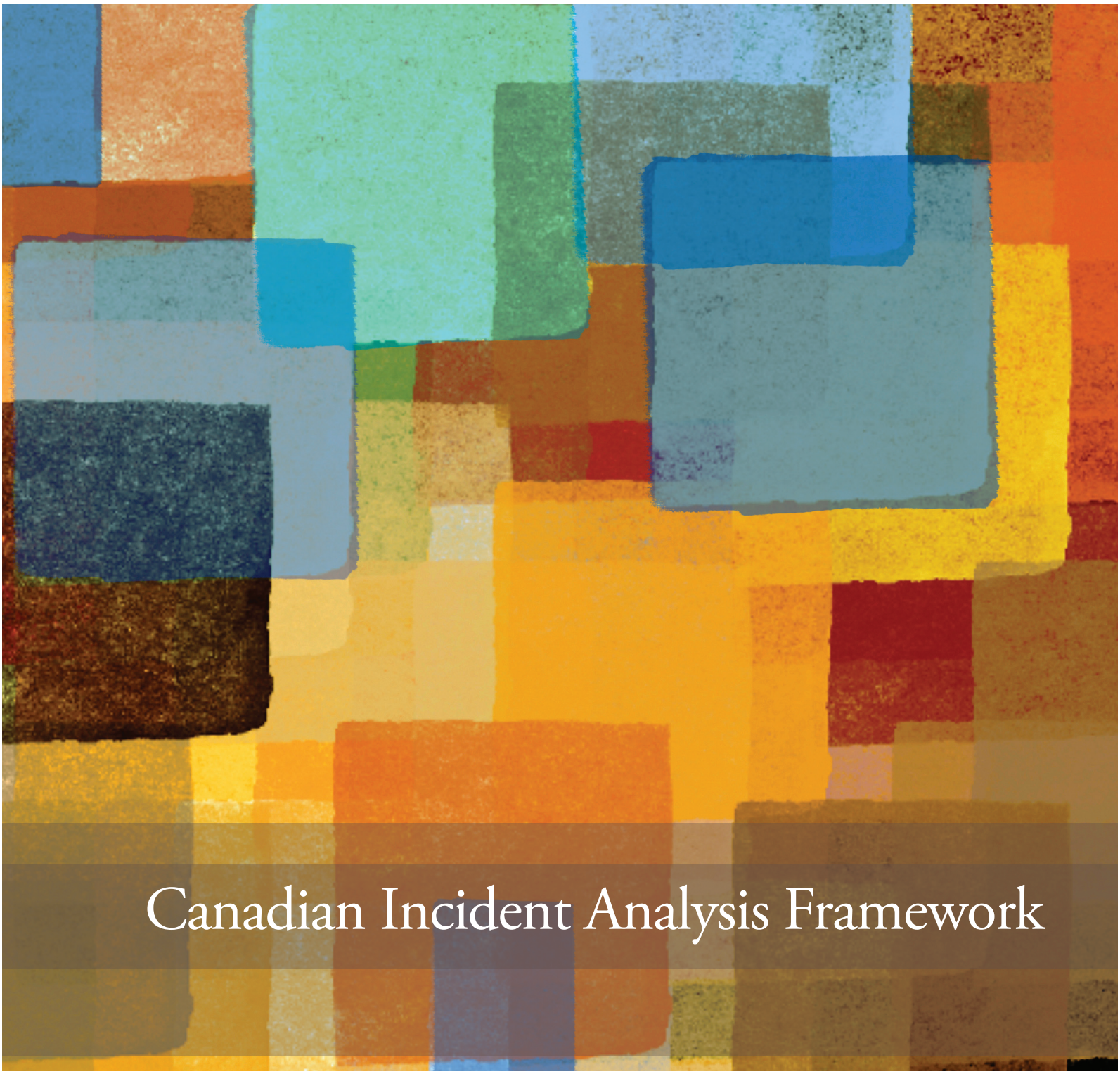

Canadian Incident Analysis Framework

CANADIAN INCIDENT
ANALYSIS FRAMEWORK

cpsi icsp
Canadian Patient Safety Institute
Institut canadien pour la sécurité des patients

ismp CANADA

Saskatchewan Ministry of Health

Canadian Incident Analysis Framework

The Framework was developed collaboratively by the Canadian Patient Safety Institute, the Institute for Safe Medication Practices Canada, Saskatchewan Health, Patients for Patient Safety Canada (a patient-led program of the Canadian Patient Safety Institute), Paula Beard, Carolyn E. Hoffman and Micheline Ste-Marie.

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THANK YOU

Thank you to patients, families, providers, operational leaders, regulators and funders for your passion and commitment to improving the safety of patient care. We invite you to share your successes and challenges on this journey.

DISCLAIMERS

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CLAIRE'S STORY

In October 2001, our eleven year old daughter, Claire passed away following surgery to remove a benign tumour in her brain. Her death was the result of a series of catastrophic failures in the management of her post-operative care. As the investigations would later reveal, Claire died as a result of serious care and system issues. Her death was avoidable.

The initial investigation into Claire's death did not provide answers to the questions that our family had, and we needed to fully understand what happened. In the weeks and months that followed Claire's death, information from the hospital and communication with us was very strained. Initially, we had to ask the hospital for this information. When it wasn't forthcoming, we felt that we had to demand it. It was all the more devastating for us because Claire's death was so tragic – our young daughter died so very unexpectedly. The physicians and others involved in Claire's care were probably very afraid of us at first, perhaps because we were angry. They could also have been afraid because of what they already knew, or might find out, and how difficult it would be to share this with us. Yes, we were grieving the loss of our beautiful daughter. Yes, we were suffering. No question. As relatively quiet and private people we didn't want the masses swarming down on us, but we did need answers about Claire's death for our own resolution to help us make some sense of this great loss.

Our communication with the hospital after Claire died was very cold. When meetings with officials finally occurred, the coldness continued which only made matters worse. The lack of understanding of what we really needed – timely information delivered in a caring manner was devastating. For us, it further complicated an already delicate grieving process. We needed compassionate people who really showed us how much they cared. We needed someone to quietly and steadily stay in contact with us. We needed a firm and timely commitment from the hospital to help find answers and to be open and honest with us so that we could understand why Claire died.

After many months of struggling, the hospital agreed to conduct a second, and this time, a very thorough, investigation. The hospital's senior leadership team – the CEO, Chief of Staff and Chief Nursing Officer – wrote to us with the findings and sent us the report. They met with us personally. They accepted accountability for what happened and openly apologized. They were extremely compassionate that day and in the many other meetings and communications that followed.

The report outlined that many errors were made by many people in a variety of disciplines. Holes in Claire's care and gaps in information were found. There were multiple failures in recognizing and responding in a timely manner to Claire's critical and deteriorating situation. Alongside each of the findings were clear recommendations. It wasn't empty rhetoric. The recommendations were written as solid, comprehensive and feasible plans that, as a nurse, I had some confidence in knowing they might help prevent a similar tragedy in the future. The recommendations were implemented and this was communicated to us. They took the time to stay in touch with us.

The recommendations included important education for ICU nurses about pediatric fluid balances, new drug protocols and a restructuring of the ICU. Families were also brought deeper into the circle of care with more open communication. The hospital supported a further investigation made by the Chief Coroner's Office of Ontario, who found similar deaths involving the same drug that contributed to Claire's death. In conjunction with the Institute for Safe Medication Practices Canada, a medication alert was developed and sent out across Canada to other hospitals. While the implementation of the recommendations took time, it happened in a way that ensured that staff understood what was being introduced so that they would accept these changes.

What I think really made a difference for us, between the initial review and the second investigation, was the leadership at the hospital. Senior leaders demonstrated their role in being accountable. They enabled us to have an open, clear, and honest understanding of the events that led to our daughter's death. This disclosure intuitively led to an apology and it also opened up a series of other actions and meetings with the people directly involved in Claire's care. This leadership was extraordinary and their actions led to improvements in the safety of care at the hospital and enabled further communication and understanding. For us as Claire's parents, it led to healing and forgiveness.

"BE LEADERS AND LEAD BY EXAMPLE. INSPIRE, ENCOURAGE AND EDUCATE OTHERS TO FOLLOW WHAT AT TIMES CAN BE UNMARKED PATHWAYS. THESE EVOCATIVE ACTIONS WILL LEAD TO CHANGES IN PATIENT CARE AND GREATER SAFETY".

Having had time for reflection, I believe our very desperate situation was eased somewhat and certainly made more hopeful because of the actions of many ferocious leaders who in a variety of positions and responsibilities did "the right thing".

The loss of Claire was immeasurable. Nothing on earth can ever replace our child and the love we shared. Now, after some 10 years have passed, my voice and my actions are aimed at many. Be leaders and lead by example. Inspire, encourage and educate others to follow what at times can be unmarked pathways. These evocative actions will lead to changes in patient care and greater safety. Do the right thing and help ensure that other patients and families will not have to endure what we and so many others have experienced in the past.

John Lewis
Claire's father[1]

EXECUTIVE SUMMARY

In healthcare, patient safety incidents that impact the lives of patients and families, as well as providers and organizations, can and do occur. In recent years, considerable focus on patient safety has been aimed at different levels: the culture of patient safety within health organizations, the knowledge associated with patient safety (methods and research), analysis of safety incidents (with resulting learning and improvements) and sharing and communicating these with others. Greater understanding of the complexities and limitations of healthcare has also surfaced (e.g. interconnections between services and care, resource demands to implement improvement initiatives, increased visibility of patient safety and the impact of stringent budgets on quality of care). Since the Canadian Root Cause Analysis Framework document was made available in 2006, there has been a continuous demand for resources to help support management, analysis, learning and improvements from safety incidents. These factors were viewed as significant triggers for the publishing of a revised version of the document.

The Canadian Incident Analysis Framework (the framework) is a resource to support those responsible for, or involved in, managing, analyzing and/or learning from patient safety incidents in any healthcare setting with the goal of increasing the effectiveness of analysis in enhancing the safety and quality of patient care. The framework provides methods and tools to assist in answering the following questions:

- What happened?
- How and why it happened?
- What can be done to reduce the likelihood of recurrence and make care safer?
- What was learned?

Key enhancements to the framework include:

- The patient/family perspective;
- Multiple methods to analyze incidents;
- A description of how analysis is intertwined with the incident management continuum;
- An innovative diagramming method to better identify contributing factors and their interconnections; and
- A new section on developing, prioritizing, validating and managing recommended actions.

The generation of this revised framework was a true collaborative effort. Representatives of the following partner organizations: Canadian Patient Safety Institute, Institute for Safe Medication Practices Canada, Saskatchewan Ministry of Health, and Patients for Patient Safety Canada (a patient-led program of the Canadian Patient Safety Institute) together with Paula Beard, Carolyn Hoffman and Micheline Ste-Marie, generously shared and blended their expertise in a symbiotic way to create this resource. Several rounds of consultations with leaders, experts and users shaped the final document by confirming the quality of some sections and offering practical guidance on improving other sections. Experts were also invited to contribute to, or revise sections of the document.

The methods and resources included in the framework are designed to support organizational learning, quality improvement, a safe and just culture and improve the success of analysis in enhancing the safety of patient care.

Terminology Used in the Framework

Patient: Is intended to encompass everyone who receives health services across the continuum of care (e.g. patient, client, resident, customer).

Provider: Refers to physicians, professional and non-professional staff, and others engaged in the delivery of health services.

Incident Analysis: A structured process that aims to identify what happened, how and why it happened, what can be done to reduce the risk of recurrence and make care safer, and what was learned.

Incident Management: The various actions and processes required to conduct the immediate and ongoing activities following an incident. Incident analysis is part of incident management.

Patient Safety Incident(s): The International Classification for Patient Safety,[3] under development by the World Health Organization (WHO), contains a common terminology to facilitate the sharing and learning of patient safety information globally. The use of WHO terminology is preferred for consistency; however, it is recognized that organizations may have reason to continue to use other terminology.

> "WE ENVISION A CANADIAN HEALTH SYSTEM WHERE PATIENTS, PROVIDERS, GOVERNMENTS AND OTHERS WORK TOGETHER TO BUILD AND ADVANCE A SAFER HEALTH SYSTEM; WHERE PROVIDERS TAKE PRIDE IN THEIR ABILITY TO DELIVER THE SAFEST AND HIGHEST QUALITY OF CARE POSSIBLE; AND WHERE EVERY CANADIAN IN NEED OF HEALTHCARE CAN BE CONFIDENT THAT THE CARE THEY RECEIVE IS THE SAFEST IN THE WORLD." [2]

Patient Safety Incident: An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.

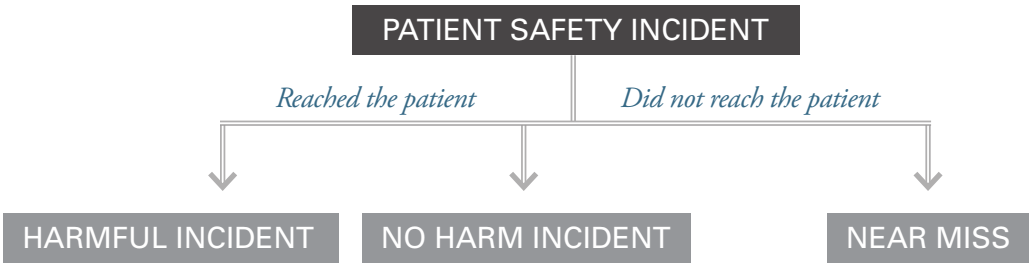
Harmful Incident: A patient safety incident that resulted in harm to the patient. Replaces "adverse event", "sentinel event" and "critical incident".

No Harm Incident: A patient safety incident that reached a patient, but no discernible harm resulted.

Near Miss: A patient safety incident that did not reach the patient. Replaces "close call".

Figure 1 explains the relationship between the four terms. It is important to note that a patient safety incident may be a harmful incident, but it does not have to be. In other words, for a patient safety incident to have occurred, a patient does not necessarily have to be harmed; however, the **potential** for harm to a patient or patients must be present.

Figure 1: THREE TYPES OF PATIENT SAFETY INCIDENTS [4]



Note to Quebec Readers:

The framework was developed by and for English and French speaking Canadians and the terms used throughout were chosen by consensus. However, given the provisions contained in the Act Respecting Health Services and Social Services (R.S.Q., chapter S-4.2) effective in Quebec, various terms had to be adapted. In order not to interfere with the word fluency, it was agreed to make adjustments in terminology. Please see the glossary *(Appendix 0)* for a list of Quebec terms and make the necessary conversions when reading the text.

INTRODUCTION

INTRODUCTION

Despite best efforts and intentions, patients are sometimes harmed and, in some cases, die as a result of the care that was intended to help and heal them.[5] While patients and their families bear the primary burden of this harm, well-intentioned healthcare providers and healthcare organizations are also impacted as a result of incidents. The impact can extend for months and even years, affecting personal health, relationships and careers. Anger, frustration and complicated grieving can result[6] when communication and information is not forthcoming and where there are gaps in learning and improvement.

In healthcare settings where there are so many competing demands on providers, incidents are often discussed, but rarely are they systematically reviewed. Incident analysis can provide a mechanism for something positive to come from these very difficult situations, thereby assisting patients, families and providers in understanding what happened and what improvements could be made to reduce the risk of similar harm to other patients in the future.

1.1 BACKGROUND

In 2006, the Canadian Patient Safety Institute (CPSI), together with its partners, the Institute for Safe Medication Practices Canada (ISMP Canada) and Saskatchewan Health, came together to develop, publish and support the Canadian Root Cause Analysis Framework[7] (RCA Framework). The work focused on system-based management and analysis of incidents that cause or nearly cause harm to patients. Subsequently, le Groupe Vigilance pour la sécurité des soins adapted the English version for the benefit of French-speaking Canadians. Over time, the partner organizations trained thousands of individuals from healthcare organizations spanning all sectors, introducing this versatile tool into practice in Canada and beyond. Hundreds of others have attended advanced and train-the-trainer workshops developing additional expertise with the RCA Framework.

Since 2006, opportunities have emerged for the RCA Framework partners to exchange ideas and learn more about incident analysis with Canadian and global experts and with users of the framework. The Canadian Incident Analysis Framework Working Group (Working Group), which includes the original authors and partnering organizations as well as new members, has integrated this new information and knowledge into this revised version, the Canadian Incident Analysis Framework.

The framework is a resource to help support individual and organizational learning, as well as quality improvement, in response to a patient safety incident(s). Organizations may also choose to use the framework to support quality assurance processes.

Target Audience: The framework is designed to be used by those responsible for, or involved in analyzing, managing and/or learning from patient safety incidents in any healthcare setting.

The **purpose** of the framework is to help individuals and healthcare organizations to determine:

- What happened.
- How and why it happened.
- What can be done to reduce the risk of recurrence and make care safer.
- What was learned and how the learning can be shared.

The **overarching goals** of the framework are:

- To enhance the safety and quality of patient care.
- To promote a culture of safety within the organization.
- To promote patient and family-centred care.
- To encourage learning and dissemination of learning within and outside the organization.
- To increase the effectiveness of incident management.
- To improve the success of incident analysis as a tool in preventing and/or mitigating harm.

1.2 KEY UPDATES

One of the key changes in this framework was to discontinue use of the term "root cause analysis" (RCA), as there was a misperception by some that the RCA Framework only generated one "root cause". The framework also moves beyond a linear representation of patient safety incident analysis by introducing concepts related to complexity theory and depicting contributing factors as clusters within a constellation, rather than as part of direct one-to-one cause-and-effect relationships.

Additionally, the revised framework builds on the use of diagrams that support incident analysis and systems thinking using a non-linear approach that includes consideration of categories of contributing factors (task, equipment, work environment, patient, care team and organization factors).

The framework also highlights the importance of recognizing that there are many sources of information flowing through a healthcare organization that can elucidate risks to the safety of patients (e.g. recommendations from accreditation reports, client concerns, insurance claims information, trigger tool data, etc.). Resources are provided to assist organizations to synthesize the findings from incident analysis with these other recommendations in a coordinated manner. This is supported by a methodical approach to prioritizing recommendations to maximize and leverage resources to achieve the safest environment.

Another key change to the framework is the attention given to the viewpoint of patients and families through the personal story of the Lewis family, a section on incident analysis from a patient/family perspective, and the provision of a checklist and advice for effective meetings with patients/families. These enhancements help to ensure that patients and families are supported, heard, understood and valued as an integral part of learning and improvement.

1.3 THE EVOLUTION OF INCIDENT ANALYSIS

From industry to healthcare

Root cause analysis (RCA) was first used by engineers in the aviation and aerospace industries as they recognized the need to develop strategies to help identify and address high-risk activities. Over the years, healthcare organizations began to adapt the RCA methodology to healthcare settings as there appeared to be a similar reliance on complex interactions and communication. More recently, it has been acknowledged that healthcare is indeed more complex than aviation and other high-risk industries[8] given the dynamic nature of the interactions between multiple providers, vulnerable patients, and complex care processes. As such, the methods now used to analyze and manage incidents have evolved to reflect the unique characteristics associated with healthcare.

Trends in the global community

Learning related to analysis of incidents comes from many sources and includes the World Health Organization (WHO) Patient Safety Programme High 5s project.[9] The project is a patient safety collaboration among a group of countries, the WHO Collaborating Centre for Patient Safety and the WHO. It is designed to assess the impact of Standard Operating Protocols (SOPs) on patient safety and the evaluation includes the use of concise, comprehensive, aggregate and cluster analysis methods. The WHO High 5s work has informed the development of this framework and similarly this framework has informed the evaluation design of the High 5s initiative.

The value of incident analysis is a continuing area of focus for the global patient safety community.[10] One of the key issues is the ability to demonstrate on a broader basis that an analysis can help generate recommended actions which, when implemented and evaluated, will enhance safe care. Peer-reviewed studies in literature now describe the effectiveness of root cause analysis locally in reducing targeted patient safety incidents.[11, 12]

Canadian jurisdictions and the global patient safety community have identified the need to access the learning that has been generated through analyses. In response, the Canadian Patient Safety Institute launched *Global Patient Safety Alerts*[13] in February 2011 to provide an easy-to-use, publicly accessible, web-based compilation of safety alerts and advisories that have been developed by a number of contributing organizations world-wide.

How the Framework was Developed

Two important activities helped initiate the development of the revised framework. The first was completion of a literature review in December 2009,[14] which was subsequently updated throughout the revision process. The review formed the foundation for the second action, an international roundtable that was held in Vancouver, British Columbia in March, 2010.[10] The objectives of the roundtable were to:

- Bring together national and international experts in the analysis of patient safety incidents.

- Exchange information on definitions of, and processes for, analysis of patient safety incidents and how they can integrate with one another.
- Gather information for revisions to the Canadian Root Cause Analysis Framework.
- Generate ideas around next steps for reaching the "ideal" state.

Summary proceedings from the roundtable are available on the Canadian Patient Safety Institute website.[10] Of particular interest are the findings that helped guide the development of this document. One example is provided below:

> *"The basic framework of the RCA is good. There is opportunity to enhance the RCA process to improve its effectiveness in assisting providers to learn from incidents and implement changes in practice. There is also opportunity to consider alternate methodologies, including concise RCA, aggregate incident review and aggregate review of RCAs to better support the process in different settings."*

Following the literature review and roundtable, several activities were carried out to ensure that the revised framework met stakeholders' needs and better reflected the realities of healthcare organizations. These activities included the following:

- Gathering of expert content from guest writers (measurement, human factors, legislation and patient perspective).
- Drafting and testing the key revisions (concise and comprehensive methods, constellation diagram, guiding questions). A team of quality improvement consultants at Fraser Health advised on how the tools they tested could be improved (via survey and interviews).
- Conducting focus groups to identify current challenges and best practices in order to inform the development of specific sections (developing and managing recommendations, and patient partnership).
- Comprehensive multi-step consultation:
    - First, invitation-based consultations with representatives from provincial Health Quality Councils, Ministries of Health, and CPSI Voting Members.
    - Second, a public consultation that included information calls and an independent third-party survey.
- Finalized and confirmed content based on the feedback received.

The findings of the independent survey confirmed that the investment in the development process was worthwhile:

"Most [respondents] (81%) find that the framework will be useful or very useful to healthcare organizations and providers".[15]

PATIENT/FAMILY PERSPECTIVE

CANADIAN INCIDENT
ANALYSIS FRAMEWORK

1.4 INCIDENT ANALYSIS AND MANAGEMENT FROM A PATIENT/FAMILY PERSPECTIVE

This section of the framework was written by a group of patients and families, members of Patients for Patient Safety Canada (a patient-led program of the Canadian Patient Safety Institute). The content is written from this perspective. It is the voice of the patient/family.

PATIENTS FOR PATIENT SAFETY CANADA | PATIENTS POUR LA SÉCURITÉ DES PATIENTS DU CANADA

The partnership between patients and families and healthcare providers is one of the most important parts of our care. When we need care we often feel very vulnerable. We may also be frightened, upset and uncomfortable. Healthcare settings are generally not that familiar to us. The conversations that we have with our healthcare providers about our health and care plan, including possible risks and outcomes, both before and after care or treatment, help reassure us and allay some of the fears that we may have. The open sharing of information helps strengthen our trust in our care team and improves the safety and experience of our care.

Safety and Patient and Family-Centred Care First

When we need the healthcare system, we expect that our care will be safe and that it will be sensitive to our needs and wishes − the principles of patient and family-centred care.[16] To us this means:

- The care we receive is safe.
- We are treated with respect.
- We are given information that we need to help us understand and make reasonable decisions about our health and our care.
- We can communicate openly and honestly with our healthcare providers and they will communicate openly and honestly with us.
- As we are able, we are involved with our healthcare team as partners in our care.

Immediate Response - Unexpected Situations

When things don't go as expected – when conditions change or when harm occurs, the principles of safety and patient/family-centred care are even more important to us. Whether this is believed at the time to be a complication, an error, an oversight, a safety incident or a case of "we just don't know right now", patients and families need the healthcare system to support them and commit to finding out what happened and to making improvements. For us disclosure, learning and making improvements for the safety of the next patient are the most important parts of this process.[4,17]

When unexpected situations occur, we need the healthcare system and our providers to:

1. Explain what unexpected event or change happened;
2. Apologize that it happened;
3. Help us understand how and why it happened;
4. Explain what will happen next and commit to us in these next steps; and

5. Include us in the fact gathering process, enabling us to contribute what we know from our perspective.

The Analysis – What, How and Why it Happened

In helping us understand what happened, we need our healthcare providers to speak to us as soon as possible, using language we understand. We need our healthcare providers to be even more compassionate in these situations by showing us that they really care about us and what has happened. An acknowledgement that 'something unexpected has happened' is so important. We could be the first to see, feel or sense something isn't right. Not responding or delaying openness creates more fear and erodes trust.

We understand that 'how and why it happened' may not be fully known at the time of initial disclosure and that more information and time may be needed to gather all the facts. Please explain this part of the process to us so that we understand what will happen next. This includes talking to us about our care plan and how our situation will be reviewed.

When analyses are needed, please include us in the fact gathering process. Invite us to meet with the analysis team so that we may provide our perspective and information that we may know about the situation. In some cases the analysis process can be very simple and straightforward. In other situations it might be more complicated and involve many different people. Where possible, please include us from the start. A review of the facts, particularly when serious harm is involved, is not complete until all of the perspectives and information from everyone involved, including the patient/family, have been gathered.

Involving us in the fact gathering stage also validates respect for our point of view as the expert in the patient experience. This emphasizes that the patient, not the system, is at the centre of concern. The goal is to make the system safer for patients through understanding, learning and improvement.

While timely analysis is critical, there may be different circumstances depending on what has happened – such as the shock of the event, significant changes in our health and implications for our family and loved ones – which may prevent us from participating in this process right away. Be understanding of our limitations and help find reasonable ways we can participate where this is our wish. The respect, empathy and understanding of what we could be going through at the time, helps rebuild our trust in providers and the healthcare organization.

Many of us will want to keep in contact with the organization during the analysis process. Please make this easy for us. Give us contact information at the time of the acknowledgement. It may help if this person is someone with whom we already feel comfortable.

Often there is information that we too would like to review as part of our ongoing care. It could be our medical record or charts, reports or results of tests that were done. When you meet with us, please make it easy for us to access these important records about our health. It is easier to communicate, understand and re-establish trust when we all have the same information.

In some situations where patients have been seriously harmed or where there may be significant system failures, it may be difficult for patients or families (and sometimes even the general public) to re-establish trust with the healthcare organization or system. Doubts may arise that analysis teams, when recruited from within the organization, will be as thorough or unbiased as outside experts. In these situations, please consider our request for an external analysis team, or for including external reviewers and experts as members of the analysis team. Having a member of the public and someone who is familiar with the perspective of the patient and family on the analysis team may also be important so that we can be assured that our interests and perspectives will be included.[18]

In more complicated situations, it may take additional time to complete all aspects of the analysis. Please make sure that we are aware of the timelines and keep us informed of any delays or changes.

Following the Analysis

After the analysis has been completed, ask to meet with us in person when this is our wish, at a time and place that is agreeable to us. If a date for follow-up was previously agreed upon, please try and keep this commitment. If a delay is expected, please inform us and give us the reason for the change. Send us the information or reports that will be discussed in advance of these meetings so that we can also review them and come to meetings prepared with our questions.

These meetings can be very emotional for us. Please do everything possible to make this time easier for us. Ask us about our perspective, and include our suggestions for learning and improvements. The patient and family view is a valuable resource for finding effective solutions. Who better to suggest improvements than those who have experienced failures in care and the system? Talk with us about next steps and how we can continue to be informed or involved in developing or promoting these improvements. To us, this shows continuing commitment to our safety and the safety of other patients.

Partners in Building Trusting Relationships

Review and incorporate all current best practices and related national guidelines in your care sites and operations, and share your learning with others.

As new ways of incorporating safety and quality into healthcare are being considered, start to involve patients and families in the process. Work with patients and families to ensure that these advisory experiences are beneficial for all parties – and especially the patient and family.[6,19]

Patients and families have important insights, information and experiences to share. There are many different ways that we can help.[20] We are patients and families. We are committed partners in the safety and quality of our care. See the checklist (*Appendix F*) for highlights of these important patient/family considerations in incident management.

ESSENTIALS OF ANALYSIS

CANADIAN INCIDENT
ANALYSIS FRAMEWORK

THE ESSENTIALS OF ANALYSIS: PRINCIPLES, CONCEPTS AND LEADING PRACTICES

2.1 PRINCIPLES

The following principles are building blocks that form the foundation for effective incident analysis, as well as incident management. Organizations are encouraged to develop, support and communicate these principles on an ongoing basis.

Safe and Just Culture

Patient safety requires that healthcare organizations build and maintain a safety culture. Safety culture is frequently defined as "the product of individual and group values, attitudes, competencies and patterns of behaviour that determine the commitment to and the style and proficiency of an organization's health and safety programs. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventative measures." [21]

A safety culture is comprised of many things, including openness, honesty, fairness and accountability. It requires and encourages the reporting of incidents and safety hazards. It supports opportunities for safety training and preparedness. It promotes understanding, learning and improvement. It requires flexibility and resilience so that people and unexpected situations and priorities can be managed in a timely and effective manner. Importantly, it includes the principles of patient and family-centred care.[22]

> "TO PROMOTE A CULTURE IN WHICH WE LEARN FROM OUR MISTAKES, ORGANIZATIONS MUST RE-EVALUATE JUST HOW THEIR DISCIPLINARY SYSTEM FITS INTO THE EQUATION. DISCIPLINING EMPLOYEES IN RESPONSE TO HONEST MISTAKES DOES LITTLE TO IMPROVE THE OVERALL SYSTEM SAFETY."[23]

The incident analysis process is most effective when it is conducted within a safety culture because providers know they will be treated fairly and will be held accountable for their actions and behaviours. The culture is largely based on an organization"possessing a collective understanding of where the line should be drawn between blameless and blameworthy actions."[24] Differences are drawn between actions of intention, recklessness and those of unforeseen circumstance or complications of care.

Culture cannot be implemented solely based on policy or procedure; rather, it needs to be consistently fostered over time, and by example, at all levels in the organization. Leadership is especially important in the initial stages of building a safety culture. Ultimately, everyone in the organization has a role in helping to build and maintain a safety culture.

Consistency and Fairness

It is paramount that all healthcare providers clearly understand how their organization will approach incidents and their analysis. It is equally important that the organization consistently apply analysis processes fairly and in the manner that they previously indicated they would follow (e.g. as articulated in policies and procedures − which should be periodically evaluated and updated). Deviation from the agreed-upon, system-focused approach has the potential to drive incident reporting underground due to a fear of negative and personal repercussions if providers report an incident and/or participate openly and honestly in analysis activities.

Team Approach

The success of incident analysis rebuilding trust and implementing solutions to make care safer depends heavily on a team approach. The patient/family and key individuals who were directly involved or associated with the incident should all have meaningful roles in the process. There may be times and circumstances when these individuals cannot fully participate, but including them if they are able and willing to participate is very important. Typically, a facilitator with expertise in incident analysis and a clinician leader with operational responsibility and a good understanding of the analysis process will share primary accountability for coordinating and conducting the analysis according to established organizational procedures. See *Section 3.6* and *Appendices A* to *D* for more information on team management.

Confidentiality

Incident analysis is most effective in a confidential environment where participants can safely report, participate and express their opinions about underlying contributing factors to the incident without fear of reprisal. Legislation that protects discussions related to the quality of care has been enacted in most provinces and territories to facilitate an environment of open sharing of opinions (*Appendix L* and *M*). Some organizations require analysis team members to sign a confidentiality agreement (*Appendix E*), as a reminder that information and opinions shared within the team are not to be transmitted or disclosed outside of the communication mechanisms stipulated by the applicable policies and/or legislation. Regardless of whether the analysis is conducted under the legal provisions of quality of care legislation, confidentiality related to the patient's identity and care details is mandatory.

2.2 CONCEPTS

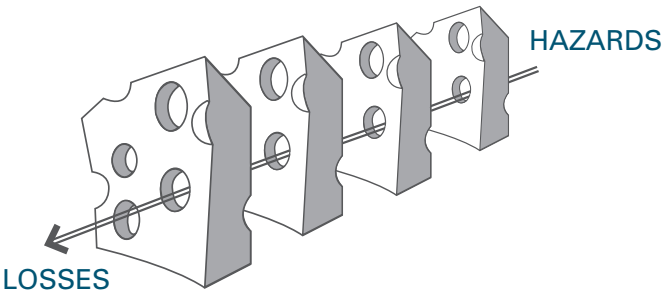
There are several concepts used throughout the framework that are intended to ensure that incident analysis and management reflects the complexities of the current healthcare system, while remaining practical. These concepts support a deeper understanding of how incidents occur in healthcare and assist the framework users in developing and focusing improvement strategies with greater precision.

The Swiss Cheese Model

James Reason's Swiss Cheese Model[24] is one of the foundational concepts which supports all aspects of incident management:

- The defences, barriers and safeguards that exist in a system are not impermeable and therefore can be penetrated when active failures (unsafe acts) and latent conditions (dormant system conditions) combine to create the opportunity for an incident. Latent conditions can be identified and corrected.
- Humans are fallible and errors are to be expected even in the best organizations because people are incapable of perfect performance every time.
- The questions to ask when an incident happens are how and why the defences in the system failed and in the case of a near miss, how did they succeed – in other words, look at the system as a whole, rather than just at the actions of individuals.
- Organizations operating in hazardous conditions have fewer than their fair share of harmful incidents (highly reliable organizations) because they relentlessly anticipate negative outcomes and prepare to deal with them at all levels in the organization.

Figure 2.1: THE SWISS CHEESE MODEL [24]



System

A system is described as the coming together of parts, interconnections and purpose.[25] Systems can be generally classified in two categories: mechanical (e.g. cars, airplanes) or adaptive (e.g. organisms, organizations). Mechanical systems have a high degree of predictability and are easier to control because they respond consistently to the same stimulus. Adaptive systems have a low degree of predictability because all parts of the system do not respond in the same way to the same stimulus. When adaptive systems are also complex, there is an additional factor that decreases predictability; one individual's actions can change the context for other individuals working within the system.[26] This can be either helpful or harmful. It can be helpful because different responses and changes in context generate innovative approaches and better solutions. It can also be harmful because this unpredictability increases variation and thus the potential for harm.

System Thinking and Human Factors

At its core, the science of human factors examine how humans interact with the world around them. It can help determine how and why things go wrong. Human factors science draws upon applied research in many areas, such as biomechanics, kinesiology, physiology and cognitive science, to define the parameters and constraints that influence human performance. This specialized knowledge is used to design efficient, human-centred processes to improve reliability and safety. Because systems-thinking and human factors impacts all levels of patient safety incident management, these concepts have been integrated throughout the framework in addition to a brief overview here.

Historically, when an incident occurred, the tendency was to look for the most obvious explanation of what and why it happened. In most cases, individual human error was identified as the cause, primarily because it was easy to identify and appeared to be easy to fix.[27] This approach ignored the underlying contributing factors that led to the incident and thus presented a shallow analysis of the circumstances. The outcome of such an analysis may have included the creation of new policies/procedures, additional training, disciplinary action and/or an expectation of increased personal vigilance. The focus was almost exclusively directed at improving individual performance and as a result, this approach was likely unsuccessful in preventing the same or similar incident from occurring again.

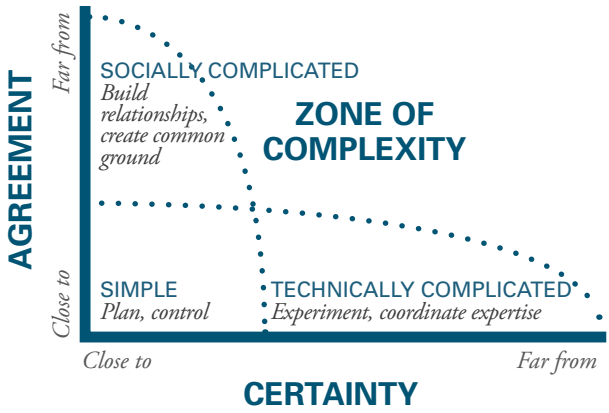
Patient safety experts are strongly advocating a way of thinking that views human error as a symptom of broader issues within a poorly designed system, such as an adverse physical or organizational environment. Dekker[28] refers to an old and new view of human error. In the old view the objective is to find the individual's inaccurate assessments, wrong decisions and bad judgement. In the new view the objective is not to find where the person went wrong, but instead assess the individual's actions within the context of the circumstances at the time. A deeper inquiry into the circumstances will yield system-based contributing factors.

Finding contributing factors that are embedded in flawed systems requires targeted strategies. Knowledge of the human factors involved is both useful and important when asking questions during the incident analysis process and can help the analysis team focus on issues related to systems and not on individual performance. An effective incident analysis always incorporates human factors.

Complexity

Complexity science examines the behaviour of adaptive systems, which is related to the degree of interconnectedness among the many parts in the system.[29] The zone of complexity is described as the area where there is a low degree of certainty, and a low level of professional or social agreement about outcomes. "Certainty" refers to the *level of technical complexity*, whereas the level of "agreement" refers to the *social complexity*.[30] Complexity of an environment can be determined by looking at its three key properties: *multiplicity* (the number of potentially interacting parts), *interdependence* (how connected the elements are), and *diversity* (the degree of their heterogeneity). Here are a few examples of how the concepts of *simple – complicated – complex* apply to managing incidents.

Figure 2.2: COMPLEXITY [30]



Simple systems contain few interactions and are extremely predictable. The same action produces the same result every time. There is also a high degree of agreement on outcomes and processes. The process for obtaining a blood sample via venipuncture would be an example of a simple system.

Complicated systems have many moving parts or tasks in a process, there are many possible interactions, but they operate in a patterned way. It is possible to make accurate predictions about how a complicated system will behave. They generally involve a number of individuals, often from different professions. The patient admission process would be an example of a complicated system.

Complex systems are characterized by features that may operate in patterned ways, but the interactions within them are continually changing. With complex systems, there is a low level of agreement on the outcomes or processes because situations involve multiple individuals or processes and there is a high degree of heterogeneity among them (e.g. different departments are involved). In addition, teams may self-organize around areas of competence, making relationships and resulting interactions even more fluid. An example of a complex system would be the process for transferring a patient between organizations (e.g. a trauma patient requiring air ambulance transport from a community hospital to a tertiary centre would require multiple handovers and inter-agency collaboration).

"The main difference between complicated and complex systems or situations is that in a complicated system one can usually predict outcomes by knowing the starting conditions. In a complex system, the same starting conditions can produce different outcomes, depending on the interactions of the elements in the system." [26]

In incident analysis, complexity should be considered when selecting an incident analysis method, analyzing contributing factors and building recommendations.

The degree of interconnectedness and the relationships between the different parts of the system also help to differentiate *complicated* and *complex* scenarios. In a *complicated* scenario, the relationships can be simulated and clarified (which increases the predictability), while in a *complex* system or situation this is not possible because the elements are not stable; they interact and influence each other continuously (making predictability impossible).

Labelling an incident as *complicated* or *complex* is one aspect to consider when deciding how it should be analyzed, and this determination should be made by consulting with those responsible for analysis. Additionally, incidents that appear to be *simple* early in the analysis process may be deemed *complicated* once more is known and the incident is better understood. It is important to refrain from making assumptions early in the process as to the degree of complexity without having a full understanding of the incident circumstances.

Sphere of Influence

Sphere of influence refers to the number and strength of interconnections between the parts of the system.[31] A particular contributing factor could be influenced by any number of other factors. For instance, an incident may result from the failure to safely transfer a patient from a bed into a wheelchair. One contributing factor may be that the lift used to facilitate the patient transfer is new to the service area. Another contributing factor may be that training did not occur before the lift was put into operation. In this case, the lack of training and the new lift influenced one another. Additional contributing factors may be the unavailability of a trainer from the supplier and that the lift was moved into service sooner than planned to replace another unserviceable lift device. All of these factors (new lift, no training, no training available from the supplier, and the urgent replacement of an unserviceable lift), when taken together, create a confluence of factors that acted upon one another and contributed to the incident.

In incident analysis, the sphere of influence should be considered when analyzing and prioritizing contributing factors, especially when using the constellation diagram.

The concept of sphere of influence is demonstrated in the analysis of incidents with the use of a constellation diagram. The constellation diagram helps those responsible for analysis to visualize the incident and factors that contributed to the incident; it is explained in detail in *Appendix H*. The sphere of influence is visualized by connecting the contributing factors that influenced one another. It is not intended to be linear in its representation. This step will support understanding of how a particular grouping of contributing factors, acting upon or in connection with one another, combined to produce a specific incident that may prove problematic for other patients in similar circumstances if not addressed.

In a complex incident, where elements constantly interact and influence each other, the constellation diagram and contributing factors identified should be considered a "snapshot" of the incident and the context. The role of the analysis team is to develop recommended actions to address the identified local factors; based on this snapshot view, decision-makers and leaders of the organization need to identify and act on findings that affect the organization as a whole.

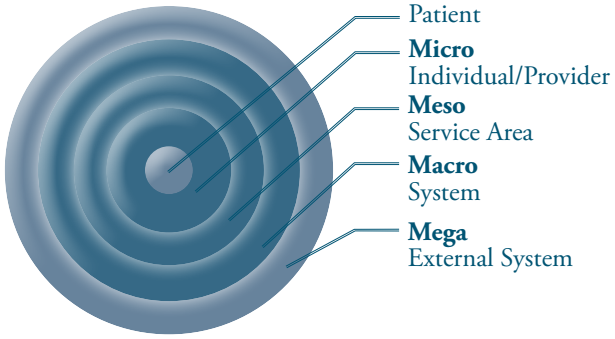
System Levels

Systems are generally viewed from various levels (stratification) because there are differences in goals, structures and ways of working in different parts of an organization. There is general agreement that the following four levels (three internal and one external to the organization) are representative of most systems,[32] however, each organization may look at these levels in a slightly different way as there may be some variation across healthcare sectors (*Figure 2.3*).

In analysis, system levels should be considered when selecting the method of analysis, analyzing contributing factors, or prioritizing recommended actions.

It is important to maintain focus on the level where activities will predominantly take place and how that level is connected with (or influences) the neighbouring levels.

Figure 2.3: SYSTEM LEVELS



- **Micro** = The point where the care providers interact with the patient (e.g. the clinical team or service area that provides care).
- **Meso** = The level responsible for service areas/clinical programs providing care for a similar group of patients, typically part of a larger organization (e.g. a home care or a cardiac care program).
- **Macro** = The highest (strategic) level of the system, an umbrella including all intersecting areas, departments, providers and staff (e.g. boards, healthcare network, integrated health system or region that includes several organizations).
- **Mega** (external) = The level outside the organizational boundaries that influences the behaviour of more than one system. The different sectors of healthcare such as regulatory bodies, licensing organizations, professional groups, liability protection providers, provincial and federal governments, national patient safety and quality organizations, the healthcare industry and the community – all fall into this category.

There are multiple connections within and among the four levels, reinforcing the need to consider these levels in order to understand and better manage patient safety incidents. Understanding how a particular system works is important to ensure that the solutions are developed with support from the right individuals and targeted, with precision, at the appropriate level of the organization. For instance, a problem may exist within a specific micro-system, such as an emergency department. Ideally, any potential solutions would be developed with input from representatives of the department. Once developed and tested in the originating emergency department, the transferability of the solution is determined; a particular solution may or may not be transferable to other emergency departments (meso-system) or to all departments (macro-system). Expansion of implementation should proceed when improvements are measured and known in one area and should be implemented cautiously and measured in other areas of the system, as results can vary widely depending on the context.

Context

Merriam-Webster defines context as the interrelated conditions in which something exists or occurs: environment, setting.[33] Context can include a combination of relevant internal and external conditions[34] specific to the incident and system that influence the incident analysis process.

When conducting the analysis or managing the incident, teams need to consider internal factors, such as pressures and priorities generated from any of the following:

- Incident data (historical reports or recommendations/actions) from the internal reporting system, patient complaints, accreditation reports, insurance claims, civil litigation, etc.;
- Short and long-term strategic priorities and action plans; and
- Resources available (human and financial), including leadership support and coordination.

External pressures such as the following also require consideration:

- Regulations, requirements, preferred practices;
- Evidence from literature (e.g. the risk and frequency of the incident, its impact and cost, evidence-based interventions);
- Information from public patient safety reports/databases (e.g. *Global Patient Safety Alerts*,[13] *ISMP Canada Safety Bulletins*[35]); and
- Anticipated demands from patients, public, media and other stakeholders.

In incident analysis, context should be considered when selecting a method of analysis, analyzing contributing factors and prioritizing recommend actions.

Without a good understanding of the context, incident analysis may not have the desired impact because the recommendations generated are not crafted to fit the reality of the organization. In order to accurately perceive the context, the involvement of organizational leadership is essential.

2.3 LEADING PRACTICES

The primary objective of incident analysis and management is to learn from the incident in order to reduce the risk of recurrence and make care safer for future patients. The goals of incident analysis are to determine: what happened; how and why it happened; what can be done to reduce the risk of recurrence and make care safer; and, what was learned.[36]

Key features of incident analysis: [9, 37]

- Timely, beginning as soon as possible after the incident;
- Inter-disciplinary, involving experts from the frontline services, patient or family, and non-regulated staff where applicable (e.g. clerical, cleaning, maintenance staff); and
- Objective and impartial.

To be thorough, an incident analysis must include: [9, 37]

- A detailed description of the incident being analyzed;

- Analysis of underlying systems through a series of "how", "why" and "what influenced this" questions, in order to determine contributing factors (those under control of the organization, as well as those that are not) and their relationship (connection points) to other contributing factors;
- Formalized recommended actions related to improvements in processes or systems;
- Documentation of the findings and recommended actions; and
- Follow-through to identify and share learning.

To be credible, an incident analysis must include: [9, 37]

- Participation from the patient/family and providers or staff associated with the incident (if they are able to contribute);
- Participation by the leadership of the organization, as well as those most closely involved in the care processes related to the incident;
- Consideration of relevant literature and other sources of information (e.g. reporting systems and internal alerts, information from external experts in the analyzed process); and
- Creation of an evaluation plan to assess implementation of recommended actions and impact achieved (if any).

2.4 AVOIDING COGNITIVE TRAPS

Cognitive biases are implicit mechanisms that influence reasoning and decision-making[38], and as a result impact the analysis process. Bias can influence the team in a number of ways, resulting in the following:[39]

- Oversimplification of what contributed to the outcome;
- Overestimation of the likelihood of the outcome;
- Overrating the significance of some factors and actions;
- Misjudging the prominence or relevance of facts/data;
- Premature completion of the analysis process; and
- Overconfidence in interpretation of known information.

Awareness of bias needs to be cultivated in those leading and participating in the analysis; every effort should be made to recognize and reduce the influence of bias. One approach to reducing bias is to include people on the analysis team who are not aware of the details of the incident under analysis, or who are naïve to the processes involved. Another is for all participants to be encouraged to listen actively to the contributions of each team member and avoid "jumping to conclusions". Additional techniques include the use of guiding questions (*Appendix G*) and the constellation diagram (*Appendix H*) as decision aids; these tools will help the team to explore multiple categories of contributing factors and understand their interconnections. Using a combination of different approaches is encouraged.

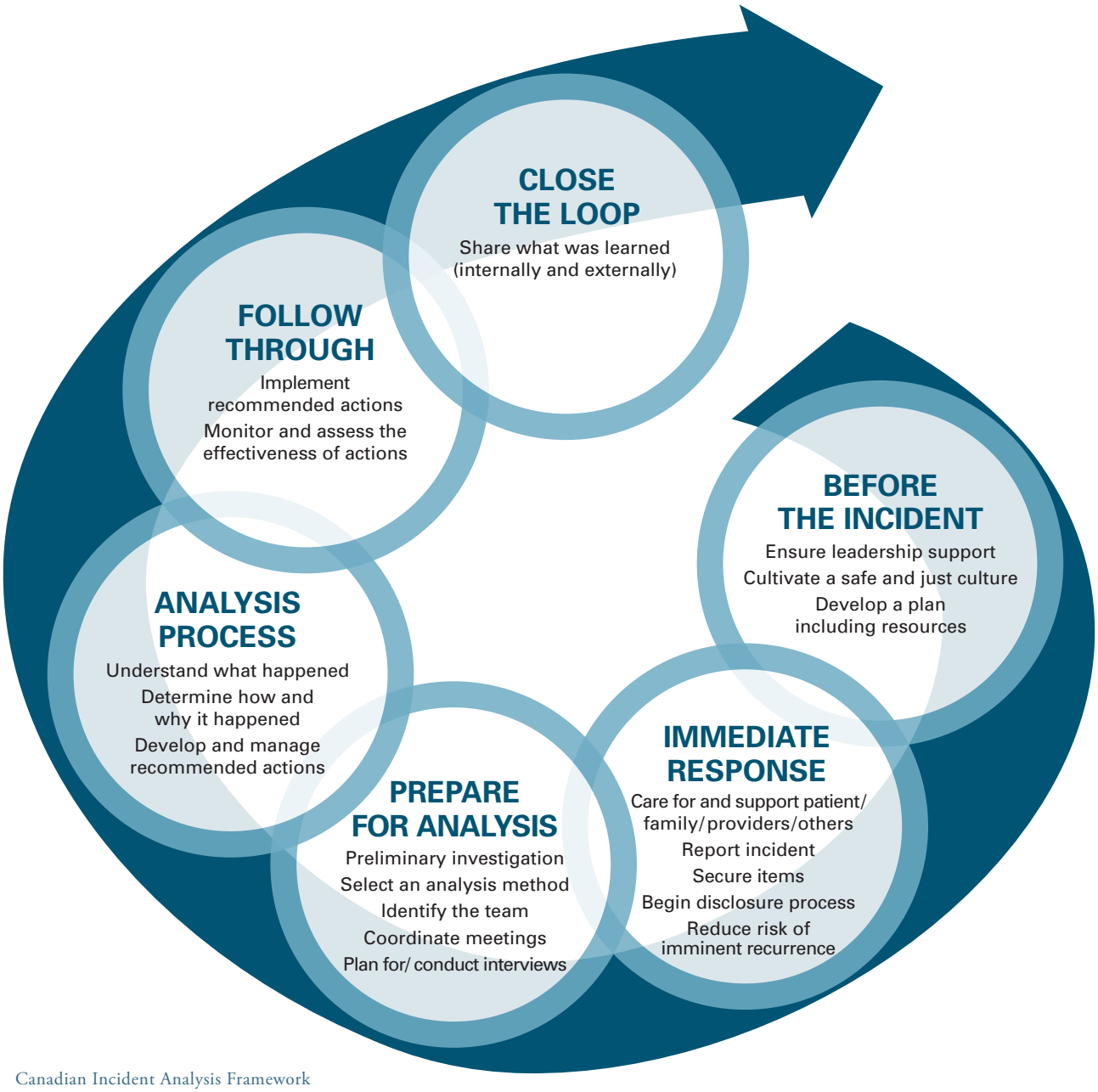
Rarely are all of the important contributing factors immediately known; thus, often the initial perceptions are found to be incorrect once a more thorough analysis that considers the whole system (work environment, organization, context) has been undertaken.[40] Identifying and addressing potential biases in the analysis supports a just and safe culture and a learning environment.

THE INCIDENT ANALYSIS FRAMEWORK

3.1 INCIDENT ANALYSIS AS PART OF INCIDENT MANAGEMENT

The purpose of this framework is to help those responsible for or involved in analyzing, managing and/or learning from patient safety incidents determine what happened; how and why it happened; what can be done to reduce the risk of recurrence and make care safer; and what was learned. In order to increase the effectiveness of analysis in improving care, incident analysis cannot be addressed in isolation from the multitude of activities that take place in the aftermath of an incident (incident management). The diagram below describes how analysis is an integral part of the incident management process. While there will be some variation in how healthcare organizations manage patient safety incidents, the basic steps will be consistent. There is interconnectivity and interdependence between the identified activities and some may take place simultaneously.

Figure 3.1: INCIDENT ANALYSIS AS PART OF THE INCIDENT MANAGEMENT CONTINUUM



Depending on the nature of the incident, these activities may be performed or conducted by a few individuals or a larger team who is assigned this responsibility (*Appendix C*). In some cases there may be different teams engaged at different times (e.g. there are different teams/members for disclosure, analysis and implementation).

As discussed earlier, the successful management of a patient safety incident is built on the principles of patient-centred care, safe and just culture, consistency and fairness, team approach and confidentiality (*Section 2.1*).

> "LEARNING FROM EXPERIENCE CAN PREVENT HARMFUL MISTAKES FROM REOCCURRING. SAFETY IS ENHANCED BY LEARNING FROM FAILURE".[41]

3.2 WHEN TO USE THE FRAMEWORK

This framework is not appropriate for all types of analyses.

The following types of incidents are **not recommended** for a system-based analysis:

1. Events thought to be the result of a criminal act;
2. Purposefully unsafe acts (an act where care providers intend to cause harm by their actions);
3. Acts related to substance abuse by provider/staff; and
4. Events involving suspected patient abuse of any kind.[37]

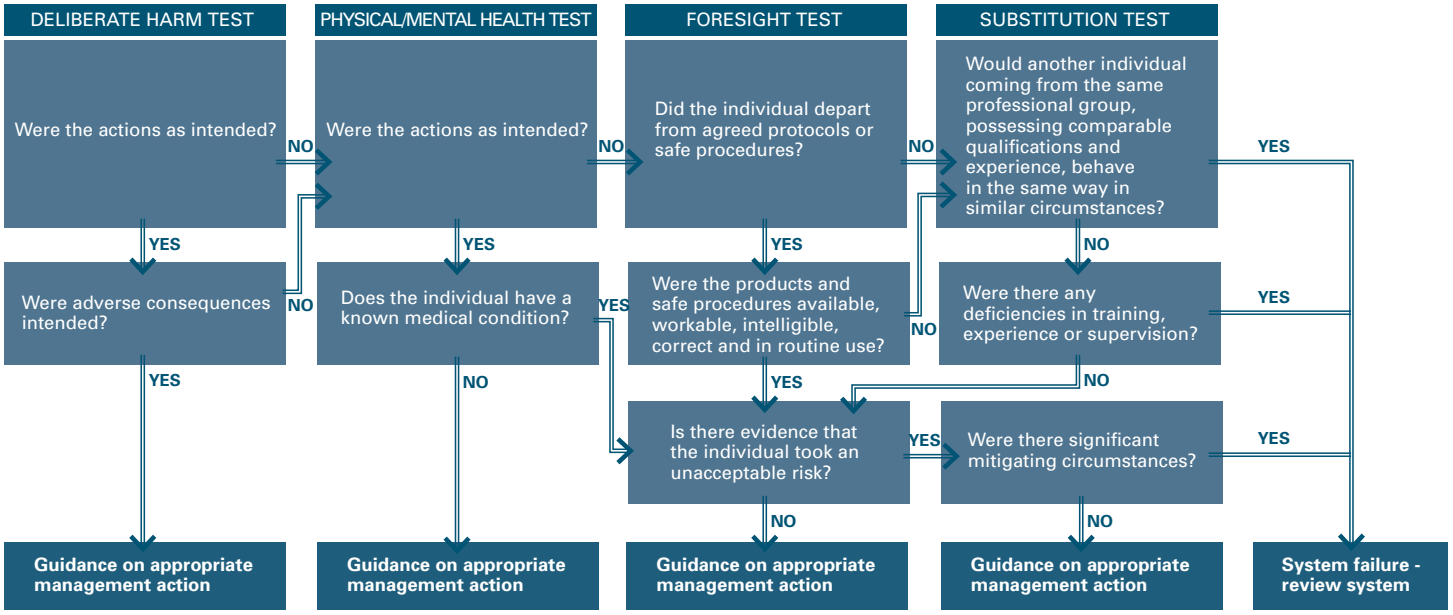
While these situations may provide examples for other system-based learning, as the content and subject matter directly relates to human resource processes (including individual performance management) and/or security systems, these situations require immediate referral to suitable administrative bodies and, where appropriate, to professional regulatory bodies for resolution.

It is important to protect the integrity of the incident analysis process from a situation where there is potential for dismissal, disciplinary action or criminal charges. In circumstances where disciplinary or other administrative action has been taken, it is still possible to run a parallel system-based incident analysis. However, it is imperative that information not be shared from one process to the other and that all participants are aware of the distinction between the two. When the parallel investigations are complete, the learning generated from each process can be valuable for improvement.

In most organizations, two types of formal reviews are generally available for unexpected clinical outcomes and patient safety incidents: system improvement reviews (often called quality reviews) and accountability reviews (also called proficiency reviews). This framework is focused on system improvement, whereas accountability reviews are directed to individual performance. Coaching and mentoring are preferred outcome actions when reviewing individual performance, unless the duty to avoid causing unjustifiable risk or harm has been breached. During the course of a system improvement review, concerns about individual performance may surface; an appropriate accountability review should be set up as a separate process to deal with the identified issues. Likewise, information about system failures revealed during an accountability review should be referred to a system improvement review.

The incident decision tree (*Figure 3.2*) has been adapted by the National Patient Safety Agency in the United Kingdom[42] to help determine when a system-based incident analysis is appropriate. It is based on the culpability model developed by James Reason.[24] An electronic version of the decision tree that includes additional detail is available online.[43]

Figure 3.2: THE INCIDENT DECISION TREE [43]



The Canadian Medical Protective Association, in *Learning From Adverse Events: Fostering a Just Culture of Safety in Canadian Hospitals and Health Care Institutions*[40] presents a different approach for determining when a system review or accountability review is appropriate and describes each type of review in detail. After collecting the facts and deciding if an analysis should be completed, the appropriate type of review can be determined by asking the following triage questions:

- Is it alleged there is a deliberate violation of sound policy by an individual provider?
- Is there a concern about the health of the provider?
- Is the dominant concern in this case about the clear lack of knowledge or skills, or significant unprofessional conduct by an individual provider?

If the answers to all of these questions are NO, a system improvement review should be launched and led by the quality improvement committee or subcommittee(s), with the focus on system (context of care) failures. If the answers to ANY of the above questions is YES, then an accountability review of individual providers should follow, led by leadership/management, with the focus on the performance of individual providers.

Occasionally providers will indicate that there is no need to analyze an incident because they believe that the harm resulted from a known complication. It is important to understand that with advances in care some complications will, over time, become preventable and, therefore, classified as patient safety incidents. Furthermore, patient safety incidents can be coupled with complications and, without conducting an incident analysis, opportunities for learning and improvement may be lost.

BEFORE THE INCIDENT

3.3 BEFORE THE INCIDENT

Pressure to act can mount quickly when a patient experiences an incident. Organizations can best handle the situation if they **develop a plan** ahead of an incident occuring that describes the steps and responsibilities for various actions (who is doing what, how and when) and indicates the resources available (policies, procedures, checklists, skills) to manage the incident. The incident management plan requires visible **leadership support** at all levels of the organization, and is reinforced by a **safe and just culture**[44] in place ahead of the incident. Plans and procedures need to be tested, updated and revised periodically to ensure they are aligned with the evolving culture, structure and processes of the organization.

Organizations that continuously build and maintain resilience in their structures, functions and way of thinking about incidents are better prepared to manage the unexpected. Five attributes characterize these organizations:

1) **Preoccupation with Failure**: To avoid failure we must look for it and be sensitive to early signs of failure.
2) **Reluctance to Simplify**: To understand the more complete and nuanced picture of an incident avoid over-simplification, labelling and clichés.
3) **Sensitivity to Operations**: Systems are not static and linear, but rather dynamic and nonlinear in nature. As a result, it becomes difficult to know how one area of the organization's operations will act compared to another part.
4) **Commitment to Resilience**: The organization must maintain function during high-demand events. Resilience has three components:
    i. Absorb strain and preserve function despite adversity.
    ii. Maintain the ability to return to service from untoward events.
    iii. Learn and grow from previous episodes.
5) **Deference to Expertise**: This includes deference downward to lower ranking members of the organization with greater emphasis on an assembly of knowledge, experience, learning and intuition rather than position in the organization. Credibility, a necessary component of expertise, is the mutual recognition of skill levels and legitimacy.[45, 46]

To build and support both resilience and responsiveness in plans, organizations are encouraged to tap into the learning generated from previous incidents (near misses are of great value),[47] improvement efforts and learning from multi-incident analyses.

IMMEDIATE RESPONSE

3.4 IMMEDIATE RESPONSE

Care for and support patient/family/providers/others

A patient safety incident can be a very traumatic experience for the patient(s) and provider(s) involved. Generally, the first action, after recognizing that an incident has occurred, is to care for and support the patient and the family, as well as ensuring the safety of other patients who may be at risk. Attending to the safety and well-being of the provider(s) involved and others is also a necessity.[4, 6]

Report incident

While each situation will be different and guided by individual organizational policies and practices, the next activity generally includes reporting the incident so that further steps can be taken to manage the incident. Organizations will have different approaches and practices for incident reporting. This typically involves completion of a paper or an electronic incident report form; however, incidents with a high potential for harm are often reported verbally as part of the immediate response. Reporting assists in understanding 'next steps' such as whether further investigation and analysis are needed, and/or whether additional resources and other actions, such as further notifications, are required. The applicable manager or other recipient of the report will, at a minimum, review the facts of the incident and gather any additional information to ensure a preliminary understanding of what happened. Any contributing factors identifiable at this point will also be documented.

Reporting is the trigger for a chain of internal notifications that, depending of the nature of the incident, will target individuals and/or units at different levels of the organization (e.g. attending physician, CEO, risk management committee, medical managers, health record staff, unit or program managers, public relations). External notifications may also be required to ensure alignment with regulations and to maintain the organization's reputation as per legislation, policy, protocols (e.g. coroner, Ministry of Health) and current context (e.g. media). Effective, timely and respectful internal and external communication can result in increased trust of all stakeholders, including the public. It is recommended that organizations develop internal guidelines for this purpose. Additional support can be found in the *Guidelines for Informing the Media after an Adverse Event*.[48] Communication internally and externally should be a continuous process that is maintained through the analysis phase and closes with sharing the learning.

Secure items

Any items related to the event need to be secured for testing and for review by the analysis team. They include, but are not limited to, biomedical equipment, IV solutions, medications, packaging, garments, etc. The items should be carefully labelled (including lot numbers and serial numbers in the event of a product recall or if further testing is needed) and placed in a designated location (or given to a designated person) where they are protected, secured and access is restricted. Photographs of the items and workspace may also prove helpful. Health records also need to be secured, and access to them should be controlled. The ward or unit typically receives a copy of the paper chart if the patient is receiving ongoing care.

HUMAN FACTORS TIP

During an analysis of an incident, it is helpful to gather materials such as equipment and any other materials used during or close to the time of the incident. Essentially, you want to look at anything that may have influenced the human-system interaction during the incident, and therefore a possible contributing factor. For instance, when examining a medication mix-up, you would want to have available and directly examine any or all of the following: the Medication Administration Record, the prescriber's order form, the medication vial or syringe and any labels, the IV pump, or other medical equipment used to deliver the medication. Look not just at the values that were written or entered, but also at the design of the materials or equipment to see if they may have been a source of confusion. Also, it may be helpful to review the organizational chart, shift schedule(s), room or floor layout, and measurements of the work environment, including room lighting or noise levels.

Begin the disclosure process

Representative(s) of the organization should begin the disclosure process with the patient and family as soon as possible. Disclosure is an ongoing process in which multiple "disclosure conversations" may occur over time, including an initial disclosure and a post-analysis disclosure. There are a variety of guidelines to assist in the disclosure process (roles, responsibilities, what to disclose, and how), such as the *Canadian Disclosure Guidelines*.[4]

Often practical support is needed and contacts should be provided to the patient/family and providers so that those who may have suffered emotionally and physically can receive early assistance. Disclosure, expressions of compassion and offering an apology are important elements of communication helping both patients/families and providers in healing and in restoring trusting relationships.[4]

Reduce risk of imminent recurrence

Local actions to reduce the risk of imminent recurrence may need to be taken immediately; additional actions typically follow after a more thorough analysis has been undertaken. Patients and families should be informed of immediate actions.

PREPARE FOR ANALYSIS

3.5 PREPARE FOR ANALYSIS

Preliminary investigation

In order to determine appropriate follow-up to an incident, including the need for analysis, an initial investigation or fact-finding is needed. The key outcome of this step will be a high-level timeline and documentation of known facts related to the incident. There will be organizational and jurisdictional variation as to the individual(s) responsible for the initial fact-finding and how this is incorporated into the organizational response to an incident. It is recommended that individuals responsible for this preliminary level of analysis and action be provided with education in incident analysis, including an introduction to human factors principles and other essential concepts (*Section 2*). They should also have access to organizational mechanisms/tools for the identification of key trends in incidents, including their contributing factors.

Once the initial investigation phase has been completed, a determination of next steps follows. In some cases, it will be clear that further system-based analysis is needed, while in others an accountability review or alternative quality improvement process may be more appropriate. See *Section 3.2* for guidance on when to conduct an incident analysis and the information immediately following for how to select an analysis method.

Select an analysis method

If based on the preliminary understanding of what happened (from incident report and initial review of facts) it is determined that an analysis is required (*Section 3.2*), then it is usually at this point that a method of analysis is determined. Three types of incident analysis are described in this framework: concise, comprehensive and multi-incident. Determination of the appropriate method is made using a range of criteria (*Section 3.6*). This decision is usually made jointly by the manager involved, together with the quality and safety lead(s), the clinical lead(s) and often senior leader(s), and others as defined in organizational policies and procedures. Each incident analysis method includes a systematic process to identify what, how and why it happened; what can be done to reduce the likelihood of recurrence and make care safer; and share learning. Assigning a person or a team who will be accountable for this work is usually the next step.

Identify the team and the team approach

Typically, a facilitator (with expertise in analysis) and a leader (with operational responsibility, who understands and supports analysis) share primary responsibility for conducting, coordinating and reporting on each analysis in accordance with applicable organizational policies. Decisions about the involvement and timing of involvement of various individuals are likely to vary from organization to organization and will be influenced by the incident context, as well as local culture and previous experience. In considering the involvement of various individuals, it is important to clearly define the roles and responsibilities of everyone who will participate in the analysis process.

Not all team members are required to be involved in all aspects of the analysis. For example, providers directly involved and patients/family members may participate in the information gathering stage and provide further input into solution development. Other direct care staff may participate in the actual analysis phase, or this may be undertaken by those directly involved. Senior leadership representatives may actively participate in the analysis or support the process at arm's length. Support and involvement of senior operational leaders in the analysis process helps to demonstrate a commitment to change at the highest levels of the organization and also helps to ensure that recommended actions are developed within the context of the broader organization. It is also useful to involve relevant external experts/consultants with specialized knowledge of the system undergoing analysis and/or the analytical process (especially for comprehensive analyses). For additional detail on team roles and management see *Appendix C*.

Analysis Team Membership

The analysis team is the group charged with incident analysis (**Appendix C**: Sample of Analysis Team Charter). Other individuals may be involved in the analysis process (e.g. through interviews, meetings, fact finding and/or consultations).

The team composition will vary depending on the incident and applicable legislative protection as well as on the organization's approach to analysis (e.g. one individual may conduct interviews and fact finding then bring the group together to confirm and get consensus on facts, contributing factors, recommended actions; or the entire process may be a team effort).

The success of the analysis depends on the involvement of those who provided care as well as of the patient/family. For a variety of reasons, which may include time needed to emotionally process what has happened or an immediate need to make care or funeral arrangements, the patient and/or family may not be ready and/or able to be involved in the analysis. Being respectful of the needs of the patient/family and keeping the lines of communication open may enable their participation at a later time. The same can be said of healthcare workers who were directly involved in the incident. However, it is essential that the patient/family and involved healthcare workers be part of the initial process of information gathering.

The key benefits are:

- An open and sincere partnership with all involved in the incident can result in healing relationships, regaining trust in each other and the system, and improving the well being of all participants.
- When the team comes together they may, and often do, discover new information not previously known by all members of the care team.
- Analysis is an invaluable method that permits those involved in an incident an opportunity to help reveal information that may lead to solutions to make care safer. This allows all involved to impact the system they work in and to take ownership of changes, rather than feeling that changes are forced upon them.

External, Internal or Mixed Teams

There are several types of analysis teams:

- External – all team members are from outside the organization.
- Internal – all members of the team are employed by the organization.
- Internal with external support – most are internal staff and a few are external.

Because the context and circumstances surrounding each incident are different, careful consideration should be given to all relevant factors before deciding on how to approach the analysis. It is important that organizations proactively develop a plan on how to approach analysis that will help teams respond quickly and effectively when an incident occurs.

Analyses involving internal teams working collaboratively with internal and/or external experts are beneficial to the culture of the organization as well as in rebuilding trust.

Coordinate meetings

It is common for a facilitator to collaborate with the analysis team leader to conduct background work and collect the necessary information for the analysis (e.g. health record, timeline, relevant policies and procedures, evidence based guidelines, etc.). The full analysis team is convened at a mutually agreeable date and time. It is recommended that all documentation provided to the team during meetings, including the sequence of events, be tracked and returned to the facilitator at the end of the analysis.

An experienced facilitator will be able to anticipate and manage issues that arise during the analysis process. Keys to success include providing a comfortable, private setting (ideally away from the care area where the incident occurred), setting "ground rules" for discussions and ensuring needed information is readily accessible.

Some suggested **ground rules** include the following:

- Respect for individuals;
- Respect for opinions expressed;
- Equal participation by all;
- Respect for the confidentiality of the discussions;
- Ask questions to clarify rather than challenging others; and
- Decisions by consensus.

Checklists provided for the team leader/facilitator (*Appendix A*) and for effective meetings with patients and families (*Appendix F*) can help leaders prepare for and manage meetings effectively.

The **principle of confidentiality** must be emphasized and maintained at all times during an analysis. Some organizations require team members to sign a confidentiality agreement prior to participating in an analysis (*Appendix E*). This agreement reinforces that information shared within the team is not to be transmitted or disclosed outside of the communication mechanisms stipulated by the Quality of Care Committee, applicable policies and/or legislation.

Plan for and conduct interviews

Interviews are key to collecting information for analysis and also help to support those directly involved in the incident. An interview is often the first opportunity that a patient, family member or healthcare provider has to share their detailed perspective about the incident. The interview process may cause anxiety and further distress; therefore, it is important to be respectful and supportive of those involved, and be clear about the purpose of the interview and what will be done with the information provided during the interview.

Interviews should be conducted as soon as reasonably possible after the incident for two reasons. First, memories fade quickly and important details may be lost over time. Second, as individuals involved in the incident discuss their recollections with one another, versions may blur together and the opportunity to obtain unique perspectives and details may be missed.

It is recommended that individual interviews occur with all staff involved in the incident as well as individual or group interviews with the patient and family members as appropriate. A cooperative approach is encouraged, using open-ended questions. Individuals should be asked to "tell their story" and possibly re-enact the incident or portions of the incident. If possible, 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 the questions and further clarification until the story has been told. It is helpful to ask individuals being interviewed if there are any factors that they think contributed to the incident (e.g. environmental factors such as lighting, noise levels, time of day, workload, etc.) as well as factors that they feel mitigated the outcome of the incident (e.g. "what went well").

It is important to record the interview in a comfortable way. Permission is needed to digitally record the interview. It should be noted that video or audio recordings tend to increase anxiety and are not generally recommended. It is preferred that interviews be conducted one person at a time so that individual perspectives about the incident are well understood for their nuances and unique points 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 are important to understanding the incident after the interview has been completed.

Finally, sincerely thank people for helping to provide an understanding of the incident and ensure that their questions about the process are answered before drawing the interview to a close.

ANALYSIS PROCESS

3.6 ANALYSIS PROCESS

3.6.1 Methods of Incident Analysis - Overview

In numerous consultations with patient safety experts and those engaged in incident analysis, it became clear that one method of incident analysis is not necessarily appropriate for all types of incidents. A literature review and environmental scan of analysis methods used in Canada and around the globe[10, 14] confirmed the emergence of a variety of methods for incident analysis in healthcare. Access to a broad range of methods is important for users, who can select the one most appropriate for their healthcare facility, context, skills, resources and type of incident. The methods included in this framework have been designed to be flexible to accommodate use in different care settings.

This framework offers two methods for analyzing individual incidents (*comprehensive* and *concise*) and one method for multiple incidents (*multi-incident*). All methods aim to determine what happened, how and why it happened, what can be done to reduce the risk of recurrence and make care safer and what was learned.

Regardless of the method used, the basic principles and steps in the analysis process are the same (*Figure 3.1*); however, the level of detail and the scope of the review will differ with each method. Below is a short description of each method, followed by guidance on how to select the appropriate method to analyse a particular incident or grouping of incidents.

Comprehensive analysis is usually used for complicated and complex incidents that resulted in catastrophic/major harm, or the significant risk thereof. Multiple sources of information are consulted, including interviews with those directly or indirectly involved in the incident as well as experts, supplemented by a literature review. A significant amount of time and resources (human and financial) can be invested to conduct the analysis. The final report produced will include a detailed chronology of the facts, contributing factors and their influences, findings from the literature search/environmental scan, context analysis, recommended actions, and where applicable, implementation, evaluation and dissemination plans. Members of the senior leadership of the organization need to be kept apprised of progress and may be directly involved in the process.

Concise analysis is a succinct, yet systematic way to analyze incidents with no, low or moderate severity of harm. Generally the incident and analysis process are localized to the unit/program where care was delivered. The sources of information consulted are the available reports, supplemented with a small number of select interviews and a targeted review of other sources of information. The analysis is completed in a short interval of time by one or two individuals. At the end of the analysis, a report is produced that contains the facts (including a brief timeline), contributing factors, a brief context analysis, and where applicable, recommended actions and a plan for evaluation and dissemination.

Multi-incident analysis is a method for reviewing several incidents at once instead of one by one, by grouping them in themes (in terms of composition or origin). Multi-incident analysis can be used for incidents that resulted in no, low or medium severity of harm as well as near misses that took place at any location in the organization (possibly in a short interval of time). It can also be used to review a group of comprehensive and/or concise analyses. This method of analysis can generate valuable organizational and/or system-wide learning that cannot be obtained through the other methods.

Multi-patient incidents – guidelines for analysis
When the outcome of an incident impacts more than one patient (e.g. incorrect equipment sterilization for an interval of time) the decision on which analysis method is the most appropriate should be made on a case-by-case basis.

3.6.2 Selecting a Method of Incident Analysis

When selecting a method to analyze incidents, consider a number of criteria including: severity of the incident, probability of recurrence, complexity of the factors that appear to have influenced the incident, extent of the impact of the incident on the organization (unit, organization or system), as well as other contextual factors (initial findings, frequency of occurrence, regulatory mandates, internal or external pressures). In the case of near misses or incidents where the outcome is not known at the time of the investigation, the worst possible outcome should be considered. Additionally, factors such as incident analysis skills and limited resources available to analysis teams require consideration. These criteria are summarized in *Figure 3.3*. See *Section 2.2* for descriptions of complexity, area of impact and context.

Figure 3.3: CRITERIA TO CONSIDER IN SELECTING AN INCIDENT ANALYSIS METHOD

CRITERIA	COMPREHENSIVE	CONCISE	MULTI-INCIDENT
Safety Assessment Score (severity and probability) (see *Figure 3.4*)	3 and some 2	1 and some 2	1, 2 and 3
Complexity Level (degree of agreement, certainty, number of interactions)	Complicated, Complex	Simple, Complicated	Simple, Complicated or Complex
Area of Impact	Team, Unit/Program, Organization, System	Team, Unit/Program, Possible Organization	Team, Unit/Program, Organization, System, Sector, Industry
Context – Internal and External Pressures	High	Low	Low, Medium or High
Resources Required/ Available (time, financial, human)	Moderate to Extensive	Limited	Moderate to Extensive
Timelines	Weeks to Months	Hours to Days	Variable

The severity of the incident should not be the only criteria for selecting an analysis method because there are situations where an incident with a high safety assessment score may be more appropriately analyzed with a concise analysis and other situations where an incident with a low score requires a comprehensive analysis.

Safety assessment score

The US Veterans Affairs Safety Assessment Code[37] is one of many incident stratification tools that link the severity of the patient safety incident with its probability of recurrence. The tool applies to all incidents (harmful, no harm and near misses).

"Key factors for the severity categories are extent of injury, length of stay, level of care required for remedy and actual or estimated physical plant costs. For harmful and no harm incidents, assign severity based on the patient's actual condition. If the event is a near miss, assign severity based on a reasonable "worst case" systems level scenario. For example, if you entered a patient's room before they were able to complete a lethal suicide attempt, the event is catastrophic, because the reasonable "worst case" is death of the patient.

In order to assign a probability rating, it is ideal to know how often it occurs at your facility. Sometimes the data will be easily available because they are routinely tracked (e.g. falls with injury, adverse drug events, etc.). Sometimes, getting a feel for the probability of events that are not routinely tracked will mean asking for a quick or informal opinion from staff most familiar with those events. At times it will have to be your best educated guess."[37]

Figure 3.4: UNITED STATES VETERANS AFFAIRS SAFETY ASSESSMENT CODE MATRIX [37]

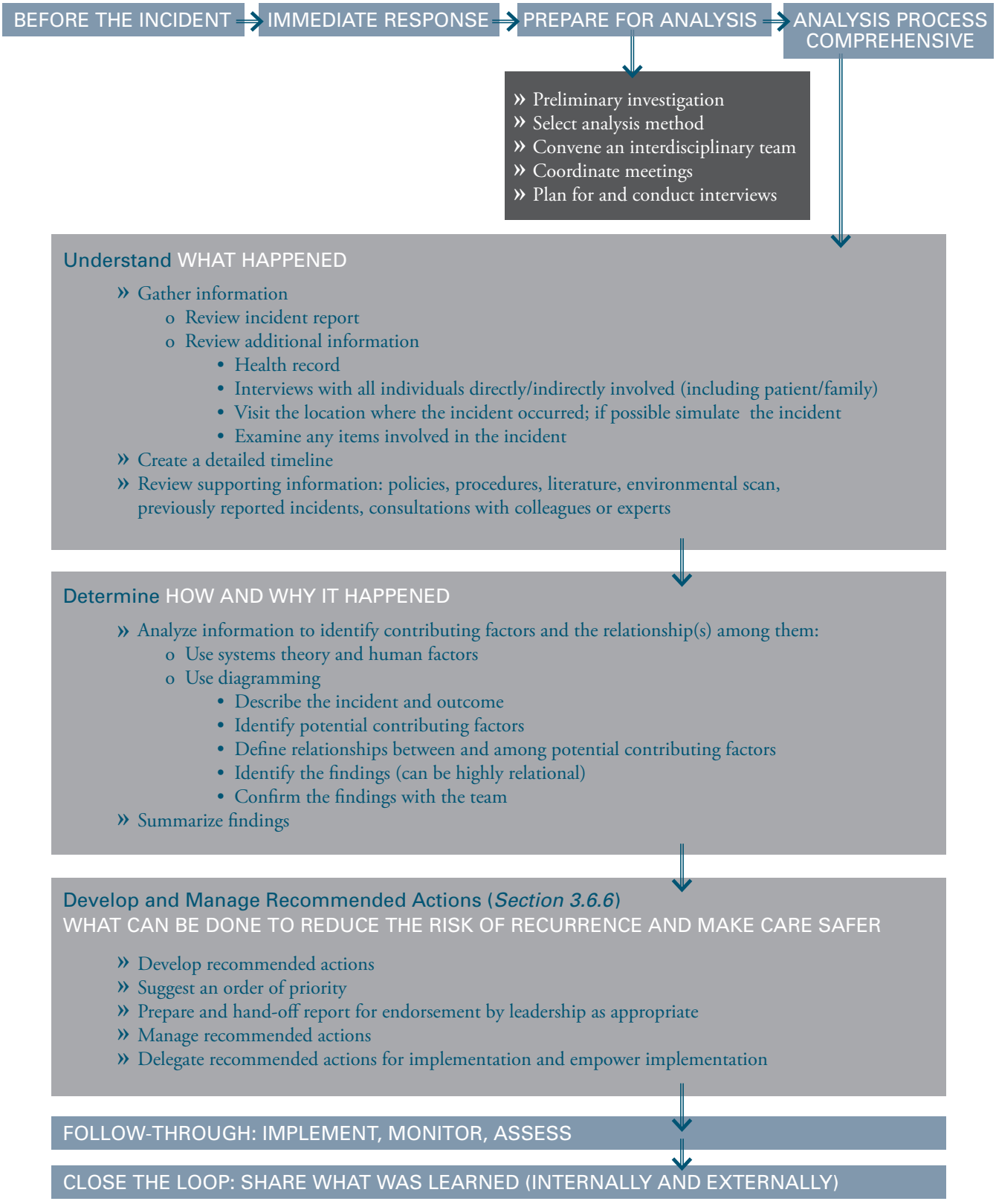
SEVERITY / PROBABILITY	CATASTROPHIC	MAJOR	MODERATE	MINOR
Frequent	3	3	2	1
Occasional	3	2	1	1
Uncommon	3	2	1	1
Remote	3	2	1	1

It is important to note that the analysis methods presented here are not mutually exclusive. For example, contributing factors derived during a concise incident analysis could also be the foundation for a comprehensive or multi-incident analysis. In the event that a comprehensive analysis was recently conducted and a new similar incident occurs, a concise incident analysis may be sufficient to determine if any new contributing factors need to be addressed.

COMPREHENSIVE ANALYSIS

CANADIAN INCIDENT
ANALYSIS FRAMEWORK

3.6.3 Comprehensive Analysis



Introduction

A detailed, or comprehensive, analysis of a single incident is generally undertaken when permanent harm or death has occurred (or a significant risk thereof), the incident is complicated or complex, the area impacted is at micro, meso, or macro level, and/or the contextual pressures are high. See *Appendix J* for a case study using the comprehensive method.

Steps in Conducting a Comprehensive Analysis

WHAT HAPPENED

Gather information

The team's first priority is to gather information relevant to the incident. This stage of the process is intended to answer the "What happened?" question and will begin to elucidate how the incident occurred. The importance of a thorough "investigation" phase cannot be over-emphasized. The team cannot proceed to understand the contributing factors related to the incident if they do not have a clear understanding of the circumstances surrounding the incident. A systematic process for assessing information needs and gathering information will help to ensure that the analysis is both thorough and credible (*Section 2.3*). It may be helpful for organizations to develop a template or checklist to help the facilitator prepare information for review by the team.

Review incident report

The incident report is typically the first formal summary of information related to an incident and is based on an initial understanding of the facts. Review of information provided in the incident report will direct the preliminary investigative approach. Other sources of information that may trigger the initiation of a comprehensive analysis include patient concerns, information identified with the use of trigger tools, audits, attention from the media/general public or coroner's reports.

Review additional information

In addition to reviewing the health record in detail, it is important to interview all providers and others who were directly or indirectly involved in the incident, including the patient and family (*Section 3.5*). Where possible, it is recommended that the team visit the location where the incident occurred; when a physical visit is not possible, photographs and videos are recommended. During the visit important details or other contributing factors that people did not remember or did not recognize as important can be identified. Items that may have been involved in the incident (e.g. syringes, labels, devices, medications) need to be secured at the time the incident is identified. If the original items are not available, the team should be given access to the appropriate items to assist them to understand what happened, and how and why it happened.

Create a detailed timeline

When all the information is gathered and reviewed, the team should be able to fill in identified gaps in the initial understanding of the incident provided by the incident report or other triggering mechanism, and then create a detailed timeline. It is common to provide this information in the form of a narrative chronological description (see case study examples, *Appendices J* and *K*). The detailed understanding will collate information from various sources, including the health record and interviews with key individuals. As the care of the patient after the incident may be relevant to mitigation of harm from the incident, it is appropriate to include details related to patient management once the incident was discovered.

Because the team will use the detailed timeline as a starting point for identifying system-based factors underlying the incident, it is crucial that the timeline include only the actual facts or processes as they occurred, and not what was supposed to happen. The detailed understanding of the incident is always different from the initial information available, reinforcing the importance of fully investigating the circumstances of an incident designated for comprehensive analysis.

Review supporting information

An incident analysis should prompt the team to review existing *policies and procedures*. This is important for two reasons. Firstly, it establishes the documented organizational expectations related to care; and secondly, it provides a baseline to evaluate current organizational practices in relation to current evidence and leading practice guidelines.

An *environmental scan* of current practices in similar organizations and a literature review (scope will vary depending on the incident) will help to provide context for the incident as well as determine if there *are any leading practices or evidence-based guidelines* relevant to the incident.

Previously reported similar incidents or near misses reported internally or by other organizations may also be identified. Incident descriptions and information about actions taken and challenges encountered by other organizations that have dealt with similar issues can assist the team in understanding contributing factors and developing recommended actions. *The Global Patient Safety Alerts* repository[13] is one great resource.

Sometimes, unique incidents have no literature citations available; in these cases, *consultation with colleagues* or experts in the same field may help to determine if the issue in question has been previously observed in everyday practice, but not published.

HOW AND WHY IT HAPPENED

Analyze information to identify contributing factors and relationships

As the team begins to understand the incident circumstances, contributing factors and relationships will begin to emerge. A series of investigative categories and "Guiding Questions" (*Appendix G*) have been adapted from work by international experts in incident analysis[37, 49, 50, 51] to provide a starting point for analysis and assist teams to ensure all relevant aspects of the incident have been reviewed in detail during the interviews and the investigation phase. This portion of the analysis is about answering the "how and why it happened?" question.

The focus at this point is to recognize all system issues that may have contributed to the incident. While it is human nature to identify factors at the intersection between the patient and provider (e.g. the micro level), the goal of the analysis is to move the team towards the meso, macro and mega levels of the system (e.g. processes, policies, environment) to ensure all the contributing factors are identified.

During this phase of the analysis, the team will need to ask questions such as, *"What was this influenced by?"* and *"What else affected the circumstances?"* The team will use the detailed timeline of the incident, supported by the principles of systems and human factors theory, to answer these questions in order to identify the contributing factors.

Use systems theory and human factors

Applying systems theory and the principles of human factors can assist in answering the above questions by focusing the analysis on the systems-based contributing factors. In particular, human factors provide the tools, methods and theories to approach these questions. The goal when applying human factors is to focus not just on the human or the system alone, but rather the interaction between the human and the system, and to look for the factors that influence that interaction. These influencing factors may be related to the equipment, task and work environment, in addition to inherent human characteristics and limitations.

Various human factors methods can be employed at this stage of the analysis process to help answer the question, "How and why it happened?" They range in complexity, time and resources needed, and expertise/experience in human factors required. Three methods are described in *Appendix N*: cognitive walkthrough, heuristic evaluation and usability testing. All three methods assist in examining the human-system interaction in detail. With **cognitive walkthrough**, perhaps the easiest and most cost-effective method to employ, participants are asked to "think out loud" while simulating the tasks that were involved in the incident. In a **heuristic evaluation**, an audit is carried out on the various parts of the systems (such as equipment, paper forms, computer systems) that were used in the tasks that were part of the incident. The audit is used to determine if human factors design principles were violated, and thus may be identified as possible contributing factors in the incident. Heuristic evaluation requires an understanding of human factors principles as they apply to different systems (e.g. computer systems). **Usability testing** provides an observation of the human-system interaction with equipment, paperwork, or processes (similar to a simulation). Participants are asked to carry out a set of tasks in a simulated environment and given the scenario as it occurred during the incident. Some level of human factors training is needed in order to plan and execute usability tests, and to interpret the results. If done correctly, the usability test provides important information about how the human-system interaction occurs in a 'real world' setting.

Use diagramming

One tool that can help the team work through the questioning process is the use of diagramming. Diagrams can help teams to identify and understand the inter-relationships between and among contributing factors. Diagramming shifts the focus away from individual performance, toward system performance and underlying factors, helping to clarify team understanding and ensuring a thorough analysis of the incident.

Ishikawa (also called "fishbone")[52] (*Figure 3.5*) and "tree"[53] diagrams (*Figure 3.6*) are utilized to support analysis; however, both these types of diagrams have limitations. Ishikawa diagrams are helpful for brainstorming and clustering factors, but do not easily illustrate complex relationships between factors. Tree diagrams have been perceived as too "linear" and their top-down approach can be misleading in terms of relative importance of identified contributing factors.

Figure 3.5: ISHIKAWA DIAGRAM

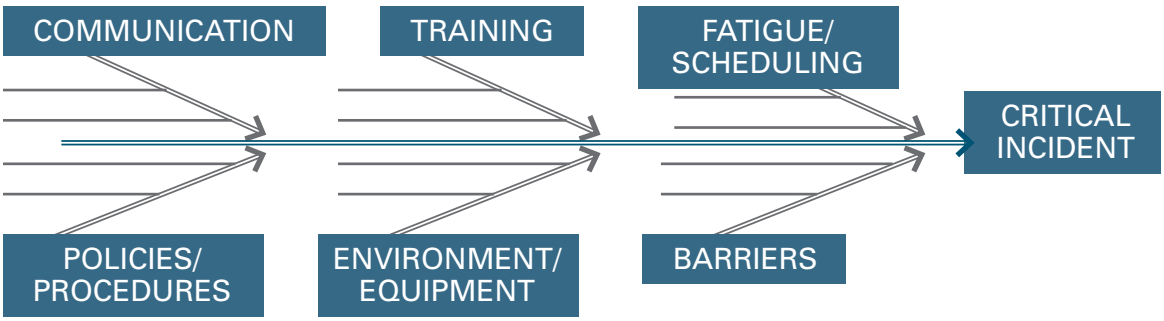
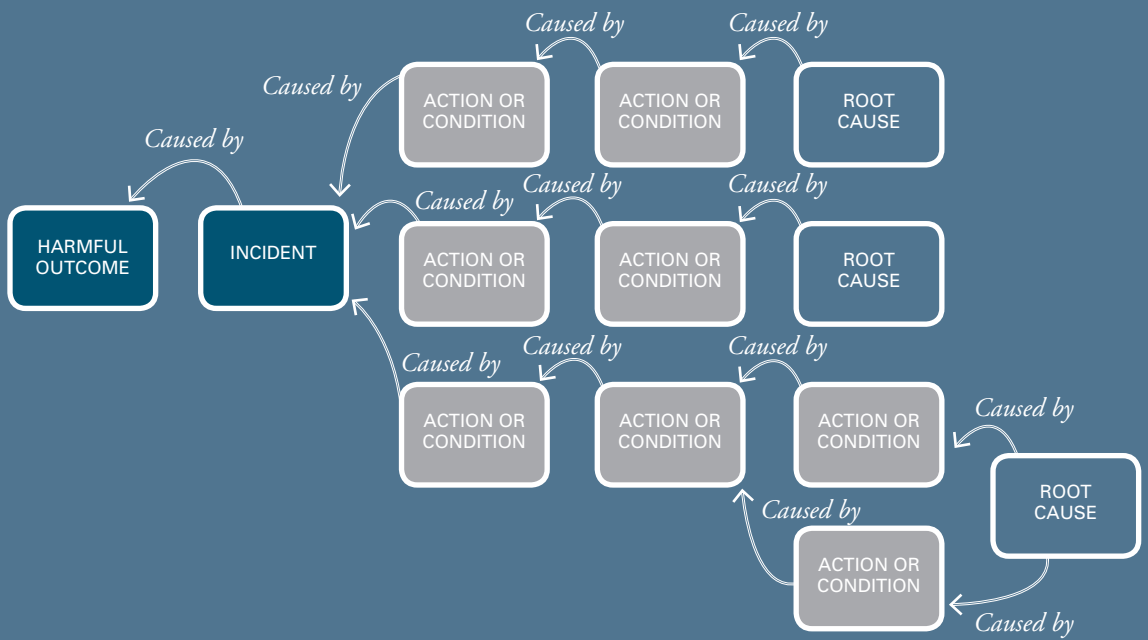
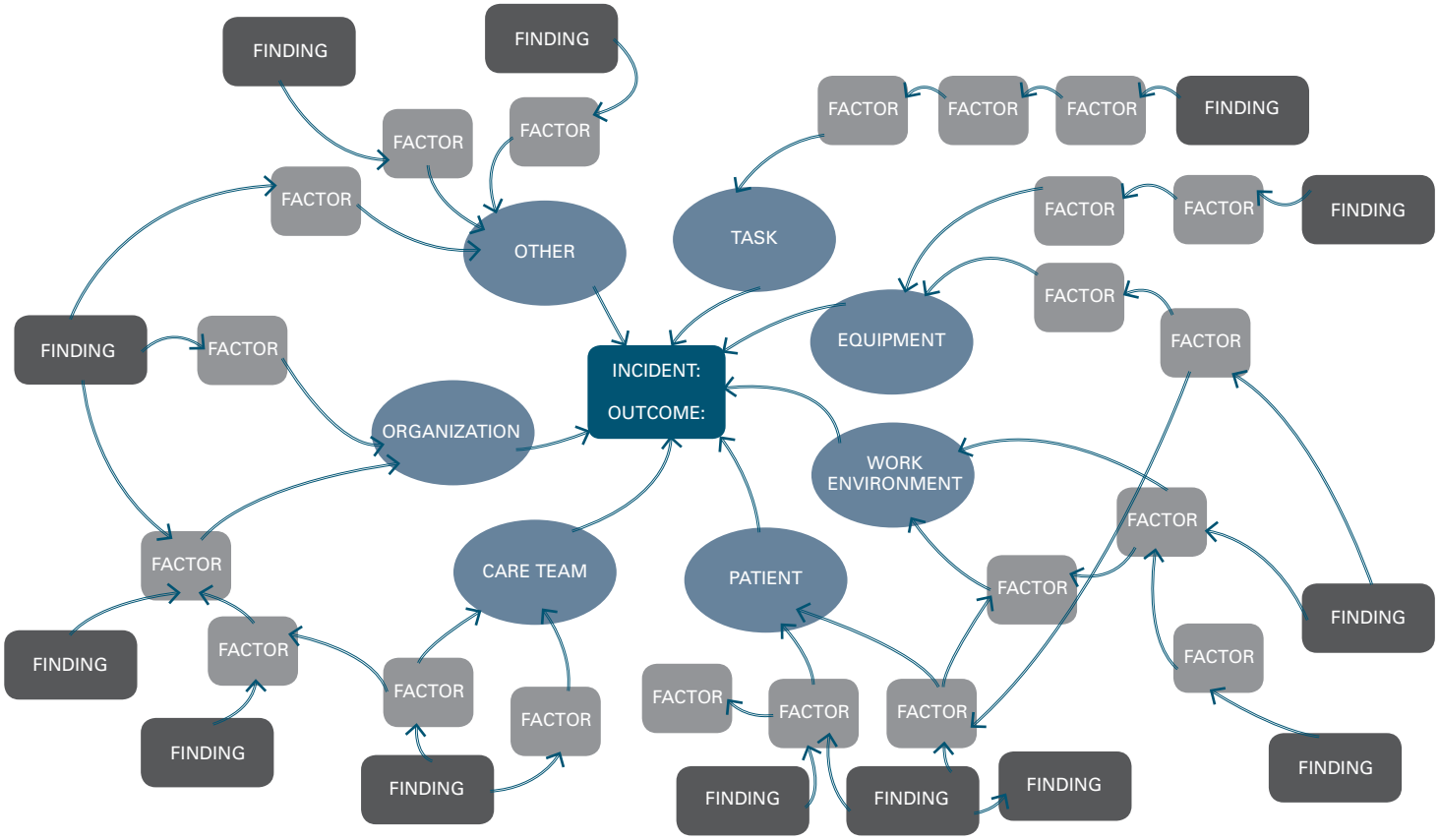


Figure 3.6: TREE DIAGRAM



To attempt to address the advantages and limitations of these two types of diagrams, the features of each were blended into an innovative diagram that evolved from the fishbone and tree diagrams into what we have called a *constellation diagram*, illustrated in *Figure 3.7*.

Figure 3.7: EXAMPLE OF A CONSTELLATION DIAGRAM



Additional details and instructions for developing a constellation diagram are provided in *Appendix H*.

Regardless of the type of diagram used to support incident analysis, the basic steps will be similar: describe the incident, identify potential contributing factors, define inter-relationships between and among potential contributing factors, identify the findings and confirm the findings with the team.

Summarize findings

Once the team has completed the analysis, a summary of what was found is prepared to clearly articulate the contributing factors related to the incident and provide the backbone for development of recommended actions. This summary is provided as a series of "statements of findings". (For those familiar with the previous RCA Framework, the statements of findings have been adapted from the previous "causal statements".)[7]

Considerations When Writing Statements of Findings

Formulation of the statements may be assigned to a sub-group of the analysis team and reviewed with the full team at a subsequent meeting. Another approach is to develop draft statements at a team meeting, which are subsequently finalized by the facilitator and clinical lead.

The statements of findings describe the relationships between the contributing factors and the incident and/or outcome. The statements focus on the contributing factors and should be as specific as possible (note that there could be a group of factors that together contributed to the incident or outcome).

The suggested statement format is as follows: *The contributing factor(s), within the context of the incident, increased/decreased the likelihood that this outcome would occur.*

A well-constructed constellation diagram will assist in the development of summary statements, working from the outside of the diagram back towards the centre. Examples of summary statements can be found in the case examples in *Appendices J* and *K*.

WHAT CAN BE DONE TO REDUCE THE RISK OF RECURRENCE AND MAKE CARE SAFER?

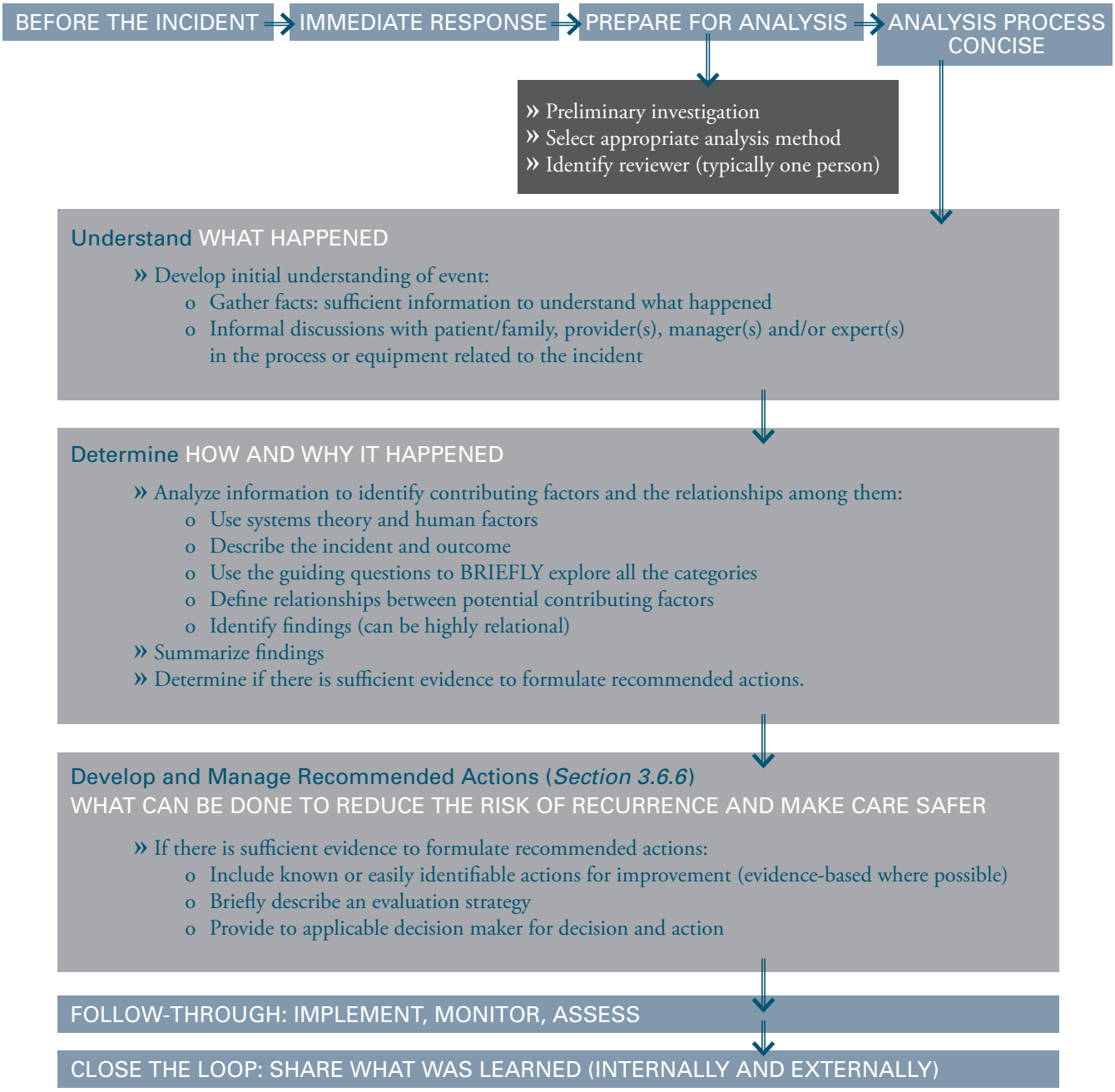
The ultimate goal of incident analysis is to take action to reduce the risk of recurrence and make care safer. Step-by-step guidance on developing and managing recommended actions is provided in *Section 3.6.6*.

WHAT WAS LEARNED

Despite the best efforts of healthcare providers across the healthcare continuum, patient safety incidents continue to occur. Additional attention is needed to identify learning from incidents within and outside individual practice settings and to sharing learning so others can take appropriate steps to provide safeguards in their own settings. *Section 3.8* provides guidance on continuous organizational learning and sharing results.

CONCISE ANALYSIS

3.6.4 Concise Incident Analysis



Introduction

Given the complexity of the healthcare environment and the significant resources required for comprehensive incident analysis, healthcare leaders and patient safety experts have begun to look for a more "concise" method of incident analysis to help meet the need for timely and accurate action on a larger number of incidents. For example, one long-term care facility implemented "mini-RCAs", an abbreviated version of the formal analysis process, when there was not enough time to do a full RCA each time a resident experienced a fall.[54] In 2008, the National Patient Safety Agency (United Kingdom) also recognized that various levels of investigation were appropriate and issued a root cause analysis tool with guidance on three levels: concise, comprehensive and independent.[55] Other abbreviated incident analysis methodologies have emerged as case conferences, also known as modified Morbidity and Mortality (M and M) rounds,[56] or unit-based safety programs.[50]

A concise incident analysis is consistent with the principles and methodology of incident analysis including a systems approach and consideration of human factors. A conscious and deliberate decision has been made to focus primarily on four aspects: the agreed-upon facts, key contributing factors and findings, actions for improvement (if any), and evaluation. See *Figure 3.8* for comparing the characteristics of concise and comprehensive incident analysis and see *Appendix K* for a case study using the concise method.

If, at any point during the concise analysis review, the facilitator feels that the investigation should be escalated to comprehensive, they should do so.

Concise approach

A concise approach is most commonly used for incidents or concerns that resulted in no or low harm to the patient. It may also focus on a new incident for which a comprehensive analysis was recently completed. Other incident analysis tools may not be used or may be used in a limited way (e.g. timeline, Ishikawa diagram, etc.).

Figure 3.8: CHARACTERISTICS OF CONCISE AND COMPREHENSIVE INCIDENT ANALYSIS[9]

CHARACTERISTIC	CONCISE	COMPREHENSIVE
Should include person(s) with knowledge of incident analysis, human factors and effective solutions development	√	√
Often facilitated by an individual with input gathered from the patient, family, staff and physicians local to the incident as organizational or external experts	√	
Conducted by an inter-disciplinary medium to large ad hoc group (may include patients, family members, staff and physicians local to the incident as well as recognized independent internal or external experts*/ consultants not involved in the incident) * External experts – experts who are external to the event but not necessarily *external to the participating organization*		√
Time taken for analysis	Short timeline (hours to days)	Longer timeline (up to 90 days)
Identifies contributing factors as well as remedial action(s) taken (if any)	√ (focus on key factors)	√
Recommendations for improvement	√ (if applicable)	√
Principles of incident analysis	Reflects the intent but may not address all	Incorporates all principles
Evaluation strategy	√ (if applicable)	√

Concise analysis is typically done by one person (facilitator) with knowledge and skill in incident analysis, human factors and effective solution development. The facilitator usually gains this expertise through a variety of formal education programs and mentored experience. The individual may be a healthcare provider and/or other process expert; however, not necessarily a risk manager or quality improvement consultant.

Steps in Conducting a Concise Analysis

WHAT HAPPENED

Obtain sufficient information to understand what happened in order to understand how and why it happened. The reviewer may have informal discussions with the patient, family member(s), healthcare provider(s), manager and/or expert(s) in the process(es) and examine the equipment involved in the incident.

HOW AND WHY IT HAPPENED

- Review the guiding questions to BRIEFLY explore all categories, being mindful to move away from the patient-provider interface to system levels in order to identify chains of contributing factors (*Appendix G*).
- Select some of the guiding questions or develop unique incident specific questions to informally discuss the incident with a few individuals (this may include the patient, family member, staff and/or physicians local to the incident as well as organizational or external experts).
- A constellation diagram may be used to facilitate a systematic approach. The process of developing a constellation diagram is intended to assist in the building of a visual representation of the incident and the system contributing factors. It is also possible to identify mitigating factors that prevented the incident from being more significant. See *Appendix H* for an explanation of the constellation diagram.
- Once all of the contributing factors have been identified it is appropriate to try to understand how these factors are clustered/linked with one another given that all incidents generally result from a cascade of events rather than an isolated contributing factor.
- Once the clusters/linkages are completed it is appropriate to transition to describing the findings and the development of recommendations, if appropriate, to make care safer for future patients in similar circumstances.
- Identify the key contributing factors that contributed to the outcome by asking why and how they are related.

It is helpful to document key factual information in the form of a high-level timeline or narrative description.

WHAT CAN BE DONE TO REDUCE THE RISK OF RECURRENCE AND MAKE CARE SAFER?

Summarize findings and determine if there is sufficient data to develop recommended actions. Are there known or easily identifiable evidence-based actions for improvement?

- If no, is there sufficient knowledge and expertise to develop local solutions for testing, evaluation and formalization?
- If yes, proceed with formalizing recommended actions and consult with the applicable decision maker for decision and action. See *Section 3.6.6* for additional information on developing and managing recommended actions.

The facilitator or other person(s) designated by the organization formalizes the action plan and ensures that an evaluation strategy is in place to determine if recommendations were implemented and sustained, as well as if there was any known impact to the safety of patients within the targeted care process(es).

Determine if a multi-incident analysis is required to effectively understand the applicable risks to patients (*Section 3.6.5*).

Track and document all key decisions and the action plan/evaluation strategy if applicable.

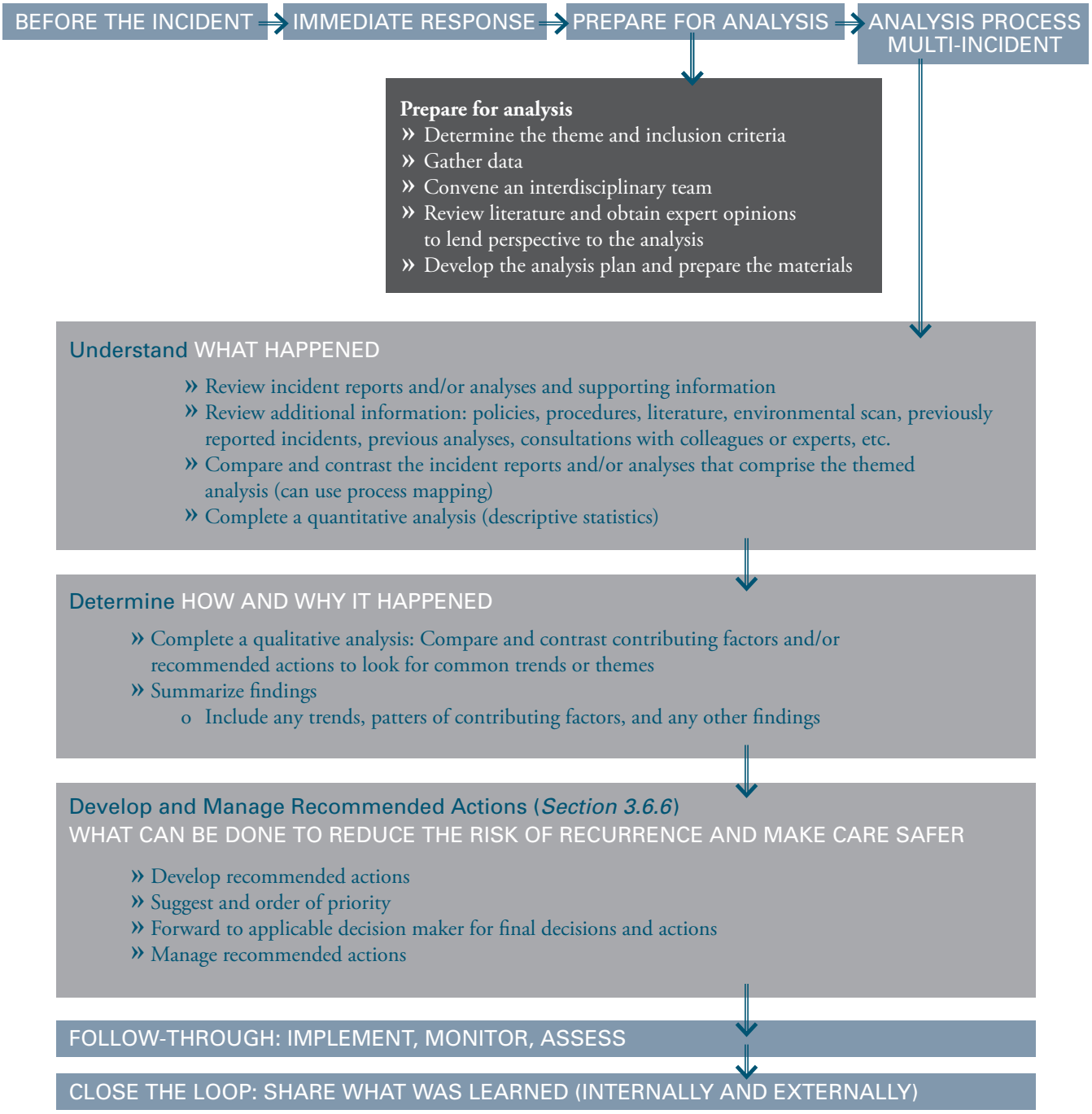
WHAT WAS LEARNED

Concise analysis can contribute important knowledge regarding a larger number of incidents and their contributing factors. The general lessons should be disseminated and findings and/or recommended actions should flow into the higher organizational level for prioritization of risks and actions for improvement within the organization.

MULTI-INCIDENT ANALYSES

CANADIAN INCIDENT
ANALYSIS FRAMEWORK

3.6.5 Multi-Incident Analyses



Introduction

In addition to individual incident analyses (comprehensive and concise), many healthcare organizations also require a methodology for analyzing multiple incidents that are identified by a particular theme. For example:

- A group of individual patient safety incidents, similar in composition and/or origin that caused no harm or lesser degrees of harm.
- A group of individual patient safety incidents that are similar in composition and/or origin that may have caused varying degrees of harm (no harm to catastrophic/major harm).
- A group of patients that are impacted by a similar contributing factor(s), and who experience the same harmful incident (to greater or lesser degrees).
- A group of completed comprehensive and/or concise incident analyses.

For the purpose of this framework, an analysis of multiple incidents is called "multi-incident analysis". Alternate terms used in the literature for this type of analysis include cluster, aggregate and meta-analysis. Common features of any multi-incident analysis include:

- Pre-defined theme or scope;
- Involvement of an interdisciplinary team including frontline providers and possibly a patient representative; and
- Use of quantitative and qualitative methodologies.

A benefit of multi-incident analyses is they have the potential to reveal trends or patterns of contributing factors that were not previously perceptible. These analyses can also reveal previous recommended actions that were or were not effective. Below are examples that describe various types of multi-incident analyses and the methodology for conducting such analyses.

Example 1: A group of low and no harm incidents or near misses that have not been analyzed
Most Canadian healthcare organizations have reporting systems in place for staff and physicians to report incidents that may have caused no harm or lesser degrees of harm. Although it is generally agreed that these incidents are valuable learning opportunities, in the absence of significant patient harm they are, too frequently, filed away with little or no review. In particular, when multiple no or low harm incidents are analyzed as a group, they have the potential to reveal trends or patterns of contributing factors that may not be identifiable by looking at a single incident. If actions are identified and taken as a result of the analysis, future incidents might be avoided.

This type of analysis would include three or more no harm, low harm and near miss incidents that have not previously been analyzed as a part of a patient safety incident analysis. For example, an analysis of 15 falls or near falls that identified common patterns of contributing factors and safety deficiencies was conducted by Zecevic A. et al and published in the Gerontologist in 2009.[57]

Example 2: A group of incidents that are similar in composition and/or origin that may have caused varying degrees of harm (no harm to catastrophic/major harm)
Some healthcare organizations may decide to analyse multiple incidents involving a predefined theme or criteria. The patient outcome of these incidents may be varied – from no harm to catastrophic/major harm. For example: all falls occurring in an in-patient acute care unit during a six month period, including eight incidents that were low harm and not analyzed and one event where there was severe patient harm and a comprehensive patient safety incident where analysis was previously conducted.

This type of analysis would include three or more near miss, no harm, low harm, or significant harm incidents occurring within a defined period of time or location. As noted above, one or more of these may have been previously analyzed using a comprehensive or concise analysis methodology.

The scope of these analyses can extend beyond organizational boundaries and jurisdictions. The Institute for Safe Medication Practices Canada (ISMP Canada) has prepared medication incident analyses using a variety of themes including the medication type, stages of the medication use process (e.g. prescribing, ordering processing, dispensing, administration, monitoring), and medication use settings (e.g. OR, ER, ICU) or subset(s) of the healthcare segment (e.g. outpatient clinics, nursing homes).

Figure 3.8: EXAMPLES OF THEMED MULTI-INCIDENT ANALYSES PUBLISHED BY ISMP CANADA [58]

- *Analysis of International Findings from Incidents Involving Fentanyl Transdermal, 2009; 9(10)*
- *Top Five Drugs Reported as Causing Harm through Medication Error in Paediatrics, 2009; 9(6)*
- *Analysis of a Cluster of Medication Incidents in Community Pharmacy, 2008; 8(8)*
- *Shared Learning – Reported Incidents Involving Hydromorphone; 2006; 6(9)*
- *Top 10 Drugs Reported as Causing Harm through Medication Error; 2006; 6(1)*

Example 3: A group of patients that are impacted by a similar contributing factor(s), who experience the same harmful incident (to greater or lesser degrees)
In recent years, Canadian jurisdictions have been alerted to situations whereby many patients experienced a similar harmful outcome that seem to be the result of similar contributing factors.

The theme of this type of analysis is a common outcome that impacted multiple patients. Although the contributing factors may be complex and unique to each incident, learning can be achieved by analyzing these multi-patient incidents. For example: medical imaging and pathology errors have impacted many Canadians in more than one province. Through multi-patient incident analyses, frailties in healthcare systems have been revealed and improvement strategies implemented. Recent examples that have received media attention

include: BC Patient Safety and Quality Council: *Investigation into Medical Imaging, Credentialing and Quality Assurance* (2011)[62], and Health Quality Council of Alberta: *Investigation into Medical Imaging, Credentialing and Quality Assurance* (2010).[63]

Example 4: A group of completed comprehensive and/or concise incident analyses
Organizations that conduct analysis of individual patient safety incidents will accumulate a rich source of information regarding identified risks, contributing factors and action plans to reduce these risks for patients. Organizations are encouraged to develop and utilize a management system to coordinate the learning and ensure what is learned about the health system is not lost or forgotten.

An analysis of multiple comprehensive and/or concise event analyses[9, 13, 37] is not unlike an aggregate or epidemiologic meta-analysis, although it does not have as precise a scientific and statistical methodology associated with it. This analysis consists of a group of completed reviews conducted on similar types of incidents. An illustration of this type of analysis is available from Queensland Health, Australia.[64]

Ideally an organization will employ a management system to coordinate the identification of overarching themes related to multiple incidents that have been analyzed. The overarching themes may include types of incidents analyzed, contributing factors identified and action plans to reduce harm to patients. For instance, there may be a number of recommended actions made by reviewers that identify the need for improved teamwork and/or communication. This may in turn lead to the design of a strategic improvement priority for the organization with designation of appropriate resources to support the effort.

Steps in Conducting a Multi-Incident Analysis:

Prepare for analysis

- Determine the theme and inclusion criteria (e.g. identify the characteristics of no or low harm incidents to be analyzed [no harm to catastrophic harm] or multi-patient incidents, or identify a theme for multiple completed analyses to be reviewed).
- Gather applicable data:
    - If applicable, conduct interviews with provider(s), patients/families, and others with knowledge of the incidents and/or care processes involved in the incidents.
- Review literature and obtain expert opinions to collect additional background and contextual information and lend perspective to the analysis:
    - Review other reporting and learning systems (such as the *Global Patient Safety Alerts*[13]) to see if similar incidents have been studied by other organizations.
- Develop the analysis plan, which will include both qualitative and quantitative analysis elements.

WHAT HAPPENED

Review the patient safety incidents and/or previous comprehensive and concise analyses to look for common trends, patterns and issues. This will include comparing and contrasting timelines, contributing factors, and recommended actions from previous incident analyses. Process mapping, a tool frequently used to support Failure Mode and Effects Analysis (FMEA)[59, 60] and Lean®[61] improvement methodology can also be used to support the identification of system weaknesses when conducting an analysis of multiple incidents.

Note the frequency of system issues or failure points and if applicable, recommended actions. This is the quantitative portion of the analysis and will include classifications such as: severity of harm, type of incident, patient diagnosis, etc.

HOW AND WHY IT HAPPENED

The qualitative analysis involves focusing on the identified contributing factors as well as similarities that may not have been apparent through an individual incident review. Narrative descriptions are particularly helpful for this portion of the review. As common patterns are identified, the team may need to further sub-categorize to clarify trends or issues.

When a group of comprehensive and/or concise analyses are reviewed both the contributing factors and the recommended actions may be included in the qualitative analysis.

Summarize findings including contributing factors and previously recommended actions that may lead to system improvement. Include any trends, patterns of contributing factors, and any other findings.

WHAT CAN BE DONE TO REDUCE THE RISK OF RECURRENCE AND MAKE CARE SAFER?

Develop recommended actions that will lead to system improvement, giving consideration to available supporting information, including evidence-based guidelines and leading practices. Identify both short term and long-term strategies. See *Section 3.6.6* for guidance in building effective recommended actions to reduce risk.

It is helpful for the team to consider a measurement and evaluation strategy before forwarding recommended actions to applicable decision makers for final decisions and delegation for implementation.

WHAT WAS LEARNED

The findings (contributing factors, trends and themes), recommended actions and their outcomes should flow into and be coordinated with the organization's risk management and improvement processes, including processes for communicating and sharing learning.

RECOMMENDED ACTIONS

3.6.6 Developing and Managing Recommended Actions

Developing and managing recommended actions involves a series of activities at several levels of the organization aimed to determine, "What can be done to reduce the risk of recurrence and make care safer?" The success of the recommended actions is dependent on the quality of findings identified in the previous analysis step (how and why it happened). It is important to consider that a few well thought out high-leverage recommendations will ultimately be more effective than a lengthy list of low impact actions. Note that in rare instances, analyses may not generate any new recommended actions (in particular, concise analyses).

Develop Recommended Actions

The analysis team has a foundational role in the development of recommended actions. Findings identified in the previous analysis step (how and why it happened) are reviewed by the team and actions proposed to address the contributing factors that allowed the incident to occur. Use of analysis diagrams (like the constellation diagram) supports teams in evaluating the best leverage points for recommended actions. The analysis team is generally responsible for proposing recommended actions, suggesting an order of priority, and consulting with others before the analysis report is handed off to those responsible for validating and implementing the actions.

Key features of effective recommended actions
Healthcare leaders and those involved in analysis in Canadian healthcare organizations expressed the need for a tool to help build more robust and precise recommended actions. The list of key features presented below, is a guide that can be adapted by teams and used locally. Effective recommended actions:

- Address the risk associated with the findings identified during the analysis.
- Utilize the most effective solution that is reasonable or possible given the circumstances (*Figure 3.9*).[65]
- Offer a long-term solution to the problem.
- Are written using the "SMART"[66] format:
    - Specific – tackle a clearly defined issue and have a clear scope;
    - Measurable – can demonstrate impact on process and outcomes;
    - Attainable – can be achieved with available resources;
    - Realistic – do a reality check to predict if it will be accepted, implemented; and
    - Timely – have a timeframe for implementation.
- Target the actions at the right level of the system and ensure the action is appropriate for that level (see *Section 2.2* for a description of system levels). If, for example, in a medication error incident one of the recommendations is to change the label design, the responsibility for implementation lies outside the organization where the incident occurred, making this a national or international effort.
- Assign responsibility at the appropriate level in the organization.
- Have a greater positive than negative impact on other processes, resources and schedules (balancing measures should be in place to ensure that unintended consequences are known and understood).

- Are based on evidence that shows the impact of this or similar action. Consider research literature, similar recommendations implemented in the organization (e.g. from accreditation, patient complaints) or externally (e.g. from the *Global Patient Safety Alerts*).[13] Aim to use 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).[67, 68]
- Provide enough context (explanation, facts) to ensure that if the action is implemented, those responsible will understand the rationale behind it.

One of the benefits of using human factors principles to assist in identifying contributing factors is that the same approach can be used to identify and evaluate the effectiveness of recommended actions. In other words, identifying systems-based contributing factors correctly should lead to systems-based solutions.

Figure 3.9: HIERARCHY OF EFFECTIVENESS

When recommending actions, many possible categories of options with varying degrees of effectiveness are available. The team should be apprised of this range (see below, listed in order from most effective to least effective) and 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, do not change the underlying conditions that lead to the incident.

From a human factors standpoint, the strongest interventions are "physical rather than procedural and permanent rather than temporary."[65] Organizations may find the assistance of human factors engineers or ergonomists helpful in determining if the proposed actions will be effective from a human factors perspective.

OPTIONS FOR CHANGE:[37,65,69]

1. Forcing Functions and Constraints
2. Automation/Computerization

HIGH LEVERAGE - MOST EFFECTIVE
(e.g. installing grab bars; ensuring that devices intended for use by different routes of administration lack connectivity)

3. Simplification/Standardization
4. Reminders, Checklists, Double Checks

MEDIUM LEVERAGE
(e.g. restricting the number of types of a device; reducing reliance on memory and vigilance; build-in redundant cues)

5. Rules and Policies
6. Education and Information

LOW LEVERAGE - LEAST EFFECTIVE
(e.g. education sessions, memos, etc.)
(while these are important, when used alone they will not result in sustained practice change)

In many cases, a systems-based recommended action involves a change or improvement to a process or protocol, work areas, software, order forms or equipment. A "mistake-proofing" step assists teams to determine whether the recommended action(s) will have the desired effect(s). In this step, team members assess whether the recommended action, if implemented, would have prevented the incident or mitigated the harm. It is also an opportunity to consider the potential for introducing unintended consequences to processes (e.g. creating unnecessary steps or added workload, possibly leading to unsafe work-arounds).

Consideration needs to be given to evaluating the impact of the actions before implementation. One way to do this is to conduct one or more of the methods described in *Appendix N*: cognitive walkthrough, heuristic evaluation or usability testing. The method selected will depend on the complexity of the sub-system being changed and the potential severity if the recommended action fails or introduces unintended consequences. In general, if the consequences are potentially more severe, it should be evaluated with usability testing or a combination of the methods, and the recommended action modified and improved before implementation. Failure Mode and Effects Analysis (FMEA)[59, 60] is another prospective analysis technique that can be used to evaluate the impact of a proposed process change.

The initial focus is on the **elimination** of risk to patients. If there are no actions that can be applied to eliminate the risk, the team should seek the most appropriate controls to reduce the possibility of recurrence. It is important to note that applying a **control** means that although checks will be in place, there still is a chance of reproducing the same or related circumstances that led to the original incident. There are occasionally circumstances under which a team may choose to **accept** one or more identified factors without further intervention. The frequency and/or severity of the incidents may not be significant, or it may be that one or more of the identified factors cannot be altered. For example, in reviewing an incident related to lack of timely access to tertiary care, the team would have to accept the fact that this level of service will not be made available in remote locations and focus attention on rapid transfer of patients when such services are needed (in other words, implement a control measure).

A few well thought out high-leverage recommendations will ultimately be more effective than a lengthy list of low-impact actions.

Suggest an order of priority for recommended actions

The need to prioritize the recommended actions is the result of several practical factors:[10,14]

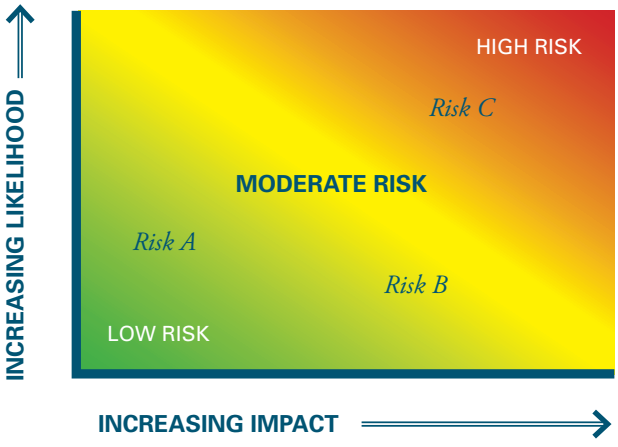
- Related to the organization:
  - Abundance of recommendations from multiple sources generated from accreditation, patient complaints, insurance claims, coroner reports and others;
  - Limited resources (budget, staff time) to ensure good follow through of quality improvement and risk management initiatives; and
  - Additional priorities and strategies described in strategic plans.
- Related to the external environment:
  - A variety of external pressures and requirements influence operations

including: required organizational practices, regulatory and policy requirements;
    - Public reporting and compliance with certain indicators; and
    - Reports of similar incidents publicly available.
- Related to the characteristics of the recommended action itself (degree of change required).

The analysis team is generally responsible for suggesting an order of priority and desired timeline for completion of recommended actions. This is later confirmed by the senior team and delegated for implementation. The following criteria may assist in the prioritization process:

- If the recommended action is not implemented, what are the risks (the worst possible outcome) for the patient, providers, organization? If possible, illustrate this using the severity assessment score (*Section 3.6.2, Figure 3.4*) or a heat map[70] (*Figure 3.10*).
- Which actions can be immediately implemented? Consider if there are quick, safe patient care wins that will empower the implementation team and others to continue. (It is important to emphasize that small wins are steps in the right direction, not the final destination.)
- Also, consider if there are existing mechanisms (initiatives, programs or other improvement efforts) in place to implement the recommended action(s). Building an inventory (via a table, spreadsheet or other venue) of current efforts in place to address this or similar issues (contributing factors) can prove valuable for improvement. The searchable inventory could be a living document maintained and used by all levels in the organization.
- If possible:
    - Recommend actions for different levels in the organizations and discuss what the most important action is at each level; and
    - Estimate the resources (human and financial) and timelines needed to implement each recommended action.

Figure 3.10: EXAMPLE OF A HEAT MAP[70]



An example of a tool that can be used to summarize the draft prioritized recommended actions is provided in *Figure 3.11*. For each column, enter a descriptor (high/medium/low or other as applicable), or a few short comments.

Figure 3.11: EXAMPLE OF TABLE TO SUMMARIZE AND PRIORITIZE RECOMMENDED ACTIONS

RECOMMENDED ACTION (category, identification, source)	RISK (severity assessment)	HIERARCHY OF EFFECTIVENESS (high, medium, low leverage)	PREDICTORS OF SUCCESS (alignment, existing mechanisms, quick wins)	SYSTEM LEVEL TARGETED (micro, meso, macro, mega)	STRENGTH OF EVIDENCE (note, if available, type)	SUGGESTED ORDER OF PRIORITY (or suggested timeframe)

Consult on the draft recommended actions

Where possible, a consultation step may be beneficial in order to ensure that the recommendations are appropriate, the identified risks have been addressed, and there is a high probability to reduce the reoccurrence of this or similar incidents. Patients/families have a unique perspective on the incident and should be invited to provide their improvement ideas to the team. Providers from the area where the incident occurred, as well as experts should also be consulted. All providing feedback on potential actions should be advised that their suggestions will be considered, but for many good reasons, may not be implemented. These reasons should be explained to the contributor.

Prepare and hand-off report

A final task of the analysis team is to include the recommended actions and the corresponding rationale (the findings of the analysis) in a report that is provided to those responsible for approving the actions, delegating them for implementation, allocating resources, empowering and monitoring implementation (most frequently a senior manager or quality committee).

Having a clear record of the analysis and relevant supporting documentation will support confidence in decisions related to the analysis. If the steps, facts, evidence and supporting documentation are tracked throughout the analysis, the writing of the report should be relatively straightforward. The report will inform the basis for those responsible to make decisions regarding recommended actions. See *Appendix I* for a report template.

Frequently, the analysis team will disband once the report is handed off. To ensure appropriate follow-up, a tracking mechanism should be put in place to trace the implementation of recommended actions and their accompanying outcomes (see *Figure 3.12* for an example).

Manage Recommended Actions

The individual or group of individuals (potentially a senior leader or organizational quality committee) receiving the analysis report is responsible to ensure that the recommended actions are validated from a strategic and operational perspective, as well as delegate and empower the implementation of approved actions. This individual or group of individuals will generally be required to support decisions related to implementation of actions to organizational leaders and other stakeholders, while demonstrating good stewardship of available resources and considering the long-term well-being of the organization.

Validate actions from strategic and operational perspectives

The analysis report, including recommended actions, needs to be evaluated by the responsible individual(s) in order to decide if and how actions should be implemented. The following three steps may be helpful in guiding their decisions:

1. Confirm actions

To facilitate confirmation of the recommended actions, the responsible individual(s) may choose to begin by **merging actions from the analysis with recommendations from other sources**. This builds on the inventory generated by the analysis team (*Figure 3.11*) and aims to ensure that actions are considered in light of strategic and operational risks and priorities. Ideally a centralized inventory is created to capture current recommendations in the organization from all sources and their status (e.g. patient complaints, trigger tool findings, insurance claims, accreditation, coroner). The inventory can be housed in a simple spreadsheet or included in the organization's patient safety or performance systems.

It may be helpful to consider sorting the recommended actions by the main categories of contributing factors (task, equipment, work environment, patient, care team, organization, other) and including high-level key information about each recommended action (e.g. estimated risk for the organization, implementation status). An inventory will assist with the prioritization steps by ensuring that the recommended actions for this incident are aligned with and not competing with other ongoing efforts in the organization. Regular maintenance of such an inventory is required.

2. Assess validity

Validating the recommended actions is done to ensure that the actions are:

- Attainable (the resources, competence and tools needed are available – if not, there is a plan to put them in place before implementation starts).
- Feasible (the culture, readiness for change, technology, legislation and other contextual factors support the action and are not competing with it).
- Cost-effective (potentially a cost benefit analysis may be needed).
- Aligned with the strategic and operational priorities of the organization (implementation of the actions will not create a void in other areas or programs).

3. Approve and set guidelines for implementation

A final validation step includes confirmation of the actions to be implemented and high-level guidelines for implementation. Guidelines for implementation should focus around the following criteria and include a brief rationale:

- Set an order of priority for the actions – what should be implemented first?
- Specify the system level targeted (micro, meso, macro or mega). Consider if the recommended actions should be generalized to other areas of the system. For example, if the incident is related to the use of a concentrated form of an injectable medication in one area of a hospital, it would be beneficial to address the management of the medication in all areas of the hospital, and also to consider the management of similar concentrated

injectable medications using the same intervention, at the same time.
- Timelines – start time and estimated duration.
- Accountability – include a senior leader and an implementation lead.
- Propose success measures, milestones and determine reporting frequency.

Once approved and validated, recommended actions are prepared for hand-off to the team and individual(s) responsible for implementation. There should be a process in place to share information about actions recommended and implemented with the patient and family as well as with the providers in the area where the incident occurred, organizational leaders, and others as needed. See *Section 3.8* for more information about learning and sharing.

Delegate recommended actions for implementation and empower implementation
The approved recommended actions are handed off to the team or individual(s) responsible to implement the action. If possible this should be done during an in-person meeting so everyone has a common understanding and is clear on the purpose, objectives and direction of the actions. Clarity is important because the senior leader and the team responsible for implementation will base their work plans on the information received about the recommended actions during the hand-off process. It is important to ensure follow-through and follow-up of the status of the actions.

The handover should not be a burden for the responsible individual(s) as it is based on the validation work done previously. Focus should now be on showing support and empowering the implementation team as there is potential that this effort may be met with resistance that is often inherent to organizational change.

Utilizing a tracking system for recommended actions is encouraged because it will support organizational leaders and others to track the status of implementation. Periodic status updates can be made available and include related actions that are being implemented. *Figure 3.12* provides an example of a tool to track the trajectory of recommended actions. An Excel® spreadsheet or Microsoft Project® software may also be helpful.

Figure 3.12: EXAMPLE OF A TOOL TO TRACK THE IMPLEMENTATION STATUS OF RECOMMENDED ACTIONS

CATEGORY	RECOMMENDATION	SOURCE AND ID#	DATE ENTERED	PROGRESS STATUS (*Figure 3.13*)	ORDER OF PRIORITY OR TIMEFRAME (end date)	TARGET AREA	RISK LEVEL	INDIVIDUAL RESPONSIBLE
TASK FACTORS								

Translating incident analysis recommendations into action and sustainable change is not easy. Real improvement will only occur when a systematic, collaborative approach is used that has explicit leadership support and sufficient resources. These resources must include quality improvement and patient safety facilitators who have received ongoing education in the applicable methodologies and have developed and honed their skills over many years of experience.

Figure 3.13: THE LARSEN SCALE

One of the tools to track progress status is the Larsen Scale.[71] The scale offers descriptive labels for the status of the project.

Considered and Rejected
Nothing Done
Under Consideration
Steps Taken Toward Implementation
Partially Implemented
Implemented as Presented
Implemented and Adapted

FOLLOW-THROUGH

3.7 FOLLOW-THROUGH

3.7.1 Implementation

The implementation of recommended actions is an important step in the incident management process, with its success contributing to the success of the analysis. Boards and senior leaders, as exemplified in Claire's story, can accelerate implementation, improvement and support a culture of safety in the organization. There are resources and governance programs available for boards that offer valuable support for fostering a culture of safety (e.g. Effective Governance for Quality and Patient Safety: A Toolkit for Healthcare Board Members and Senior Leaders).[2]

Implementation can be very challenging if the actions are not focused on the contributing factors, do not have clear objectives, are not communicated (handed over) clearly, and are not visibly supported by the senior team. Capacity to take on new initiatives in healthcare is limited – frontline teams are always busy caring for patients and implementing current improvement efforts, and managers feel inundated with corporate or regional projects that are added to the day-to-day operations. To add to the existing pressures, it is expected that all approved recommended actions will be implemented in a timely manner.

Use of a change management[72] or improvement tool can help to facilitate implementation of recommended actions in a way that will support success (See the tools, templates and other resources in the *Safer Healthcare Now!* Improvement Frameworks Getting Started Kit).[73] The Model for Improvement[74] is one approach that has been used successfully by thousands of healthcare organizations in many countries to improve numerous and different healthcare processes and outcomes. The model has two parts:

- Three fundamental questions:
    - What are we trying to accomplish?
    - How will we know that a change is an improvement?
    - What changes can we make that will result in improvement?
- The Plan-Do-Study-Act (PDSA) cycle to test and implement changes in real work settings.

Complexity science (*Section 2.2*) suggests trying multiple approaches and shifting time and attention to those strategies that appear to be effective. The PDSA process of small cycles of change to implement quality improvements is one example of an activity that enables experimentation within a scientific approach.[74] The organization should also consider pilot testing or usability testing of interventions prior to broad implementation, especially in situations where substantial changes in process are planned.

An easy to use and tested tool developed by The Boston Consulting Group can assist with identifying and minimizing the risk of implementation failure. Their experts have determined that the outcome of change initiatives is driven by four elements: the (D)uration of the project, the performance (I)ntegrity of the team; the organizational (C)ommitment to change, and the additional (E)ffort required of staff members. The tool is available online at: http://dice.bcg.com/dice.html [75]

Ideally, implementers will share the progress of their efforts with members of the analysis team and the unit/program/organization where the incident originally occurred. Once implementation is complete, the results of the evaluation and learning should be shared with others. See *Section 3.8* for more information about sharing learning.

3.7.2 Monitor and Assess the Effectiveness of Recommended Actions

The purpose of implementing system changes is to make the system safer. However, some recommended actions – even well intentioned and well thought changes − may not have the desired effect in practice. Thus the effectiveness of the implemented recommended actions must be monitored to determine if the changes helped make the system safer, had no or limited impact on the safety of the system, or in the worst-case scenario, the changes actually made the system less safe. If surveillance indicates that, for whatever reason, the changes did not have the intended effect, the organization needs to revisit the recommended actions to identify alternative solutions or to improve the impact of earlier solutions. Organizations invest considerable resources in investigating incidents in order to alter the conditions which led to these events. Monitoring the impact of recommended actions of an incident analysis promotes organizational learning and staff commitment to improving care. Avedis Donabedian noted that "rather than being a policing activity, monitoring implements professional accountability and contributes to rational management by documenting the quality of the product".[70]

Monitoring the effectiveness of recommended actions requires measurement. One way to identify useful measures is to ask staff how they would know if an action was effective. Staff may be more familiar with existing data or have ideas about how to observe and record actions that the analysis team may not recognize.[65] Data that is available from existing databases or reports can be useful as well as data that can be recorded with simple audit tools used on a regular basis. The most useful measures of recommended actions are those that assess outcomes. Outcome measures provide direct evidence of the effectiveness of the actions taken and not just the completion of preventative measures. For example, as a result of a multi-incident analysis of fall incidents, an organization should monitor the ongoing incidence of falls. And, since one result of the increasing attention to falls prevention is likely to be increased reporting of falls, the team also needs to monitor the incidence of falls with harm.

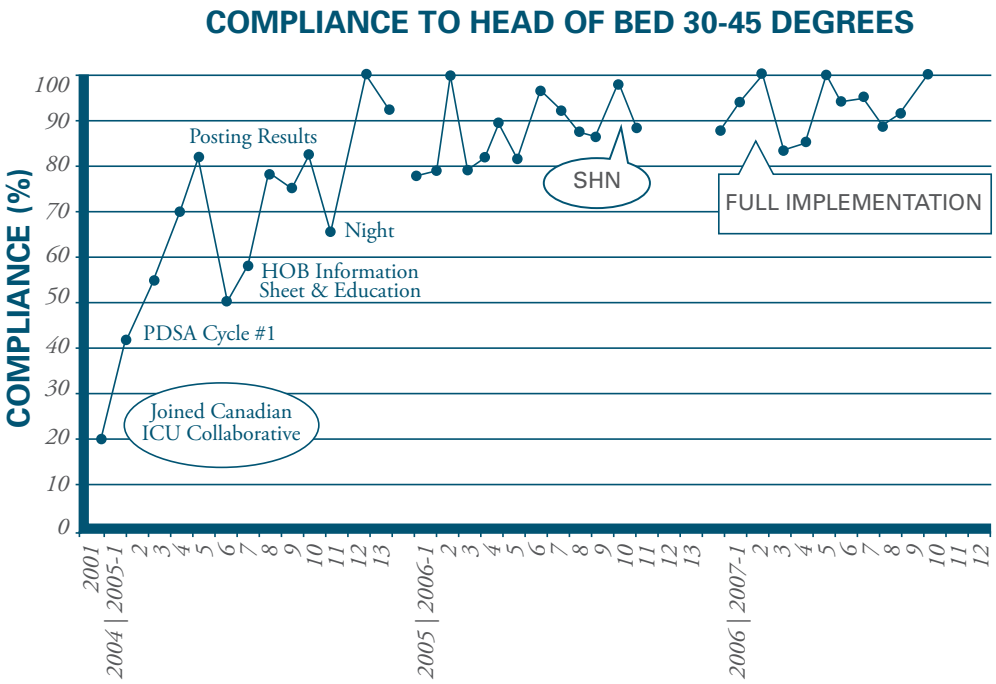
Outcome measures should be complemented with process measures that assess the extent to which recommended actions are implemented. To continue with the falls example, an organization could monitor the percentage of newly admitted patients who were assessed for fall risk. Or, if one recommended action determined the need for patients to wear appropriate footwear, staff could monitor patients on a regular basis to observe the number who are wearing appropriate footwear. A balance of outcome and process measures allows the individual or group charged with monitoring the recommended actions to interpret their impact and to revise or reinforce them if they fail to have the desired impact.

Evaluation or measurement?
The methodology involved in evaluation is more complex than the one for measurement because its intent is larger: to make judgments, improve or further develop [program] effectiveness, inform decisions and/or increase understanding.[77] Measurement is one of the many components in evaluation and quality improvement.

Many incidents are rare, so monitoring weekly or monthly incidence is uninformative. In this case more advanced strategies such as control charts that monitor time between incidents[76] can be used. In settings where control charts are not available, teams can use measures of processes that identify important preventative measures as substitutes or proxies for outcomes. For example, in many ICUs the incidence of bloodstream infections has fallen precipitously following the implementation of the central line insertion and maintenance protocols. In these ICUs the best measurement strategy may be the monitoring of these protocols (e.g. What percentage of central lines are monitored using the "maintenance bundle"?), coupled with the analysis of incidents of catheter-related bloodstream infections to identify potential additional countermeasures.

Process measures should be displayed in run charts to permit quick assessment of performance over time. Run charts have several advantages: they are easy to create without specialized software; they are straightforward to interpret; and they provide more information than bar charts or tables that do not show performance over time (and can hide undesirable patterns of performance including short-term improvements that then deteriorate).[72] Annotated run charts include notes that help in understanding the factors that contributed to the change in performance (see example below). Run charts are even more useful if they are interpreted using a series of rules that signify non-random patterns.[78, 79]

Example of an annotated run chart[72]



The principal goal of measurement in monitoring recommended actions is improvement.[80] Measurement for improvement emphasizes a practical approach with "just enough" data in small sequential samples.[73] Small samples taken frequently can be more informative than large samples taken less often (and are also easier to incorporate into staff work). Measures need to be clearly defined and the strategies for collecting these data need to be developed with the staff that will collect them. Collecting data on a process before changes are introduced is helpful in demonstrating whether the changes are improvements and whether the improvements are sustained over time. For example, the team that is monitoring recommendations on falls prevention might agree to review 10 patient charts on each of two units each week and record how many charts indicate whether a falls risk assessment has been completed. The sampling strategy and timeframe for measurement must be clearly stated. It is important to set realistic performance thresholds (e.g. a target for 100 per cent compliance should not be set unless it can be met).

Measurement may take the form of voluntary reporting, intervention tracking, direct observation of performance, chart review, computerized tracking and surveys. Regardless, it is important that measures be carefully defined, that data collection be designed to be practical and that staff are provided with information on why measurement is important and how it can be incorporated into their work. See *Figure 3.14* for key questions in designing a strategy to collect data.

Measurement sometimes looks like "just more work" and measurement that is not well designed, incomplete or hastily done will not be informative. But good measurement helps to assure that improvements are made to ensure safer care environments, and can translate into better outcomes for patients and more effective working environments.

Figure 3.14: USEFUL QUESTIONS IN DESIGNING DATA COLLECTION

1. Have I defined the data so that I get exactly what I want?
2. How accurate is it and does it matter?
3. How can the data help me?
4. Can I rely on it being consistent?
5. What will I do with the data?
6. Does my collection strategy work?
7. How will I display the data I collect?

CLOSE THE LOOP

3.8 CLOSE THE LOOP

Sharing what was learned is the ultimate objective of the analysis and is represented as the last element of the continuum in the framework. Sharing the learning both within the organization (with patients/families, those involved in the incident, the analysis team and others as needed) and outside the organization is key to preventing additional harm and making care safer. Without learning and sharing, the organization is still vulnerable as the same or similar incidents could happen again and no other external systems or organizations have the benefit of the learning. Results of analyses should roll up into organization-wide reporting and be shared with the senior leadership, board and the public.

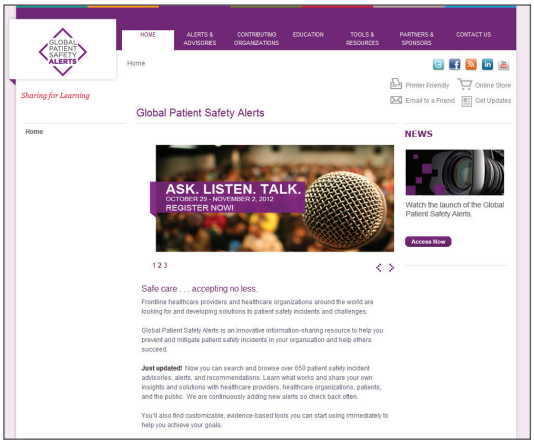
The incident management process needs to be continuously monitored to ensure that it is effective and reliable. Consistent monitoring helps to identify areas for further improvement.

Continuous Organizational Learning and Sharing Results

Learning from an incident, understanding and articulating what can be done to prevent its recurrence and heal relationships are the ultimate goals of the patient safety incident management process. It is of utmost importance that the learning is fed back and forward through multiple communication channels. Organizations may wish to conduct a multi-incident analysis of several completed incident analyses where similar incidents can be re-examined to draw larger scale conclusions (*Section 3.6.5*).

Feedback loops must be created for each incident analysis to share the learning with the various individuals and groups who assisted with analysis and implementation activities. The patient/family and providers in the service area where the incident occurred should be informed about what changes have been implemented and with what results. The incident analysis team will want to know which of the contributing factors they identified were acted upon. Likewise, the implementation team will want to know which of the changes (actions) they implemented had the greatest impact.

Figure 3.15: EXAMPLES OF REPOSITORIES



This information may be shared in multiple ways, including memos, storytelling, huddles or any other way the organization is comfortable communicating. The need for timely communication is an aspect that cannot be overlooked. Individuals should be specifically assigned this important task so that is completed in a timely manner.

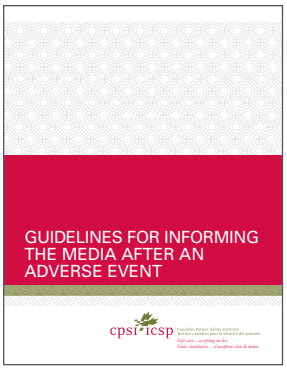
Feed-forward communication loops where the learning is shared externally are just as important because the same or similar incidents can occur in any organization, system or country and the learning from one organization should be transmitted to others to prevent harm. External communication should include what happened, why, what was the organization's response, what actions (or changes) were implemented, and with what results.

Alerts, advisories or memos are common tools for feed-forward communication. Sharing de-identified learning with others (in a manner that complies with privacy legislation) is highly recommended to prevent similar harm and also to help others with their incident management. For example, *ISMP Canada Safety Bulletins*[35] are developed from reported medication incidents to share learning across Canada. *Global Patient Safety Alerts*[13] includes summaries of the ISMP Canada bulletins as well as alerts and advisories from global sources that are relevant to Canadian providers (*Figure 3.15*).

Informing the public about patient safety incidents also requires consideration and is a crucial process, in the event that the incident has been or will be publicly disclosed. Critical information for the public includes actions taken to reduce recurrence and their results. Background and context about the incident should also be included. An example of a guideline document for public disclosure, which includes an information sharing checklist developed by the Canadian Patient Safety Institute, is *Guidelines for Informing the Media after an Adverse Event* and is publicly available (*Figure 3.16*).[48]

"IN THE COURSE OF REVIEWING OUR OWN MISTAKE, WE ALSO SOUGHT INFORMATION ACROSS THE COUNTRY ABOUT OTHER, SIMILAR TRAGEDIES...THERE HAVE BEEN AT LEAST THREE OTHER CHILD DEATHS IN THIS COUNTRY SINCE 1989 AS A RESULT OF VINCRISTINE BEING INJECTED IN ERROR INTO THE SPINAL FLUID. THESE OCCURRED IN NOVA SCOTIA, QUEBEC AND ONTARIO. EACH WAS FULLY INVESTIGATED IN THE INSTITUTION WHERE IT OCCURRED, BOTH INTERNALLY AND BY PROVINCIAL CORONERS. YET WE FOUND THAT THE DETAILS OF THESE ERRORS HAVE NOT BEEN COMPREHENSIVELY SHARED BETWEEN PROVINCES, CORONERS' OFFICES OR HOSPITALS. WE WERE NOT ABLE TO LEARN FROM OUR MISTAKES, NOR DID WE HAVE THE OPPORTUNITY TO LEARN FROM THOSE OF OUR COLLEAGUES."[81]

Figure 3.16: GUIDELINES FOR INFORMING THE MEDIA AFTER AN ADVERSE EVENT



Most healthcare organizations have more than one individual responsible for managing different activities in the incident management process (as described in *Figure 3.1*) and as a result a substantial key to success is ensuring good hand-over processes between steps, as well as follow-through, and completion of all the steps in the process. Excellent communication among the individuals and teams responsible for responding, reporting, analyzing, implementing, evaluating and communicating the learning from the incidents is essential to success.

Reflecting On and Improving the Quality of Analysis and Management Processes

Organizations are encouraged to periodically dedicate time and resources to review and evaluate how the incident analysis and incident management processes function. The purpose of this effort is to ensure the processes are appropriate, reliable, effectively use resources and staff, and strive to improve care. In addition, the learning can assist in developing protocols, checklists and other resources that help teams manage incidents.

Factors that influence the quality of analysis include:[82]

- Timeliness of completing the analysis
- Quality of recommended actions (*Section 3.6.6*)
- Implementation of recommended actions (completion status)
- Effectiveness of the actions implemented in reducing harm recurrence (monitor)
- Sharing what was learned (internal and external)
- Presence of one or more effective mitigating factors (barriers)
- Provider's perception of care safety

When defining the quality criteria organizations need to keep in focus the possible unintended consequences resulting from several factors – for example, conducting simpler and fewer analyses.

Non-monetary incentives, (e.g. awards[83]) that recognize those teams that demonstrate improved performance can have a significant role in increasing engagement in the process and therefore improve the quality of the analysis. Quality of incident analysis is extremely important in restoring trust and rebuilding relationships among all involved in an incident and in building a safe culture in the organization.

CONCLUSION

Safe patient care is a fundamental aspect of providing quality healthcare services. The Canadian Incident Analysis Framework has great potential to improve the safety of care processes in healthcare organizations. It can help organizations, and the people who provide hands-on patient care, to perform a system-based analysis of patient safety incidents that includes the identification of contributory factors, determination of recommended actions to reduce risk, development of action plans, along with measurement strategies to evaluate the effectiveness of the plan.

Striving to identify and address the underlying reasons why incidents occur will lead to a greater understanding of hazards in the system and, ultimately to a safer healthcare system for all. This is an integral part of moving the culture of the entire healthcare organization from blame to understanding, learning and improvement.

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APPENDICES


CLOSE THE LOOP
Share what was learned (internally and externally)
BEFORE THE INCIDENT
Ensure leadership support
Cultivate a safe and just culture
Develop a plan including resources
IMMEDIATE RESPONSE
Care for and support patient/family/providers/others
Report incident
Secure items
Begin disclosure process
Reduce risk of imminent recurrence
PREPARE FOR ANALYSIS
Preliminary investigation
Select an analysis method
Identify the team
Coordinate meetings
Plan for/ conduct interviews
ANALYSIS PROCESS
Understand what happened
Determine how and why it happened
Develop and manage recommended actions
FOLLOW THROUGH
Implement recommended actions
Monitor and assess the effectiveness of actions

APPENDICES

A. TEAM MANAGEMENT CHECKLIST

TEAM MANAGEMENT CHECKLIST	
PLANNING	
☐	Team members identified and confirmed
☐	Room booked
☐	Refreshments ordered
PREPARATION	
☐	Confidentiality agreement
☐	Project charter
☐	Health record
☐	Related policies and procedures
☐	Incident timeline (copies numbered 1/10, 2/10, etc)
☐	Flip charts, sticky notes, markers
☐	Agenda and goals; pre-reading if required
☐	Ground rules
FOLLOW-UP	
☐	Additional meeting(s) scheduled: _____
☐	Report preparation delegated to: _____ Target date: _____
☐	Documents collected

B. CHALLENGES AND STRATEGIES DURING THE INCIDENT ANALYSIS PROCESS

A variety of challenges may emerge during the analysis process. The table below outlines some barriers that may affect the implementation of an analytical process and suggests various strategies to consider if these barriers are encountered.

CHALLENGES	STRATEGIES
No organizational analytical policy/guideline in place	Develop and implement an organizational analysis policy guideline. Use leading practice examples to stimulate and facilitate the process.
Insufficient expertise in analysis within the organization	Approach key risk management and quality improvement individuals in the organization to offer education and support in conducting an analysis (numerous courses and workshops are available in Canada and the United States). Use an external analysis expert to establish a strong foundation of knowledge and skill.
Lack of awareness and understanding of analysis	Develop and implement an education program on the analysis policy/process. Target several sessions to physician and staff opinion leaders, as well as senior leadership and board members.
Analysis team - Group dynamic issues	
Fear	Provide a copy of the applicable analysis policy to all members of the team prior to the first meeting.
Blaming language (including self-blame)	Ensure the facilitator, leader or knowledgeable peers are available to clarify questions or concerns.
Dominant personalities	Refer to the ground rules. Do not tolerate the use of blaming language. Do not permit one person or persons to dominate the discussion.
Lack of participation	Respect that participation is voluntary. As the process becomes established the participation rate will increase.
Pre-determination of correct solution or changes	Guide the team to explore alternative solutions (perhaps found in the literature review).
Unwilling to explore specific system improvements/changes	Use examples (such as those provided in this document) to illustrate the process. Support innovative thinking.

C. ANALYSIS TEAM MEMBERSHIP, ROLES AND RESPONSIBILITIES

Leader: someone knowledgeable about the general type of incident and has organizational authority to implement the process.

Attributes:
- Has strong analytical and clinical skills in the subject area.

Responsibilities:
- Keeps team focused on incident.
- Provides support for cultural change.
- Supports team members in their analysis.
- Removes barriers faced by team members.

Facilitator: quality specialist or risk manager with knowledge and self-confidence.

Attributes:
- Expertise in analytical methods and techniques.
- Skilled at group dynamics.
- Skilled at delegation.
- Skilled at group consensus building.

Responsibilities:
- Coordinates team meetings.
- Keeps team focused on event.
- Facilitates constructive dialogue.
- Monitors timelines.
- Ensures that analysis process is followed per organizational protocol.
- May be responsible for ensuring completion of final report.

Individuals knowledgeable about subject area:
Depending on the type of incident, this will vary. Clinical and non-clinical staff (including those involved in the incident and several who were not) provide valuable insight. For instance, teams for suicide incidents may include physical plant or architecture staff, housekeepers, nurses, security personnel, etc. Teams analyzing medication events may include pharmacists, biomedical engineers, information technologists, physicians, nurses, unit clerks, pharmacy technicians, etc. Teams for patient falls may include physiotherapists, rehabilitation staff, nurses, nursing aides, etc.

Attributes:
- Extensive knowledge of the subject area.
- Credibility within organization.
- Analytical, open-minded.
- Interested.

Responsibilities:
- Provide information relevant to the different steps involved in the incident.
- Provide information on the usual process.
- Help identify contributing factors and actions relevant to current practice.

Patient/family or representative:

Attributes:

- Understanding of the incident from a perspective different from others in the team.
- Ability to communicate their perspective and understanding of the incident.

Responsibilities:

- Provide their opinion, knowledge of the incident and other information to facilitate the identification of what happened, how and why it happened, and what can be done to prevent recurrence.
- Participate in constructive dialogue.

Senior leadership:

Attributes:

- Authority for decision-making.
- Drives the safety culture by example.

Responsibilities:

- Ensures that actions are implemented once approved.
- Ensures that staff are scheduled away from normal duty to participate in analysis.
- Ensures that results of analysis are communicated broadly.
- Ensures that healthcare providers and patient/family or representative involved are supported.

Other staff or consultants:

Include outside agencies as appropriate (home care, EMS, vendors, etc.). They can provide information that is not available to members inside the organization.

Attributes:

- Specific knowledge of equipment, technology, etc. that may have contributed to event or may be required for actions.

Responsibilities:

- Provide expert opinion and knowledge to facilitate identification of contributing factors and/or development of recommended actions.

D. SAMPLE ANALYSIS TEAM CHARTER

Date
From:
Subj: Analysis Team Charter Memo
To:

1. This memo confirms that an Analysis Team will be convened to determine the contributing factors for the patient safety incident analysis briefly described below.

_____

_____

Date Incident Occurred ___/___/___ Date Organization was Aware of Incident ___/___/___
The analysis method is (check one): Comprehensive_____ Concise _____ Multi-Incident ___

2. As part of the process, the team will be responsible for developing a final report and recommendations based on their expert analysis. All analyses are quality assurance, focused processes, and the team's products (e.g. interviews, preliminary and final reports, etc.) are considered confidential, privileged and protected under XYZ Act.

Note: If in the course of conducting the analysis it appears that the patient safety incident(s) under consideration may have been related to an intentional unsafe act or acts, the appropriate organizational representative will be contacted to determine if an administrative review, or other type of review process, should occur. See Section 3.2 for additional information.

3. List of disciplines and/or services anticipated to be involved in this analysis:

_____

_____

_____

_____

4. List of potential internal (e.g. facility) and external experts or consultants:

_____

_____

_____

_____

5. Resources available to the team (e.g. room number, flip charts, laptop computer, etc.)

_____

_____

6. The team's final report is due on: ___/___/___

(Adapted from the Veterans Affairs National Center for Patient Safety, in the Canadian Root Cause Analysis Framework)[7]

E. SAMPLE CONFIDENTIALITY AGREEMENT

Name (please print): _____

Affiliation with _____ : _____

(Insert name of organization) (Position)

1. I understand that the organization has custody and control of information, which it must protect for ethical, legal and proprietary reasons. This document represents my commitment to treat any information which is entrusted to me during the analysis process in a manner that respects the privacy of providers, patients and involved organizations, including information that does not identify individual healthcare providers, institutions or patients.

2. I will treat all analysis information related to the incident, as well as any administrative, financial, employee or other information as confidential information. This includes information held in any format, such as fax, email, discussions and other records. This obligation does not apply to information in the public domain.

3. I agree to respect the following rules regarding the treatment of information with which the organization is entrusted:

   (a) I will not access information related to the incident unless I need to know it to perform my current job duties or to meet my professional responsibilities as part of the analysis process.
   (b) I will not disclose information related to the analysis process except to perform my job or meet my responsibilities to the organization.
   (c) I will not engage in discussions about information arising from the analysis process in public or in any area where it is likely to come to the attention of others who are not entitled to receive such information, such as: hallways, elevators, washrooms, cafeteria, locker rooms, lounges, public reception areas, etc.
   (d) I will not allow another person to use my authorized access (e.g. username and password) to gain access to information regarding the analysis.
   (e) I will only access, process and transmit information using authorized hardware, software and other equipment.

4. I understand that the organization reserves the right to conduct audits to ensure information is protected against unauthorized access, use, disclosure, copying, modification and disposal.

5. I have read this confidentiality agreement and understand that the conditions as described in this agreement will remain in force even if I cease to have an association with the organization.

_____ _____

Signature Date

(Adapted from the ISMP Canada Organizational Confidentiality Agreement, with permission)

F. CHECKLIST FOR EFFECTIVE MEETINGS WITH PATIENTS/FAMILIES

(Developed by Patients for Patient Safety Canada a patient-led program of the Canadian Patient Safety Institute)

This checklist has been developed to help prepare healthcare leaders and providers for meetings with patients/families when a patient safety incident is being discussed.

The most important attributes that leaders and providers can bring to these meetings are compassion, a willingness to listen and understand, and the ability to be supportive.

PATIENTS FOR PATIENT SAFETY CANADA | PATIENTS POUR LA SÉCURITÉ DES PATIENTS DU CANADA

When something unexpected occurs:

- Acknowledge the event to the patient/family right away with an apology.
- Ask about any immediate needs that the patient/family may have as a result of the unexpected situation (e.g. temporary assistance with housing, transportation, child care, grief or psychological support, etc.). Assist where possible.
- Commit to find out what happened and how and why it happened.
- Explain the analysis process (what will happen next).
- Assist the patient/family in accessing information they request (e.g. test results, medical records).

Keep in touch:

- Provide the patient/family with a contact person for questions or updates.
- Connect with the patient/family at agreed upon intervals if this is their desire.
- Inform the patient/family if there are changes or delays in the process.

Enable participation in the analysis process:

- Ask the patient/family if they would like to meet with the review/investigation team.
- Arrange for an interview with the investigators and the patient/family at a time/place that is agreeable and comfortable for the patient/family. Try to plan for this at the start of the analysis process.

Prepare for meetings with patients and families:

General:

- Ask the patient/family what location would be most comfortable and when they would be able to meet.
- Ask the patient/family who they would like to be at the meeting. Provide a list of participants and their positions in advance of the meeting.
- Confirm meeting details. Assist with planning (e.g. parking, place to meet, to help them find the room, etc.).
- Provide contact information (e.g. phone, cell phone) in case something changes.
- Ask if there are other considerations that would be helpful for this meeting (e.g. ordering a taxi, parking pass, assisting with child care, accessible entrances, etc.).
- Ensure the meeting room and location are appropriate (e.g. not on the unit or in the facility where the incident occurred) and large enough to accommodate the participants.
- Consider holding meetings with the provider team in a different location or after the meeting with the patient/family to avoid the perception that the meeting

has already begun without them. Arrange for water, coffee/tea, tissue and a comfortable place for the patient/family to sit that is easily accessed from the door.

For review of analysis findings:

» Inform the patient/family that the review has been completed and where applicable, send copies of the reports to them.
» Ask if they would like to meet in person to discuss the report.

Prepare the team for meetings with patients and families:

» Ensure the team knows the location of meeting, time and date.
» Ensure the team attending are able to stay for the whole meeting.
» Ensure each team member knows what their role is and what is expected of them.
» Appoint a facilitator – to open the meeting, support the patient/family, ensure that there is an opportunity for questions to be asked, and close the meeting.

During the meeting with patients and families:

» Greet the patient/family at the agreed upon time and meeting place (arrive early) and escort them to the meeting room. Do not begin the meeting before the patient/family arrives.
» Provide orientation to the building (e.g. washrooms, coffee shop, cafeteria), as appropriate.
» Begin the meeting by appreciating the patient/family attending the meeting and with supportive statements (e.g. statements of compassion, apology).
» Introduce the team and all family members attending.
» Discuss how the meeting will be structured.
» Encourage the patient/family to ask questions and clarify information.
» Ask the patient/family for their perspective/insight during the meeting.
» Be compassionate and understanding of the patient/family's situation, especially if they get emotional during the meeting.
» At the end of the meeting, if appropriate, ask if the patient/family would be interested in staying in touch with the organization and updated on the progress of any of the recommended improvements.
» Summarize the meeting discussion. Include the key points raised or asked from the patient/family.
» Offer a plan and timeline for any further follow-up, if required.
» Thank the patient/family for attending the meeting – for their questions, their patience, their insight and information.
» Escort the patient/family from the meeting room to their means of transportation. Repeat building orientation (washrooms, coffee shop, parking lot, etc). Provide parking token or arrange for reimbursement.

Follow-up:

» Unless the patient/family have indicated otherwise, follow-up with a phone call a few days later to see if there are other questions, feedback or information.
» Follow-up with the patient/family on any outstanding items or questions.
» Follow-up with the patient/family as appropriate on learning, implementation of improvements, other opportunities to contribute to quality and safety.

G. INCIDENT ANALYSIS GUIDING QUESTIONS

A set of guiding questions is provided below to guide the identification of contributing factors, hazards and mitigating factors during the "how and why did it happen" stage of incident analysis. 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 incident to take place. Teams are encouraged to note, analyze and report the system barriers that worked well (mitigating factors) and therefore should be reinforced and recognized so they will continue to prevent future harm.

The questions are grouped around categories of factors 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 (*Section 2.3*). The categories were developed by researching and adapting categories used in analysis throughout the world[37, 49, 50, 51] and refined through pilot testing and consultation with a human factors specialist.

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. For each category consider what other factors may have contributed to the incident and include them in the analysis.

Tips:

- The guiding questions are provided as examples; this is not an exhaustive list.
- The guiding questions are different than the interview questions.
- For every guiding question, ask how it impacted the incident.
- If the answer to a guiding question suggests that the safeguard was not in place or did not work, probe further with additional questions (e.g. "Why is this the case?", "If so, how did this/these contribute to/impact the incident?").

Task (care/work process):

» Were there previous or predicted failures for this task or process?
» Were specialized skills required to perform the task?
» Was a fixed process or sequence of steps required (e.g. order sets, checklists)? Did it exist and was it followed?
» Was a protocol available, was it up-to-date, and was it followed in this case?
» Were there constraints or pressures (e.g. time, resources) when performing the task?
» Was the information required to make care decisions available and up-to-date (e.g. test results, documentation, patient identification)?
» Was there a risk assessment/audit/quality control program in place for the task/process?
» Other?

Equipment (including information and communication systems):

- Were the displays and controls understandable?
- Did the equipment automatically detect and display problems? Was the display functional?
- Were the warning labels, reference guide and safety mechanisms functional and readily visible/accessible?
- Were the maintenance and upgrades up-to-date?
- Was the equipment standardized?
- Would the users describe this equipment as "easy-to-use"?
- Were the communication systems (phone, pager, software, hardware, etc.) available and operational?
- Other?

Work environment:

- Did noise levels interfere with the alarms?
- Was the lighting adequate for the task?
- Was the work area adequate for the task(s) being performed (e.g. space, layout, location and accessibility of resources)?
- Other?

Patient(s) characteristics:

- Did the patient(s) have the information to assist in avoiding the incident? If not, what would have supported the patient in assisting their care team?
- Did factors like age, sex, medications, allergies, diagnosis, other medical conditions, contribute to the incident? How did they contribute?
- Did any social or cultural factors contribute to the incident? What factors? In which way?
- Was language a barrier?
- Other?

Care team:

Caregiver(s):

- Were the education, experience, training and skill level appropriate?
- Was fatigue, stressors, health or other factors an issue?
- Was the workload appropriate?
- Were appropriate and timely help or supervision available?
- Other?

Supporting team (all involved in care process):

- Was there a clear understanding of roles and responsibilities?
- Was the quality and quantity of communication (verbal and/or written) between team members appropriate (clear, accurate, free of jargon, relevant, complete and timely)?
- Were there regular team briefings/debriefings about important care issues?
- Was team morale good? Do team members support each other?

- Were the communication channels available and appropriate to support the needs of the team (e.g. email, pager, and phone)?
- Other?

Organization:

Policies and priorities:

- Were the relevant policies and procedures available, known, accessible, and did they meet the needs of users?
- Were there work-arounds to the documented policy/procedure?
- Was there a mechanism in place to identify and resolve gaps between policy and practice?
- Were the strategic priorities of the organization clear to all?
- Other?

Culture:

- Was everyone (patients, clinicians, other staff) comfortable to speak-up about safety concerns?
- Was there visible support from leadership and board for safe patient care?
- Was communication between staff and management supportive of day-to-day safe patient care?
- Were incidents considered system failures with people not blamed?
- Other?

Capacity (resources):

- Did scheduling influence the staffing level, or cause stress, fatigue?
- Was there sufficient capacity in the system to perform effectively (e.g. access to resources)?
- Were formal and/or incentives appropriate?
- Other?

Other - consider:

- Were there any local conditions or circumstances that may have influenced the incident and/or an outcome?
- Were there any sector specific conditions or circumstances that may have influenced the incident and/or outcome?
- Other?

H. CREATING A CONSTELLATION DIAGRAM

The diagramming step of the analysis process is focused on recognizing all system issues that may have contributed to the incident rather than just the factors that are apparent and closer to the point of incident occurrence. Diagramming can assist teams to better understand systemic factors and the inter-relationships between them, better visualize these relationships, and help avoid the trap of hindsight bias. Diagramming is one of the elements that can increase the credibility, reliability and effectiveness of analysis in making care safer.

Many readers will be familiar with the use of Ishikawa (also called "fishbone")[52] and "tree"[53] diagrams to support analysis; however, both these types of diagrams have limitations. Ishikawa diagrams are helpful for brainstorming and clustering factors, but do not easily illustrate complex relationships between factors. Tree diagrams have been perceived as too "linear" and their top-down approach can be misleading in terms of relative importance of identified contributing factors.

Figure H.1: ISHIKAWA (FISHBONE) DIAGRAM

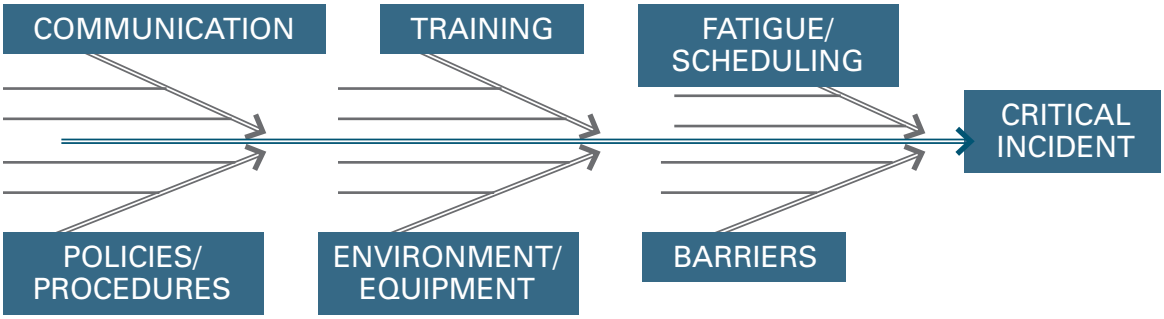
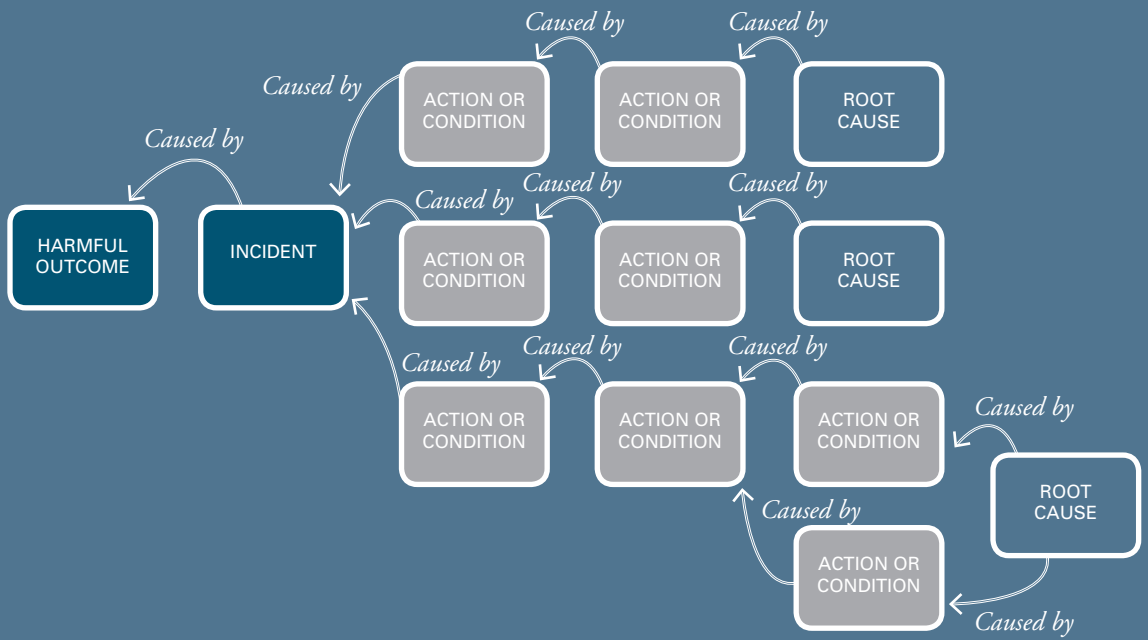


Figure H.2: "TREE" DIAGRAM



In an attempt to address the advantages and limitations of these two types of diagrams, the features of each were blended into a "constellation diagram", a new diagramming method developed by the authors. A literature search did not identify any references to constellation diagrams in the context used here (diagramming contributing factors in analyzing incidents); however there are references to diagramming and analysis methods (including statistical analysis) that emphasize the identification of groups of elements as well as their inter-relationships (e.g. the functional resonance accident model,[84] concept[85] and cognitive[86] mapping, social network analysis[87]).

Through its suggested categories of factors and use of guiding questions, the new diagram offers a systematic way to analyze contributing factors at the system level. In addition, the unique visual representation of the constellation diagram encourages and facilitates the identification of inter-connections and the sphere of influence among contributing factors, which will assist in identifying the contributing factors with the biggest impact on patient safety.

Improving safety and quality of care in complex adaptive healthcare systems is dependent on the ability to see how the parts of the system influence each other so the limited resources available can be focused with more precision to where the greatest risks are identified. The constellation diagram offers flexibility to accomplish this, more than the Ishikawa and tree diagrams.

There are five steps involved in developing a constellation diagram of a patient safety incident:

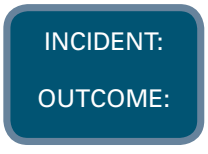
Step 1: Describe the incident.
Step 2: Identify potential contributing factors.
Step 3: Define inter-relationships between and among potential contributing factors.
Step 4: Identify the findings.
Step 5: Confirm the findings with the team.

The development and recording of the diagram can be done using the local resources available, such as a hand-drawn diagram that can be scanned in an electronic format, a photograph of sticky notes, as well as using software like Word®, Excel®, Visio®, Mindmap®, or others

Step 1: Describe the incident

a. Briefly summarize the incident and harm/potential harm in the centre of the diagram (typically fewer than 10 words). (*Figure H.3*)

Figure H.3: DESCRIBE THE INCIDENT



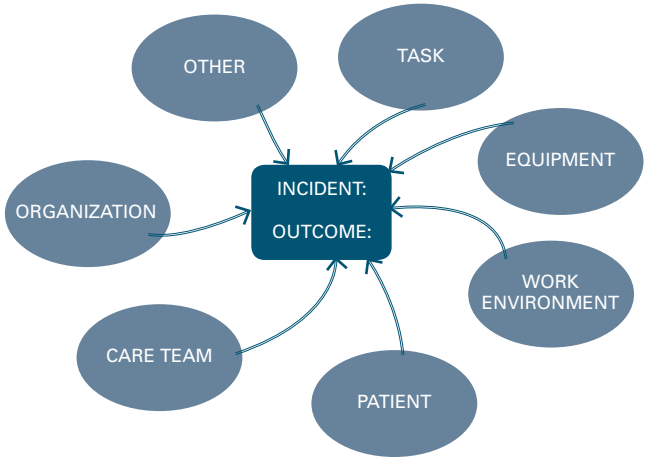
It is crucial for the team to clearly define the starting point for the analysis. This is usually a harmful outcome that the team wants to prevent. It is often, but not always, the actual outcome. For example, in the case of a near miss, the incident may have been recognized prior to the patient being involved. Alternatively, an incident may have occurred, but was

recognized and action taken prior to harm resulting. In both of these circumstances, the analysis team would identify the starting point for analysis as the potential harm, as no harm actually occurred.

Step 2: Identify potential contributing factors

a. Add the contributing factor categories (task, equipment, work environment, patient, care team, organization, etc.) to the diagram in a circle around the incident/outcome description. (*Figure H.4*)

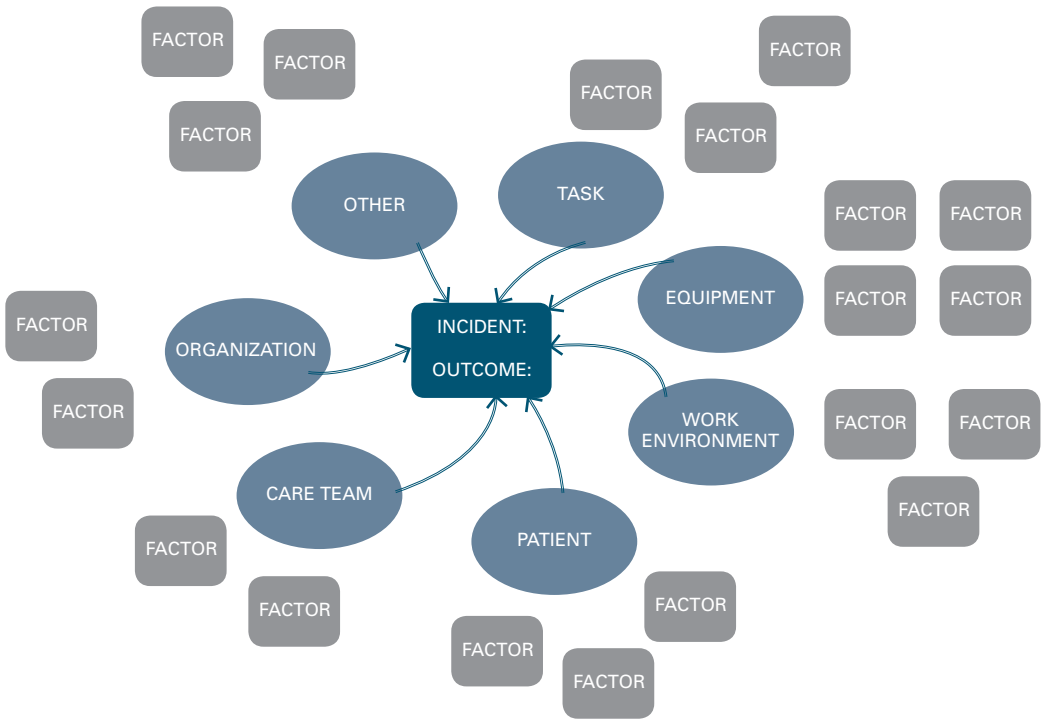
Figure H.4: ADD CONTRIBUTING FACTOR CATEGORIES



b. Use the example guiding questions provided (*Appendix G*), and other questions as appropriate, to identify potential contributing factors.

c. Place each potential contributing factor on a sticky note and group the factors near the category title (*Figure H.5*).

Figure H.5: IDENTIFY POTENTIAL CONTRIBUTING FACTORS



When identifying potential contributing factors, focus on systems-based factors, and not people-focused ones to ensure that likewise, the recommended actions are not people-focused. Keeping in mind human factors principles and systems theory, analysis should focus on "how" certain human actions occurred, not just that they occurred.

For instance, in the course of analyzing an incident in which an incorrect medication was administered, it was determined that the nurse was in a hurry. The fact that the nurse was in a hurry is a factual detail of what happened, and not a contributing factor. The contributing factor(s) are those that may have caused them to be in a hurry. Examples could include: too many tasks were assigned (the nurse was assigned too many complex patients); or the patient's medication needs conflicted with shift change (the patient was admitted right before the shift ended and the nurse wanted to give the patient their pain medications so that they did not have to wait until after the shift change). By focusing on the systems-based contributing factors, the analysis team will be able to identify higher-leverage solutions. Recommended actions should be consistent with one of the main tenets of human factors: fit the task or system to the human, not the other way around.

Step 3: Define inter-relationships between and among potential contributing factors

a. For each potential contributing factor ask, "How and why did this happen?"; "What was this influenced by?"; and "What else influenced the circumstances?".
b. Add the answers to these questions to develop "relational chains":
    i. Some contributing factors may be directly linked with each other,

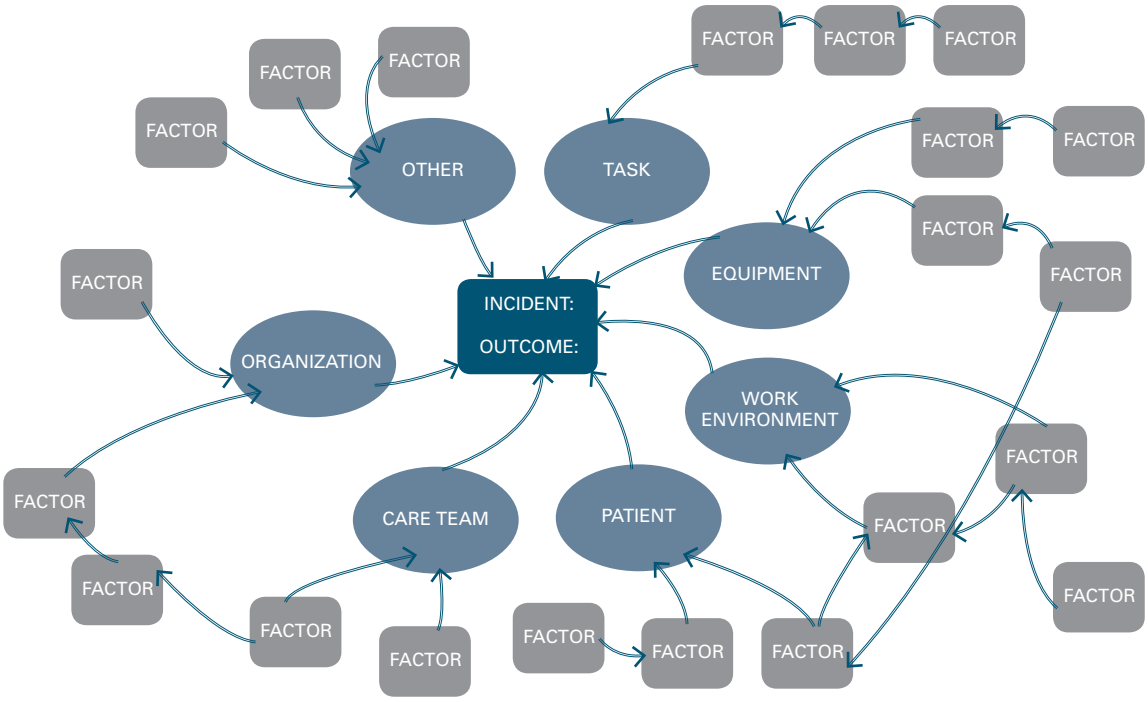
within the same category to create a chain.

ii. Some answers may come from different contributing factor categories; if so, show the linkage by drawing lines.

c. Continue to ask "why" and "what influenced it" questions until no further information can be generated.

Once the team has identified potential contributing factors using the categories of guiding questions, the second phase of analysis begins. Asking "What was this influenced by?", and "What else influenced the circumstances?", the team then expands the constellation diagram to include "relational chains" of contributing factors as shown in *Figure H.6*. This questioning process continues until there are no more questions, knowledge becomes limited, or until the issues identified fall outside the scope of the analysis. Expect that factors from different chains will be inter-related and may influence each other.

Figure H.6: DEFINE RELATIONSHIPS BETWEEN POTENTIAL CONTRIBUTING FACTORS



Step 4: Identify the findings

The next step in the analysis process is to identify the findings that are central to the incident. The team should expect to identify several findings – there is seldom, if ever, only a single reason why an incident occurred.

Findings will be identified in three categories:

a. Factors that, if corrected, would likely have prevented the incident or mitigated the harm – these will be the basis for developing recommended actions (note that these factors may require actions at different levels of the system).

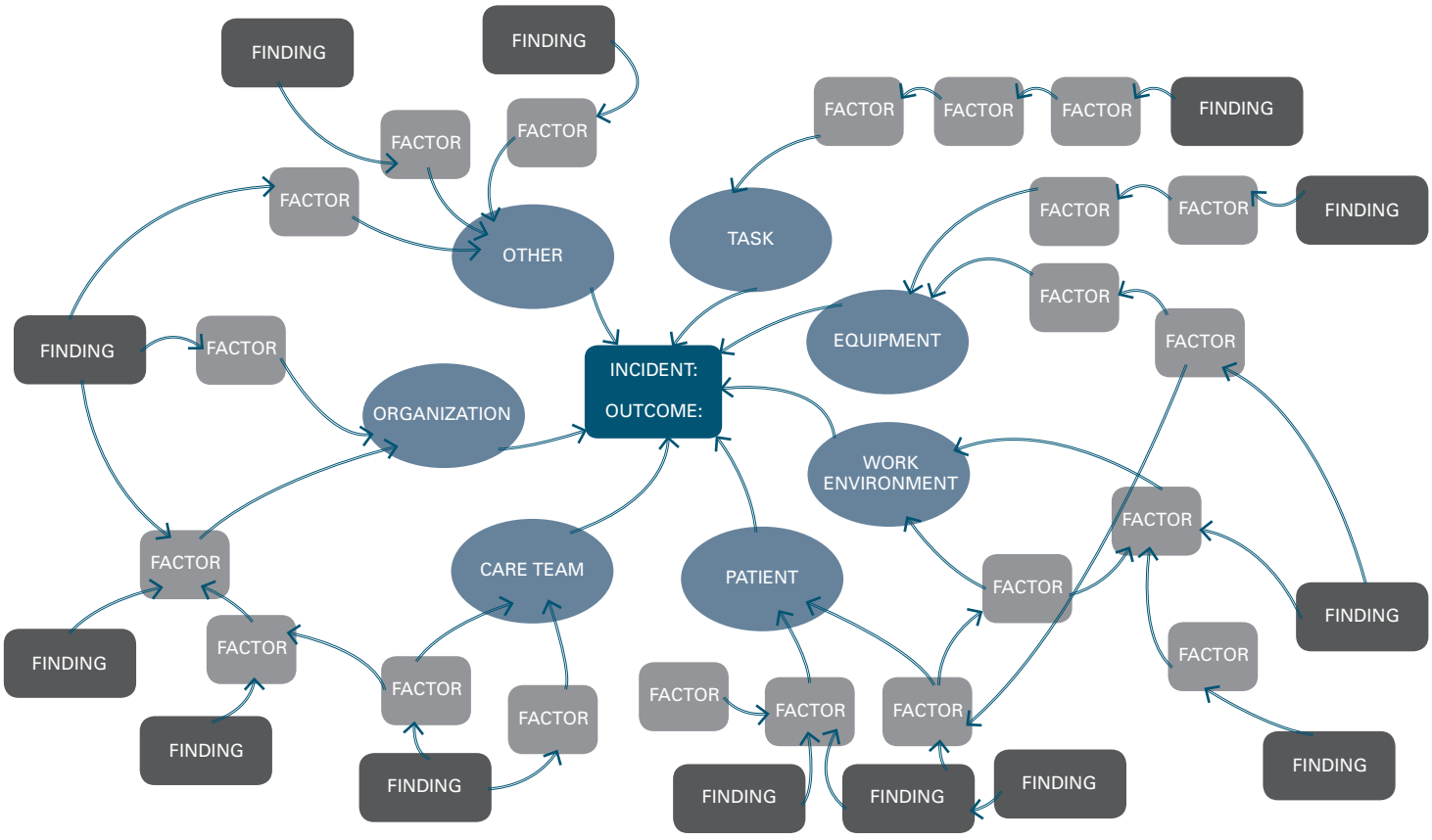
The question to be asked is: *"If this factor was eliminated or corrected, would it have likely reduced the risk of incident recurrence and/or harm?"* While it is possible that many contributing factors will be identified in the analysis, certain factors, if corrected, have the greatest probability to prevent the incident altogether, or mitigate harm from the incident. It is common for these factors to be "**highly relational**"; in other words, relationships or potential relationships between a number of the identified factors appear to have combined to enable an incident to occur, there is a sphere of influence amongst them. These findings will be the basis for developing recommended actions (note that actions may be required at different levels of the system).

b. Factors that if corrected, would not have prevented the incident or mitigated the harm, but are important for patient/staff safety or safe patient care in general. These issues should be included in the team's findings and brought to the attention of the appropriate individuals for follow-up and documented in the analysis report for future review and action as appropriate.

c. Mitigating factors – factors that didn't allow the incident to have more serious consequences and represent solid safeguards that should be kept in place.

An example of a completed constellation diagram is illustrated in *Figure H.7* below.

Figure H.7: COMPLETED CONSTELLATION DIAGRAM



Step 5: Confirm the findings with the team

a. Ensure consensus and support for the development of recommended actions.

The team should agree on the findings before moving forward to develop recommended actions. If there is a lack of immediate agreement, it is important to discuss and work through any disagreements to strive to arrive at consensus before proceeding. If key individuals involved in the incident are not participants on the analysis team, it is helpful to ask for their feedback on the findings of the analysis team as part of the process for verifying the findings. This stage of the process should also include a "back-checking" step; in other words, consider the impact of correcting the identified vulnerabilities (e.g. "If this factor had not been present or had been corrected, would the incident still have occurred?").

I. INCIDENT ANALYSIS REPORT TEMPLATE

Report date: *Prepared by:*

Incident:
Outcome:
Date of Incident: File Name (ID):
Type of Incident: Severity (Outcome):
Date(s) of Analysis Meeting(s) (If applicable):
Program(s)/Unit(s): Facility:

SUMMARY of Incident [brief description]

BACKGROUND AND CONTEXT [e.g. brief description of care/treatment provided, size of service, how long service has been provided, composition of clinical team, etc.]

SCOPE/TERMS OF REFERENCE

ANALYSIS TEAM

METHODOLOGY [Investigation and Analysis]

Type of analysis (select one)

- » Concise
- » Comprehensive
- » Multi-incident or multi-patient

» Conducted under legislative framework (e.g. quality of care legislative protection) [check if yes]

SUMMARY OF FINDINGS – [List + brief description]

1. ..
2. …
3. …

RECOMMENDED ACTIONS – Prioritized [Include reference to the findings above (e.g. 1.1, 1.2), category of contributing factors (task, equipment, work environment, patient, care team, organization, other), scope (or target area) and risk level]

APPENDICES:

- » Timeline
- » Constellation diagram
- » Full list of recommended actions
- » Implementation plan
- » Evaluation plan
- » Arrangements for shared learning
- » References reviewed (including literature, standards, guidelines)

Adapted from the guide to investigation report writing (National Patient Safety Agency)[88]

J. CASE STUDY - COMPREHENSIVE ANALYSIS: ELOPEMENT FROM A LONG-TERM CARE HOME

Background

The scenario for analysis is an elopement incident that occurred in the secured dementia unit of a long-term care (LTC) home. The home is located in a community in central Canada. In the summer months, temperatures regularly reach 35 degrees Celsius and in the winter, it may be as cold as minus 30 degrees Celsius.

In this home, residents deemed to be at risk of wandering are fitted with electronic monitoring bracelets and there are monitoring alarms at the main entrance, at the front of the care unit (located adjacent to the front door of the building), as well as at a fire exit at the back of the care unit, which is at the rear of the building. The fire exit is kept locked at all times and is also equipped with an alarm that sounds when the door is opened. The electronic monitoring bracelets are checked every couple of weeks to ensure they are functioning properly.

Incident

At supper time, a dietary aide noticed that a 75-year old female resident was not in the dining room; a care aide was asked to look for her but could not find her in the LTC home. A Code Yellow was called. On notifying the police, it was learned that the resident had been found, cold and confused, walking on a highway two kilometres away and that police were trying to determine where she lived. The resident had been taken to a local emergency department for assessment and treatment.

Immediate response

The Director of Care and Administrator were notified and took the following actions:

1. Contacted the resident's family to advise them of the incident.
2. Instructed staff to:
    a. Ensure the safety of other residents by testing all door alarms and electronic monitoring bracelets;
    b. Secure the health record for this resident;
    c. Quarantine the resident's electronic monitoring bracelet upon her return to the home; and
    d. Test the emergency exit alarms.
3. Met with the involved staff the next morning to conduct a preliminary debrief to gather and establish known facts, and provide emotional support, including advising about the availability of the employee assistance program (EAP), and the ability to arrange incident debriefing with EAP providers.
4. Ensured completion of appropriate documentation in the health record and incident report.

Figure J.1: PATIENT SAFETY INCIDENT REPORT

MY COMMUNITY LONG-TERM CARE HOME

Unit: *Memory Lane* Date of Event: *Anydate* Time of Event: *1840h*	Resident Identification (Name, Age, Gender) N00000123 *Jane Smith F* *123 Anystreet,* *Anytown, Canada* *DOB 15/12/1936* *Dr. Susan Jones - Physician*

Event Description: (Concise facts only, how event was found) *76-year-old female resident cared for on secured dementia wing found by police walking along the highway approximately two km from the home.*	**Discovered By:** ☐ RN ☐ RPN ☐ Pharmacist ☐ Pharmacy Tech ☐ MD **X** Other police

Patient - Relevant information or interventions taken for this patient. ☐ Check none necessary or describe:
Resident found cold (dressed only in light clothing and slippers on a cool evening [temperature 10˚C]) and appeared confused. Taken to hospital by police - treated with warm blankets and given IV fluids.

Outcome:
- ☐ Good Catch
- ☐ No Harm
- **X** Harm (Required extra monitoring or interventions)
- ☐ Harm Major/Sentinel Event (Notify manager or delegate immediately)
- ☐ Death (Notify manager or delegate immediately)

Primary Notifications:

	Date	**Time**	**Not Applicable**	**Comments**
Physician	Day of event	1915h		
Director of Care	Day of event	1900h		
Patient	Day of event	n/a		
Family	Day of event	1840 and 1845h		
Other				

Prepare for analysis

In the days following the incident, the Director of Care and the Quality/Patient Safety Coordinator reviewed the known facts related to the incident. In consultation with the home administrator, a decision was made that a comprehensive review would be required. This decision was communicated to the resident's family by the Director of Care.

Once a decision was made to undertake a comprehensive analysis of the incident, a team was convened that included the following individuals:

a. Unit manager
b. Quality/patient safety coordinator
c. Staff physician
d. Registered nurse
e. Registered practical nurse
f. Care aide
g. Resident council representative

Analysis process – What happened

Prior to the first meeting with the analysis team, the Director of Care and the Quality/ Patient Safety Coordinator:

1. Interviewed all staff directly and indirectly involved (e.g. all staff working the day and evening shift that day, including dietary aides, care aides, physician, nurse, etc.).
2. Interviewed others who may have helpful information (e.g. the resident's family, other family visitors).
3. Reviewed the resident's health record for information about the resident's condition that could be relevant;
4. Reviewed organizational policies and procedures related to monitoring of residents with cognitive deficits.
5. Contacted other local long-term care homes for copies of policies and procedures related to monitoring of residents with cognitive deficits and reviewed the current provincial guidelines.

At the first meeting with the analysis team, the team:

1. Reviewed information gathered by the Director of Care and the Quality/ Risk Coordinator:
    - Information from the incident report:
        - 75-year-old female LTC resident found walking on highway two km from LTC home by local police. Resident is cold and confused.
            - Temperature 10 Celsius.
            - Resident dressed in light clothing and slippers.
        - Resident transported to local emergency department for assessment and treatment.
        - Police receive call from LTC home indicating that resident is missing – police advise that resident has been transported to hospital.

    - Resident assessed in ED; treated with warm blankets and IV fluids; observed overnight.
    - Resident returned to LTC home the following morning after breakfast.
  - Policies and procedures related to monitoring of residents considered an elopement risk.
  - Results of a literature search and environmental scan for current best practices related to management of residents who are at risk for elopement.

2. Visited the unit in the LTC home and walked around pertinent areas including the resident's room, the dining room and the lounge, checking for the location of exits and alarms; conducted a "safe" simulation of the incident.

3. Examined electronic monitoring devices available for use and reviewed manufacturer's instructions.

4. Created a detailed timeline of the incident (*Figure J.2*).

Figure J.2: DETAILED TIMELINE FOR ELOPEMENT INCIDENT ("Final Understanding")

DATE/TIME	INFORMATION ITEM	COMMENT/SOURCE
4 months prior to incident	• 75-year-old female resident admitted to the secured dementia unit of the home • Medical history: Type II diabetes, dementia • Admission medications: Metformin 500 mg three times daily, Donepeziil 5 mg daily, and multiple vitamin daily • Initial nursing assessment: impaired cognition, poor decision-making skills, mild confusion, walks independently with a cane • Assessed as an elopement risk and an electronic monitoring bracelet was placed on her right wrist	Health record; staff interviews
6 weeks prior to incident	Resident has become increasingly confused and agitated. Assessed by physician who ordered Risperidone 0.25 mg at bedtime.	Nursing progress notes
4 weeks prior to incident	Resident found outside the home in the early evening. Resident was in the staff parking lot at the back of the building and was found by a staff member coming in for the evening shift. Staff on duty did not recall hearing any alarms sound. The resident's electronic bracelet was tested and found to be working.	Nursing progress notes; staff interviews
2 weeks prior to incident	Resident very confused and attempting to leave unit; redirected numerous times by staff. Physician contacted; order received to increase Risperidone to 0.25 mg twice daily.	Nursing progress notes
Day of incident 1145h	Resident told nurse who gave noon medications that she "was going home". Staff planned for resident to eat lunch in the dining room and then nap in her room per her usual routine. She was last observed eating lunch.	Staff interviews
1305h	Back door alarm sounded; reset by staff without checking as one staff member had just left the desk on lunch break and usual practice was to exit through back door to gain easy access to the parking lot.	Staff interviews
1600h	Care aide went to check on resident to get her ready for supper but did not find her in her room; assumed she was already in the common room watching TV.	Staff interviews
1730h	Dietary staff noticed that resident was not in the dining room. Discussed with care aide who went to check her room.	Staff interviews
1740h	Care aide unable to locate resident. Checked other care units and walked around perimeter of building but could not locate her.	Health record, staff interviews
1755h	Care aide reported to charge nurse that resident is missing. Overhead announcement of Code Yellow. Full search of entire facility initiated.	Health record; staff interviews

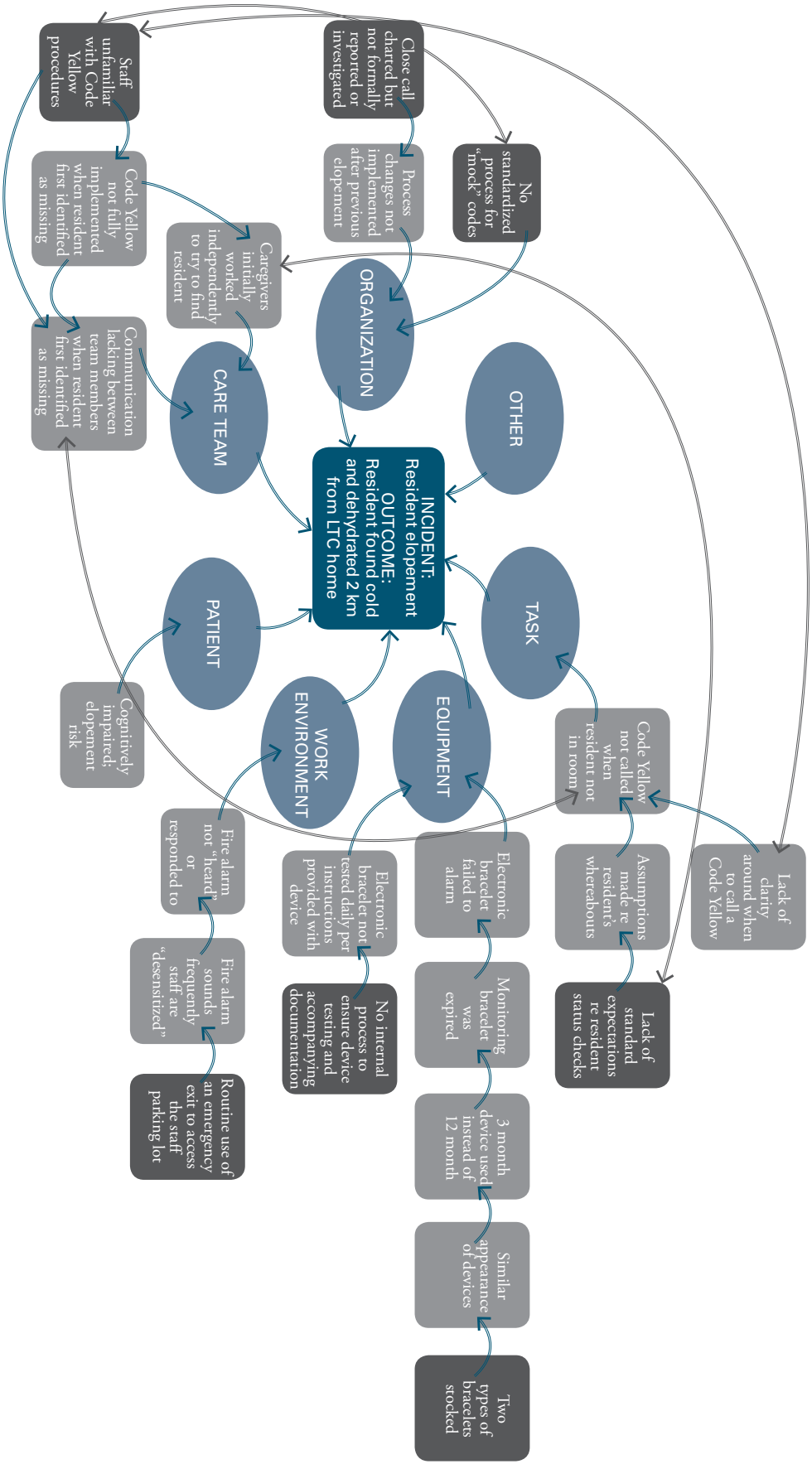
DATE/TIME	INFORMATION ITEM	COMMENT/SOURCE
1840h	Staff unable to locate resident on the grounds. Resident's family contacted. Evening staff are arriving so three of the day shift staff get in their personal vehicles and begin searching the surrounding area. Call made to local police. Police advise that an elderly woman was found walking on the highway two km from the home at approximately 1800h and that she has been transported to hospital for assessment as she was cold (dressed only in light clothing and slippers, temperature 10˚C) and appeared confused.	Health record; staff interviews
1845h	Resident's family contacted to advise that resident has been found and is at local emergency department.	Health record; staff interviews
1850h	Charge nurse contacts local emergency department for report on resident condition. Resident has had IV fluids initiated and has been given warm blankets.	Health record; staff interviews
1900h	Charge nurse contacts Director of Care to provide report of situation.	Health record; staff interviews
Day after incident 0930h	Resident returned to LTC home from hospital.	Health record
1030h	Electronic alert bracelet removed and tested. Found not to be working. It was later determined that the resident had been fitted with a 90-day device, rather than a 12-month device as intended.	Health record

Analysis process: How and why it happened

At the second analysis team meeting, the team used information provided in the timeline and their understanding of the incident from the simulation to create a constellation diagram (*Figure J.3*). The following steps are required to create a constellation diagram:

a. Describe the incident:
    i. Outcome: Resident found cold and dehydrated two km from LTC home.
    ii. Incident: Resident elopement.
b. Identify potential contributing factors using contributing factor categories and guiding questions.
c. Define relationships between contributing factors.
d. Identify findings.
e. Validate the findings with the team.

Figure J.3: CONSTELLATION DIAGRAM OF ELOPEMENT INCIDENT



Summary of findings

The analysis team identified the following findings:

Task

- Lack of standard expectations regarding resident status checks decreased the likelihood that the resident elopement would be detected in a timely way.

Equipment

- Two types of electronic monitoring bracelets with similar appearance stocked in the LTC home increased the likelihood that the incorrect device would be selected and applied.
- No standardized internal process to ensure testing of electronic monitoring bracelets with accompanying documentation decreased the likelihood that the bracelet would be identified as non-functioning prior to an elopement incident.

Work environment

- Routine use of an emergency exit to access the staff parking lot decreased the likelihood that the alarm function would be effective as staff became "desensitized" to frequent alarms.

Patient

- The resident's cognitive impairment decreased the likelihood that she would be aware of the risk of leaving the facility.

Care team

- Communication lacking between team members when resident first identified as missing, combined with lack of familiarity with Code Yellow procedures decreased the likelihood that a Code Yellow would be initiated immediately.

Organization

- Lack of a formal process to report and investigate close calls decreased the likelihood that the previous incident in which the resident eloped but was found immediately, would be followed-up to identify process changes to prevent future occurrences.
- Lack of a standardized process for regular "mock" codes to provide ongoing training and assess staff understanding of processes decreased the likelihood that staff would be familiar with Code Yellow procedures.

Other

- No other factors identified.

Analysis process: What can be done to reduce the risk of recurrence and make care safer?

The analysis team proposed the following recommended actions:

Task (T)

- T1: Establish routine procedures for confirming and documenting whereabouts of residents with cognitive deficiencies.

Equipment (E)

- E1: Develop a standardized process for daily checks, with documentation, of electronic monitoring bracelets.
- E2: Standardize devices used to monitor residents at risk of elopement to either the 90-day or 12-month model.

Work environment (W)

- W1: Implement magnetic card access technology to enable staff use of the emergency exit door, eliminating frequent nuisance alarms.

Organization (O)

- O1: Work with frontline staff to develop and apply criteria for reportable incidents.
- O2: Develop a protocol for reviewing high risk near miss incidents to ensure that learning is applied to prevent recurrence (e.g. use concise incident analysis method).
- O3: Ensure staff members are familiar with the Code Yellow protocol through a scheduled in-service and ongoing inclusion in orientation sessions.
- O4: Ensure staff members are proficient in the use of the Code Yellow and other emergency protocols through quarterly unscheduled mock code exercises.

Prioritize actions

RECOMMENDATION (category)	RISK (severity assessment)	HIERARCHY OF EFFECTIVENESS (high, medium, low leverage)	PREDICTORS OF SUCCESS (alignment, existing mechanisms, quick wins)	SYSTEM LEVEL TARGETED (micro, meso, macro, mega)	NOTE IF EVIDENCE IS AVAILABLE, AND WHAT TYPE	CONFIRM VALIDITY, FEASIBILITY	ORDER OF PRIORITY (or timeframe)
T1: Establish routine procedures for confirming and documenting whereabouts of residents with cognitive deficiencies	High	Medium	Medium	Micro	No	Medium	Within 30 days
E1: Develop a standardized process for daily checks, with documentation, of electronic monitoring bracelets	High	Medium	High	Micro	Yes, other unit is doing daily checks successfully	High	Within 30 days
E2: Standardize devices used to monitor residents at risk of elopement to either the 90-day or 12-month model	Medium	High	Low	Meso	Yes, *Global Patient Safety Alerts*	Medium	Within 6 months
W1: Implement magnetic card access technology to enable staff use of the emergency exit door, eliminating frequent nuisance alarms	Medium	High	Medium	Meso	No	Medium	Within 12 months
O1: Work with frontline staff to develop and apply criteria for reportable incidents	High	Low	High	Meso	No	Medium	Within 6 months
O2: Develop a protocol for reviewing high risk near miss incidents to ensure that learning is applied to prevent reoccurrence (e.g. use concise incident analysis method).	High	Low	High	Macro	No	High	Within 6 months
O3: Ensure staff are familiar with the Code Yellow protocol through a scheduled in service and ongoing inclusion in orientation sessions	High	Low	High	Micro	No	High	Within 30 days
O4: Ensure staff are proficient in the use of the Code Yellow protocol through quarterly unscheduled mock Code Yellow exercises	High	Low	High	Meso	Yes, simulation research paper XYZ	High	First mock code to be held within 3 months

Follow-through

Evaluate implementation

The Director of Care reviewed the status of implementation of recommended actions one year after the incident analysis was completed.

RECOMMENDATION	SOURCE AND ID#	DATE ENTERED	PROGRESS STATUS	TIMEFRAME (end date)	TARGET AREA	RISK LEVEL	INDIVIDUAL RESPONSIBLE
E1: Standardized daily device checks with documentation	IA # 1D	Sept.13	Implemented as presented Oct.1	Oct. 1	All residents	High	Director of Care
E2: Standardize devices to either the 90-day or 12-month model.	IA #1E	Sept.13	Under consideration		All residents	High	Director of Purchasing
W1: Magnetic card access technology for emergency exits	IA # 1F	Sept.13	Nothing done		All emergency exits	Med	Director of Purchasing
O1: Development and application of criteria for incident reporting	IA # 1G	Sept.13	Partially implemented	New reporting form implemented in June	All staff	High	Director of Care
O2: Protocol for review of high risk near miss incidents	IA #1H	Sept.13	Partially implemented	Two near miss events reviewed (May and July)	All staff	High	Director of Care
O3.1: Code Yellow in service for all staff	IA # 1A	Sept.13	Implemented as presented	Completed Oct.15 and 20	All staff in home	High	Director of Care
O3.2: Code Yellow inclusion in orientation	IA # 1B	Sept.13	Implemented as presented	January orientation session	All new staff	High	Director of Human Resources
O4: Quarterly unscheduled mock Code Yellow exercises	IA # 1C	Sept.13	Steps toward implementation	One mock code held Feb. 20	All staff in home	High	Patient safety leader

K. CASE STUDY - CONCISE ANALYSIS: MEDICATION INCIDENT

Background

The scenario takes place in a community with a hospital and busy home care service. The hospital faxes new and updated home care referrals to a central fax line. The referral form provides demographic patient information, diagnosis, a list of discharge medications and physician orders for home care. Monday to Friday during business hours, a home care coordinator reviews the faxed document and accesses the Home Care Central Record for any existing clients. The coordinator then reviews the information in the documents and schedules the applicable home care visits. After business hours and on weekends, the home care nursing staff periodically check the faxes, and sort them by ongoing clients or new clients. Referrals updating the status of ongoing clients are given directly to one of the nurses responsible for that geographic area of the community.

Pharmacists and technicians dispense medications from the drug stores in the community. Technicians are responsible for processing prescriptions in the computer and preparing and labelling medications as well as inventory management functions. Pharmacists are responsible for reviewing the patient medication profile and completing the final check of the medications before they are dispensed for pick-up or home delivery.

Some attending physicians at the community hospital fax prescriptions to patients' drug store so that patients and families can easily pick-up any needed medications on the way home.

Incident

The incident (*Figure K1*) involves a 76-year-old male home care client receiving a leg ulcer dressing change every five to seven days. The patient is obese and has a history of angina, high blood pressure and deep vein thrombosis. He has limited mobility and was in hospital for eight days with a diagnosis of community-acquired pneumonia. The patient was discharged on a Saturday with a referral sent through the home care fax line to advise of his return home. His list of medications were noted on the form as: Nifedipine 10 mg TID (calcium channel blocker), Atenolol 50 mg BID (beta blocker), Coumadin 2 mg OD (anticoagulant), ASA 81 mg OD (antiplatelet), doxycycline 100mg OD x 6 days (antibiotic), nitrospray prn and DuoDERM® dressing to leg ulcer weekly.

Additional background information: patient was weak and slightly short of breath at discharge.

Analysis process – What happened

Based on the incident report (*Figure K1*), a review of the home care record, hospital chart and referral form, the facilitator responsible to conduct this concise analysis started to draft a timeline of the incident (*Figure K2*). The interviews conducted with the client, pharmacist and RNs, together with an examination of the drugs involved in the incident, helped confirm and expand the timeline.

Figure K.1: PATIENT SAFETY INCIDENT REPORT

MY COMMUNITY HOME CARE SERVICE

Home Care	Client Identification (Name, Age, Gender) N000321 *John Smith, 76 yrs.* *77 Anystreet,* *Anytown, Canada* *Dr. Susan Jones*
Date of Event: *Any day*	
Time of Event: *1400 hrs*	

Event Description: *Client was found in bathroom by RN on arrival at 0900 for dressing change. Moderate amount of bright red blood in toilet and floor. Ambulance called and transferred to Emergency Dept.* *Reporter just called ED and spoke with Charge Nurse. Patient's INR 5.8. Upon review of medication bottles it was determined that patient was unintentionally taking 5 mg of Warfarin daily as he did not know that Coumadin was the same medication as Warfarin so took "previously" ordered dose of 3 mg (Warfarin) and "newly" prescribed dose of 2 mg (Coumadin) as well.*	**Discovered By:** ☐ LPN ☐ RPN **X** RN ☐ Pharmacist ☐ Pharmacy Tech ☐ MD ☐ Other
Type of Error: ☐ Omission **X** Dosage ☐ Wrong Conc / Strength ☐ Wrong patient ☐ Wrong Rate ☐ Wrong Drug ☐ Wrong Route ☐ Wrong Time ☐ Technique ☐ Monitoring Error (e.g. sliding scale, allergy missing) ☐ Expired ☐ Narcotic Count Discrepancy	Other type (describe):
Stages Involved: ☐ Physician Ordering ☐ Transcription **X** Dispensing / Delivery **X** Administration / Documentation ☐ Monitoring	(Check all that apply)
Name of Drug(s) / Product(s) / Route / Strength: Drug ordered: Coumadin 2 mg OD Drug received: Warfarin/Coumadin 5 mg OD due to error in taking medications from two bottles (Coumadin and Warfarin)	Number of doses involved: 5
Patient - Relevant information or interventions taken for this resident. ☐ Check none necessary or describe: Client transferred to ED by ambulance. Admitted to Medicine Unit.	
Outcome: ☐ Good Catch ☐ No Harm **X** Harm (Required extra monitoring or interventions) ☐ Harm Major / Sentinel Event (Notify Manager or delegate immediately) ☐ Death	
Notification Primary Physician notified? **X** Yes Date: Date discovered Time: 0900 ☐ Next Visit Patient Informed? ☐ Yes Date: _____ Time: _____ **X** No Family Notified? ☐ Yes Date: _____ Time: _____ **X** No	

Figure K.2: WHAT HAPPENED: MEDICATION INCIDENT - FINAL TIMELINE

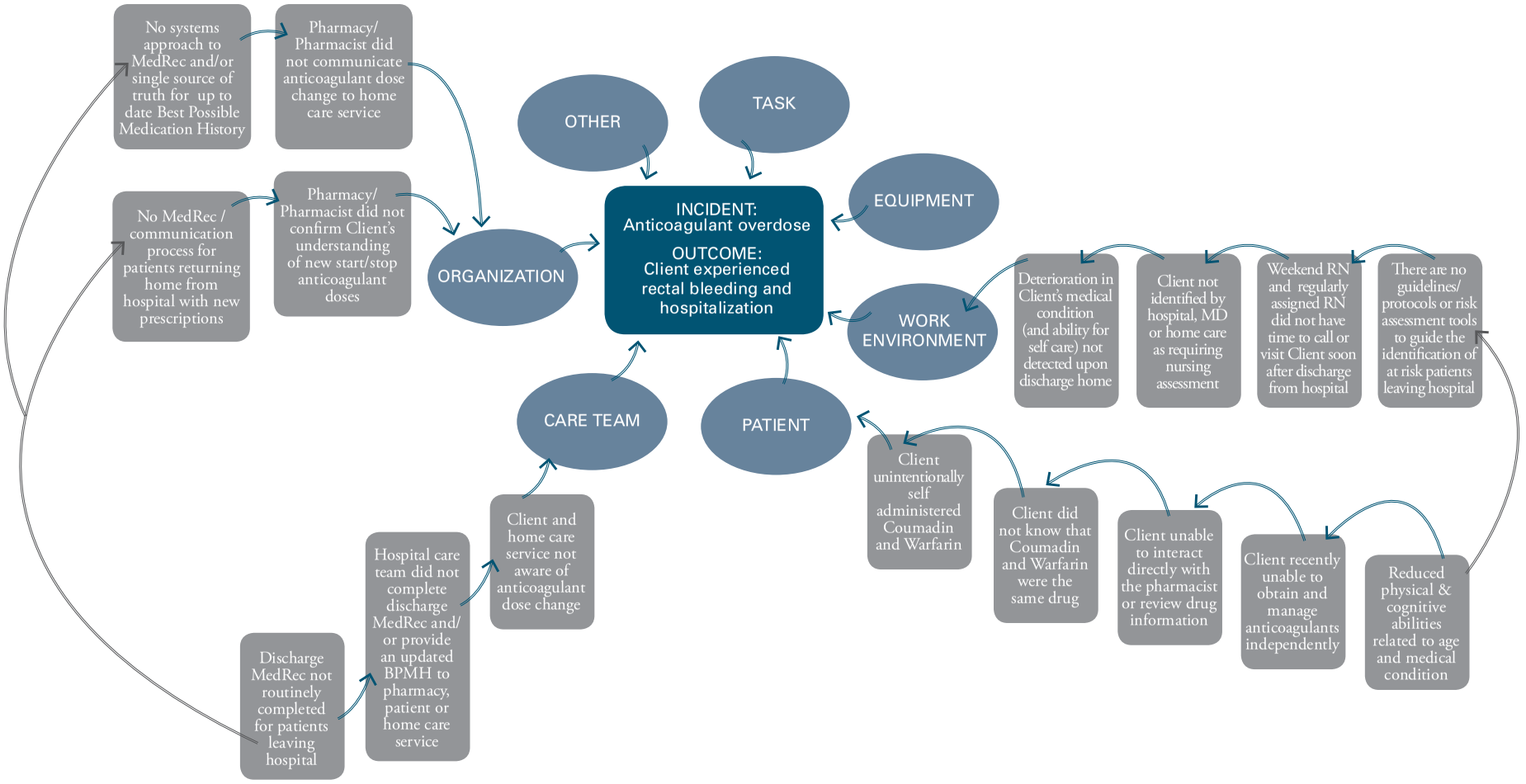
DATE/TIME	ITEM	COMMENT/ SOURCE
History	Client receiving weekly home care visit by RN for leg ulcer dressing change every five to seven days for approximately six weeks. Occasionally forgetful about caring for dressing and short-term memory mildly impaired, however able to manage own medications.	
Friday - 14 days prior to event	RN makes home visit to change client's leg dressing. She notes that he is feverish and short of breath with congested cough. RN contacts client's family physician and transfer to hospital is arranged. Patient is admitted with community-acquired pneumonia.	Home care record
5 days prior to event	Patient is discharged from hospital and returns to apartment. INR testing during hospital stay resulted in Warfarin dose being reduced to 2 mg OD. Physician referral lists medications Nifedipine 10 mg TID (calcium channel blocker), Atenolol 50 mg BID (beta blocker), Coumadin 2 mg OD (anticoagulant), ASA 81 mg OD (antiplatelet), Doxycycline 100mg OD x 6 days (antibiotic), Nitrospray prn and DuoDERM® dressing to leg ulcer weekly and request to resume dressing change schedule as well as request for assistance with weekly bath. Referral received by fax on Saturday. RN responsible for that area of the community on the weekend does not know the client however she reviewed referral and home care record. Minimal changes noted so slotted for RN visit for dressing change in five days (Thursday) and home care aide booked to make home visit for assistance with bath in six days (Friday). She leaves a voice mail for the regularly scheduled RN in the area to advise her of the client's return home however that RN is off work for several days before receiving the message. She has significant backlog of messages and workload so does not take any action with this information.	Hospital chart and referral form RN interview (regularly scheduled in the area)
5 days prior to event	Neighbour picked up client to bring him home. She agreed to pick up the new prescription when getting groceries later that day. The pharmacist at the drug store gave a patient information sheet with the new prescription. The neighbour provided this to the client. Client exhausted on the day he returned home from hospital. Grateful to neighbour for ride home and getting his prescription as well as groceries. He does recall the neighbour saying to read the information sheets but couldn't find his glasses and was too tired. He noted the two "new pills" and daily dose directions. He added them to his medication regimen until the one pill bottle was empty.	Client interview

DATE/TIME	ITEM	COMMENT/ SOURCE
5 days prior to event criteria for reportable incidents	At the drug store: • Pharmacy technician processes filling the prescription in computer. • Pharmacist notes the change in Warfarin/Coumadin dose from 3mg OD to 2mg OD so ensures that new bottle of tablets provided for ease of self-administration. All medications are filled for dispensing to ensure that patient has sufficient supply for upcoming month. • Pharmacist attempts to explain dosing information to neighbour. Highlights the dose change on the patient information sheets as well as the potential of increased anticoagulant effect with the combination of Doxycycline and Warfarin.	Pharmacist interview
4 days prior to event	Client continues to feel tired and not eating or drinking very much. Spends much of the day resting in bed or watching TV.	Client interview
2 days prior to the event	Client indicates he felt weak and was also a bit concerned about the colour of his urine. He was also a bit embarrassed about seeing some blood on the toilet paper after he moved his bowels. He assumed it was his haemorrhoids giving him trouble again.	Client interview
2 days prior to the event	Client feeling weaker and more concerned about colour of urine and more blood in stool. Doesn't want to bother neighbour so decides to wait until nurse visits in two days for dressing change.	Client interview
1 day prior to the event	Slept in bed most of day and doesn't recall many other details.	Client interview
Day of event at 0900 hrs	Client was found in bathroom by RN on arrival at 0900 for dressing change. Moderate amount of bright red blood in toilet and floor. Ambulance called and transferred to Emergency Dept.	RN interview
Day of event 1400 hrs	RN called ED and spoke with Charge Nurse. Patient's INR 5.8. Upon review of medication bottles it was determined that patient was unintentionally taking 5 mg of Warfarin daily as he did not know that Coumadin was the same medication as Warfarin so took previously ordered dose of 3mg and newly prescribed dose of 2 mg as well.	RN interview
2 days after event	Client remains in hospital but is recovering and should be ready to return home soon.	Hospital chart

Analysis process – How and why it happened

The facilitator created a constellation diagram (*Figure K3*) to visualize and better understand the factors that contributed to the incident and their interconnections. The factors were confirmed by consultation with those engaged in the incident and operational and/or medical leaders. This step was very helpful in summarizing the findings and developing recommended actions.

CONSTELLATION DIAGRAM OF CONTRIBUTING FACTORS



Summarize findings

Task

- No key findings

Equipment

- No key findings

Work environment

- The lack of a standardized home care risk assessment tool or protocol increased the likelihood that clients discharged from hospital back to the community would not be accurately triaged to ensure appropriate and timely home care services are provided.

Patient

- The deterioration in the client's physical and cognitive abilities increased the likelihood of a medication error in his self medication management.

Care team and organization

- The lack of a formalized, system-wide and communicated Discharge Medication Reconciliation process (including an updated Best Possible Medication History) decreased the likelihood that the client would receive the appropriate and timely support required for safe medication management.
- No other factors identified

Analysis process – What can be done to reduce the risk of recurrence and make care safer

Work environment (W)

- W1: Establish a standardized home care risk assessment tool for screening patients that are transitioning back to the community from hospital. Consider the feasibility and effectiveness of the regularly assigned home care nurse beginning the screening process with a call from the acute care nurse planning for the patient discharge then completing the assessment with a telephone or in-person client assessment.

Care team and organization (CO)

- CO 1: Develop, implement and evaluate a system-wide Discharge Medication Reconciliation Process. Consider using a pilot test approach initially to determine a successful strategy for spread.

Prioritize actions

RECOMMENDATION (category)	RISK (severity assessment)	HIERARCHY OF EFFECTIVENESS (high, medium, low leverage)	PREDICTORS OF SUCCESS (alignment, existing mechanisms, quick wins)	SYSTEM LEVEL TARGETED (micro, meso, macro, mega)	NOTE IF EVIDENCE IS AVAILABLE, AND WHAT TYPE	CONFIRM VALIDITY, FEASIBILITY	ORDER OF PRIORITY OR TIMEFRAME
W1: Develop, implement and evaluate a standardized home care risk assessment tool for screening patients that are transitioning back to the community from hospital	Medium	Medium	Medium	Micro, Meso, Macro	Expert opinion, related risk assessment tools validated in peer reviewed literature	Medium	Within 3 months
CO 1: Develop, implement and evaluate a Discharge Medication Reconciliation Process Pilot	Medium	Medium	High	Micro, Meso, Macro, Mega	Yes, peer reviewed research and expert opinion	Medium	Within 6 months

Follow-through

An evaluation was completed by the QI Director one year after the incident analysis was completed:

RECOMMENDATION	SOURCE AND ID#	DATE ENTERED	PROGRESS STATUS	TIMEFRAME (end date)	TARGET AREA	RISK LEVEL	INDIVIDUAL RESPONSIBLE
W1.1. Develop standardized home care risk assessment tool	IA # 1A	Jun. 5	Implemented as presented	Developed and approved Aug. 30	Home care	Medium	Home Care Executive Director
W1.2. Implement standardized home care risk assessment tool	IA # 1B	Jun. 5	Implemented as presented	Implemented Oct. 30	All current and new staff	Medium	Home Care Executive Director
W1.3 Evaluate standardized home care risk assessment tool	IA # 1C	Jun. 5	Steps toward implementation	In progress	Chart audit – home care	Medium	QI Director
CO 1.1. Develop MedRec Pilot	IA # 1D	Jun. 5	Implemented as presented	Developed and approved Oct.1	Home care	Medium	QI Director
CO 1.2. Implement MedRec Pilot	IA # 1E	Jun. 5	Implemented as presented	Implemented Nov.1			Medical Director for Home Care
CO 1.3 Evaluate MedRec Pilot	IA # 1F	Jun. 5	Steps toward implementation	In progress			Medical Director for Home Care
CO 1.4 Share MedRec evaluation with organizational decision makers for decision regarding spread to system-wide implementation	IA # 1G	Jun. 5	Not implemented				Medical Director for Home Care

L. INCIDENT REPORTING AND INVESTIGATION LEGISLATION

(Accurate at the date of publication – please check if there are any updates)

Saskatchewan

The Government of Saskatchewan passed legislation requiring the reporting and investigation of critical incidents in healthcare as of September 15, 2004. These provincial guidelines define a critical incident as: "a serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health service provided by, or a program operated by, a regional health authority (RHA) or a healthcare organization (HCO)"[i].

Manitoba

The Manitoba government passed legislation in 2005 to amend the Regional Health Authorities Act. The amendments require that critical incidents be reported and define a critical incident as an:

"unintended event that occurs when health services are provided to an individual and results in a consequence to him or her that (a) is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital or unusual extension of a hospital stay, and (b) does not result from the individual's underlying health condition or from a risk inherent in providing the health service"[ii]. Note that this definition does not include near misses and requires an individual to suffer a serious and undesired consequence to be considered a critical incident.

According to the new provincial legislation, if a critical incident occurs in Manitoba, the Regional Health Authority, health corporation, or prescribed healthcare organization, must ensure that appropriate steps are taken to fully inform the individual of the:

1) Facts of what actually occurred;
2) Consequences of the critical incident, as they become known; and
3) Actions taken and the actions that will be taken to address the consequences of the critical incident.

A complete record of the critical incident must be made promptly and must be made accessible to the individual(s) involved[ii].

This legislation also established requirements for reporting and investigating a critical incident. The health corporation, or prescribed healthcare organization, must:

1) Notify the Regional Health Authority, who then must notify the Provincial Health Minister of the critical incident;
2) Consult with the Regional Health Authority and establish a critical incident review committee to investigate and report the critical incident. This committee has the power to compel the production of information, including personal health information; and
3) Provide the report of the critical incident review committee to the Regional Health Authority and the Provincial Health Minister.

Records and information relating to a critical incident review committee are protected under the Manitoba Evidence Act.

Quebec

The Quebec government also has legislation surrounding institutional disclosure and risk management activities related to the provision of safe health services. Amendments to an Act Respecting Health Services and Social Services[iii], were passed in December 2002. Section 8 requires disclosure of an accident that occurred during the delivery of healthcare and having *"actual or potential consequences for the user's state of health or welfare and of the measures taken to correct the consequences suffered, if any, or to prevent such an accident from recurring".*

For the purposes of this Section and Sections 183.2, 233.1, 235.1 and 431 and unless the context indicates otherwise, "accident" means an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personnel member, a professional involved or a third person. Section 235.1 requires that *"The board of directors of an institution shall, by by-law, establish rules to be followed when an accident occurs, so that all the necessary information is disclosed to the user, to the representative of an incapable user of full age or, in the event of the user's death, to the persons referred to in the first paragraph of Section 23. The board of directions shall also establish, in the same manner, support measures, including the appropriate care, to be made available to such a user, such a representative or such persons and measures to prevent such an accident form recurring".*

There is a different meaning for the terms "accident" and "incident"; they are not interchangeable. The meaning of the term "incident" is given in the Section 183.2 of the Act: *"incident means an action or situation that does not have consequences for the state of health or welfare of a user, a personnel member, a professional involved or a third person, but the outcome of which is unusual and could have had consequences under different circumstances… ".* For the purposes of this Section and Sections 233.1, 235.1 and 431 and unless the context indicates otherwise, "incident means an action or situation that does not have consequences for the state of health or welfare of a user, a personnel member, a professional involved or a third person but the outcome of which is unusual and could have had consequences under different circumstances".

Event reporting (accident and incident) is ruled by Section 233.1 requiring that *"Any employee of an institution, any person practising in a centre operated by an institution, any person undergoing training in such a centre or any person who, under a service contract, provides services to users on behalf of an institution must, as soon as possible after becoming aware of any incident or accident, report it to the executive director of the institution or so a person designated by the executive director. Such incidents or accidents shall be reported in the form provided for such purposes, which shall be filed in the user's record. The executive director of the institution or the person designated by the executive director shall report in non-nominative form, all reported incidents or accidents to the agency at agreed intervals or whenever the agency so requires".*

The Act further requires the creation of a risk management committee *"to identify and analyze the risk of incident or accident – make sure that support is provided to the victim and the close relatives of them – establish a monitoring system… for the purpose*

of analyzing the causes of incidents and accidents, and recommend to the board of directors of the institution measures to prevent such incidents and accidents from recurring and any appropriate control measures".

Ontario

The Hospital Management Regulation was amended in 2010 and 2011 to include requirements relating to disclosure and reporting of critical incidents. A critical incident is defined as *"an unintended event that occurs when a patient receives treatment in the hospital that results in death, or serious disability, injury or harm to the patient, and does not result primarily from the patient's underlying medical condition or from a known risk inherent in providing the treatment."*[iv] Critical incidents must be disclosed to the medical advisory committee and administrator. As well, the patient or the patient's representative must be told:

1) The material facts of what occurred with respect to the critical incident;
2) The consequences for the patient of the critical incident, as they become known; and
3) The actions taken and recommended to be taken to address the consequences to the patient of the critical incident, including any health care or treatment that is advisable.

Following disclosure, the administrator must establish a system for ensuring that the incident is analyzed and a plan developed with systemic steps to avoid or reduce the risk of further similar critical incidents. The administrator must provide aggregate critical incident data to the hospital quality assurance committee at least two times per year. Patients or their representatives must also be told *"the systemic steps, if any, that the hospital is taking or has taken in order to avoid or reduce the risk of further similar critical incidents".* This disclosure is subject to the protections in the Quality of Care Information Protection Act, 2004.

Healthcare Quality Improvement Legislation

Each jurisdiction in Canada has applicable legislative and regulatory frameworks which detail the processes to improve the quality of healthcare services. An overview of legislative protection for quality of care information is provided in *Appendix M* to highlight its importance and relevance to those individuals and organizations conducting a patient safety incident analysis. The information is accurate as of the date of publication; however, it is subject to change over time. Examples are included only to help explain key concepts.

The information presented in this framework is not intended as a substitute for legal advice. It is imperative that a committee which seeks protection for confidential discussions be established in accordance with all legislative stipulations, to address the risk of being compelled to disclose information. Legal counsel should be consulted to interpret the governing legislation applicable to each jurisdiction.

Incident analysis is based on an inter-disciplinary approach, with involvement of those closest to the process. It works best in a confidential environment where designated

persons can collect, analyze, and share information. Quality of care protection is meant to create a confidential environment where discussions and documentation are protected and cannot be disclosed in a legal proceeding. There are a variety of terms used in legislation to identify committees that receive protection for confidential discussions. For example, Alberta uses the term "quality assurance committee", Saskatchewan uses the term "quality improvement committee", while Ontario uses the term "quality of care committee." In other jurisdictions, there is no definition of "committee" but the functions of the committee are set out in legislation (see, for example, the Evidence Acts for New Brunswick and Nova Scotia). For ease of reference, the term quality of care committee will be used throughout this document. Quebec uses the terms «Risk Management Committee».

Generally, relevant information must be disclosed in the course of a civil action unless it is "privileged". The main classifications of privilege include solicitor client and litigation privilege. Communications between a lawyer and client are protected from disclosure. Litigation privilege applied when information is generated for the predominate purpose of litigation.

The following issues should be considered when establishing committees for incident analysis:

A. What type of healthcare body is establishing the committee?

Some legislation limits protection to quality of care committees created by hospitals. In others, protection is granted to quality of care committees created by other healthcare bodies. Some jurisdictions permit the Provincial Health Minister to designate quality of care committees.

For example, under Ontario's Quality of Care Information Protection Act[v] hospitals and other health facilities may create quality of care committees. In New Brunswick, the Evidence Act[vi] provides protection for committees established by hospital corporations.

Both Alberta and British Columbia provide examples of the Provincial Health Minister designating quality of care committees by regulation. The committees designated in British Columbia[vii] are the following:

a) The Industry Reference Group on Notification or Look back related to Hepatitis C/HIV;
b) The Maternal and Perinatal Mortality Review of the British Columbia Reproductive Care; and
c) The Critical Incident Report Subcommittee of the Quality Assurance Committee of the British Columbia Anaesthetists' Society.

The Provincial Health Minister in Alberta[viii] has named the following committees as quality of care committees:

a) The Committee on Reproductive Care established by the Alberta Medical Association;
b) The Physicians Performance Committee established by the College of Physicians and Surgeons of Alberta;

c) The Perinatal Morbidity Review Committee established by the Northern and Central Alberta Perinatal Program Advisory Committee; and
d) The Ambulance Medical Review Committee.

B. Whose communications are protected?

Generally, communications relating to quality of care that do not involve a quality of care committee are not entitled to protection.

For example, Ontario's Quality of Care Information Protection Act[v] only protects information prepared by, or for, a committee that has been designated as a quality of care committee. Before acting as a quality of care committee, it must be designated as such in writing by the health facility or entity that established, appointed, or approved it. The terms of reference of the committee and its designation must be publicly available.

C. What communications and information are protected?

Protection is generally extended to information, documents and opinions. In some statutes, only documents that have been prepared exclusively or primarily for the quality of care committee will receive protection.

For example, the Saskatchewan Evidence Act[ix] does not protect records that are:

1) Prepared for the purpose of providing a health service to an individual;
2) Prepared as a result of an incident that occurred in a facility operated by a health services agency or in the provision of a health service by a health services agency, unless the facts relating to that incident are also fully recorded on a record described in subclause (i); or
3) Required by law to be kept by the health services agency.

As well, protection is extended to reports, documents or records that are:

1) Prepared exclusively for the use of, or made by, a committee; or
2) Used exclusively in the course of, or arising out of, any investigation, study or program carried on by a committee.

Nova Scotia's Evidence Act[x] does not employ a dominant purpose or exclusivity test. Under Ontario's Quality of Care Information Protection Act, information that is collected by, or prepared for, a quality of care committee is protected if it was prepared for the "sole or primary purpose" of assisting the committee; or when it relates "solely or primarily to any activity" of the quality of care committee.

D. What committees are protected?

Some statutes identify protected committees according to their purpose, while others only provide protection for particular committees established by statute. The activities of ad hoc committees or individuals acting outside of bylaws or other established parameters are not likely to be protected. In some jurisdictions, official designation is required for a committee's communications to receive protection. To ensure transparency, it is advisable that quality of care committees be designated by resolution of the organization's board or senior management, consistent with the hospital's by-laws and structure on creating committees.

E. What is the subject of the communication at issue?
Generally, statutes require that a committee's activity be motivated by the desire to improve healthcare services.

For example, for committees to be established and protected under Ontario's Quality of Care Information Protection Act[v] they must have a view to improve or maintain: 1) the quality of healthcare, or 2) the level of skill, knowledge, or competence of the healthcare provider. Under Quebec's Act Respecting Health Services and Social Services,[iii] an institution must establish a risk management committee that seeks, develops, and promotes ways to identify and analyze incident or accident risks to ensure the safety of users. Under Quebec's Act Respecting Health Services and Social Services, an institution must establish a risk management committee that seeks, develops, and promotes ways to identify and analyze incident and accident risks to ensure the safety of users.

F. Who is seeking the quality assurance records?
Some statutes protect quality assurance records from subpoena, discovery, or disclosure in an action, while other laws provide broader protection.

For example, The Alberta Evidence Act[xi] states that a witness in an action is not liable to be asked, and shall not be permitted to answer, any question as to any proceedings before a quality assurance committee. Additionally, the witness 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.

Ontario's Quality of Care Information Protection Act[v] provides that quality of care information may only be disclosed to management if the committee considers it appropriate for the purposes of improving or maintaining the quality of healthcare provided in the facility. The information may also be disclosed if it will eliminate or reduce a significant risk to a person or group of persons.

Quebec's Act Respecting Health Services and Social Services[iii] provides that no person may have access to the minutes of the risk management committee except the committee members, the representatives of accreditation bodies or the representatives of a professional order. Quebec's Act Respecting Health Services and Social Services[iii] provides that:

"Notwithstanding the Act respecting Access to documents held by public bodies and the Protection of personal information Chapter A-2.1, the records and minutes of a risk management committee are confidential. No person may have access to the minutes of a risk management committee except the members of the committee, the representatives of accreditation bodies in the exercise of functions pertaining to the accreditation of the health services and social services provided by institutions or the representatives of a professional order in the exercise of the functions assigned to the by law".

The following steps should be taken after a committee has been established (either by the committee itself or by another ad hoc group):

- Once policies for committee records are in place, all personnel involved in committee activities should be educated as to the importance of following those policies meticulously. All participants in a quality of care review should be reminded that it is a privileged and confidential review that is being conducted for quality of care purposes.
- All quality of care committee minutes should be prepared carefully and in accordance with the provincial legislation. Committee minutes should document conclusions, and not the details of the actual discussion or personal comments made by committee members.
- All documentation that is created should clearly state that it is a privileged and confidential quality of care review document.

Freedom of Information and Protection of Privacy Legislation

All provinces and territories have public sector legislation dealing with freedom of information and protection of privacy. Many of them cover hospitals or regional health authorities. The overall purpose of freedom of information and protection of privacy legislation[xi] is to provide a right of access to information in accordance with the principles that information should be available to the public and necessary exemptions from the right of access should be limited and specific. The right of access in freedom of information and protection of privacy legislation is very important because that right encourages and enhances transparency and accountability in decision-making by public bodies.

In Ontario, the *Freedom of Information and Protection of Privacy Act* [xii] (FIPPA) was recently amended to provide a right of access to the records in the custody or under the control of a hospital where the records came into the custody or under the control of the hospital on or after January 1, 2007. FIPPA was also amended to permit hospitals to refuse disclosure of *"information provided to, or records prepared by, a hospital committee for the purpose of assessing or evaluating the quality of health care and directly related programs and services provided by the hospital"*. This is a discretionary exemption and, as such, hospitals must consider whether access should be allowed in the particular circumstances of each access request. Finally, the exemption in FIPPA does not affect the protection provided by the *Quality of Care Information Protection Act* (QCIPA). The purpose of the amendment was to permit hospitals to refuse access to quality of care information that is not already protected by the QCIPA.

References:

i. Government of Saskatchewan, Ministry of Health. Saskatchewan Critical Incident Reporting Guideline, 2004. Regina, SK: Government of Saskatchewan; 2004. Available from: www.health.gov.sk.ca/critical-incident-guidelines

ii. Regional Health Authorities Act, C.C.S.M., c. R34; Part 4.1, Patient Safety, Manitoba. Available from: http://web2.gov.mb.ca/laws/statutes/ccsm/r034e.php

iii. An Act Respecting Health Services and Social Services, R.S.Q., ch S-4.2, Quebec. Available from: http://canlii.ca/t/ldmc

iv. Public Hospitals Act, R.R.O. 1990, Reg. 965, Hospital Management, Government of Ontario. Available from: http://canlii.ca/t/l40j

v. Quality of Care Information Protection Act, 2004, S.O. 2004, ch 3, sch B, Government of Ontario. Available from: http://canlii.ca/t/kpdf

vi. New Brunswick Evidence Act, R.S.N.B. 1973, c.E-11, s. 43.3. Government of New Brunswick. Available from http://canlii.ca/t/88lk

vii. B.C. Reg 363/95. Government of British Columbia. Available from: http://canlii.ca/t/kpxk

viii. Alberta Evidence Act, Quality Assurance Committee Regulation, Alta Reg. 294/2003, Government of Alberta. Available from: http://canlii.ca/t/jb1l

ix. Evidence Act, SS 2006, c E-11.2, Government of Saskatchewan. Available from: http://canlii.ca/t/kvb0

x. Evidence Act, RSNS 1989, c 154, Government of Nova Scotia. Available from: http://canlii.ca/t/jpj0

xi. Alberta Evidence Act, RSA 2000, c A-18, Government of Alberta. Available from: http://canlii.ca/t/kxcs

xii. Freedom of Information and Protection of Privacy Act, R.S.O. 1990, c. F-31, s.18(1)(j). Government of Ontario. Available from: http://canlii.ca/t/2d9.

M. LEGISLATIVE PROTECTION FOR QUALITY OF CARE INFORMATION IN CANADA

(Accurate at the date of publication – please check if there are any updates)

Alberta

Alberta Evidence Act, R.S.A. 2000, c.A-18, s.9
Quality Assurance Committee Regulation, Alberta Regulation 294/2003
Health Information Act, R.S.A. 2000, c.H-5, ss.35(1)(g), 35(2)-(3)
Health Quality Council of Alberta Act, S.A. 2011, c.H-7.2, s. 6

British Columbia

Evidence Act, R.S.B.C. 1996, c.124, s.51
Designation Regulation, British Columbia Regulation 363/95 as amended

Manitoba

Manitoba Evidence Act, R.S.M. 1987, c.E150, ss.9, 10 (C.C.S.M., c.E150)
Personal Health Information Act, C.C.S.M. c. P33.5, ss. 11(1)(d), 22(2)(e)

Northwest Territories

Evidence Act, R.S.N.W.T. 1988, c.E-8, ss.13, 14, 15

New Brunswick

Evidence Act, R.S.N.B. 1973, c.E-11, s.43.3

Newfoundland / Labrador

Evidence Act, R.S.N.L. 1990, c.E-16, s.8.1

Nova Scotia

Evidence Act, R.S.N.S. 1989, c.154, ss.60, 61

Nunavut

Evidence Act, R.S.N.W.T. 1988, c.E-8, ss.13, 14, 15, as duplicated for Nunavut by s.29 of the Nunavut Act, S.C. 1993, c.128

Ontario

Quality of Care Information Protection Act, 2004, S.O. 2004, c.3, Sched. B
Definition of 'Quality of Care Committee' Regulation, Ontario Regulation 297/04
General Regulation, Ontario Regulation 330/04
Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Sch. A, s. 51(1)(a)

Prince Edward Island

Health Services Act, R.S.P.E.I. 1988, c. H-1.5, ss. 26-31
Medical Act, R.S.P.E.I. 1998, c.M-5, s.38.7

Quebec

Act Respecting Health Services and Social Services, R.S.Q., c.S-4.2, ss. 183.3, 183.4. 233.1 and for medical activities section 218

An Act respecting health services and social services, R.S.Q., c.S-4.2, ss. 183.1, 183.3, 183.4, 190, 213, 214, 218

Saskatchewan

Health Information Protection Act, S.S. 1999, c.H-0.021, s.27(4)(g)

Evidence Act, S.S. 2006, c.E-11.2, s.10

Regional Health Services Act, S.S. 2002, c. R-8.2, s.58

Critical Incident Regulations, R.R.S. c.R-8.2 Reg. 3

Yukon

Evidence Act, R.S.Y. 2002, c.78, s.13

N. THREE HUMAN FACTORS METHODS THAT CAN BE USED IN INCIDENT ANALYSIS

Various human factors methods can be employed in the analysis process to help answer the question, "How did it happen?" They range in complexity, time and resources, and expertise (in human factors) needed. All three methods (described below) assist in examining the human-system interaction in detail. With **cognitive walkthrough**, perhaps the easiest and most cost-effective method to employ, a participant is asked to "think out loud" while simulating the tasks that were involved in the incident. In a **heuristic evaluation**, an audit is carried out of the various parts of the systems (such as equipment, paper forms, computer systems) that were used in the tasks that were part of the incident. The audit is used to determine if human factors design principles were violated, and thus may be identified as possible contributing factors in the incident. Heuristic evaluation requires an understanding of human factors principles as they apply to different systems (e.g. computer systems). Finally, **usability testing** can be used, in which human-system interaction with equipment, paperwork, or processes are observed (similar to a simulation). Participants are asked to carry out a set of tasks in a simulated environment given the scenario in the incident. Some level of human factors training is needed in order to plan and execute usability tests, and to interpret the results. However, the information is extremely helpful and detailed because, if done correctly, the usability test examines how the human-system interaction occurs in the real world.

Cognitive Walkthrough

As noted above, this is perhaps the quickest to conduct and takes the least amount of time, resources and human factors expertise to complete, as compared to the two other methods discussed here. Cognitive walkthrough can be used to help identify contributing factors in the analysis phase, or it can be used to help assess the effectiveness of recommended actions. In either case, it is used to help discover the details of the cognitive and physical activities that took place (or may take place, in the case of evaluating a recommended action).

To carry out a cognitive walkthrough, recruit participants who are either representative of the person(s) involved in the incident (e.g. pharmacist or nurse) or the actual workers involved, to simulate the set of tasks surrounding the incident. Ask the participant to "think out loud" as they simulate, or walk through each step of that task. The key is that they verbalize what they are thinking as they are doing it. Throughout the simulation, it is helpful to ask prompting questions such as, "What were you looking to do at this point?", "What did you have to figure out?", "Where did you find the information you needed?", "What did you have to think about next?", "What made you think you needed to do that?", "How obvious was it to you?" or "How confident were you that you did it correctly?".

The success of a cognitive walkthrough is heavily dependent on:

- The participant feeling comfortable to express their thoughts without fear;
- The proper identification of the task or activities that participants will simulate (if the task is too narrowly defined, it will limit the amount of information you can find); and
- The facilitator of the cognitive walkthrough keeping their opinions to themself and not "leading" the participant (the facilitator should only tell the participant what task to perform, but NOT "how" they should perform the task, nor how they "should have" performed the task).

If possible, recruit between one and six people to participate in the walkthrough. It is best to have four to six participants because it will capture a wider cross section of the human-system interaction. However, one participant is better than none, and even one person will provide extremely rich information for the incident analysis.

At the end of the cognitive walkthrough, the person conducting the activity will have a more detailed understanding of the cognitive and physical activities that led to the incident and what aspects of the system may have failed to support these activities, and thus may have been contributing factors.

Alternately, if the cognitive walkthrough was conducted to evaluate proposed recommended action, the walkthrough will provide some insight into their effectiveness. It may also help to determine if the recommended action has created some unintended and undesirable consequences. For instance: Does it take additional unnecessary mental effort? Does it make the task overly complex or tedious? Does it create confusion or uncertainty? Does it create risk for other kinds of errors? Depending on the response to these questions, it may be necessary to modify or select an alternate recommended action to pursue (and possibly evaluate again using any of the three human factors methods described in this Appendix).

Heuristic Evaluation

This method requires some knowledge of human factors design principles and how to apply them to specific systems (e.g. computer systems). It may take approximately the same amount of time to conduct as the cognitive walkthrough, though possibly longer depending on complexity), and does not require participants or other special arrangements. This method can be useful in the analysis phase to help identify contributing factors, or to help evaluate recommended action before they are implemented.

In a heuristic evaluation, an audit of the system is performed to determine if human factors design principles are violated. The principles cover a wide range of issues related to whether the design of the system fits the task or human. The audit can identify where human-system interaction is negatively influenced.

The results of a heuristic evaluation can provide very detailed information about contributing factors and how they can be changed to improve the risk for errors. Also, the method can be used to help develop and design the recommended action.

Usability Testing

Among the three methods described here, usability testing likely takes the most time and resources. It also requires some expertise in human factors to plan, execute and analyze the results. However, simple usability tests can be performed that are not as time-and-resource consuming and can yield very helpful information about contributory factors, or about whether a recommended action is effective.

In a usability test, participants are recruited to carry out a specific task (or set of tasks). The test can be carried out in a simulated setting, or in some cases the actual work area. Then information related to how the task (or set of tasks) is executed is gathered, such as time on

task, number (and nature) of steps, or errors. This allows for observation of how the human-system interaction plays out, and where difficulties are encountered (contributing factors). A formal usability test may require anywhere from 20 to several hundred participants and take weeks, if not months of planning. However, for the purpose of gathering information for an incident analysis, a less formal approach can be taken and fewer participants recruited, because the aim is to gain a qualitative understanding of possible contributing factors. Four to six participants would be desirable, but even involving only one or two participants may yield helpful qualitative information for the incident analysis.

Similar to the other methods described, usability testing can be used for both identifying contributing factors as well as for evaluating the effectiveness of recommended actions.

Example of using human factors to guide an incident analysis:
When examining an incident in which a nurse incorrectly sets up a medical device, it is important to identify the contributing factors. An action such as "the nurse pushed the wrong button" is not a contributing factor; it is a factual description of what happened. The goal in the analysis is to determine how and why this happened. To approach this question using human factors, it is necessary to examine the equipment's user interface and look for design features that may have influenced this action. For instance, as part of a heuristic evaluation, questions you could ask include:

- Was the button close to the one they intended to push?
- Was it labeled in a manner that led them to believe that pushing that button was the correct action?
- Were the instructions that were displayed on the screen unclear as to what button they needed to push next?
- Was the button label inconsistent with the terminology used in the displayed instructions?
- Was the button grouped closely with other buttons that are typically used in the task the nurse was performing (leading her to believe that it was to be used in this task)?
- Was the button's appearance similar to (and possibly confusable with) other buttons?
- Were there other confusing features on the interface that may have caused a misunderstanding or confusion?

You could also look at materials that were involved in setting up the device. For instance, if an order form was used, you would examine its ease-of-use. Not only it's readability and legibility, but also, how it relates to the task of setting up the device. For instance:

- Does the nurse refer to the order form during device set-up?
- What information does the nurse use to help with the set-up?
- Is the information provided in a logical order that matches what they need to do with the device?
- Is the terminology used on the order form consistent with what's used on the device?
- Is there any information that may be confusing?
- Does the organization of the information on the order form match the flow of the task?

Next, one would explore the nature of the task and how that may have influenced the human-system interaction, for instance, time pressure, performing multiple tasks at once, complexity of the steps, and so forth. Also, the environment, work area layout, organizational context, team, and patient factors also may influence how work is carried out and thus may be the source of contributing factors. The guiding questions in ***Appendix G*** provide a starting point for examining the factors that may have played a role in the incident.

A cognitive walkthrough to observe nurses setting up the device will also provide information on aspects of the process that may be confusing or where information is not readily available, leading to interruptions in the process that may also lead to errors.

O. GLOSSARY

Ameliorating action - an action taken or circumstances altered to make better or compensate any harm after an incident.

Actions taken to reduce risk - actions taken to reduce, manage or control any future harm, or probability of harm, associated with an incident.*

Contributing factor - a circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident.*

Detection - an action or circumstance that results in the discovery of an incident.*

Findings are:

1) Factors that, if corrected, would likely have prevented the incident or mitigated the harm – these will be the basis for developing recommended actions (note that these factors may require actions at different levels of the system);
2) Factors that if corrected, would not have prevented the incident or mitigated the harm, but are important for patient/staff safety or safe patient care in general; and
3) Mitigating factors – factors that didn't allow the incident to have more serious consequences and represent solid safeguards that should be kept in place.

Framework - a conceptual structure, provisional design or modelled representation of reality.

Forcing functions - something that prevents the behaviour from continuing until the problem has been corrected.*

Harm - impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes disease, injury, suffering, disability and death.*

Hazard - a circumstance, agent or action with the potential to cause harm.

Hindsight bias -the tendency to oversimplify and assign simple (human error) causes to events during post-event investigations (e.g. knowing the outcome of an event skews our perception of contributing factors).*

Incident (patient safety incident) - an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.

Incident analysis - a structured process that aims to identify what happened, how and why it happened, what can be done to reduce the risk of recurrence and make care safer, and what was learned.

Incident management - the various actions and processes required to conduct the immediate and ongoing activities following an incident. Incident analysis is part of incident management.

Incident type - a descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features.*

Method - a systematic process, procedure, manner, or orderly sequence.

Mitigating factor - an action or circumstance which prevents or moderates the progression of an incident towards harming a patient.*

Near miss - an incident which did not reach the patient.*

Organizational outcome - the impact upon an organization which is wholly or partially attributable to an incident.*

Patient - in this document it refers to residents, clients or customers of a healthcare service. (A person who is a recipient of healthcare.)*

Patient outcome - the impact upon a patient which is wholly or partially attributable to an incident.*

Provider - in this document it refers to physicians, professional and non-professional staff and others engaged in care.

Resilience - the degree to which a system continuously prevents, detects, mitigates or ameliorates hazards or incidents.*

Tools - devices or instruments (concrete or abstract) with which an operation is performed.

**Definitions are taken from the Conceptual Framework for the International Classification from Patient Safety. WHO, 2009*

The International Classification for Patient Safety,[3] under development by the World Health Organization (WHO), is a framework and terminology to facilitate the sharing and learning of patient safety information globally. A purpose of the International Classification for Patient Safety Framework is to harmonize language about patient safety so that providers, organizations and countries can start to classify like incidents similarly, enabling the patient safety community to share and compare information about incidents in order to learn from each other's experiences. The Canadian Patient Safety Institute encourages the use of these preferred terms for consistency and clarity, but also recognizes that organizations may have reason to continue to use other terminology.

Note for Québec readers:

TERMS USED IN THE CANADIAN FRAMEWORK	TERMS USED IN QUEBEC
Patient	User
Incident disclosure	Accident disclosure
Harm	Consequence
Patient safety incident	Accident resulting from the provision of healthcare or social services
Harmful incident	Accident with consequences for the user
No harm incident	Accident without consequences but the user was affected
Near miss	Incident or near miss
Harmful incident, no harm incident, and near miss	Events

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