A Coordinated Approach to Reviewing Clinical Adverse Events and Close Calls

This document has been created to provide additional detail for steps included in the AHS Patient Safety Policy Suite Procedures: Immediate and Ongoing Management of Clinical Adverse Events

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The Alberta Health Services Coordinated Approach to Reviewing Clinical Adverse Events and Close Calls Systems Analysis Methodology is based on:

- The Systematic Systems Analysis: A Practical Approach to Patient Safety Reviews1 (Duchscherer, C, Davis, JM. Calgary: Health Council of Alberta; 2012); and
- The Incident Analysis Collaborating Parties. Canadian Incident Analysis Framework2 (Edmonton, AB: Canadian Patient Safety Institute; 2012)
SYSTEMS ANALYSIS METHODOLOGY HANDBOOK

INTRODUCTION
When patients are harmed as a result of the care they receive through Alberta Health Services (AHS), the organization has a responsibility to understand how the harm happened and where appropriate, respond to improve the healthcare system. This handbook has been developed to assist and support AHS staff and medical staff to retrospectively review Clinical Adverse Events, Hazards and Close Calls using Systems Analysis Methodologies (SAM). It is not an administrative review of individual healthcare provider performance.

Using these methodologies, the complex interactions of all the components within the health system are considered, not the individual contributions of healthcare providers that have or may have led to harm. This creates opportunities to identify vulnerabilities in structures, processes and practices that can be improved and ultimately make care safer.

PURPOSE
This framework provides staff and medical staff with:
- a standardized methodology including a common analysis language; and
- standardized analysis tools for reviewing Clinical Adverse Events and Close Calls

RATIONALE
The rationale for developing standardized Systems Analysis Methodologies is to support staff and medical staff in their efforts to review events to determine: what happened, how it happened, and what can be done to improve care for future Patients. The goals established for a provincial standardized process for reviewing events are outlined in Appendix A: Goals And Strategies.

Patient safety improvement takes a combined effort to better understand the risk of harm to patients and to implement effective strategies that reduce harm. To capture the best understanding of a Clinical Adverse Event, SAM supports the inclusion of many perspectives. There are opportunities to include:
- the patient/family involved
- staff and medical staff directly associated with a Clinical Adverse Event
- content experts as appropriate
- students and/or volunteers directly associated with a Clinical Adverse Event
- leaders who have accountability for the area of care that is the focus of the review, and
- those who may be instrumental in operationalizing system improvements

Some or all of these individuals are:
- interviewed to build the initial understanding of what occurred
- part of an Analysis Team tasked with identifying potential contributing factors, and
- included in the development or validation of recommendations to address the system issues identified

THE DECISION TO CONDUCT A QUALITY ASSURANCE OR PATIENT SAFETY REVIEW

Many Clinical Adverse Events are the result of preventable human error and although individuals are accountable for their own performance, they do not carry the burden for system deficiencies over which they have no control. In some instances, more than one type of review may be necessary (e.g. an Administrative Review and a Systems Analysis Review). The discretion of performing each type of review is left to the Accountable Leader and should be decided independently of the outcome.
A review using SAM is recommended for events where system deficiencies that are amenable to quality improvement and learning, where system deficiencies are suspected and resulting recommendations could improve care for future patients.

DETERMINING THE APPROPRIATE REVIEW

When a Clinical Adverse Event has occurred, the Accountable Leader conducts an initial assessment to determine the most appropriate type of review for that particular event (see Figure 1: Overview of AHS Response to Clinical Adverse Events). An “AHS Appropriate Accountability Decision Support Tool” has been developed in the form of an electronic algorithm to guide users in their decision process.

The AHS Appropriate Accountability Decision Support Tool provides a standardized approach to determining appropriate accountability when ‘something goes wrong’. It provides a starting point for Managers, Leaders, and HR Advisors to determine next steps, whether it be to conduct a Systems Review/Patient Safety Review (system issues) OR follow through on processes for an Administrative Review (individual accountability), OR both. This tool forms part of the Quality & Patient Safety Integrated Curriculum’ and is also available on My Learning Link. For more information please email qhi@albertahealthservices.ca.

SECTION 9

When factual information is insufficient to help determine the opportunities for improvement of the system a Quality Assurance Review (QAR) is requested. Quality Assurance Reviews are protected by Section 9 of the Alberta Evidence Act. In these cases it is often necessary to interview individuals and engage in speculative discussion to better understand what may have happened.

Specifically, Section 9 states that,

[1] A witness in an action, whether a party to it or not,
   a. is not liable to be asked, and shall not be permitted to answer, any question as to any proceedings before a quality assurance committee, and
   b. is not liable to be asked to produce and shall not be permitted to produce any quality assurance record in that person’s or the committee’s possession or under that person’s or the committee’s control

More information on the steps specific to conducting a Section 9 protected Quality Assurance Review (QARs) can be found in the Quality Assurance Review Handbook. Essentially Section 9 affords QAR members protection from disclosing speculative discussions in a “proceeding”. This document deals generally with the approach to Reviews regardless of whether they are conducted with or without protection.

There is no need to establish Section 9 protection when the available facts (e.g. clinical records, dispatch recordings) are sufficient to understand what happened and to identify the opportunities for system improvements. This unprotected type of review is known as a Patient Safety Review.

In both a QAR and a Patient Safety Review the facts and key findings can be shared with Patients and families as part of the AHS Disclosure of Harm Policy and procedure.

A clear boundary between Quality Assurance Reviews and Administrative Reviews must be maintained.

An 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.

(AHS Procedure: Ongoing Management of Clinical Adverse Events, 2017)
Quality Assurance Reviews and Administrative Reviews are conducted Independent of one another but may be undertaken at the same time. Information should not be shared between the QAR and the Administrative Review.

Figure 1: Overview of AHS Response to Clinical Adverse Events

Immediate and Ongoing Management of Clinical Adverse Event Steps

It is important for leaders within AHS to understand the differences among these processes (discussed below), as each has a distinct objective and outcome, and meets the needs of different stakeholders.
THE SAM PROCESS

Individuals with responsibility for coordinating or leading activities related to QARs and Patient Safety Reviews should receive training in System Analysis Methodologies. Training provides additional support for standardizing the AHS approach to Reviews. A variety of courses are available including an online education session through my learning link that provides an overview of the process. A more substantial commitment includes a full day case-based workshop generally targeted at patient safety staff and Quality Assurance Chairs but is available to others upon request of the Patient Safety Department. All sessions will refer to the use the analysis tools and the formation of teams as appropriate to the environment. Review teams will find value in using all the components included in this handbook.

Figure 2: The Systems Analysis Methodology Process
METHODOLOGY

There are three methodologies described within this handbook that can be used to review Clinical Adverse Events. These methodologies are designed to suit the scope of a Clinical Adverse Event or multiple Clinical Adverse Events, and provide flexibility for the user.

- The **Concise** method is commonly used for a succinct review of Close Calls or Clinical Adverse Events that result in no, low, or moderate harm to the Patient or may focus on a new event for which a Comprehensive analysis was recently completed. The concise method is generally used for reviews conducted by one or two individuals.
- The **Comprehensive** method is used for a thorough review of a single Clinical Adverse Event and involves a team approach.
- The **Aggregate** method involves a thorough review of multiple Clinical Adverse Events and/or Quality Assurance Reviews. This method is resource intensive and involves a team approach.

Each methodology has been designed to suit a unique application. As events become more complex, there is a greater degree of analysis required and inclusion of knowledgeable interdisciplinary analysis team members will assist in the deconstruction of the event and support a full understanding and the identification of system vulnerabilities that can be targeted for improvement.

All three methods can be used for either a QAR conducted under Section 9 of the Alberta Evidence Act (AEA) or reviews that do not require this legislated protection, such as a Patient Safety Review. The methods and accompanying tools included in this handbook allow for user flexibility to conduct the reviews while supporting the AHS values and applying the foundational principles of systems thinking, a team approach, just culture and confidentiality.

1. Concise Method of Review

The **Concise Method** is a succinct way to review Clinical Adverse Events or Close Calls that resulted in no, minimal or moderate harm to the Patient. Given the complexity of the healthcare environment and the potentially significant resources required for conducting a review using the Comprehensive Method, this succinct method of review will help meet the need for timely and accurate action on a larger number of Clinical Adverse Events.

Concise reviews are usually conducted at the local unit or program level. This method may be used to review events involving severe harm to the Patient if the circumstances warrant it. For example, prior to the implementation of recommendations resulting from a previous Comprehensive review, a similar event occurs. In this example, one to two individuals may analyze the Comprehensive review report and determine that the recommendations, if in place would have prevented the subsequent Clinical Adverse Event. Alternatively individuals may determine the need for additional recommendations for improvement and are empowered to proceed with making such recommendations as they relate to the new Clinical Adverse Event.

Sources of information that should be consulted when conducting a **Concise Review** include: Reporting and Learning System (RLS) reports, the health record supplemented with a small number of informal discussions and targeted reviews of other sources of information.

One or two individuals complete the **Concise Review** in a short interval of time. At the end of the review, a short report is produced and provided to the applicable operational and/or medical leaders. It will include a brief case description, the findings, contributing factors/system hazards, and where applicable, recommendations for improvement and accompanying evaluation strategy.

If the review has taken place outside of **Section 9** protection, the report is attached to the applicable RLS report so the system learning is available for sharing across the organization. If the review has been conducted within **Section 9** protection, the report and its findings are presented to the appropriate Quality Assurance Committee (QAC).
**Recommended Steps in the Concise Method**

- A specific Clinical Adverse Event or Close Call is identified for review using the Concise Method.
- The individual conducting the review seeks relevant information to ensure the facts of the event are clear and accurate. Informal discussions may be held with the Patient, family member, healthcare provider, manager and/or experts in the processes or equipment involved. As part of the decision-making process on whether a systems review is appropriate, a timeline of events based on facts obtained from the Patient’s medical chart is completed. A timeline tool is available to support development of an initial timeline.
- RLS and other targeted sources of information are examined.
- Analysis tools including the SAFER Matrix Tool (see [Figure 5: The AHS modification of the SAFER Matrix](#)) or Constellation Map (see [Figure 6: Constellation Map System Components](#)) and the System Analysis Guiding Questions are used to facilitate a systematic approach to identifying contributing factors.
- Findings are summarized and may be validated with staff and medical staff as appropriate.
- If there is sufficient evidence to formulate recommendations, they are written using the SMARTS criteria. A limited scan of the literature may be conducted to inform any recommendations arising from the review. Recommendations, if there are any, should be prioritized utilizing the Prioritization Tool.
- A short report is produced that includes a brief description of the case, the findings, contributing factors/system hazards, and any recommendations for improvement. The report is provided to the applicable operational and/or medical leader for an implementation decision and dissemination if applicable. If the review has taken place outside of Section 9 protection the report is attached to the applicable RLS report so the system learning is available for sharing across the organization. Summary reports from reviews under Section 9 protection are presented to the appropriate QAC.
- A database maintained by the Patient Safety Learning and Improvement team and referred to as the Recommendation Tracker, is utilized to monitor and analyze recommendations from a variety of reviews including QARs, Fatality Reviews, Health Quality Council of Alberta Reviews, and select Patient Safety Reviews and Human Factors Reviews.

If, at any point during a review using the Concise Method, the reviewer believes that the investigation should be escalated to the Comprehensive Method, they should do so in discussion with the requestor of the review.

Refer to the *Concise Method Flow Map* on the next page and to the *Concise Method Checklist*. 
Concise Method Flow Map

INITIATION
- A decision has been made to conduct a review of the Clinical Adverse Event or Close Call
- Most commonly used for events that resulted in no, minimal or moderate harm to the Patient
- May be used to review events causing more significant harm if appropriate to the circumstance (e.g. an event repeats prior to implementation of recommendations resulting from a previous comprehensive or aggregate review)

Understand WHAT HAPPENED
An understanding of the event is developed:
- Facts are gathered to understand what happened
- Information may be obtained through discussing the event with the Patient/family, healthcare provider(s), manager(s) and/or expert(s) in the process or equipment related to the event

Understand HOW and WHY IT HAPPENED
Identification of key contributing factors:
- Information gathered is analyzed with consideration of all system components
- A modified SAFER Matrix\(^1\) or Constellation Map\(^2\) may be used to identify potential contributing factors and the relationships between them.
- Findings are summarized and may be correlated with Staff and Medical and Midwifery staff as appropriate

Develop Recommendations – WHAT CAN BE DONE TO MAKE CARE SAFER
If there is sufficient evidence to formulate recommendations:
- Recommendations are developed to address hazards identified using the SMARTS format
- An evaluation strategy may be described

Produce a Report
- A short report that includes the summary of findings, contributing factors/system hazards and any recommendations and evaluation strategies is produced
- Provide the report to the applicable Accountable Leader and/or Responsible Administrative Leader for a decision regarding implementation and dissemination. If the review has taken place outside of Section 9 protection, the electronic report should also be attached to the applicable electronic RLS report so the system learnings are available for sharing across the organization
- A database maintained by the Patient Safety Learning and Improvement team and referred to as the Recommendation Tracker, is utilized to monitor and analyze recommendations
2. Comprehensive Method of Review

The Comprehensive Method is used for a thorough review of a Clinical Adverse Event or Close Call and involves team members in both the investigation (Investigation Team) and analysis (Analysis Team) portions of the review. The Clinical Adverse Event reviewed may have resulted in any level of severity of harm to the Patient, but usually the Patient has experienced severe harm or has died.

Recommended Steps in the Comprehensive Methodology

INVESTIGATION AND PREPARATION

- As part of the decision-making process on whether a systems review is appropriate, a timeline of events based on facts obtained from the Patient’s medical chart is completed (see the Timeline Template). The scope of the review and completion target date is agreed upon.
- Members are identified that can assist in the review, including content experts (see Appendix C: Process For Engaging Experts), a Review Lead, and potential members of the Analysis Team.
- If possible, the Patient and/or family members are interviewed first (see Appendix B: Suggestions For Conducting Interviews).
- Interviews are conducted with staff and medical staff who were involved with the event.
- Persons with content expertise are also interviewed to understand not only what happened, but what should have happened.
- The initial timeline is revised with the information obtained from the interviews and other information sources to create a draft final timeline. All information included in the Timeline is de-identified. Only the original source, date and time are included.
- Other resources are researched for possible solutions (e.g. literature searches, organizational policies, contacting similar external healthcare organizations, reviewing similar events in Recommendation Tracker).
- The Review lead uses the AHS modification to the SAFER MATRIX TOOL to track and record information for each component of the healthcare system that is identified throughout the investigation and preparation phase of the Comprehensive Method.

ANALYSIS

- Members of the Analysis Team are confirmed and may include content experts, a Review Lead, a Facilitator, two or three of the healthcare providers most familiar with the Clinical Adverse Event, one or two healthcare providers from the unit or program that were not involved and the Patient (or Patient representative as appropriate), as well as the applicable senior operational and medical leaders who will most likely be responsible for implementing change as a result of the review. For more information on the roles of an Analysis Team, see Appendix E: Roles Within The Systems Analysis Teams.
- The Analysis Team is briefed on SAM and expectations for reviewing the Clinical Adverse Event within a just culture (see the Just Culture Principles).
- The Analysis Team meets, generally for at least one, two hour meeting and may schedule subsequent meetings as required.
  a. During the initial meeting of the Analysis Team the draft final timeline is reviewed and clarifications and additions are made as appropriate in order to finalize the document.
  b. All documents including pictures, health information, policies and procedures and relevant findings from the literature are brought to the meeting and made available to all participants of the Analysis Team. The Review Lead with support from the Facilitator is responsible to ensure all of the necessary information is available. When the review is conducted under Section 9 of the Alberta Evidence Act the Review Lead must also ensure that documents are appropriately labeled as, “PRIVILIGED AND CONFIDENTIAL” and “PREPARED FOR OR BY THE QUALTIY ASSURANCE COMMITTEE” and secured to meet the legislative requirements.
  c. When the draft final timeline is complete, the Analysis Team is ready to begin brainstorming utilizing the Constellation Map and System Analysis Guiding Questions. A Constellation
Map represents the system factors that led up to and were in place during the Clinical Adverse Event. The Facilitator helps the team identify these factors (contributing and mitigating) by continuing to ask how and why did this happen, what was this influenced by and what else influenced the circumstances, until no further information can be generated. (A large whiteboard or sticky notes can be used to generate the Constellation Map)

d. Clusters of contributing factors are identified, that if improved, would make care safer. These clusters are themed and will form the basis for recommendation development.

e. Statements describing the system-related issues are formulated from the themes of clustered contributing factors.

f. Recommendations are developed that meet the SMARTS criteria to address the hazards identified in statements describing the system-related issues. These are validated with the analysis team by consensus.

g. Recommendations are prioritized using the Prioritization Tool, ensuring consensus and support among the Analysis Team members and any other operational lead who has not yet been involved but who would be responsible for implementing recommendations.

- A Review Summary report is prepared and presented to the QAC (if the review is Section 9 protected) or the review requestor (in the case of a non-protected review). It is suggested that potential recommendation owners are included at the QAC meeting to hear the case discussion and integrate additional information into their action plans.

- Recommendations from the review are tracked via the Recommendation Tracker in most cases.

- If the review will not be tracked through the Recommendation Tracker the report is attached to the applicable RLS report so the system learning is available for sharing across the organization.

Refer to the Comprehensive Method Flow Map on the next page and to the Checklist section for a COMPREHENSIVE METHOD Checklist.

Also see Appendix D: Case Example Using The Comprehensive Analysis Methodology.
**Comprehensive Method Flow Map**

**Initiation**
- Initial timeline is completed and known facts about the event have been assessed by the Accountable Leader who has requested a SAM to be completed in consultation with the Responsible Administrative Leader and Patient Safety staff as appropriate.
- Facilitator and/or Review Lead have met with the requestor of the review to fully understand the issues that are to be examined, the scope of the review and an estimated date for completion.
- Identification of membership for the Investigation Team and Analysis Team as appropriate.

**Understand WHAT HAPPENED**
Investigation Team activities may include:
- Interview relevant staff involved directly or indirectly involved in the Clinical Adverse Event
- Visit to the event site and examination of any products or equipment evaluated
- Interview the family/Patient if possible
- Research relevant policies, literature, similar events reported elsewhere
- Discuss with other experts as needed (i.e. IT, pharmacy)

Investigation Team completes:
- A final timeline of the best understanding of what occurred
- A modified SAFER Matrix\(^1\) containing information gathered during the investigation (including suggestions and opinions) covering all components of the healthcare system

**Understand HOW and WHY it HAPPENED**
A meeting of the Analysis Team is convened:
- Written information including the case description, final timeline and additional supporting information are made available ahead of the meeting
- The completed modified SAFER Matrix\(^1\) is reviewed and amended from the team’s input
- The team is guided by the Facilitator to complete the Constellation Map\(^2\) to identify potential contributing factors and their relationships and linkages covering all system categories
- Similar contributing factors are clustered, themed and validated by consensus within team
- Summary of findings statements are formulated for which recommendations can be developed

**Develop Recommendations – WHAT CAN BE DONE TO MAKE CARE SAFER**
Either in the initial meeting of the Analysis Team or in subsequent meetings of the Analysis and Investigation Teams:
- Recommendations are drafted to address the hazards identified in the summary of findings statements
- Recommendations to be written in the SMARTS format
- An order of priority for the recommendations is suggested

**Produce a Report**
- A short report that includes the summary of findings, contributing factors/system hazards and any recommendations and evaluation strategies is produced
- A report is provided to the applicable Accountable Leader and/or Responsible Administrative Leader for a decision regarding implementation and dissemination. If the review has taken place outside of Section 9 protection, the electronic report should also be attached to the applicable electronic RLS report so the system learnings are available for sharing across the organization.
- Recommendations from the review are tracked via the Recommendation Tracker. If the review will not be tracked through the Recommendation Tracker the report is attached to the applicable RLS report so the system learning is available for sharing across the organization.
3. Aggregate Method of Review

The Aggregate Method may be used to review two or more Clinical Adverse Events or Close Calls of any severity level. A trend may have been identified by similarly themed RLS reports, similar Clinical Adverse Events or Urgent Notification to an Emerging Issue document. The group of similar events may also include previous reviews that have already generated recommendations. A review conducted using the Aggregate method is often resource intense and many, but not all will be performed under the direction of a QAC.

Recommended Steps in the Aggregate Method

- The Accountable Leader determines the need for a review using the Aggregate method in consultation with a Facilitator and the Review Lead. The identification of groupings of events of a similar nature is often a sign that a review using the SAM aggregate method would be appropriate.
- An initial timeline may be developed to organize the various reviews and events in chronological order.
- The scope of the review is decided upon by determining the specific case inclusion criteria – Some things to be considered:
  - Who: Is it particular to a certain demographic? (e.g. is this an age range, is it program specific?)
  - Where: Is the problem local? By site? By Zone? Is it Provincial?
  - When: Set the criteria for the data collection. Is this related to a recent change in process? Include data from before and after the change?
  - Are there other sources of data (i.e. reporting systems) to consider?
  - If there were previous reviews, what system issues have been identified? Are these the same issues to be considered in this review?
- Members are chosen for the Investigation and Analysis Team. Depending on the scope, members may be selected across programs, sites and zones.
- Depending on the complexity of the review, terms of reference may be created and a completion date agreed upon.
- A meeting plan is developed. If the team members are required to travel, ample time is given to make arrangements.
- The Investigation Team is gathered to prepare the analysis - obtain the data, sort/filter and verify the themes and trends.
- The analysis plan is developed (what do the previous reviews tell us (if applicable), what does the current information tell us, what has previously been done to address the issue (if applicable), was it successful, does it have a broader implementation potential?)
- If possible, interviews with the Patient(s) or family member(s) are conducted. (See Appendix B: Suggestions For Conducting Interviews)
- Interviews with staff and medical staff that were associated with the events are conducted.
- Interviews are conducted with content experts familiar with the care processes being reviewed to understand not only what happened, but what should have happened.
- Relevant policies are researched and any new changes are noted as well as checking for other Quality Improvement Projects or Human Factors reports in this area.
- A literature search is performed and connections made with external healthcare organizations to see if there are similar issues to learn from or solutions to consider.
- Recommendations from previous reviews (or Quality Improvement Projects or Human Factors Reports) are examined to determine if they address the original hazards that had been identified. Previous implementation outcomes are assessed for effectiveness.
- Recommendations from previous reviews are identified that would have applicability in the aggregate Review.
- The Investigation Team confirms that these recommendations would be appropriate in their areas. This may involve further analysis (e.g. process mapping).
• Materials are prepared. An additional timeline may or may not be helpful. The AHS modification of the SAFER MATRIX TOOL\(^1\) may help to organize the information and ensure all the health system components have been considered.
• The Analysis Team is convened to share the analysis plan details and the completed AHS modification of the SAFER MATRIX TOOL\(^1\).
• Using the Constellation Map\(^2\) and System Analysis Guiding Questions, the Facilitator helps the team identify potential contributing and mitigating factors by asking how and why did this happen, what was this influenced by and what else influenced the circumstances, until no further information can be generated.
• Clusters of contributing factors are identified, that if improved, would make care safer. The clusters are themed.
• Summary of findings statements are formulated from the themes of clustered contributing factors.
• Recommendations are developed using the SMARTS format to address the hazards identified by the summary of findings statements. The recommendations are validated with the team.
• Recommendations are prioritized using the Prioritization Tool (see the section on Recommendation Assessment And Prioritization)
• Ensuring consensus and support among the Analysis Team members and any other operational lead who has not yet been involved but who would be responsible for implementing recommendations.
• A Review Summary report is prepared and presented to the QAC (if the review is Section 9 protected) or the review requestor (in the case of a non-protected review). It is suggested that potential recommendation owners are included at the QAC meeting to hear the case discussion and integrate additional information into their draft action plans.
• Recommendations from the aggregate review are generally tracked in Recommendation Tracker.

Refer to the Aggregate Method Flow Map on the next page and to Checklist section for an Aggregate Method Checklist.
The Aggregate methodology may be used to review two or more events (of any severity) or Close Calls that have previously been reviewed (e.g. QAR was performed) but may also include events that have not been reviewed.

**Examples:** Review of RLS data identifies hundreds of events involving the same event type and process category or Unit Manager is aware of three similar medication events.

- These events or Close Calls may have occurred during a defined period of time or location, or encompass several locations
- Analysis is expected to involve system issues of high complexity
- Facilitator and/or appointed Review Lead meet with the requester of the review to fully understand the issues that are to be examined including: the scope of the review, case inclusion criteria and an estimated date for completion
- Teams are identified and may include local and external content experts, Staff and Medical and Midwifery staff

**Understand WHAT HAPPENED**

Investigation Team activities include:
- Gathering applicable data (further instruction under development)
- Conducting interviews with content experts familiar with the care processes
- Researching relevant policies, literature, similar external healthcare organizations
- Develop the analysis plan and prepare the materials

Investigation Team completes:
- A modified SAFER Matrix\(^1\) containing information gathered during the investigation (including suggestions and opinions) covering all components of the healthcare system is compiled

**Understand HOW and WHY it HAPPENED**

A meeting of the Analysis Team is convened:
- Previous reviews have been analyzed to draw out similarities in recommendations and assess and evaluate the outcomes of implemented recommendations
- Care processes are compared and contrasted
- The team is guided by the Facilitator to complete the Constellation Map\(^2\) process to identify potential contributing factors and their relationships and linkages covering all system components
- Identify clusters of similar contributing factors and validate by consensus within the team
- THEME the clusters of contributing factors and develop summary of finding statements for which recommendations can be developed

**Develop Recommendations – WHAT CAN BE DONE TO MAKE CARE SAFER**

Analysis and Investigation Teams will:
- Draft recommendations to address the hazards identified in the summary of findings
- Recommendations to be written in the SMARTS format
- An order of priority for the recommendations is suggested

**Produce a Report**

- A short report that includes the summary of findings, contributing factors/system hazards and any recommendations and evaluation strategies is produced
- Provide the report to the applicable Accountable Leader and/or Responsible Administrative Leader for a decision regarding implementation and dissemination. If the review has taken place outside of Section 9 protection, the electronic report should also be attached to the applicable electronic RLS report so the system learnings are available for sharing across the organization
- Recommendations from the aggregate review are generally tracked in Recommendation Tracker

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\(^1\) SAFER Matrix

\(^2\) Constellation Map
RECOMMENDATIONS

Regardless of the review methodology utilized the most frequent output will be recommendations for improvement.

Development of Recommendations

Developing and managing recommendations is a multi-step process that starts with the Analysis Team drafting recommendations based on the system related issues identified in the analysis and suggesting an order of priority. The Analysis Team should validate the drafted recommendations with those involved in the event and others (e.g. experts, patients/family) as needed.

Recommendations are implemented successfully if they make sense at all levels in the organization, can be approved by decision-makers who will then empower and resource others to implement and evaluate their effectiveness in reducing risk. Recommendations will have impact if they resonate with the local team involved in the event.

How to Develop Recommendations

The Analysis Team develops the first draft of recommendations and ensures that they are valid and reliable. The list of key features below is a guide when building the recommendations.

The ultimate goal of any system review process is the development of recommendations to eliminate or at a minimum mitigate the potential for recurrence of a similar event. In order to develop a recommendation that is specific in targeting an identified hazard, the Analysis Team identifies the system issue or hazard and then identifies proposed recommendations to eliminate or control the potential for an event.

SOME FEATURES OF HIGHLY EFFECTIVE RECOMMENDATIONS:

- Addresses the safety problem associated with the recommended action
- Offer a long term solution to the problem
- Are written using the “SMARTS” format
  - Specific – are clear on what action is to be undertaken and where appropriate include a description of the intended results
  - Measurable – can demonstrate impact on process and outcomes and are written in such a way that the responsible owner can determine how and when implementation has occurred
  - Attainable andAssignable – ensure the recommendation is both achievable and that implementation can be assigned to an individual
  - Relevant – ensure that the recommendation is applicable to the identified safety issue. Will the recommendation, when implemented, directly impact that safety issue?
  - Timely – have a timeframe for implementation
  - Spread – should this recommendation be considered for broader implementation? If so, who should be considering implementation?

- Responsibility Recommendation Owners can be accepted by someone who is accountable for its success at the appropriate level in the organization. The Recommendation Owner is usually a member of the Analysis Team.
- Have a greater positive than negative impact on other processes, resources, and schedules
- Are based on evidence (where possible) showing the impact of this or similar action. Consider research literature, similar recommendations implemented in the organization (e.g. from accreditation, Patient concerns) or externally (e.g. from the Global Patient Safety Alerts). Aim for the highest level of evidence available (randomized controlled trials are the highest, followed by controlled observational studies, uncontrolled studies, opinion of experts and opinion of peers)
Summary report provides enough context (explanation, facts) to ensure those responsible will understand the rationale behind the recommendation

**Impact of Recommendations**

When recommending actions, many possible categories of options with varying degrees of effectiveness are available. The team should consider this range and be encouraged to recommend the most effective solution that is reasonable and/or possible given the circumstances. Note that items such as training and policy development are necessary components, but when used alone, may not change the underlying conditions that led to the event.

From a human factors standpoint, the strongest interventions are “physical rather than procedural and permanent rather than temporary.” Consultation with the Patient Safety Human Factors team may be helpful in determining if the proposed actions will be effective from a human factors perspective.

AHS Patient Safety utilizes a recommendation impact assessment scale to assign an impact score to proposed recommendations. This impact assessment scale encompasses:

- A modified ISMP Hierarchy of Effectiveness
- Strength of evidence
- Proximity of impact to Patient care
- Critical questions

Inevitably there is a trade-off with all recommendations. While recommendations at the highest level are the most effective, they are also often the most difficult to implement because of their complexity. They are also likely to be more costly, more resource-intensive, and take longer to implement.

In contrast, lower-level recommendations can usually be implemented relatively quickly and easily, often with minimal impact on resources, but are less effective in contributing to long-term improvements to Patient safety. Thus, there is a challenge of developing recommendations that will have the greatest impact on safety and that will also be acceptable to operational leaders. In this regard, it is highly recommended that a person in a leadership position who is familiar with the environment, and will likely be responsible for implementation be part of the review team.
A word about words
Strive to write recommended actions that are clear and specific on what action is to be taken. The addition of qualifying words to the beginning of recommended actions can significantly alter the interpretation and overall impact of a recommended action.

EXAMPLE

Design and implement a standardized process for tracking and labeling all infusion lines.

vs.
Consider designing and implementing a standardized process for tracking and labeling infusion lines.

In this example, including the word “consider” lowers the strength of the recommended action from a 6 (simplify/standardize) to a 1 (inform) on the Impact assessment tool and implies that the recommended action is considered “implemented” upon holding a meeting to discuss the pros and cons of moving forward with implementation. Therefore the overall impact of implementing this proposed recommendation is low.
FOUNDATIONAL CONCEPTS FOR CONDUCTING REVIEWS USING SAM

The following principles are foundational in conducting SAM reviews:

SYSTEMS THINKING

In any healthcare setting there are multiple levels of ‘systems’ in operation at all times. All the parts of these systems – for example, the staffing system, work processes, and the equipment – interact and contribute to the complexity of the setting. This complexity is increasing and has to be acknowledged as part of the context for the review of Clinical Adverse Events.

The Patient Safety team includes specialists in Human Factors, a discipline that examines how humans interact with the world around them and can help identify systems-based reasons for how things go wrong. While it is human nature to identify factors at the intersection between Patient and provider, (the “sharp end” or micro level), the goal of the review is to move the team outward through all levels of the system to ensure all the contributing factors/system hazards are determined. See the Principles section for more information on human factors in systems analysis.

Figure 3: Healthcare System Levels
Patient Safety has evolved within a rich history of theories and practices across industries and disciplines. A foundational understanding is that events unfold that may on the surface appear to be the ‘results’ of specific actions taken on the part of individuals. These individuals are operating within the context of a complex system. It is the examination of this complex system that supports an understanding of contributing factors that then can be targeted for improvement. The focus of SAM is on identifying opportunities for system changes to achieve a widespread and lasting impact, not on blaming individuals or simply training them.

SAM provides guidance for the examination of multiple system components to ensure the context of the event is understood.

**TEAM APPROACH**

To capture the best understanding of a Clinical Adverse Event, SAM supports the inclusion of many perspectives. There are opportunities to include:

- the Patient/family involved
- staff and medical staff directly associated with a Clinical Adverse Event
- content experts as appropriate
- Student practitioners and/or volunteers directly associated with a Clinical Adverse Event
- leaders who have accountability for the area of care that is the focus of the review, and
- those who may be instrumental in operationalizing system improvements

Some or all of these individuals are:

- interviewed to build the initial understanding of what occurred
- part of an Analysis Team tasked with identifying potential contributing factors, and
- included in the development or validation of recommendations to address the system issues identified

Participation in a QAR is voluntary and the roles and contributions of these individuals will vary based on their level of comfort, skills, preferences and availabilities. As well, individuals that were not involved or directly impacted but could contribute in an advisory or content expert role may be included in a SAM. Professionals with an expertise in Human Factors are one example.

*Of special note:* Individuals that are not employees of AHS may be invited to participate in a SAM. For those individuals who are not AHS employees it is an expectation that they sign a confidentiality agreement (see the Confidentiality Agreement in the Templates section).

In SAM there is a role for a Facilitator with training in analytical methods, group process and consensus building to assist with the review process. This is particularly important given a SAM analysis team would include those directly involved in the Clinical Adverse Event, leaders accountable for the area of care that is the focus of review and those instrumental in operationalizing improvements.

It can be very important to include the Patient and/or family perspective in a review. This may be accomplished by interviewing the Patient and/or family to gain their understanding of the event and their thoughts regarding possible improvements. As well, a representative Patient or family member may be included in the review team to capture their important perspectives. It is important to note that these individuals would also be expected to sign a confidentiality agreement (see the Confidentiality Agreement in the Templates section).

**JUST CULTURE**

The way in which individuals react to unique circumstances is demonstrated through their behaviours and decisions, thereby shaping and influencing our organizational culture. The AHS values of respect, accountability, transparency, safety, learning, engagement and performance need to be demonstrated in follow-up to a Clinical Adverse Event. A consistent and standardized approach to the assessment of accountability and a systems analysis which focuses on reviewing what occurred in context of the
event and responding to the individuals involved with care, dignity, support and respect regardless of the outcome of the event will have a positive impact on the growth of a just culture.

A Just Culture\(^{10}\) supports an environment where everyone feels safe, encouraged, and enabled to discuss quality and safety concerns - reporting and learning are key elements. This means that reporting is conducted within a psychologically safe environment where there is demonstrated respect and support for the individual, and the potential for human and systems fallibility is acknowledged.

**CHARACTERISTICS OF A JUST CULTURE IN AHS:**

- **environment of psychological safety**
- **climate of mutual trust and respect**
- **atmosphere that supports open dialogue**
- **acknowledgement of human fallibility**
- **open and honest communication of unanticipated events, issues, errors,**
- **appropriate accountability**
- **evaluation first of the system and, if warranted, the individuals involved, and**
- **support of Patients, families, staff and medical staff involved in unanticipated event**

In practicing the four Just Culture Guiding Principles and seven process principles (see the Just Culture Guiding Principles section) through all aspects of a review we live the AHS organizational values. Through Just Culture, we will:

- be **respectful** in how we engage with those involved
- be **transparent** in the evaluation processes used
- hold our system, ourselves and others **accountable**, and
- learn from mistakes and close calls to improve **safety** and **performance**

Staff and medical staff are encouraged to participate on review teams in order to learn and improve, however their presence is not mandatory. They will only be willing to participate if they feel supported by the managers, supervisors and medical leaders and by the teams who are supporting the review.

A separation must exist between any Systems Analysis review and any review of an individual’s performance.

**CONFIDENTIALITY**

Information shared within reviews using the SAM needs to occur in a confidential environment. If the review is being conducted under a Quality Assurance Committee there is specific legislation (Section 9 of the *Alberta Evidence Act*)\(^{3}\) protecting the information from disclosure in court proceedings. Whether conducted under this protection or not, everyone is responsible for protecting personal information about patients and healthcare providers under the Health Information Act\(^{11}\) (HIA).

The role of the facilitator in this process is key to assisting those involved to feel safe to freely express their opinions about possible contributing factors. Those in management positions need to understand that information shared by their staff in conversations during a systems review cannot be used for disciplinary purposes, and whenever an individual is involved both in an Administrative Review and a system review, the supervisor present for the Administrative Review shall not have any involvement in the Systems Analysis review.
AHS APPROACH TO CLINICAL ADVERSE EVENT MANAGEMENT

Event reviews using SAM are one of the activities aligned with activities that are defined within the AHS Immediate Management and Ongoing Management for Clinical Adverse Events procedures, and the recommendation management process. Systems Analysis is a core activity that is closely connected to the activities that precede it (respond to, disclose and report the event) and succeed it (synthesize with other risk information, implement, evaluate, and share learnings).

Families may have questions following a Clinical Adverse Event that they pose to operational leaders. Findings and recommendations from a Quality Assurance Review or a Patient Safety Review can be shared with families by the Responsible Administrative Leaders in disclosure conversations once the review has been accepted by the QAC.

An independent process may be needed to address family questions and assist them in reaching resolution. The AHS Patient Relations Department is available at any time during business hours to provide support and collaboration with staff, management and physicians related to a Patient concerns resolution. Further information regarding the AHS Patient Relations Department is available on Insite.
A Serious Clinical Adverse Event is defined as 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.

### Clinical Adverse Event
- Patient support: clinical, emotional, practical and spiritual needs
- Staff support: first aid or medical aid, transfer care when necessary, emotional support
- Environment: ensure area is safe, consider PLEASE quarantine, medication dispensing error protocol
- Documentation: report event in RLS, clinical adverse event management is documented separately from health record, mandatory notification for certain events, report in MySafetyNet for staff injury

### Immediate Event Management
- Ensure steps for immediate management have occurred and complete the Urgent Notification to an Emerging Issue form
- Provide ongoing support and communication with patient/family and staff
- Internal notification of other AHS Leaders as appropriate and any external legislated mandated reporting

### Ongoing Event Management
- The Accountable Leader conducts an initial assessment to determine the appropriate response:
  - Local Quality Improvement Process
  - Educational Case Review
  - Human Factors evaluation
  - Patient Concerns Resolution Process
  - Systems Analysis - choose methodology
  - Administrative Review
  - Safety Alert or Safer Practice Notice
*Note: may choose more than one response*

### Evaluate & Determine Response

### Learn, Share, Inform
- Synthesize with other risk information
- Implement and evaluate risk reduction strategies
- Share learnings (*a Patient Safety Learning Summary is one way to share learnings)*

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**Figure 4: AHS APPROACH to Serious Clinical Adverse Event Management**

<table>
<thead>
<tr>
<th>Concise Method</th>
<th>Comprehensive Method</th>
<th>Aggregate Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accountable Leader may choose to do as a protected Quality Assurance Review (under Section 9 of the AEA) or an unprotected Patient Safety Review</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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*Note: Section 9 of the AEA*
ANALYSIS | USE OF THE AHS MODIFICATION OF THE SAFER MATRIX TOOL

The components of the healthcare system were first described using the terms “Structure”, “Process”, and “Outcome” by Donabedian. The tabular format of the SAFER (Systems Analysis and Factor Evaluation Review) Matrix provides a tool for the Investigation Team to ensure they have considered all the health system components in assessing their understanding of the event. This model of investigation was first developed, used and described by Jan Davies and is the basis of the HQCA’s Systematic Systems Analysis: Practical Approach to Patient Safety Reviews.

The AHS modification of the SAFER Matrix is a tool to guide the consideration of all components of a healthcare system during the investigation and preparation phase of the Comprehensive Method and the Aggregate Method and may be used in isolation of the Constellation Map in the Concise Method.

The health system components included in the AHS modification of the SAFER Matrix are:
- Patient
- Healthcare providers
- Team
- Task
- Equipment
- Environment
- Organization
- Other (local conditions, regulatory agencies, etc.)

**Figure 5: The AHS modification of the SAFER Matrix**

<table>
<thead>
<tr>
<th>Health System Components</th>
<th>Structure</th>
<th>Process</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Why did this happen?</td>
<td>How did this happen?</td>
<td>What happened?</td>
</tr>
<tr>
<td>Patient</td>
<td>Structural Components</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Healthcare Providers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Team</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Task</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Environment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
A very brief description of how the AHS modification of the SAFER Matrix is used is as follows:

Relevant information gathered during the investigation phase is entered under one of the three columns for each component, as appropriate. The SAFER Matrix allows you to develop a picture of the system at the time of the event. It reminds you to think about all components of the healthcare system and how each of those systems works together.

The AHS modification of the SAFER Matrix allows the Review Lead or Investigation Team to build an understanding of the Clinical Adverse Event as information is gathered from interviews etc.: Structure, Process and Outcome are the main phases of any event; Structure comes from the past and drives the Process which results in an Outcome.

[1] Structure
- Information related to the ‘beginning’ or starting point of the system is included in the structure
- For the Patient, this may include basic information such as age, co-morbidities, and allergies. For the Organization category the presence (or absence) of relevant policies and procedures would be listed
- Often this information is in answer to the question: Why did this happen?

[2] Process
- Information is entered relating to what occurred in this category (i.e. what the Patient did or underwent, decisions made or actions undertaken by the caregiver, equipment malfunctions, etc.)
- This column answers the question: How did this happen?

[3] Outcome
- This includes any information about “What happened” in terms of the outcome.
- There will likely be information about a Patient (i.e. Patient died), but there may not be information for some of the other categories in this column

The SAFER Matrix is completed by putting information into the Patient “Outcome” first as we probably know the Outcome of the patient. Next complete the Patient “Process” (what the patient did or underwent) finally the Patient “Structure” (details about the patient). After the Patient “Structure, Process and Outcome are completed fill in the details of Structure for all of the other Health System Components (Health Care Providers, Team etc.). This pattern of completion allows you to formulate a framework prior to inputting the remainder of the information into the “Process.”

OPINIONS

The AHS modification of the SAFER Matrix is populated with facts as well as speculation and opinions gained from interviews, discussions and inquiries during this stage. It is important that the person who was the source of the opinion or speculation has consented to this information being shared (in a de-identified format).

The AHS modification of the SAFER Matrix should be used by the Review Lead in conjunction with the Constellation Map for a Comprehensive Review and an Aggregate Review. The AHS modification of the SAFER Matrix is used to validate that all of the information gathered during the investigation and preparation phase has been considered by the Investigation Team in building their understanding of the event prior to the development of a Constellation Map.
TOOLS | CONSTELLATION MAP

The Constellation Map is intended to be developed in a group setting by the Analysis Team when using the Comprehensive Method and may be helpful when conducting a review using the Aggregate Method. The map can also be completed by an individual who is using the Concise Method for a review of a single or multiple events. The process of developing the Constellation Map is intended to assist the team in building a visual representation of the Clinical Adverse Event and the system factors that may have contributed to the Clinical Adverse Event. It is also possible to identify mitigating factors that prevented the Clinical Adverse Event from being more significant.

Once all of the contributing factors have been identified it is appropriate to try to understand how these factors are linked/clustered with one another given that Clinical Adverse Events generally result from a cascade of events rather than an isolated contributing factor. Once the linkages/clusters are completed a draft summary statement that encompasses the theme of the cluster is developed. These clusters are the basis for recommendation development.

The following step by step process is intended to guide the development of a Constellation Map.

**Step 1: Describe the event**

- Briefly summarize the Clinical Adverse Event and harm/ potential harm in the center of the diagram (typically fewer than 10 words)
- Add the eight health system components to the diagram in a circle around the event/ outcome description. (Figure 6)

*Figure 6: Constellation Map System Components*
STEP 2: IDENTIFY POTENTIAL CONTRIBUTING FACTORS

The Review Lead or Facilitator may choose to use the guiding questions (see the System Analysis Guiding Questions) for each of the eight health system components to brainstorm and identify findings that may lead to the development of contributing factors of the event and place them around each of the components. Alternatively the Analysis Team may not require the guiding questions to support development of the Diagram. Regardless the guiding questions should be available to the Facilitator during the development process.

   a. The team is asked to brainstorm potential contributing factors
   b. For each potential contributing factor, ask “how and why did this happen”; “what was this influenced by”; “what else influenced the circumstances”
   c. Continue to ask “how” and “what influenced it” questions until no further information can be generated

STEP 3: DEFINE RELATIONSHIPS BETWEEN POTENTIAL CONTRIBUTING FACTORS

Once the findings have been placed around the health system components, questions can be asked that will identify linkages between the system components

STEP 4: IDENTIFY CLUSTERS OF CONTRIBUTING FACTORS THAT IF IMPROVED, WOULD MAKE CARE SAFER FOR FUTURE PATIENTS

   d. Identify the factors that, if corrected, would likely make care safer or mitigate the harm for future Patients in similar circumstances – these clusters will form the basis for developing recommendations
   e. Develop statements that describe the system-related issues that clearly articulate the hazards identified from the cluster of contributing factors related to the Clinical Adverse Event. These statements provide the basis for recommendations and are included in the Summary Report

STEP 5: DEVELOP RECOMMENDATIONS AND VALIDATE THE FINDINGS WITH THE TEAM

   f. Develop key recommendations that could make care safer for future Patients. A few well-designed recommendations are favoured over numerous weaker recommendations. Ensure consensus and support for the identified recommendations among the Analysis Team
   g. Identify and consult with recommendation owners who will be responsible to ensure that the recommendations are implemented in a timely manner

STEP 6: PRIORITIZE RECOMMENDATIONS

   h. Using the Impact and Effort Screening questions (see Step 3: Assess the Potential Effort Required to Implement the Recommendation), assign a score to each recommendation
   i. Use the prioritization matrix (see Step 4: Prioritize Each Recommendation) to display and compare the assessment results
   j. Sort recommendations by assessed priority
   k. Ensure consensus and support for the prioritizing of recommendations among the Analysis Team (Note: This is not a definitive decision making tool as other factors may require consideration)
TOOLS | SYSTEM ANALYSIS GUIDING QUESTIONS

A set of guiding questions provided below to guide the identification of potential contributing factors. Note that these guiding questions are provided as examples; this is not an exhaustive list. They are intended to assist with checking the availability and strength of safeguards at all levels in the organization and guide the analysis towards the identification of system vulnerabilities that aligned in such a way that allowed for the Clinical Adverse Event to take place.

The questions are designed to focus the analysis on the interaction between humans and the system, and in this way help identify system-level contributing factors at various levels in the organization.

The way the list is used is a matter of personal preference. Some may choose to use the questions below to guide information gathering and interviews, while others may prefer to use them to cross-reference the information already collected. The goal of this exercise is to go through the questions to find if the safeguards were in place and functioning. If the answer to a statement suggests that the safeguard was not in place or did not work, probe deeper with additional questions (for example: “If so, discuss how this/these may have contributed to or impacted the event” or “Why is this the case?”). For each of the health system components consider what other factors may have contributed to the event and include them in the analysis.

<table>
<thead>
<tr>
<th>Health System Components</th>
<th>Example Guiding Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task</td>
<td>Was a protocol available?</td>
</tr>
<tr>
<td></td>
<td>Were test results available to make care decisions?</td>
</tr>
<tr>
<td></td>
<td>What was the level of skill required to perform the task?</td>
</tr>
<tr>
<td></td>
<td>Were there any time constraints?</td>
</tr>
<tr>
<td></td>
<td>What was the chance of failure?</td>
</tr>
<tr>
<td></td>
<td>Was a fixed sequence essential?</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
<tr>
<td>Equipment</td>
<td>Were the displays and controls understandable?</td>
</tr>
<tr>
<td></td>
<td>Does the equipment detect and display problems?</td>
</tr>
<tr>
<td></td>
<td>Is the maintenance/ upgrade up-to-date?</td>
</tr>
<tr>
<td></td>
<td>Is equipment located in the appropriate place and is it accessible?</td>
</tr>
<tr>
<td></td>
<td>Is the equipment standardized or made of several different modules?</td>
</tr>
<tr>
<td></td>
<td>Are the warnings/ labels understandable?</td>
</tr>
<tr>
<td></td>
<td>Is the safety mechanism functional and appropriate?</td>
</tr>
<tr>
<td></td>
<td>Was enough training provided for this equipment?</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
<tr>
<td>Organization</td>
<td>Policies and procedures:</td>
</tr>
<tr>
<td></td>
<td>• Is there a standardized process (order set/ checklist)? Is it up to date?</td>
</tr>
<tr>
<td></td>
<td>• Is the standard/ policy available and workable?</td>
</tr>
<tr>
<td></td>
<td>Was training/ orientation provided?</td>
</tr>
<tr>
<td></td>
<td>Do people work around official policy? Is there a feedback mechanism for staff when policy and practice don’t match?</td>
</tr>
<tr>
<td></td>
<td>Is there a risk assessment/ audit/ quality control program in place for the process?</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
<tr>
<td>Environment</td>
<td>Do noise levels interfere with voice alarms?</td>
</tr>
<tr>
<td></td>
<td>Is the available lighting adequate for the task(s)?</td>
</tr>
<tr>
<td></td>
<td>Is the area adequate for people and equipment?</td>
</tr>
<tr>
<td></td>
<td>Is there clutter or inadequate storage?</td>
</tr>
<tr>
<td></td>
<td>Information systems:</td>
</tr>
<tr>
<td>Health System Components</td>
<td>Example Guiding Questions</td>
</tr>
<tr>
<td>--------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>Patient identification, documentation, available to all and up to date?</td>
<td></td>
</tr>
<tr>
<td>What is the level of automation? Was training provided?</td>
<td></td>
</tr>
<tr>
<td><strong>Scheduling and staffing levels:</strong></td>
<td></td>
</tr>
<tr>
<td>Were there any scheduling changes that influenced the staffing level or resulting in stress, fatigue?</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Team</td>
<td></td>
</tr>
<tr>
<td>Is this a regular team?</td>
<td></td>
</tr>
<tr>
<td>Are the roles defined?</td>
<td></td>
</tr>
<tr>
<td>Are there authority gradients?</td>
<td></td>
</tr>
<tr>
<td>What is the quality and quantity of communication between team members (verbal and/or written): i.e., clear, accurate, relevant, goal directed, sufficient, timely? Are there regular briefing, debriefings?</td>
<td></td>
</tr>
<tr>
<td>Did the existing documentation provide a clear and comprehensive picture?</td>
<td></td>
</tr>
<tr>
<td>How is the culture and morale?</td>
<td></td>
</tr>
<tr>
<td>Was the communication between staff and management adequate?</td>
<td></td>
</tr>
<tr>
<td>Was the communication between professions adequate, accurate, complete, and free of jargon?</td>
<td></td>
</tr>
<tr>
<td>Are communication systems (pager, phone) available and operational?</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Caregiver</td>
<td></td>
</tr>
<tr>
<td>What is their position, education, experience and training?</td>
<td></td>
</tr>
<tr>
<td>Was there fatigue, stressors, task saturation, overload, health, or other factors?</td>
<td></td>
</tr>
<tr>
<td>What remunerations and/or other incentives (formal and informal) were in place?</td>
<td></td>
</tr>
<tr>
<td>Did they seek help or supervision?</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Patient</td>
<td></td>
</tr>
<tr>
<td>Consider the: age, sex, medications, allergies, diagnosis, other medical conditions</td>
<td></td>
</tr>
<tr>
<td>Were there any social/cultural factors involved?</td>
<td></td>
</tr>
<tr>
<td>Was there a language barrier?</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Are there any other local conditions or circumstances that may have influenced the outcome?</td>
<td></td>
</tr>
<tr>
<td>Are there any sector specific conditions or circumstances that may have influenced the outcome?</td>
<td></td>
</tr>
<tr>
<td>Regulatory agency influences?</td>
<td></td>
</tr>
</tbody>
</table>
TOOLS | RECOMMENDATION ASSESSMENT AND PRIORITIZATION

In response to a recommendation from the Health Quality Council of Alberta, AHS Senior Executive commissioned the creation of a prioritization tool to assist Operations in their deliberations on how to proceed with accepted recommendations from internal or external safety reviews. The prioritization tool is most frequently utilized by the Patient Safety Learning and Improvement Team however Analysis Teams supported by Patient Safety Representatives are encouraged to consider using the tool to assess recommendations at the earliest point in the development process.

This tool is meant to be used as a framework for sorting recommendations by assessed priority. It is based on an assessment of the potential impact and effort required to implement the proposed solution. The tool is a filtering style tool that helps compare various solutions by putting them in a ranked order. It is not a definitive decision-making tool as other factors may require consideration. The tool is derived and modified from a prioritization matrix used in the AHS Improvement Way methodology for quality improvement practice. As this tool can be utilized to validate that good recommendations are being developed for operations prior to releasing the recommendations for acceptance and implementation, this tool has been included here.

The prioritization tool is composed of four sections that are completed sequentially:

1. Introductory Screening Questions
2. Assessment of Potential Impact for each Recommendation
3. Assessment of Potential Effort required to implement each Recommendation
4. A Matrix to Display and Compare the Assessment Results

In industries where defect rates can be measured and hence probabilities of error can be predicted, the ability to quantify risk is relatively easy. In healthcare, Clinical Adverse Events are more random and exact counts of occurrence rates are hard to predict. Some aspects of events require immediate remediation and actions will have already been taken long before the review is completed and recommendations are created. The severity side of the risk calculation is influenced by individual Patient characteristics and a wide range of environmental variables.

The application of a risk matrix for assigning priorities using frequency and severity is less certain than occurs in industrial or project management applications. In a typical 4 x 5 risk matrix, there is an attempt to estimate the likelihood of occurrence of an event and the likely severity of the outcome. This presents some difficulties in application. To begin with, estimating risk is based on how often the underlying event might occur which is largely based on opinion. An estimate of the potential severity of the outcome inevitably can be argued to be fatal in all cases if variations in Patient circumstances and medical conditions plus the specific healthcare setting are taken into consideration.

Once a Clinical Adverse Event has occurred, the focus of attention is on prevention not on quantifying the risk. At a local management level, risk management translates into the question of what do we have to do to prevent this from happening again? In user testing of this new tool, what the operational leaders were looking for is some way of determining if one recommendation would have more impact than another one on preventing future harm, and what was feasible to implement given their level of accountability, support from senior executive, available resources and people to work on the implementation.

In an ideal world with unlimited resources and time, all safety recommendations would be well researched and evaluated for their effectiveness on removing hazards and there would be unlimited capacity to fully implement all quality assurance recommendations. In our current reality, a best effort approach is utilized to determine what recommendations will be the most effective in addressing the identified hazard(s).
As long as recommendations vary in their effectiveness to remove hazards and in the ability to be supported by resourcing and sustainability, then priorities will continue to be a part of decision-making processes that are not wholly driven by traditional risk analysis tools.

Implementing safety recommendations is closely aligned with quality improvement processes and methods. Therefore, the tools were created for prioritizations that were closely aligned with the conceptual thinking and methodology currently being disseminated through the AHS Improvement Way.

The prioritization question in the perspective of operational leaders is: What is feasible to do that will have the greatest impact on preventing this safety hazard from happening again?

**STEP 1: SCREEN THE RECOMMENDATIONS**

Answering these questions is especially important if the potential operational owner has not been involved in the development of the recommendation and therefore may not have the same contextual understanding of the event.

These screening questions must be complete before proceeding to Step 2.

1. Is the required action clear? YES NO
2. Is it clear how this recommendation would reduce or remove potential harm? YES NO

**Implication:** If you answered YES to both these questions, proceed to Step 2
If you answered NO to one or both questions, go to Step 1; do not proceed to Step 2.

[1] Contact the person who asked you to implement the recommendation and discuss any needed modifications to clarify the required action and/or the effect on potential harm.

[2] Results of this discussion (e.g. revision, rejection, acceptance) must be communicated back to the Patient Safety Department - Contact your local Clinical Safety Leader, or email quality.assurance@albertahealthservices.ca
### STEP 2: ASSESS THE POTENTIAL IMPACT OF EACH RECOMMENDATION

<table>
<thead>
<tr>
<th>IMPACT INDICATORS</th>
<th>RESPONSE OPTIONS</th>
<th>SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength: How effective will the action be at removing the underlying safety hazard?</td>
<td>Indeterminate</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Inform (audit, consider, discuss, research, notify staff)</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Educate (training, orientation, credentialing)</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Rules and Policies (new or revise)</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Reminders/Checklists/Signs</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Constrain/Isolate (control access)</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Simplify/Standardize (standard operating procedures, reduces # of steps)</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Automation (add equipment, devices, alarm systems, computerization)</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Forcing functions/System Re-engineering</td>
<td>8</td>
</tr>
<tr>
<td>Think about the type of solution that is proposed to be implemented.</td>
<td>None or Unknown</td>
<td>0</td>
</tr>
<tr>
<td>What is the strength of evidence to support this recommendation?</td>
<td>Review Team Opinion</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Documented Best Practices</td>
<td>2</td>
</tr>
<tr>
<td>What is the proximity to point of care? How close to actual patient is the impact?</td>
<td>Indeterminate (Unknown)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Regulatory Agency or Government</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Organizational/Administrative Level of AHS</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Clinical Care Interface</td>
<td>3</td>
</tr>
<tr>
<td>If implemented, would this recommendation reduce the degree of harm that could occur to the patient?</td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Sometimes</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>If implemented, would this recommendation push the hazard further away from the point of patient care?</td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Sometimes</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>If implemented, would this recommendation reduce the number of patients that could be exposed to the hazard?</td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Sometimes</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>If implemented, would this recommendation make the hazard easier for staff to detect?</td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Sometimes</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>2</td>
</tr>
</tbody>
</table>

**TOTAL IMPACT SCORE (0-21)**

<table>
<thead>
<tr>
<th>IMPACT TOTAL SCORE</th>
<th>IMPACT LEVEL</th>
<th>MATRIX PLACEMENT (IMPACT AXIS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 3</td>
<td>Minimal</td>
<td>1</td>
</tr>
<tr>
<td>4 – 7</td>
<td>Very Low</td>
<td>2</td>
</tr>
<tr>
<td>8 – 11</td>
<td>Slight</td>
<td>3</td>
</tr>
<tr>
<td>12 – 15</td>
<td>Moderate</td>
<td>4</td>
</tr>
<tr>
<td>16-21</td>
<td>High</td>
<td>5</td>
</tr>
</tbody>
</table>

=TOTAL
### STEP 3: ASSESS THE POTENTIAL EFFORT REQUIRED TO IMPLEMENT THE RECOMMENDATION

<table>
<thead>
<tr>
<th>EFFORT INDICATORS</th>
<th>RESPONSE OPTIONS</th>
<th>SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the time required to implement proposed recommendation?</td>
<td>Within a few weeks</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>3 to 6 months</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>6 to 12 months</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Greater than one year</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Very long range</td>
<td>4</td>
</tr>
<tr>
<td>Financial Resources</td>
<td>Within current funding</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Extra source or Contingency funding</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Requires new project funding</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Requires new government funding</td>
<td>3</td>
</tr>
<tr>
<td>Human Resources</td>
<td>Feasible with current staffing</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Requires additional temporary staffing</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Requires 1 or more permanent positions to be created</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Requires addition of external consultants plus dedicated staff</td>
<td>3</td>
</tr>
<tr>
<td>Breadth and depth of collaboration and conjoint planning required with all stakeholders</td>
<td>Local involvement of 1 or 2 business/care units</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Work across several sites within a program or network</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Work across an entire zone</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Work province wide</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Work with AHS and external regulatory agencies or private industry together in consultation</td>
<td>4</td>
</tr>
</tbody>
</table>

**TOTAL IMPACT SCORE (0-14)**

<table>
<thead>
<tr>
<th>EFFORT TOTAL SCORE</th>
<th>IMPACT LEVEL</th>
<th>MATRIX PLACEMENT (EFFORT AXIS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 2</td>
<td>Lowest Effort</td>
<td>1</td>
</tr>
<tr>
<td>3 – 5</td>
<td>Slight Effort</td>
<td>2</td>
</tr>
<tr>
<td>6 – 8</td>
<td>Moderate Effort</td>
<td>3</td>
</tr>
<tr>
<td>9 – 11</td>
<td>High Effort</td>
<td>4</td>
</tr>
<tr>
<td>12 – 14</td>
<td>Huge Effort</td>
<td>5</td>
</tr>
</tbody>
</table>
STEP 4: PRIORITIZE EACH RECOMMENDATION

Using the Prioritization Matrix, enter the Effort (y-axis) and Impact (x-axis) values calculated from the scoring tools into the appropriate box below. The box in which the recommendation fits will identify a priority category. The matrix can be used to assess the priority category of a single recommendation, or compare different recommendations. If more than one item lands in the same box, refer to the total score for Impact + Effort.

Interpretation

This is not a definitive decision tool for whether to implement a recommendation or not, but provides guidance on ranking to help decide where to start and whether more resources may be needed. If two or more recommendations end up in the same box, the relative placement may help discriminate small differences between them with respect to impact. Other factors may override the priority result such as:

- Directives from CEO or Senior Executive
- Public awareness and media scrutiny
- Alberta Health Directives

The Quality Healthcare Improvement division of AHS is currently developing a modification of this prioritization tool that can be utilized to prioritize recommendations from multiple sources (i.e. Quality Assurance Reviews, Accreditation, Fatality Inquiries etc.) In time it is anticipated that recommendations arising from a SAM could be re-prioritized at an organizational level.
CHECKLIST | CONCISE METHOD

The Concise Method is a succinct way to review Clinical Adverse Events or Close Calls that resulted in no, minimal, or moderate harm to the Patient. This succinct method of review meets the need for timely and accurate action. Concise reviews are usually conducted at the unit or program level and completed in a short interval of time by one or two individuals.

☐ Seek relevant information to ensure the facts of the event are clear and accurate. (See the Timeline chart as an example of recording information collected)

☐ Conduct informal discussions with Patient, family member, healthcare provider, manager and/or experts in the processes or equipment involved. Include the de-identified interviews in the Timeline where additional information about the incident is required

☐ Examine RLS and other targeted source of information

☐ Identify contributing factors using the SAFER Matrix Tool¹ (see Figure 5: The AHS modification of the SAFER Matrix¹) or Constellation Map² and System Analysis Guiding Questions.

☐ Summarize findings and validate with staff and medical staff as appropriate

☐ Use SMARTS criteria to formulate recommendations (if sufficient evidence is available)

☐ Produce short report that includes a brief description of the case, the findings, contributing factors/system hazards and any recommendations for improvement

☐ Provide report to applicable Operational or Medical leader for an implementation decision and dissemination (if applicable); Summary reports from QAR reviews under Section 9 protection are presented to the appropriate QAC for acceptance. This Summary Report and Recommendations may now be shared with the public and healthcare providers

☐ Attach the report to the applicable RLS report so that systems learnings are available and shared across the organization. For reviews protected under Section 9 the Summary Report and Recommendations are available through the REC Tracker

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¹ SAFER Matrix Tool
² Constellation Map
³ System Analysis Guiding Questions
CHECKLIST | COMPREHENSIVE METHOD

The Comprehensive method is used for a thorough review of a Clinical Adverse Event or Close Call and involved team members in both the investigation (Investigation Team) and analysis (Analysis Team) portions of the review. The Clinical Adverse Event reviewed may have resulted in any level of severity of harm to the Patient, but usually the Patient has experienced severe harm or has died.

☐ Accountable Leader creates an initial timeline (also a draft) of events based on facts obtained from the Patient’s medical chart
☐ Appoint a Review Lead and identify the scope of the review and target date for completion
☐ Identify potential members of the Analysis Team, and content experts (see Appendix C: Process For Engaging Experts); brief Analysis team on systems analysis methodology and expectations for reviewing the Clinical Adverse Event within a Just Culture (see Just Culture Principles)
☐ Interview Patients and families first (see Appendix B: Suggestions For Conducting Interviews)
☐ Interview staff and medical staff who were involved in the incident and those persons with content expertise to understand what happened and what should have happened
☐ Create a draft final timeline with information from the interviews. Include the de-identified interviews in the Timeline where additional information about the incident is required. All information included in this Timeline is de-identified
☐ Examine RLS and other targeted source of information for possible solutions (literature reviews, recommendation tracker, etc.)
☐ Identify contributing factors using the SAFER Matrix Tool¹ (see Figure 5: The AHS modification of the SAFER Matrix¹)
☐ Analysis Team brainstorming using the Constellation Map² and System Analysis Guiding Questions to identify the systems factors that led up to and during the Clinical Adverse Event
☐ Summarize findings and validate with staff and medical staff (Analysis Team) as appropriate
☐ Use SMARTS criteria to formulate recommendations (if sufficient evidence is available)
☐ Produce short report that includes a brief description of the case, the findings, contributing factors/system hazards and any recommendations for improvement
☐ Provide report to applicable Operational or Medical leader for an implementation decision and dissemination (if applicable); Summary reports from QAR reviews under Section 9 protection are presented to the appropriate QAC for acceptance. This Summary Report and Recommendations may now be shared with the public and healthcare providers
☐ If the review has taken place outside of Section 9 protection, the report is attached to the applicable RLS report so the system learnings are available and shared across the organization. For reviews protected under Section 9 the Summary Report and Recommendations are available through the REC Tracker.
CHECKLIST | AGGREGATE METHOD

The Aggregate Method is used to review two or more Clinical Adverse Events or Close Calls of any severity level. A review conducted using the Aggregate Method is often resource intensive and many, but not all will be performed under the direction of a QAC.

☐ Accountable Leader determines the need for a review using the Aggregate Method in consultation with a Facilitator and the Review Lead
☐ Develop an initial timeline to organize various reviews and events in chronological order
☐ Determine scope of the review and determine the specific case inclusion criteria
☐ Identify potential members of the Investigation and Analysis Team
☐ Create Terms of Reference and identify agreed upon completion date
☐ Arrange meeting of Investigation Team to prepare the analysis – obtain the data, sort/filter and verify themes and trends
☐ Develop an Analysis Plan
☐ Interview Patients and families, if possible (see Appendix B: Suggestions For Conducting Interviews)
☐ Conduct interviews with staff and medical staff who were involved in the incident and those persons with content expertise
☐ Research relevant policies, Quality Improvement projects and Human Factors reports and recommendations from previous review that have applicability
☐ Investigative Team prepares materials for analysis. May involve developing an additional timeline, or using the SAFER Matrix Tool¹ (see Figure 5: The AHS modification of the SAFER Matrix¹) to organize the information
☐ Analysis Team convened to review Investigative Team materials and analysis plan
☐ Analysis Team brainstorming using the Constellation Map² and System Analysis Guiding Questions to identify the systems factors that led up to and during the Clinical Adverse Event
☐ Clusters are identified and themed; summary of finding statements are formulated
☐ Recommendations developed using SMARTS criteria to address hazards identified by the summary of findings statements
☐ Recommendations are prioritized using the Recommendation Assessment and Prioritization ensuring consensus and support among the Analysis Team members and Operational Leads responsible for implementing the recommendations
☐ Review Summary report prepared and presented to the QAC (if the review is Section 9 protected) or the review requestor (in the case of a non-protected review)
☐ Attach the report to the applicable RLS report so that systems learnings are available and shared across the organization. For reviews protected under Section 9 the Summary Report and Recommendations are available through the REC Tracker
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 Immediate and Ongoing Management of Clinical Adverse Event Policy and procedures. 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. Any review examining the actions and behaviours of Medical and Midwifery staff shall be managed in accordance with the Alberta Health Services Medical and Midwifery staff Bylaws and Rules.

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

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..

Aggregate method of review involves a thorough review of multiple Clinical Adverse Events and/or Quality Assurance Reviews. This method is resource intensive and involves a team approach.

Analysis Team means a group of individuals selected from those directly associated with the Clinical Adverse Event and leaders who likely will have responsibility for implementing recommendations subsequent to the analysis. This group will also consist of a Review Lead, Facilitator and potentially content experts and Patient or family representatives.

Close Call means an event in which a Patient is exposed to or involved in a situation with the potential for harm. For one or more reasons the danger did not reach the Patient (that is, no harm occurred).

Comprehensive method of review is used for a thorough review of a single Clinical Adverse Event and involves a team approach.

Concise method of review is commonly used for a succinct review of Clinical Adverse Events or Close Calls that result in no, minimal, or moderate harm to the Patient or may focus on a new event for which a comprehensive analysis was recently completed. The Concise Method is generally used for reviews conducted by one or two individuals.

Facilitator means an individual with training in analytical methods (SAM), group dynamics and consensus building. Most often this individual is a Clinical Safety Leader, Clinical Quality Consultant or Senior Patient Safety Specialist.

Findings means a conclusion reached after examination or investigation.

Hazard means something, or a set of circumstances, that if left unchanged, could harm a Patient or contribute to harm.

Investigation Team means the group of individuals, usually led by a SAM trained Clinical Safety Leader, Clinical Quality Consultant or Senior Patient Safety Specialist who is also frequently the Analysis Team Facilitator and includes key knowledgeable staff from impacted AHS programs. This group of individuals is responsible for creating the initial and final draft timelines, conducting literature reviews, interviews and integrating the information for the Analysis Team. The Investigation Team also provides a draft list of Analysis Team members to the Review Lead for consideration.

Medical staff means physicians, dentists, oral and maxillofacial surgeons, podiatrists, or scientist leaders who have an Alberta Health Services Medical staff appointment.
Patient means all persons who receive or have requested health care or services from Alberta Health Services and its healthcare providers. This term is inclusive of residents and clients.

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.

Review Lead means an Administrative Leader assigned responsibility for completion of the QAR by the QAC Chair. If the SAM is completed outside of Section 9 then this individual is designated by the Accountable Leader.

Review Summary means a standardized report format that includes the de-identified case description, relevant findings, systems issues identified and the recommendations that will be sent back to the requestor of the review. It contains only the elements of the review that can leave Section 9 protection.

Responsible Administrative Leader means the administrative or medical leader responsible for the immediate or ongoing care of the Patient at the time of the event. For example, individuals in this position may be program manager, a non-clinical manager or zone clinical section chief. As the investigation proceeds, a more senior person may assume the role of most Responsible Administrative Leader.

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

Systems Analysis means a review that looks retrospectively at a Close Call, event or group of events in order to understand the underlying system issues with a view to make care safer for future Patients.
### APPENDIX A: GOALS AND STRATEGIES

<table>
<thead>
<tr>
<th>Goals of the Systems Analysis Methodology</th>
<th>Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase the capacity for conducting reviews in a consistent and effective manner throughout the organization using SAM</td>
<td>Development of education for staff from all areas of healthcare to gain the necessary skills to understand and participate in the use of SAM  Patient Safety and Clinical Quality Staff will continue to support operations in the facilitation of reviews; however SAM may be used by managers, educators, physician leaders and other staff as appropriate</td>
</tr>
<tr>
<td>Increase the number of Clinical Adverse Events that are systematically reviewed</td>
<td>Inclusion of a variety of methods to fit the scope of the review required: Concise, Comprehensive, and Aggregate</td>
</tr>
<tr>
<td>Produce stronger recommendations</td>
<td>Inclusion of a recommendation prioritization tool that measures both potential impact and effectiveness</td>
</tr>
<tr>
<td>Produce fewer recommendations per Quality Assurance Review or Patient Safety Review</td>
<td>Introduction of an analysis step in the methodology that synthesizes multiple contributing factors for appropriate action</td>
</tr>
<tr>
<td>Recommendations generated are implemented more efficiently and effectively</td>
<td>Integration of potential operational leads for recommendation implementation through a team approach</td>
</tr>
<tr>
<td>Promote a just culture</td>
<td>Collaborative participation of staff and medical staff (including those directly involved in the event as well as administrators and leaders) in a supportive environment that allows them to speak freely (to gain an understanding of the system factors together)</td>
</tr>
<tr>
<td>Promote systems thinking</td>
<td>Consideration of multiple system components in every review using SAM</td>
</tr>
</tbody>
</table>
APPENDIX B: SUGGESTIONS FOR CONDUCTING INTERVIEWS

Interviews are key to collecting information for analysis in an environment that supports a just culture. An interview is an opportunity for a Patient, family member or healthcare provider to share their detailed perspective about the event. The interview process may cause anxiety for some individuals and therefore it will be important to be clear about the purpose of the interview and what will be done with the information provided during the interview.

When interviewing Patients and/or family members there are two important considerations:

1. Confirm with the review requestor that the patient/family has been provided the name with an AHS person as a single point of contact as per the Ongoing Management of Clinical Adverse Events procedure.

2. Interviews with the Patient/family should occur first before interviews with any healthcare providers involved in the event.

   Note: Patient Safety has a letter to send to interviewees to explain the process; this letter is often sent to the manager to give to the staff.

- Interviews should be conducted as soon as reasonably possible after the event for two reasons:
  - Memories fade quickly and important detail may be lost over time.
  - As individuals involved in the event discuss their recollections with one another versions may blur together and the potential exists to lose unique perspectives and detail.
- Interviews should occur with all staff involved in the event as well as the Patient and family members as appropriate.
- A cooperative approach is encouraged using open-ended questions.
- Ask Individuals to “tell their story” and possibly re-enact the event or portions of the event.
- Do not interrupt while the interviewee is telling their story as this increases the likelihood that parts of the story may be missed. Instead hold further questions until the story has been told after which it may be necessary to clarify or ask for additional detail.
- Record the interview in a way that is comfortable for the person being interviewed. Video or audio recordings tend to increase the anxiety and are not generally recommended.
- Permission is needed to digitally record the interview.
- Interviews should be conducted one person at a time so that individual perspectives about the event are well understood for their nuance and unique point of view.
- Interviewers should provide information about the analysis process, any next steps and encourage further follow up if the interviewee recalls any other details they feel important to understanding the event after the interview has been completed.
- In concluding the interview, review the points the interviewee has made that will be shared with the review teams.
- Thank people for helping to provide understanding of the event and ensure that their questions about the process are answered before drawing the interview to a close.
APPENDIX C: PROCESS FOR ENGAGING EXPERTS

ENGAGING EXPERTS EXTERNAL TO ZONES FOR THE PURPOSE OF CONTRIBUTING TO QUALITY ASSURANCE REVIEWS

TEAM APPROACH - ROLE OF THE CONTENT EXPERT
Members of Investigation and Analysis Teams are identified who can assist in the review, including content experts who may contribute to the understanding of leading and emerging practices related to the care components and systems under consideration during a Quality Assurance Review (QAR). There are several considerations when determining who should participate as a content expert.

**EXPERT DEFINED:**
An expert is a person with extensive knowledge or ability based on research, experience, or occupation and in a particular area of study. Experts are called in for advice on their respective subject. An expert can be, by virtue of credential, training, education, profession, publication or experience, believed to have special knowledge of a subject beyond that of the average person, sufficient that others may officially rely upon the individual's opinion. AHS employees or contracts with numerous experts therefore the QAC Chair will need to decide whether it is most appropriate to select an expert external to AHS or if the duties are such that an internal expert may be acceptable.

When is it Appropriate to include an Expert?
- When the appropriate expertise does not exist within AHS
- When it may be necessary to include a content expert impartial to the process
- When the absence of outside expertise is unlikely to bring the review to resolution for the healthcare provider and the Patient/family

Types of Expert Consultation:
- A single opinion about a particular AHS process or practice (consult)
- Ongoing contributions to the review as a whole (team member)

Payment for Expert Consultation:
- Will be the responsibility of the program or zone requesting the expert consultation
APPENDIX D: CASE EXAMPLE USING THE COMPREHENSIVE ANALYSIS METHODOLOGY

The facts, contributing factors, modified SAFER Matrix\(^1\), Constellation Map\(^2\), findings, recommendations and resulting prioritization included with this case are provided as examples only and reflect the opinion of the writers. Other results may be possible however themes raised and recommended actions will be similar.

BACKGROUND:

This scenario takes place in rural Alberta. A 54-year-old male (Jim), who works as a carpenter in his shop on the farm, calls for his son (Bob) shortly after he experiences a bee sting at 1100 hours on Sunday August 5\(^{th}\) while walking from his shop to the house to make his lunch. Bob is aware of his dad’s past history of an anaphylactic reaction to bee stings. Neither Bob nor Jim can find the epi-pen Jim normally has in the junk drawer in the kitchen. Jim begins to develop shortness of breath with wheezing, swollen lips and difficulty swallowing.

Bob calls Emergency Medical Services (EMS) for his dad. Pre-arrival instructions are provided via dispatch. An EMS Unit clearing from a call near Jim’s home is dispatched and arrives 12 minutes after first being dispatched.

Additional background information: Jim is a one-pack a day smoker and has a known history of hypertension and is non-compliant with his antihypertensive regimen. His family physician would like Jim to start desensitization therapy for his bee sting allergy but Jim cannot afford to pay out-of-pocket and the therapy is not covered on the Alberta Health payment schedule.

An Advanced Life Support crew with a 10-year Primary Care Paramedic (PCP) and an Advance Care Paramedic (ACP) who graduated six months ago and has just completed his orientation arrive at Jim’s home. This is the first time the ACP has been responsible for an anaphylaxis patient in the field. Regardless, he graduated at the top of a very competitive class at SAIT and was a PCP for three years prior to returning to Paramedic school. He was particularly proud of how well he had done at the Advanced Cardiac Life Support course 10 months ago.

Most medications in the EMS Unit are stocked in the Medication cupboards. Two kits, one for oxygen, a second for medications and the cardiac monitor are brought in by EMS to Jim’s house.

During the course of on-site treatment there is a medication Clinical Adverse Event. The ACP has already notified the physician and his immediate supervisor but also files a reporting and learning system (RLS) report at the end of his shift.
Reporting and Learning System: Report

AHS Reporting & Learning System for Patient Safety: Report to Supervisor

* Mandatory Field

<table>
<thead>
<tr>
<th>Details of the Person Reporting the Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Full Name</td>
</tr>
<tr>
<td>*Preferred Method of Communication</td>
</tr>
<tr>
<td>Job Function</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Details about the Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Date of the Problem (dd/MM/yyyy)</td>
</tr>
<tr>
<td>Time (hh:mm) (24 hr)</td>
</tr>
<tr>
<td>*Zone</td>
</tr>
<tr>
<td>*City/Town</td>
</tr>
<tr>
<td>*What area of healthcare did this happen in?</td>
</tr>
<tr>
<td>*Facility</td>
</tr>
<tr>
<td>*Exact Location</td>
</tr>
</tbody>
</table>

*Describe what happened*
A roughly 10 fold overdose of epi - 1 mL of (1:1000) IM was accidentally administered to a patient through IV. While responding to a bee sting anaphylactic reaction, 0.3 mg (1:1000) Epi IM had already been administered to the patient. I noticed that the patient was also presenting with hives so I prepared an ampoule of Diphenhydramine (50 mg) in a 1 cc syringe and set it aside while I helped my partner secure the IV. Just as I was intending to administer the Diphenhydramine two big dogs came rushing into the kitchen and jostled the patient and our supplies. The patient's son got the dogs away and I picked up the syringe and administered the 1 mL dose of what I thought was Diphenhydramine intravenously. Unknowing to me, the PCP had prepared a second ampoule of Epi (1:1000) in a 1 cc syringe and had set it on the drug kit. When the dogs jostled our supplies the syringe I had prepared with 1 mL Diphenhydramine must have fallen under the stretcher as that is where we found it later when we were preparing to transport the patient.

Outcome for Patient
Patient immediately developed chest pain, increased HR and BP as well as projectile vomiting. Transported to hospital where he has been admitted.

*Who did you notify about this problem?*
Don Jones, Farmtown EMS Supervisor

Suggestions for Notifications
If the Patient is usually cared for in a location other than where the problem happened, please indicate the location.

If your supervisor is located in a different area, please indicate that area.
### Your Opinion(s)

<table>
<thead>
<tr>
<th>In your opinion why does the problem exist?</th>
<th>Maybe the drug kits should contain epi-pens for one-time administration instead of opening and drawing up a full mL ampoule into a syringe</th>
</tr>
</thead>
<tbody>
<tr>
<td>In your opinion what could be done to make care safer?</td>
<td>Formal procedures around administration of epinephrine (1:1000). Dose is for 0.3 mg at a time every 5 minutes if necessary. Some staff draw up the full ampoule into a syringe and then administer it 0.3 mLs at a time using the same syringe. Some staff only draw up 0.3 mL at a time to avoid an accidental overdose. Also mandatory labeling of syringes could be beneficial.</td>
</tr>
</tbody>
</table>

### Additional Information

| *Was a Patient directly involved or affected? | Yes |
| *Were any medications directly involved in the problem? | Yes |
| *Was any medical equipment/product suspected of causing Patient harm or near harm? | No |
| *Was a fall involved in the problem? | No |

### Medication Details

| *What are you reporting about? | Medications |
| *Name of Medication/ IV Solution/ Vaccine | Diphenhydramine (50 mg) |
| Name of Incorrect Medication/IV Solution/ Vaccine | Epinephrine (1:1000) |
| *Are you reporting about a dose error? | Yes |
| *Incorrect Dose | 1.0 mg given IV |
| *Correct Dose | 0.3 mg given IM |

### Patient Affected

| *Last Name | Phillips |
| First and Additional names | Jim |
| Date of Birth (dd/MM/yyyy) | 2 July 1958 |

### INITIATION PHASE

- Request for Initial Timeline (facts from the Health Record)
- A Clinical Adverse Event was reported by the EMS paramedic to his supervisor, who in turn contacted the Director of Any Zone EMS. In her role as an Accountable Leader, the Director of EMS requested an initial timeline to determine the need for a systems analysis.
# Initial Timeline | Case Number: SA Case example

## Event Summary

<table>
<thead>
<tr>
<th>Brief Case Description: (type of care setting, Patient population, event, outcome)</th>
<th>Patient presented in his home at 1112 hours with severe allergic reaction to bee sting. During the course of treatment the paramedic administered 1.0 mg (1:1000) Epinephrine intravenously in error. The patient immediately developed chest pain, increased HR and BP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Clinical Adverse Event:</td>
<td>August 5, 2012</td>
</tr>
</tbody>
</table>

## Identification

| Age: | 54 |
| Date of Birth: | July 2, 1958 |
| Gender: | Male |
| Presenting or primary condition(s) / diagnosis: | Severe allergic reaction to bee sting |
| Medical History: | Past history of anaphylactic reaction to bee stings, hypertension (non-compliant with regimen), 1 pack a day smoker |
| Current Medications: | Codeine 30 to 60 mg po q. 4-6 h. prn for cough suppression Zopiclone 7.5 mg po nightly pm |
| Known Allergies: | Bee sting |

## Timeline

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Event / Finding / Result</th>
<th>Source of info</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 5, 2012</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11:00</td>
<td>Call received in dispatch regarding anaphylactic reaction to bee sting. Advanced life support crew dispatched to site</td>
<td>Dispatch record</td>
</tr>
<tr>
<td>11:12</td>
<td>EMS arrives 12 minutes after initial call. Patient c/o severe shortness of breath, urticaria, wheezes with decreased lung sounds all lobes. Paramedic administers 0.3 mg epinephrine (1:1000) IM, starts nebulizer of 5mg salbutamol and 500mcg ipratropium bromide, while PCP takes vital signs. BP 70/40, HR 135, RR 36 starts EKG: Sinus tachycardia</td>
<td>Dispatch Record EMS Record</td>
</tr>
<tr>
<td>11:17</td>
<td>The patient is cyanotic with RR of 48; there is oral swelling noted and hives.</td>
<td>EMS Patient Record</td>
</tr>
<tr>
<td>11:18</td>
<td>Bolus of 1 L saline is started</td>
<td>EMS Patient Record</td>
</tr>
<tr>
<td>11:19</td>
<td>Patient is showing mild improvement in vitals and breathing easier, however, urticarial rash is very apparent.</td>
<td>EMS record</td>
</tr>
</tbody>
</table>
### Decision to request a review:
The Accountable Leader reviewed initial timeline and assessed that the medication error was likely based on system failures. A Review Lead was chosen. The Facilitator, Review Lead and Accountable Leader agreed on scope and for the purposes of this review this was defined as processes and tools used to document and communicate EMS medication preparation and administration on site and in transit. They set a timeline for completing the review at 90 days.
**INVESTIGATION PHASE**

**Identification of membership for the Investigation Team:**
- Review Lead (EMS Quality Assurance Strategist)
- Facilitator (Clinical Safety Leader trained in SA Methodology)
- Paramedic

**Information gathered by the Investigation Team:**
- Obtained photocopies of the original EMS and ED charts.
- Captured pictures of the medication vials and syringes:

<table>
<thead>
<tr>
<th>EMS Visit</th>
<th>Epinephrine 1:1000</th>
<th>Diphenhydramine</th>
<th>See Also Product monograph</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><img src="image1.png" alt="Epinephrine" /></td>
<td><img src="image2.png" alt="Diphenhydramine" /></td>
<td><img src="image3.png" alt="Product Monograph" /></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EMS Visit</th>
<th>1 cc syringes drawn up with medications</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><img src="image4.png" alt="Syringes" /></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EMS Visit</th>
<th>1 cc syringes with med ampoules</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><img src="image5.png" alt="Syringes with Ampoules" /></td>
</tr>
</tbody>
</table>
- Interviewed the Patient, family, EMS crew
- Interviewed those directly involved in this Patient’s care at the time of the Clinical Adverse Event:
  - The paramedic that administered the medication
  - Reviewed any relevant policies and
  - Conducted a literature search/ review other sources for best practices in treatment of anaphylactic reactions by EMS
- Information gathered was organized:
  - Interview information added to the initial timeline to create a final timeline

### Final Timeline | Case Number: SA Case example

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Event / Finding / Result</th>
<th>Source of info</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 5, 2012</td>
<td>Bee sting. Patient’s son looks for Patient's epi pen but cannot find it. Patient deteriorates quickly developing shortness of breath and pressure in his chest. Patient has history of anaphylaxis. Patient’s son calls EMS.</td>
<td>EMS Patient Record Patients son</td>
</tr>
<tr>
<td>11:00</td>
<td>EMS arrives 12 minutes after initial call. Patient c/o severe shortness of breath, urticaria, wheezes with decreased lung sounds all lobes. Paramedic administers 0.3 mg epinephrine (1:1000) IM, starts nebulizer of 5 mg salbutamol and 500 mcg ipratropium bromide, while PCP takes vital signs. BP 70/40, HR 135, RR 36 starts EKG: Sinus tachycardia</td>
<td>Dispatch Record EMS Record</td>
</tr>
<tr>
<td>11:12</td>
<td>The Patient is cyanotic with RR of 48; there is oral swelling noted and hives. Paramedic is thinking that he will need to switch to IV administration of epinephrine and that Patient requires diphenhydramine</td>
<td>EMS Patient Record Paramedic Interview</td>
</tr>
<tr>
<td>11:15</td>
<td>PCP prepares second syringe of epi (1:1000) having noticed that paramedic had discarded first unfinished ampoule. Since the Patient was not improving he thought they would need more. He set the prepared syringe on the drug kit</td>
<td>Paramedic Interview</td>
</tr>
<tr>
<td>11:16</td>
<td>Paramedic prepares ampoule of diphenhydramine in a 1 cc syringe and sets aside while he helps partner secure the IV. Bolus of 1 L saline is started</td>
<td>EMS Patient Record</td>
</tr>
<tr>
<td>11:17</td>
<td>Two large dogs (blue healers) come through the kitchen door of the farm house and rush to Patient jostling Patient and supplies. They are barking at EMS crew until Patient’s son pulls them out of the house and closes the door</td>
<td>PCP interview</td>
</tr>
<tr>
<td>11:18</td>
<td>Patient is showing mild improvement in vitals and breathing easier, however, urticarial rash is very apparent. Paramedic requests PCP to prepare Epinephrine (1:10,000) for administration of 0.1 mg IV</td>
<td>EMS record and Paramedic Interview</td>
</tr>
<tr>
<td>11:19</td>
<td>Paramedic administers 1mL diphenhydramine (50 mg) intravenously</td>
<td>EMS record</td>
</tr>
</tbody>
</table>
| 11:20 | Patient develops crushing chest pain at a 9 out of 10 with EKG changes sinus tachycardia with a widening QRS at 190 BPM, BP | EMS record/ interviews Patient,
### Final Timeline | Case Number: SA Case example

<table>
<thead>
<tr>
<th>Timeline</th>
<th>Event Description</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:25</td>
<td>Supportive care provided for Patient during rapid transport to rural hospital 10 km from Patient’s farm. Patient monitored throughout. Chest pain drops to 2 out of 10; EKG shows Sinus tachycardia at 135 bpm. Patient seen briefly in rural ED and referral made to tertiary site.</td>
<td>ED Patient record</td>
</tr>
<tr>
<td>11:50</td>
<td>Patient transferred to tertiary centre with improved VS enroute, BP 150/90, EKG: Sinus tachycardia @120bpm, RR 22, nausea and vomiting subsided; chest pain is a 1 out of 10. EMS crew relieved and second crew transferred Patient.</td>
<td>EMS Record</td>
</tr>
<tr>
<td>August 7, 2012</td>
<td>Patient recovered well in tertiary centre and was discharged.</td>
<td>Tertiary Record</td>
</tr>
</tbody>
</table>

The AHS modification to the SAFER Matrix\(^1\) was completed iteratively during the investigation phase.
### Health System Components

<table>
<thead>
<tr>
<th><strong>Patient</strong></th>
<th><strong>Healthcare providers</strong></th>
<th><strong>Team</strong></th>
<th><strong>Task</strong></th>
<th><strong>Equipment</strong></th>
<th><strong>Environment</strong></th>
<th><strong>Organization</strong></th>
<th><strong>Other</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Anaphylactic reaction to a bee sting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ No epi pen available</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Rapidly decompensating</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ History of Hypertension</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Did not go for desensitization therapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Structure</strong></td>
<td><strong>Process</strong></td>
<td><strong>Outcome</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Why did this happen?</td>
<td>How did this happen?</td>
<td>What happened?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structural Components</td>
<td>Given incorrect dosage of epinephrine (approx. 10x overdose given IV (wrong route))</td>
<td>Immediately developed chest pain, increased heart rate and blood pressure. Assessed at rural ED and transferred to tertiary center. Released two days after admission</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New paramedic</td>
<td>Lack of experience in anaphylactic crisis</td>
<td>Medication mix up</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No process to ensure correct communication between team members for medication prep</td>
<td>Both team members preparing medications and not communicating to each other that they had done so</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decision to move to IV epi by paramedic not communicated to PCP</td>
<td>Paramedic prepared one med and PCP prepared the other. No double check preformed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication labels available but not used</td>
<td>Two 1 cc syringes prepared but not labeled with type of medication</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High stress and many distractions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remote onsite location</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ No policies requiring a double check of medication or labeling of prepared medications</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>▪ Desensitization therapy not covered</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Systematic Allergy Prevention and Evaluation Report (SAFER) Matrix**

---

Jim cannot afford therapy

Unable to control anaphylactic reaction to bee sting
ANALYSIS PHASE

[1] Identification of membership for the Analysis Team:
- Review Lead (EMS Quality Assurance Strategist)
- Facilitator (Clinical Safety Leader trained in SAM)
- Paramedic
- PCP
- EMS Medical Director
- EMS Director of Quality and Patient Safety
- Patient or Family representative

[2] Analysis Team meeting:
- Prior to this face-to-face meeting, the following information was circulated to the team: information about the SAM, goals for this Analysis Team meeting and information regarding confidentiality as well as the initial timeline and if appropriate, the modified SAFER Matrix.
- The team reviewed the information gathered in the Investigation Phase and made some amendments to the final timeline.
- The Facilitator then worked with the group to complete a Constellation Map illustrating contributing factors and their relationships. The group worked together to create Statements for each cluster as appropriate and develop recommendations.
Figure 7: Constellation Map

OVERDOSE (10 FOLD) OF EPI LEADING TO A HYPERTENSIVE CRISIS

PATIENT
- HX of Hypertension
- Rapid Decompensation
- Can’t find EPI pen
- Allergy to bees
- Unable to afford desensitization therapy
- New Medic
- Never seen crisis anaphylaxis

CAREGIVER

TEAM
- EMT and paramedic both preparing meds
- No double check performed

ORGANIZATION
- Desensitization therapy not covered on AB health fee schedule
- No process for med communication on EMT team
- No clearly defined roles/responsibilities for EMT/EMT-P partnerships

EQUIPMENT
- Medication labels are available but not used
- Same type of syringe used for two different medications

ENVIRONMENT
- Remote Location
- High stress and dog barking distractions

OTHER
- No double check performed
- Decision to change route of EPI administration not communicated
- Practice of drawing up full mL EPI and delivering 0.3 mL doses as needed
- Practice inconsistent amongst EMS staff
**RECOMMENDATION PHASE**

Recommendations were developed from the summary statements that contain actionable contributing factors.

<table>
<thead>
<tr>
<th>Summary Statement 1</th>
<th>Recommendation 1.1</th>
</tr>
</thead>
</table>
| Inconsistent and variable processes surrounding the use of medication labels on syringes used for medication administration in EMS increased the likelihood that two medications with the same appearance would be mixed up and incorrectly administered. | **Recommendation 1.1**  
Develop and implement a procedure requiring the use of medication labels on all syringes used for the preparation and administration of medications by EMS.  
*To be completed by March 31, 2013*  
*Proposed Owner: EMS Director of Quality and Patient Safety* |

<table>
<thead>
<tr>
<th>Summary Statement 2</th>
<th>Recommendation 2.1</th>
</tr>
</thead>
</table>
| The current practice of drawing up a full 1.0 mL of epinephrine (1:1000) into a syringe to deliver in 0.3 mL doses over time increases the likelihood that a medication overdose could occur. | **Recommendation 2.1**  
Investigate and if appropriate implement the option of EMS drug kits being equipped with 0.3 mg prefilled syringes of epinephrine (1:1000) for intramuscular administration and discontinue if appropriate the use of 1 mL ampoules.  
*To be completed by January 1, 2013*  
*Proposed Owner: EMS Director of Quality and Patient Safety* |

<table>
<thead>
<tr>
<th>Summary Statement 3</th>
<th>Recommendation 3.1</th>
<th>Recommendation 3.2</th>
</tr>
</thead>
</table>
| The lack of formalized team training that includes defined roles and responsibilities specific to PCP/ACP partnerships during infrequent crisis responses requiring the administration of high alert medications increased the likelihood that team communication regarding the preparation and administration of medications would be compromised and insufficient. | **Recommendation 3.1**  
Initiate a working group to determine the feasibility of assigning defined roles and responsibilities to PCP/ACP partnerships during a crisis response such as anaphylaxis and implement as appropriate.  
*To be completed by December, 2013*  
*Proposed Owner: EMS Director of Quality and Patient Safety*  
**Recommendation 3.2**  
Develop and implement an e-Sim scenario for infrequent crisis response that would be inclusive of defined roles and responsibilities for PCP/ACP partnerships as part of an orientation package to teamwork in EMS.  
*To be completed by June 1, 2014*  
*Proposed Owner: EMS Director of Quality and Patient Safety* |

<table>
<thead>
<tr>
<th>Summary Statement 4</th>
<th>Recommendation 4.1</th>
</tr>
</thead>
</table>
| The exclusion of desensitization therapy on the Alberta Health payment schedule increases the likelihood that Patients will continue to experience preventable harm from anaphylactic reactions. | **Recommendation 4.1**  
Initiate a working group to develop a business case for Alberta Health that would be inclusive of the cost of covering desensitization therapy for bee stings in the payment schedule versus the cost of care for Patients experiencing an anaphylactic reaction.  
*To be completed by June 1, 2014*  
*Proposed Owner: EMS Director of Quality and Patient Safety* |
The Recommendations were prioritized in a matrix using the tools provided in the Recommendation Assessment And Prioritization as follows:

<table>
<thead>
<tr>
<th>Recommendation Description</th>
<th>Impact</th>
<th>Effort</th>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop and implement a procedure requiring the use of medication labels on all syringes used for the preparation and administration of medications by EMS.</td>
<td>5</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>Investigate and if appropriate implement the option of EMS drug kits being equipped with 0.3 mg prefilled syringes of epinephrine (1:1000) for intramuscular administration and discontinue if appropriate the use of 1 mL ampoules.</td>
<td>4</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Initiate a working group to determine the feasibility of assigning defined roles and responsibilities to PCP/ACP partnerships during a crisis response such as anaphylaxis and implement as appropriate.</td>
<td>3</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Develop and implement an e-Sim scenario for infrequent crisis response that would be inclusive of defined roles and responsibilities for PCP/ACP partnerships as part of an orientation package to teamwork in EMS.</td>
<td>2</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>Initiate a working group to develop a business case for Alberta Health that would be inclusive of the cost of covering desensitization therapy for bee stings in the payment schedule versus the cost of care for Patients experiencing an anaphylactic reaction.</td>
<td>2</td>
<td>3</td>
<td>6</td>
</tr>
</tbody>
</table>

PRODUCING A REPORT

- A short report that includes the brief case description, findings, contributing factors/system hazards and any recommendations is produced.
- Provide the report to the applicable operational and/or medical leader for an implementation decision and dissemination if appropriate. If the review has taken place outside of Section 9, protection of the report is attached to the applicable RLS report so the system learnings are available for sharing across the organization. If the review was completed under the direction of a QAC and Section 9 protection, the Quality Assurance Review Summary is presented to the QAC for acceptance.
APPENDIX E: ROLES WITHIN THE SYSTEMS ANALYSIS TEAMS

ALL ROLES:
- Need knowledge of SAM and the requirement for confidentiality
- May get just-in-time education related to SAM and Section 9 requirements as needed

REQUESTOR:
- The person who requests a review using SAM following a Clinical Adverse Event or Close Call
- Believes there are systematic weaknesses in either structures or processes that support Patient care delivery that are amenable to improvement
- Provides a clear rationale for the request outlining the nature of the hazard(s) or potential system failure(s) the Requestor is concerned about
- Responsible for developing or requesting an initial timeline of factual events in order to determine whether a systems review is warranted

REVIEW LEAD:
- Appointed by QAC Chair for QA Reviews (recommended)
- May be included for other reviews
- Operational leader knowledgeable about type of setting or clinical specialty involved
- Either knowledgeable of SAM or receives just in time training from CSL/CQC
- Facilitates Medical and Midwifery staff and Staff participation
- Contributes operational and/or medical perspective to review

FACILITATOR:
- Trained in SAM – CSL, CQC or other AHS employee.
- May have no knowledge of setting or content issues
- Primary role is to support and assist with SA to completion:
  - Investigative phase – collects information for team
  - Analysis Phase – may lead the facilitated session with Team
  - Recommendation Phase – may contact stakeholders who have not yet participated
  - Review Summary – ensures this has been completed

CONTENT EXPERTS:
- Knowledgeable about setting or content of issues
- May participate at any phase in review
- Investigation Team:
- Consists of a Review Lead, Facilitator and Content Expert
- Completes the initial activities of an investigation:
  - Interviews
  - Literature search
  - Other supporting documents search
  - Synthesizes information to complete the final timeline and a modified SAFER Matrix
ANALYSIS TEAM:
- Have knowledge of the SAM processes
- Include an Operational Review Lead, Facilitator, Content Experts, other staff or consultants, and Administrators. May also include the Patient, family member or Patient representative
- Responsible for:
  - Reviewing the information prepared by the Investigation Team
  - Building the Constellation Map
  - Summarizing the findings
  - Developing recommendations

STAFF AND MEDICAL STAFF INVOLVED DIRECTLY OR INDIRECTLY IN THE EVENT:
- Invited to participate in Analysis Phase
- May be interviewed in Investigation phase and their opinions (de-identified, with their permission) included in information presented to the Analysis Team

ADMINISTRATORS:
- Leaders who have accountability for the area of care that is the focus of the review
- Invited to participate in Analysis Phase
- Can contribute an operational perspective at any phase in review
- Will not be given any opinions gathered from staff they have accountability for without the permission of those staff members

POTENTIAL RECOMMENDATION OWNERS:
- Contribute operational knowledge specific to their role
- Included as active participants in the Analysis Phase or in the development of recommendations that follows
- If accepted as Recommendation owners will send updates of the Recommendations to the REC tracker quarterly
CONFIDENTIALITY AGREEMENT FOR NON-AHS EMPLOYEES PARTICIPATING IN A SAM

This agreement is between you and Alberta Health Services. By authorizing this, you will be subject to legally binding terms and conditions. Carefully read all of the terms and conditions set out below. Signing this agreement indicates your acceptance of the terms and conditions of this agreement and that you intend to be legally bound by them.

CONFIDENTIALITY AGREEMENT

WHEREAS:
[1] Alberta Health Services is bound as a Custodian as defined in the Health Information Act, (HIA), and as a Public Body as defined in the Freedom of Information and Protection of Privacy Act, (FOIP).
[2] The HIA defines an Affiliate of a Custodian as an employee, a healthcare provider with privileges, a volunteer, or a student of the Custodian; or those who provide services under contract for a Custodian.

I AGREE THAT:
[1] I am an Affiliate of Alberta Health Services (as defined in the HIA).
[2] All Health Information (as defined in the HIA), all Personal Information (as defined in the FOIP, or any other privacy legislation in effect), that I collect, use, retain and/or disclose in my role as an Affiliate of Alberta Health Services is private and confidential.
[3] It is my responsibility as an Affiliate of Alberta Health Services to know and follow relevant information privacy and information security policies in effect in Alberta Health Services.
[4] I will take all reasonable steps to act in accordance with applicable Alberta Health Services policies, bylaws, collective agreements, the HIA, the FOIP, and any other privacy legislation in effect and to keep private and confidential and prevent the unauthorized collection, use and/or disclosure of all Health Information and/or Personal Information that I come into contact with in my role as an Affiliate of Alberta Health Services. Such steps include, without limitation, taking reasonable security precautions against such risks as unauthorized access, collection, use, disclosure, alteration or disposal.
[5] If I knowingly collect, use and/or disclose Health Information or Personal Information in my role as an Affiliate of Alberta Health Services in contravention of Alberta Health Services policies, bylaws, collective agreements, the HIA, the FOIP, and any other privacy legislation in effect, I may be subject to disciplinary action, termination and/or guilty of an offence under the HIA, the FOIP, and any other privacy legislation in effect.
[6] I am responsible to keep confidential all Health Information and Personal Information for as long as required by the HIA, the FOIP or other relevant privacy legislation in effect.
[7] I agree to notify Alberta Health Services as soon as reasonably possible if I am aware of a breach of this agreement.
[8] As part of my role as a volunteer within the Region, I understand that I may be asked to participate in reviews or committees whose intent may be to perform quality assurance activities as sanctioned by the Alberta Evidence Act. I agree that I will abide by all applicable legislation and terms of reference in relation to such committees. All information known to me incidental to these activities will be kept confidential and will not be discussed with other outlets such as the media.
[9] I agree that all information gathered through my function will not be used in furtherance of any action against or involving the Region.

By signing below I accept the terms & conditions of this agreement and intend to be legally bound by them.

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Signature: ________________________________ Witness Signature: __________________________
Date: _____________________________________ Date: _____________________________________
# TEMPLATES | TIMELINE

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PRINCIPLES | HUMAN FACTORS: TIPS FOR SYSTEMS ANALYSIS

Human Factors\textsuperscript{20} can provide an understanding and appreciation of human capabilities and limitations to assist in the examination of human interactions with other people, machines and systems in order to understand performance and improve systems design. Improvements may range from physically changing the design of a software interface, sign, form, or medical device to changing the entire design of a room in a facility to optimize safety and efficiency.

A Human Factors viewpoint enables the investigator of a Clinical Adverse Event to look at the broad range of factors which may have contributed to the Clinical Adverse Event. These factors may be related to the Patient, personnel, environment or equipment, organization, or regulatory agencies/authorities.\textsuperscript{21} Thus, the specific human error which may have occurred directly leading up to the event should be viewed as a symptom of a larger problem within the system and broader contributing factors should also be identified. This viewpoint encourages the investigator to examine factors that contributed to the event at all levels of the system and to develop safeguards to prevent a similar event from occurring in the future. These safeguards are generally system level changes that go beyond imploring a worker to be more vigilant.

**HUMAN FACTORS HAS BEEN DEFINED AS:**

\textit{“The scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance. Human Factors [specialists] contribute to the design and evaluation of tasks, jobs, products, environments and systems in order to make them compatible with the needs, abilities and limitations of people.”}\textsuperscript{22}

If a Human Factors viewpoint is not maintained during a Systems Analysis, it may be very easy for the investigator to fixate on a single human error that ‘caused’ the event. This type of determination would likely lead to punitive action against a single person, increased training or the development of organizational policies that do not address the deeper underlying issues. Adopting such a viewpoint is not likely to reduce the possibility of another event, or to increase safety within the environment.

As an investigator, it is important to recognize shortcuts that humans automatically use to process information, and how these may result in unintended biases during an Event Analysis.

- **Hindsight Bias**\textsuperscript{22} is the tendency to perceive past events as somehow more foreseeable and more avoidable than they actually were. As investigators we are more likely to perceive that the Clinical Adverse Event or close call should have been easy to prevent and therefore attribute blame to the person who ‘didn’t see it coming’

- The **Fundamental Attribution Error**\textsuperscript{22} is the tendency to attribute others poor performance to their ability, while attributing our own poor performance to the situation or circumstance. In a review, this may be manifested in the investigator blaming a person rather than examining the larger system in which the behaviour occurred.

- The **Principle of Least Effort**\textsuperscript{22} indicates that we are likely to attribute the cause of a Clinical Adverse Event to the people involved in the situation than to identify larger systems issues because it may be difficult and require more effort to gain a true understanding of where the system may have broken down to allow the Clinical Adverse Event.

- **Cognitive Tunneling**\textsuperscript{23} is the tendency to ignore or underutilize subsequent information once a hypothesis has been generated. Similarly, **Confirmation Bias** leads us to seek out information that is consistent with our hypothesis while ignoring or underrating future information that is contrary to our hypothesis.
At AHS, Human Factors specialists study how healthcare providers work and then try to design processes and equipment that contribute to a high-quality, safe healthcare system. With multi-disciplinary backgrounds including psychology, kinesiology and engineering, the AHS Human Factors Team studies how people perceive and interact with other people, processes and the environment. The AHS Human Factors Team is actively engaged in evaluation and design, employing human factors principles to improve Patient and staff safety, improve efficiency, and reduce the possibility of unexpected outcomes for Patients. Human Factors principles and evaluative methodologies have been incorporated into numerous areas of AHS.

The AHS Human Factors Team is part of Patient Safety, Clinical Performance Improvement, Quality and Healthcare Improvement. If you have any questions or would like Human Factors involvement in a project or Systems Analysis you are working on, please contact a member of the Human Factors team for support: humanfactors@ahs.ca.
PRINCIPLES | JUST CULTURE

We acknowledge as a group, that we at Alberta Health Services (AHS) commit and intend to provide safe and healthy care and/or work environments. However, we also know that despite our best efforts, things can sometimes go wrong. As such, we all have an important role to play in identifying, reporting and addressing issues or concerns about our health system and/or organizational processes, and to share what we learn, in support of continuous quality and safety improvement. When everyone knows what to expect, we can work together to look at the context of the situation, identify the contributing factors, make system and/or organizational changes, and share our learning.

The just culture philosophy supports an environment where everyone feels safe, encouraged and enabled to discuss quality and safety issues where reporting and learning are key elements. This means that reporting is conducted within a psychologically safe environment where there is demonstrated respect and support for the individual, and the potential for human and systems fallibility is acknowledged. Everyone can trust that those within the organization will demonstrate, through their behaviours and decisions, a fair and consistent approach to responding to issues raised.

In practicing the Just Culture we live the AHS organizational values. Through a just culture, we will:

- be respectful in how we engage with those involved;
- be transparent in the evaluation processes used;
- hold our system, ourselves and others accountable; and
- learn from mistakes and close calls to improve safety and performance.

JUST CULTURE GUIDING PRINCIPLES (7)

When there is a need to review a situation, whether in a clinical or non-clinical area:

[1] AHS will ensure a fair and consistent approach to evaluating what occurred in context, and responding to the individuals involved
[2] Everyone will be able to trust that AHS has effective processes in place to support this fair and consistent approach, and that these processes will be followed
[3] Actions will be evaluated in consideration of the circumstances and context of what occurred, rather than results and outcomes
[4] Individuals will not be held accountable for system and/or organizational errors over which they have no control and will be treated with care, compassion, support, respect and dignity
[5] AHS Leaders are accountable for ensuring system and/or organizational changes/improvements are made based on our learnings and the best evidence available. Throughout that process, they will engage with those who work within/are impacted by the system and/or organization (including Patients, families, staff and medical staff)
[6] Individuals will feel enabled, empowered and supported to openly discuss and report what occurred
[7] Individuals will be held appropriately accountable for reckless behavior or intent to harm

ORGANIZATIONAL COMMITMENT

AHS will provide the necessary resources, supports and tools to enable staff and medical staff to become aware of, understand and apply the Just Culture Guiding Principles.
References

   http://www.albertahealthservices.ca/PDFs/if‐hp‐edu‐qps‐integrated‐curriculum.pdf


3. Alberta Evidence Act, R.S.A. 2000, c.A-18,s.9

4. AHS Policy: Disclosure of Harm. Effective Date 2011 Feb 23

5. AHS Procedure: Disclosure of Harm. Effective Date 2011 Feb 23

6. Doran, G. T. There is a SMART way to write management objectives. AMA Forum Nov. 1981

7. The AHS Improvement Way (AIW) Facilitator’s Guide. P. 52


11. Health Information Act, R.S.A. 2000, c.H-5, ss.35(1)(g), 35(2)-(3)


17. HQCA Quality Assurance Review of the Three Medication and One Expressed Breast Milk Incidents, March 2010

18. AHS Procedure: Reporting of Clinical Adverse Events, Close Calls and Hazards. Effective November 2017


