Guide: Initial Response Huddle</u> (<u>Acute</u> or <u>Continuing Care</u>) is encouraged.



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- 1. Safety and Support of the Patient/Resident and Family Involved in the Event
 - 1.1 Ensure the medical needs of the patient/resident are being attended to in collaboration with members of the inter-professional team, as appropriate, and with relevant informed consent. Refer to Covenant Health policy # VII-B-50, Consent to Treatment/Procedure(s). When a medication administration error is involved, include pharmacy consultation to assist with the clinical management of the patient/resident, as appropriate.
 - 1.2 Ensure appropriate emotional, practical, and/or spiritual support is provided to the patient/resident and family.
 - 1.3 Communicate the occurrence of the event and resultant plan of care and support, including Goals of Care Designation Order, to all **health care providers** involved in the current care of the patient/resident, so that appropriate patient/resident care and monitoring will occur.
- 2. Safety and Support of Other Patients/Residents
 - 2.1 Take appropriate steps to maintain safe conditions for care, including but not limited to:
 - 2.1.1 When a **medical device** is involved, follow the <u>Medical Device P.L.E.A.S.E. Process</u> to remove the device(s) from service and to request investigation of the device(s).
 - Note: If the patient/resident 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 (see Covenant Health policy # VII-B-410, <u>Death</u>).
 - 2.1.2 When a **medication dispensing error** is involved:
 - If applicable, remove and secure the medication(s) involved;
 - Notify the local Pharmacy manager immediately;
 - Do not return medication(s) into circulation until advised by Pharmacy that it is safe to do so.
 - 2.1.3 When the physical environment is involved:
 - · Take immediate steps to decrease risk; and
 - Report as soon as possible to Facilities Management.
 - 2.2 Determine whether any additional patients/residents and families have been affected by the event and provide support, as appropriate, while maintaining the privacy of the patient/resident(s) and others involved in the event.
- 3. Safety and Support of Staff and Medical Staff
 - 3.1 Ensure immediate first aid and/or medical aid is offered to any staff and/or medical staff, if required.
 - 3.2 Ensure any staff injury is reported to Covenant Health Occupational Health, Safety and Wellness. See Covenant Health's *Employee Incident/Injury Flowsheet*.



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- 3.3 Assess staff and medical staff needs, and transfer patient/resident care to alternate providers if necessary:
 - 3.3.1 If staff are temporarily unable to continue to provide safe patient/resident care, support them to stop working and access alternate staffing to replace them and/or to meet increased activity/acuity, as needed.
 - 3.3.2 If medical staff are unable to continue to provide safe patient/resident care, they will 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 Covenant Health Medical Staff Bylaws and Medical Staff Rules.
- 3.4 Offer support to the involved staff and medical staff.
 - 3.4.1 When possible, arrange a quiet and private area for communication and documentation to occur.
 - 3.4.2 Provide and/or arrange for immediate emotional support to assist in coping with the event, as appropriate. Contact other leaders, as applicable (e.g. volunteer coordinator, clinical instructor).
 - 3.4.3 Provide information about resources for support and encourage staff and medical staff to seek assistance. Assist with accessing resources as required.
 - Critical Incident Stress Management (CISM) for appropriate peer support;
 - Spiritual Care:
 - Other peer support programs, as available (e.g. GNCH Physician Peer Support Program);
 - The Employee and Family Assistance Program (EFAP); and
 - The Physician and Family Support Program (PFSP).

4. Disclosure of Harm

- 4.1 If there has been harm, potential for future harm, or changes in care or monitoring as a result of the event, refer to Covenant Health Procedure # *III-45.PROC.1*, <u>Disclosure of Harm Procedure</u>.
- 5. Documentation of Clinical Adverse Event Management
 - 5.1 Ensure the CAE is documented in the patient/resident's **health record** as per Covenant Health policy, # *III-120*, *Clinical Documentation*. Documentation shall include:
 - 5.1.1 Known facts;
 - 5.1.2 The patient/resident care plan resulting from the event;
 - 5.1.3 Notification(s) of others (e.g. most responsible health practitioner, manager); and
 - 5.1.4 The facts of any disclosure conversations that have occurred (see Covenant Health's *Disclosure of HarmProcedure*).



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- 5.2 Other aspects of the event management shall be documented separately from the health record.
- 5.3 When there has been a clinically <u>serious</u> adverse event, the clinical leader should ensure there is a record of the names and contact information of all:
 - 5.3.1 Staff, medical staff, students and volunteers involved with the event;
 - 5.3.2 Staff and medical staff working on the unit at the time of the event; and
 - 5.3.3 Members of the public (e.g. other patients/residents, visitors) who may have exclusive information that may help in understanding factors contributing to the event (e.g. witnessed the event).
- 5.4 CAEs, close calls, and hazards should be reported in the **Reporting and Learning Systemfor Patient Safety** (RLS).
 - 5.4.1 For all medication-related reports, include Pharmacy under the "Who else should this patient safety report be shared with" section of the RLS report.

6. Notification and Handover

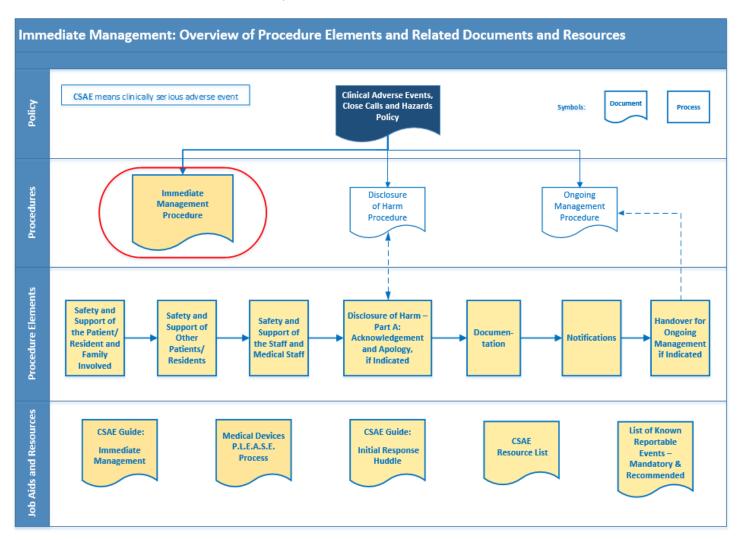
- 6.1 For a clinically <u>serious</u> adverse event, notify the following individuals as soon as possible, and no later than 24 hours of being aware of the event:
 - 6.1.1 The most responsible health practitioner; and
 - 6.1.2 The immediate manager/manager on-call.
- 6.2 Complete immediate internal and external reporting, as applicable (see <u>List of Known</u> <u>Reportable Events Mandatory and Recommended</u>).
- 6.3 Immediate management can be concluded when:
 - 6.3.1 The outcome for the patient/resident is not serious (e.g. hazard, close call, **no apparent** harm, or minimal harm);
 - 6.3.2 There is no need for further investigation; and
 - 6.3.3 The event has been resolved to the satisfaction of the patient/resident.
- 6.4 If the criteria outlined in element 6.3 are not met, the clinical leader will hand overmanagement of the event to the **responsible administrative leader** who will perform Covenant Health's *Ongoing Management of Clinical Adverse Events, Close Call and Hazards Procedure.*



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Overview of Procedure Elements, Related Guidance Documents and Resources



See Appendix A for a detailed overview of Immediate Management actions.

Definitions

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) dissatisfaction with health care management or require a change in patient/resident care, to death or disability.

Clinically Serious Adverse Event (CSAE) means an event that could, or does, result in an unintended injury or complications arising from health care management, with outcomes that may include (but are not limited to) death or serious harm.

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



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

Facts means details of an event that are indisputably the case or have been agreed upon following appropriate investigation.

Family(-ies) means one or more individuals identified by the patient/resident as an important support, and who the patient/resident 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/resident, resulting from the care and/or services provided, that negatively affects the patient/resident's health and/or quality of life.

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

Health record means the Covenant Health legal record of the patient/resident's diagnostic, treatment and care information.

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

Learner means a **student**, intern or resident health care provider trainee under the supervision of another health care worker, licensee or practitioner.

Medical device means an item, whether used alone or in combination, including software, intended by the manufacturer for use on patients/residents, for any of the following purposes:

- a) Diagnosis, prevention, monitoring, treatment, or alleviation of, or compensation for a disease, an injury or handicap;
- b) Investigation, replacement, or modification of the anatomy or of a physiological process; and/or
- c) Control of conception.

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

Medication administration error means an error in providing the medication to the patient/resident (i.e. primary source clinical area).

Medication dispensing error means an error in the preparation or distribution (i.e., primary source Pharmacy department).

Minimal harm means an outcome that 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.



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Most responsible health practitioner means the health practitioner who has responsibility and accountability for the specific treatment/procedure(s) provided to a patient/resident and who is authorized by Covenant Health to perform the duties required to fulfill the delivery of such a treatment/procedure(s) within the scope of his/her practice.

No apparent harm means the outcome is not symptomatic or no symptoms are detected and no treatment is required.

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

Responsible administrative leader means the most senior administrative or medical leader involved in helping to manage the clinical adverse event, close call, or hazard procedure. For example:

a) Nurse Manager or Program Manager and/or medical lead/director, clinical section chief or clinical department site chief;

Or

b) Non-clinical manager, site/facility lead, Director, Senior Operating Officer and/or facility chief, facility/community medical director, clinical section chief, clinical department head, Associate Chief Medical Officer or Chief Medical Officer.

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

Student means those individuals enrolled in an entry-level health care discipline education program leading to initial entry-to-practice as a regulated or non-regulated health care provider.

Related Documents

Covenant Health policy # *III-145*, <u>Clinical Adverse Events, Close Calls, and Hazards</u> and supporting documents:

Covenant Health procedure # III-45.PROC.2: <u>Disclosure of Harm</u>

Covenant Health procedure # III-45.PROC.3, <u>Ongoing Management of Clinical</u> Adverse Events, Close Calls and Hazards

Clinically Serious Adverse Event Guide - Immediate Management - Acute Care

Clinically Serious Adverse Event Guide – Immediate Management – Continuing Care (in development)

Clinically Serious Adverse Event Guide - Initial Response Huddle - Acute Care

Clinically Serious Adverse Event Guide – Initial Response Huddle – Continuing Care (in development)

Clinically Serious Adverse Event Resource Guide

<u>Management of Known or Suspected Medical Device Malfunction (P.L.E.A.S.E.</u>

Process)

Initial Disclosure Pocket Guide (in development)

List of Known Reportable Events – Mandatory and Recommended

Covenant Health *Emergency Disaster Site Codes*

Covenant Health OHS&W Employee Incident/Injury Flow Sheet

Covenant Health Our Commitment to Ethical Integrity



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Covenant Health policy # II-135, <u>Reporting of Work-Related Incidents, Injury, Illness</u>
Covenant Health policy # III-5, <u>Reporting/Investigating Legal Actions and Potential Legal Actions</u>

Covenant Health policy # III-35, Just Culture

Covenant Health policy # III-120, Clinical Documentation

Covenant Health policy # VII-B-50, Consent to Treatment/Procedure(s)

Covenant Health policy # VII-B-245, Controlled Substances

Covenant Health policy # VII-B-350, Advance Care Planning: Goals of Care Designation

Covenant Health policy # VII-B-365, <u>Family Presence During Cardiopulmonary</u>

Resuscitation

Covenant Health policy # VII-B-410, Death

Covenant Health policy # X-5, Privacy Accountability

References

Accreditation Canada Leadership Standards (Accreditation Canada, 2019)

Alberta Health Services Patient Safety Policy Suite (Alberta Health Services, 2017)

Alberta Quality Matrix for Health (Health Quality Council of Alberta, 2005) Canadian Disclosure Guidelines (Canadian Patient Safety Institute, 2011)

Continuing Care Health Service Standards (Alberta Health, 2018)

Critical Incidents & Multi-Patient Events: Risk resource guide (Healthcare Insurance

Reciprocal of Canada, 2015)

Freedom of Information and Protection of Privacy Act (Alberta)

Health Ethics Guide, 3rd Ed. (Catholic Health Alliance of Canada, 2012)

Health Information Act (Alberta)

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Your feedback about this document and its contents is welcomed. Submit feedback to covenantpolicy@covenanthealth.ca



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Overview of the Immediate Management Process

Appendix A

Link to larger printable version

