

TITLE

IMMEDIATE AND ONGOING MANAGEMENT OF CLINICALLY SERIOUS ADVERSE EVENTS

DOCUMENT

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N/A

CATEGORY

Patient Safety

NEXT REVIEW

May 4, 2015

If you have any questions or comments regarding the information in this guideline, please contact Patient Safety at quality.assurance@albertahealthservices.ca.

OBJECTIVES

- To describe the immediate and ongoing roles and responsibilities of **staff, medical staff, and responsible administrative leaders**, within Alberta Health Services, when a **clinically serious adverse event** occurs.
- To provide an overview of the steps which should be taken to ensure that the immediate and longer term needs of the **patient**, staff and medical staff involved in a clinically serious adverse event are managed appropriately and that time-sensitive activities are initiated when necessary.
- To be used as a resource for managing events in less clinically serious circumstances at the discretion of the responsible administrative or other **accountable leader(s)**.

APPLICABILITY

This guideline applies to all Alberta Health Services employees, members of the medical staff, midwifery staff, students and other persons acting on behalf of Alberta Health Services (including contracted services providers as necessary). This guideline does not limit any legal rights to which you may otherwise be entitled.

GUIDELINE

Clinically serious adverse events require immediate response and investigation as per this guideline. An effective and compassionate approach to the immediate and ongoing management of clinically serious adverse events requires that staff and medical staff follow the key elements of this guideline.

Note 1: Order of steps to be taken is recommended below. Actual steps must reflect the needs of each individual situation. (See Appendix A *Alberta Health Services Immediate and Ongoing Management of Clinically Serious Adverse Events Algorithm*.)

Note 2: Individuals involved shall make all reasonable efforts to meet the timelines mentioned.

1. Immediate Management

- 1.1 The **most involved clinician(s)** and/or responsible administrative leader shall ensure these activities are undertaken following a clinically serious adverse event (see Appendix B *Immediate Management Checklist*):
- respond to the patient's immediate health care needs;
 - ensure the environment is safe for other patients, staff and medical staff; and,
 - secure and remove equipment, medication, supplies and/or products involved, as required.
- 1.2 In the case of suspected equipment malfunction or defective supplies:
- request an assessment from the most appropriate department (i.e., Clinical Engineering, Pharmacy, Corporate Procurement Supply Management);
 - request photos as appropriate and all identifying and retrievable data from equipment prior to the equipment being repaired;
 - specific lot numbers should be removed from circulation and secured for subsequent investigation. The equipment shall not be released to any third party without prior consultation with Alberta Health Services Legal & Privacy; and,
 - item(s) should not be put back into circulation until it has been determined that it did not contribute to the clinically serious adverse event or until it has been approved for re-circulation by the most appropriate department (i.e., Clinical Engineering, Pharmacy, Contracting, Procurement & Supply Management). All issues or suspected issues related to equipment, supplies and/or products should be reported into the **reporting and learning system for patient safety** (reporting and learning system).
- 1.3 Secure the patient **health record**.
- All relevant sections of the patient health record are copied for investigative purposes and the original is retained in Health Records.
- 1.4 Protect other patients, staff and medical staff.
- If possible, ensure measures are taken to prevent recurrence of the event.
- 1.5 Offer support to patient, **family**, staff and medical staff. Individuals involved in a clinically serious adverse event may be emotionally distraught and as such should be treated with care, compassion, support, respect and dignity.
- 1.6 Immediate support is offered to patients and families. This support may include:

- a) physical support such as assistance with gaining access to telephone, transportation, accommodation;
 - b) emotional support such as the presence of someone to help calm, cope with daily life activities, restore confidence, build trust, and provide access to psychological or psychiatric counselling or assistance in preparing for and coping with lifestyle changes;
 - c) spiritual support such as assisting with finding a spiritual leader or member of a specific faith or cultural community; and,
 - d) identify an Alberta Health Services person as the single point of contact for ease of the patient/family communicating with Alberta Health Services.
- 1.7 Support is offered to the staff and medical staff.
- a) Support for staff and medical staff involved in a clinically serious adverse event reflects Alberta Health Services commitment to patient safety within a just culture.
 - b) While fact collection is vital, It is important to evaluate the **adverse event** in the context of the situation and circumstances in which it occurred.
 - c) Arrange a quiet and private place for all communication, documentation and debriefing to occur.
 - d) Transfer patient care responsibilities to other staff and medical staff, as appropriate.
 - e) Provide information about assistance programs and encourage the staff and medical staff to seek assistance (See Appendix C *Supports for Staff and Medical Staff Following a Clinically Serious Adverse Event*).
 - f) Complete appropriate Workplace Health and Safety activities if staff and medical staff are injured or ill due to a clinically serious adverse event (See Appendix C *Supports for Staff and Medical Staff Following a Clinically Serious Adverse Event*).
 - g) For legal issues or questions contact Alberta Health Services Clinical Law Services (See Appendix C *Supports for Staff and Medical Staff Following a Clinically Serious Adverse Event*).
- 1.8 Notification.
- a) Ensure **most responsible health practitioner** and accountable leader are notified of the clinically serious adverse event within 24 hours.
 - b) Consider the following information when contacting the accountable leader(s):

- Monday – Friday (0800 – 1700 hours) – contact Director and/or the Zone Clinical Department Head (or delegate) responsible for the area of operation.
- After hours (1700 – 0800 hours), weekends (Friday 1700 hours – Monday 0800 hours) and holidays – contact the local administrator on call.

1.9 The disclosure process is initiated and event is documented.

- Disclosure is a multistep process that begins with acknowledgment, apology and an offer to share known facts about the clinically serious adverse event.
 - Conduct an initial disclosure meeting with patient and/or family, in accordance with Alberta Health Services Policy *Disclosure of Harm* and Procedure *Disclosure of Harm*.
- Documentation in the health record will include only known facts.
 - Conjecture or opinions as to why an event may have occurred shall not form part of the documentation.

Note: Document the time of activity, patient assessments, treatment provided and response to treatment, and all communication notifying others of the clinically serious adverse event (e.g., family, most responsible health practitioner, manager).

- Confirm that a report has been submitted to the reporting and learning system.

2. Ongoing Management

2.1 The accountable leader shall ensure:

- steps under immediate management have taken place;
- clear lines of communication about the clinically serious adverse event exist;
- that an *Urgent Notification to an Emerging Issue - Report Form* is submitted (see Appendix D *Ongoing Management Checklist*);

Note: The completion of an *Urgent Notification to an Emerging Issue - Report Form* does not replace the need for the completion and notification of a continuing care reportable incident in the event of a continuing care reportable incident.

- other external legislated/mandated reporting is completed; and,
- that he/she is identified to the most responsible health practitioner, responsible administrative leader and most involved clinician(s).

2.2 The accountable leader shall support and communicate with:

a) patient/family by:

- confirming the name and contact information of a single point of contact for Alberta Health Services;
- confirming that disclosure of facts occurs if there has been any **harm**, risk of potential future harm or if there is any change in the patient's condition, care and/or monitoring as a result of the clinically serious adverse event;
- confirming ongoing support has been offered;
- ensuring that patient/family understand the follow-up processes that will occur, and the associated estimated timelines; and,
- informing the patient/family that **Patient Relations Department** and the Patient Concerns Officer may be reached for any ongoing concern resolution.

b) staff and medical staff by:

- reviewing immediate supports that have been provided or offered and determining what, if any, other needs should be addressed to support the staff and medical staff and teams; and,
- ensuring that a discussion is held at an appropriate time between the responsible administrative leader and most involved clinician(s) about next steps, including:
 - the care and support that the patient/family is receiving, and,
 - the most involved clinician(s) may be contacted for purposes of review or analysis, as part of the follow-up process to a clinically serious adverse event.

2.3 The accountable leader shall evaluate the clinically serious adverse event.

a) Conduct initial assessment and if applicable request a timeline regarding the clinically serious adverse event.

- If applicable, receive a timeline outlining the facts of the clinically serious adverse event within five (5) business days of the date of becoming aware of the event. (See Appendix E *Timelines for the Quality Assurance Review of Clinically Serious Adverse Events*.)
- Review facts from timeline and discuss with others to determine appropriate follow-up review processes.

- b) Determine appropriate response to clinically serious adverse event, including, but not limited to:
- **quality assurance review** (Note that a quality assurance review is generally completed at the request of a clinical operations leader but must be constituted by a Quality Assurance Committee and will take the form of an **aggregate**, a **comprehensive** or a **concise review**);
 - local process improvement initiative;
 - case review for educational purposes;
 - quality improvement project;
 - **Patient Concerns Resolution Process**;
 - **administrative review**; and,
 - the development of a safety alert or a safer practice notice.
- c) Where there is possible contribution of a systems factor to the clinically serious adverse event, then within ten (10) business days from the date of becoming aware of the adverse event:
- discuss the situation with the Chair (in some cases this individual may be the accountable leader) of the appropriate Quality Assurance Committee in consultation with the associated Clinical Safety Leader in order to determine whether a quality assurance review should be complete;
 - consider the following potential outcomes when determining to do a quality assurance review:
 - where factual information available is insufficient to determine opportunities for improvement, and,
 - where speculative discussion is believed to be helpful to understand what may have contributed to the clinically serious adverse event;
 - determine with the Chair of the appropriate Quality Assurance Committee if a quality assurance review will be completed; and,
 - once the quality assurance review is accepted by the Chair of the Quality Assurance Committee, he or she should assign a lead to conduct the quality assurance review within five (5) business days.

3. Quality Assurance Review and Administrative Review

- 3.1 When a decision is made to proceed with a quality assurance review, the accountable leader will complete a *Quality Assurance Review: Request and*

Acceptance Form and send to the Chair of the appropriate Quality Assurance Committee.

- a) The assigned lead should begin the quality assurance review within five (5) business days of the quality assurance review being accepted by the Chair of the Quality Assurance Committee. He or she should assign a lead to conduct the quality assurance review.
- b) The Chair of the quality assurance review is responsible for ensuring the concise or comprehensive quality assurance review is complete within 90 business days from the date the request was accepted by the Chair and an aggregate quality assurance review is complete within 180 business days.
- c) If the quality assurance review process encounters delays, the Quality Assurance Committee Chair may contact the appropriate accountable leader for assistance.
- d) The Chair of the Quality Assurance Committee and the accountable leader may request an extension in writing and citing rationale, from the Executive Vice-President responsible for Quality and Healthcare Improvement.
- e) The quality assurance review is determined to be complete when the agreed upon facts and finalized recommendations are sent to the requestor of the quality assurance review.

3.2 When a decision is made to review the actions of individuals involved in a clinically serious adverse event, consider conducting an administrative review. (See Appendix F *Administrative Review Decision Tree*.)

- a) The *Administrative Review Decision Tree* is premised on the Alberta Health Services values of trust and respect which support an open and just culture where staff and medical staff feel comfortable in reporting errors without fear of punishment.
- b) An administrative review examines the actions and behaviours of an individual and should be conducted by a person with administrative responsibilities for the actions of the individual(s) involved.
- c) The outcome of an administrative review will only be released when required by applicable legislation.
- d) An administrative review is not conducted under the auspices of a Quality Assurance Committee.

3.3 A clear boundary between quality assurance reviews and administrative reviews must be maintained.

- a) Quality assurance reviews and administrative reviews are conducted independent of one another but may be undertaken at the same time.

- b) Information shall not be shared between the quality assurance review and the administrative review.
- c) If a quality assurance review team has reason to believe that the actions and behaviours of an individual need to be reviewed by administration, the Chair of the Quality Assurance Committee shall seek confirmation that an administrative review is being conducted.
- d) If an administrative review has not already been requested, the Chair of the Quality Assurance Committee can make a recommendation to the administrator who requested the quality assurance review that he/she evaluate the need for an administrative review.

DEFINITIONS

Accountable leader means the individual who has ultimate accountability to ensure the consideration and completion of the listed steps in the immediate and ongoing management of the clinically serious adverse event process. 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.

Administrative review means a process that examines the actions and behaviours of individuals during a patient safety event. Any review examining the actions and behaviours of medical staff shall be managed in accordance with the *Alberta Health Services Medical Staff Bylaws and Rules*.

Adverse event means an event that could or does result in unintended injury or complications arising from health care management, with outcomes that may range from death or disability to dissatisfaction, or require a change in care (such as prolongation of hospital stay).

Aggregate review means a thorough review of multiple adverse events and/or quality assurance reviews that usually involves a team approach.

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

Comprehensive review means a thorough review of a single adverse event that usually involves a team approach.

Concise review means a succinct review commonly used for incidents that resulted in no or low harm to the patient or may focus on a new event for which a comprehensive analysis was recently completed often conducted by one or two individuals.

Family(-ies) means one or more individuals identified by the patient as 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.

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

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

Most involved clinician(s) means the health care provider(s) most involved in the care and treatment of the patient at the time of the event. This definition is intended to encompass all individuals, regulated and unregulated, who provide clinical care and services across Alberta Health Services.

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

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 Concerns Resolution Process means the process of review and resolution of concern(s) raised by patients/complainants within Alberta Health Services.

Patient Relations Department means the department of Alberta Health Services, led by the Patient Concerns Officer and Executive Director, who facilitates the Patient Concerns Resolution Process as guided by the *Patient Concerns Resolution Process Regulation 124/2006* and supports patients and staff/management/medical staff involved in the process.

Quality assurance activity means a planned or systematic activity the purpose of which is to study, assess or evaluate the provision of health services with a view to the continual improvement of a) the quality of health care or health services, or b) the level of skill, knowledge and competence of health service providers.

Quality assurance review means a quality assurance activity conducted under the terms of Section 9 of the *Evidence Act* (Alberta).

Reporting and learning system for patient safety (reporting and learning system) means the electronic software program designated by Alberta Health Services to report patient 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 immediate and ongoing management of clinically serious adverse events process. For example:

- a) nurse manager or program manager and/or program medical lead/director, zone clinical section chief, zone clinical department site chief, or,

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- b) non clinical manager, site/facility lead, director, executive director or vice president and/or program medical lead/director, facility/community medical director, zone clinical section chief, zone clinical department head, senior medical director, zone medical director.

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

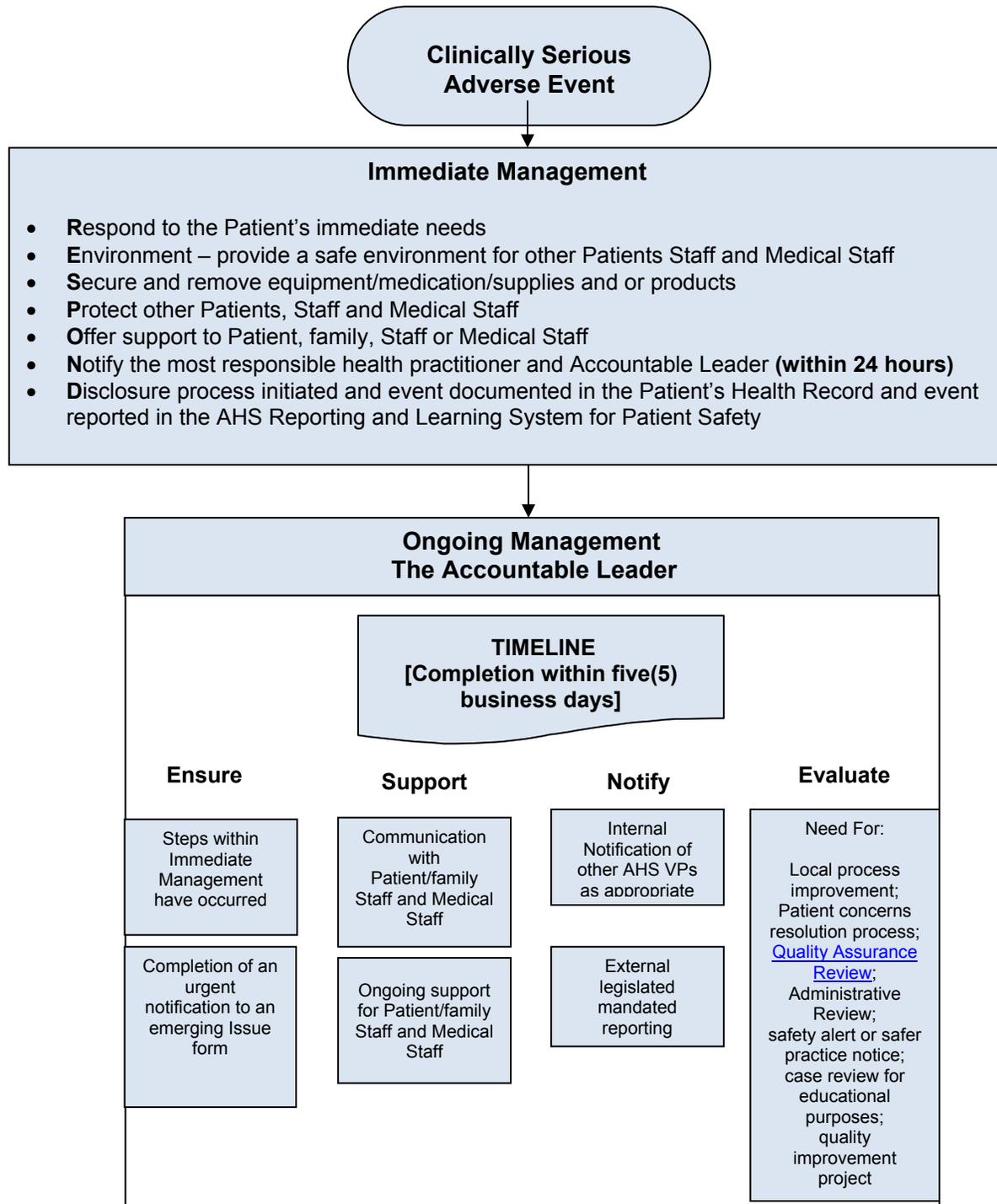
- Appendix A *Alberta Health Services Immediate and Ongoing Management of Clinically Serious Adverse Events Algorithm*
- Appendix B *Immediate Management Checklist*
- Appendix C *Supports for Staff and Medical Staff Following a Clinically Serious Adverse Event*
- Appendix D *Ongoing Management Checklist*
- Appendix E *Timelines for the Quality Assurance Review of Clinically Serious Adverse Events*
- Appendix F *Administrative Review Decision Tree*
- Alberta Health Services *Disclosure of Harm Policy*
- Alberta Health Services *Disclosure of Harm Procedure*
- Alberta Health Services *Reporting of Patient Adverse Events, Close Calls and Hazards Policy*
- Alberta Health Services *Patient Concerns Resolution Process Policy*
- Alberta Health Services *Patient Concerns Resolution Process Procedure*
- Alberta Health Services *Quality Assurance Committee Chair Handbook*
- *Patient Concerns Resolution Process Regulation 124/2006 (Alberta)*
- *Evidence Act (Alberta)*
- *Health Information Act (Alberta)*
- Alberta Health Services *Quality Assurance Review: Review and Acceptance Form*
- Alberta Health Services [Urgent Notification to an Emerging Issue Report](http://insite.albertahealthservices.ca/untei/et-untei-report.doc)

REVISIONS

N/A

APPENDIX A

Alberta Health Services Immediate and Ongoing Management of Clinically Serious Adverse Events Algorithm



APPENDIX B

Immediate Management Checklist

All of these steps should be considered for clinically serious adverse events

Give a brief case description of the event:

- R**espond to the patient's immediate needs
 - Care for the patient
 - Ensure interventions, treatments, and consultations are provided
- E**nvironment – Provide a safe environment for others
- S**ecure and remove equipment/medication/ supplies/ products (that may have contributed to the event)
 - Equipment/medication/supplies/products are secured Yes No N/A
(so that it is not reused until it can be properly tested)
 - Location of sequestered equipment/medication/supplies _____
 - Contact Clinical Engineering (Biomedical Equipment Technologist) / Pharmacy/Contracting Procurement for ongoing instruction.
 - Secure the patient health record
- P**rotect other patients, staff and medical staff
 - Ensure measures are taken to prevent recurrence of the event (if applicable)
- O**ffer support

Patient/Family	Staff and Medical Staff
<input type="checkbox"/> Provide a quiet space for family	<input type="checkbox"/> Provide a quiet space
<input type="checkbox"/> Ensure patient/family have adequate support (social work, pastoral care, friends)	<input type="checkbox"/> Consider the needs of the staff and medical staff (e.g. Relieve the staff and medical staff from his/her immediate patient care responsibilities)
	<input type="checkbox"/> Access crisis intervention support (Employee & Family Assistance Program)
- N**otify the most responsible health practitioner (if applicable) and accountable leader (within 24 hours)

Most Responsible Practitioner Name _____	Date/Time _____	/ _____
Accountable Leader Name _____	Date/Time _____	/ _____

Disclosure process initiated and event documented

- Disclosure conversations:

With Whom	By Whom	Date/Time
:	:	/
_____	_____	_____

Support the clinicians and administrators in reviewing and planning the immediate disclosure.

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- Submit a report of the event in the Alberta Health Services Reporting and Learning System (RLS) for Patient Safety
- Ensure documentation of the “clinically serious adverse event” in the patient’s health record occurs.
 - o Observations noted on the patient health record will include the “facts” (including times) of the event, Patient assessments, treatment provided, response to treatment and all communication notifying others of the event, e.g., physician and manager notification.
 - o Ensure that the staff and medical staff directly involved is provided the appropriate environment to document the facts accurately and within a timely manner.

APPENDIX C

Supports for Staff and Medical Staff Following a Clinically Serious Adverse Event

Employee and Family Assistance Program (EFAP) – Is a voluntary, confidential short-term counselling and advisory service that connects staff and medical staff and their families to a network of dedicated professionals.

- Professional counselling is available at no cost.
- If long-term or specialized care is required, a professional advisor will assist with referral to an affordable community resource.
- Online Alberta Health Services resources: <http://insite.albertahealthservices.ca/964.asp>

For immediate support for an entire team and/or for a crisis response intervention, contact Shepell FGI Service which will triage the service request to regional supports.

It may be appropriate to refer a *physician* who is the most involved clinician to the Physician and Family Support Program (PFSP). The PFSP is operated through the Alberta Medical Association and encourages well-being and works to improve the physical, emotional, and spiritual health of physicians, residents, medical students and their families.

For WorkPlace Health and Safety Resources

<http://insite.albertahealthservices.ca/2933.asp> for resources and
<http://insite.albertahealthservices.ca/Files/hr-whs-imp-process.pdf>

Clinical Legal

Provincial Legal Intake Line: 1-800-943-0904 or by email:
Legal.clinical@albertahealthservices.ca.

APPENDIX D

Ongoing Management Checklist

All of these steps should be considered for clinically serious adverse events

Case description of the event

- Accountable leader – Individual with ultimate accountability to manage/lead this event**

Name: _____

- Ensure that applicable steps in the immediate management algorithm have been undertaken (R.E.S.P.O.N.D.)**

(see Appendix "A" Alberta Health Services *Immediate and Ongoing Management algorithm*)

Note issues arising/follow-up required _____

- Ensure completion of an Urgent Notification to an Emerging Issue Form**

- Single point of contact:** Patient/Family: _____

AHS Contact: _____

- Name of Ongoing Disclosure contact** _____

- Others to Inform?**

Internal Notification

External Notification

Other

ie. Mandated Legislation Reporting,
Protection of Persons in Care Act

Name _____

- Confirm if there is a need for ongoing support:**

a. Patient/Family

b. Staff and Medical Staff

- Timeline Completed**

What type of response is required?

a. Quality assurance review under Section 9 of the *Alberta Evidence Act*?

If yes, name of assigned Quality Assurance
Committee/Chair

- See QAC Chair Handbook for details.

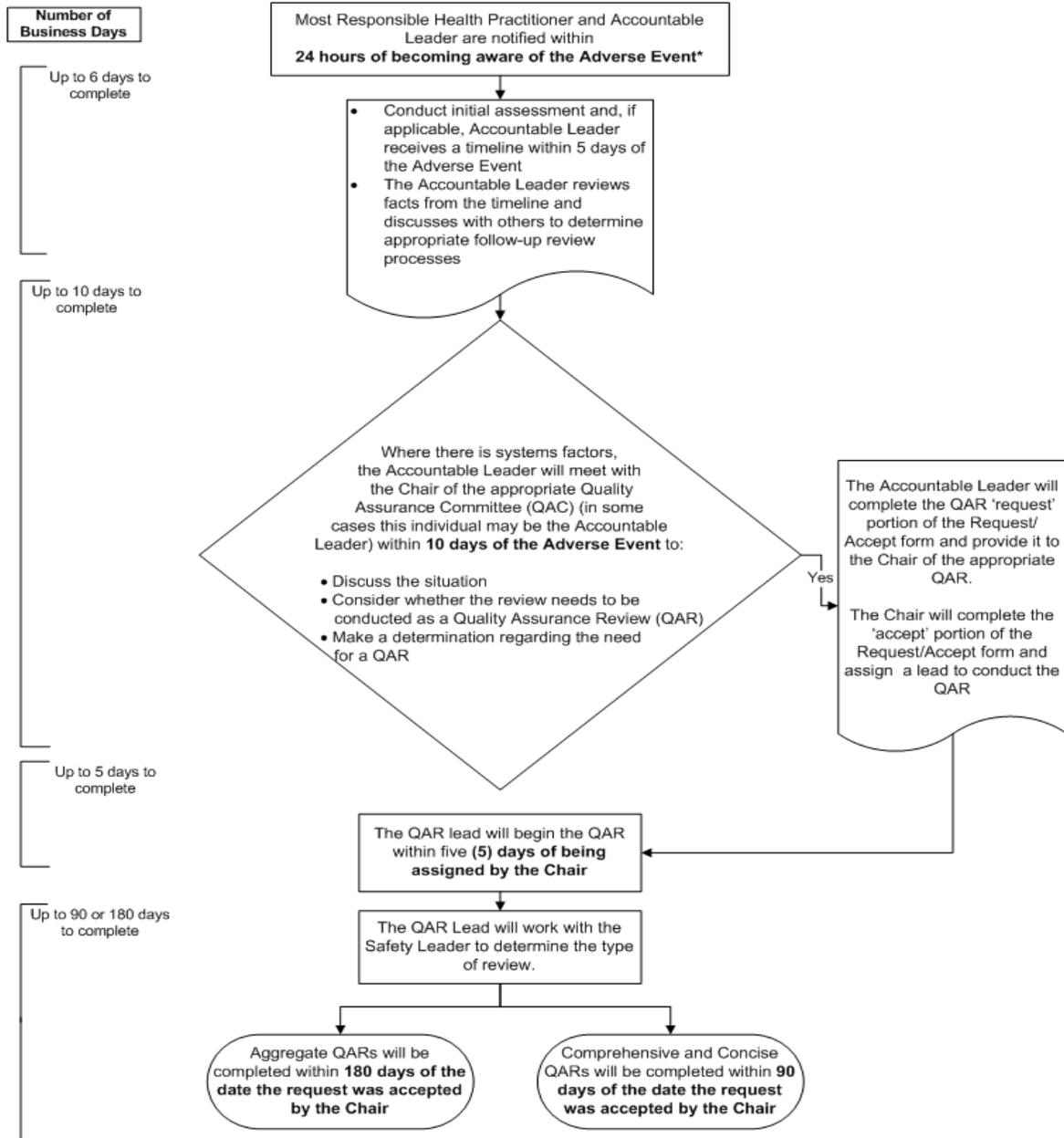
b. Other review? (e.g., administrative review, local process improvement, case
review for educational purposes, quality improvement project, Patient Concern
Resolution Process)

If yes, type of review and
responsible lead

Notes

APPENDIX E

Appendix E - Timelines for the Quality Assurance Review of Clinically Serious Adverse Events

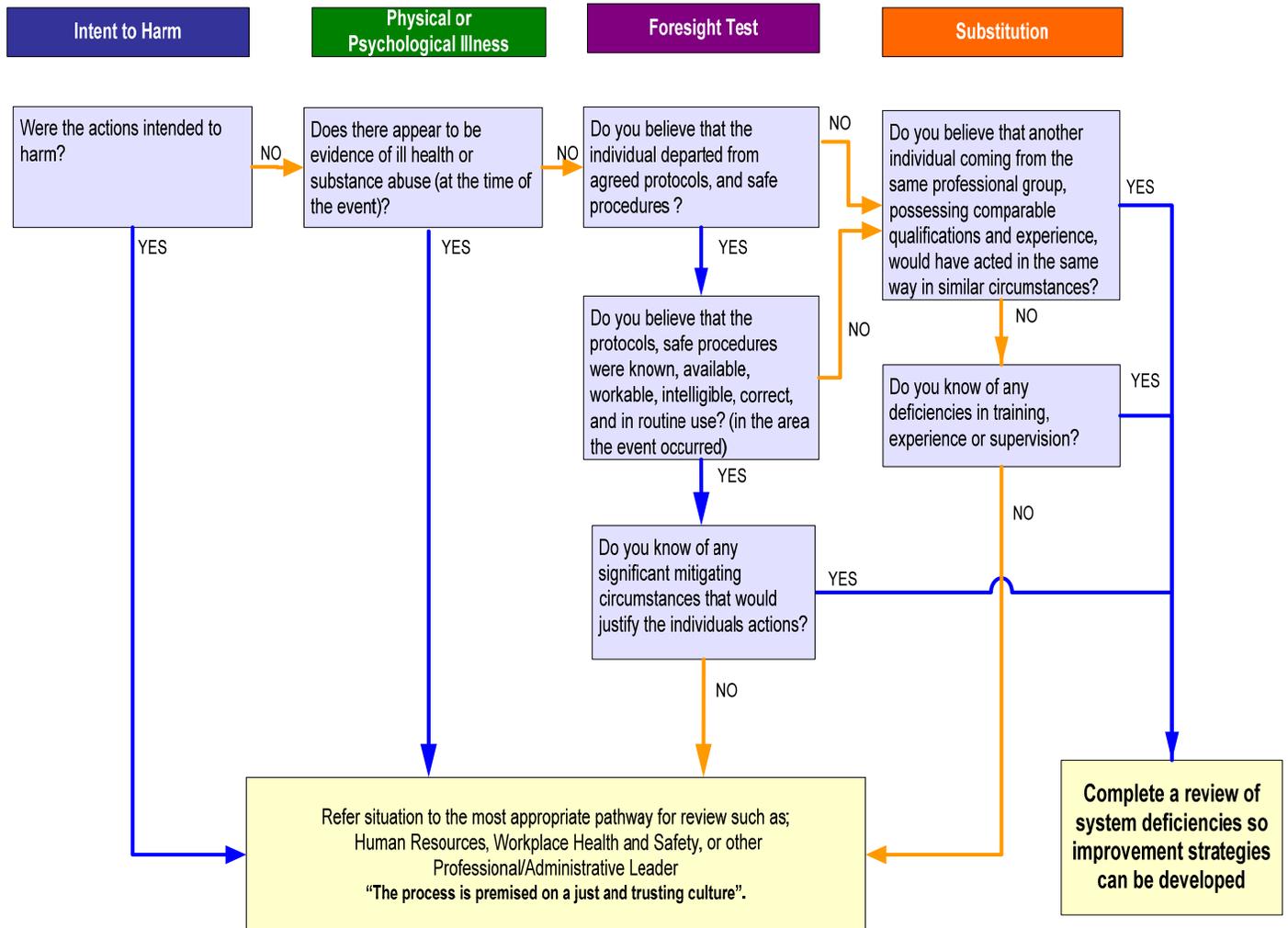


*In cases where the adverse event was recognized and reported at a later date, the timeline will be based on the date the event was reported to the Accountable Leader.

APPENDIX F

Administrative Review Decision Tree

This tool is to be used as an appendix to the Guideline for the Immediate and Ongoing Management of Clinically Serious Adverse Events that will assist Managers in determining a fair and consistent course of action following a Patient safety event



Modified from © National Patient Safety Agency 2009 Incident Decision Tree
 Retrieved on June 9, 2010 from <http://www.msnpa.nhs.uk/td2/ljg0xno55baeior55uh1fvi25/help.aspx?JS=1>