CANADIAN INCIDENT ANALYSIS FRAMEWORK

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The Essentials of Analysis: Principles, Concepts and Leading Practices

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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]

> "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]

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]

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

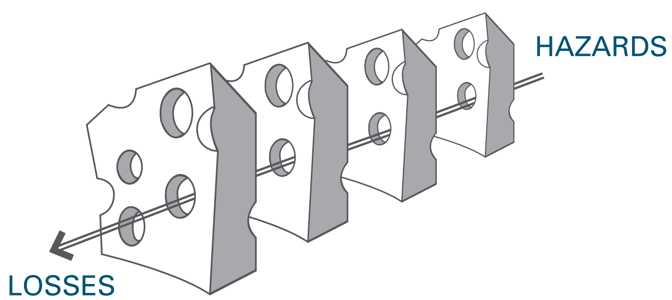
There are several concepts used throughout the framework that are intended to ensure that incident analysis and management reflects the complexities of the current healthcare system, while remaining practical. These concepts support a deeper understanding of how incidents occur in healthcare and assist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

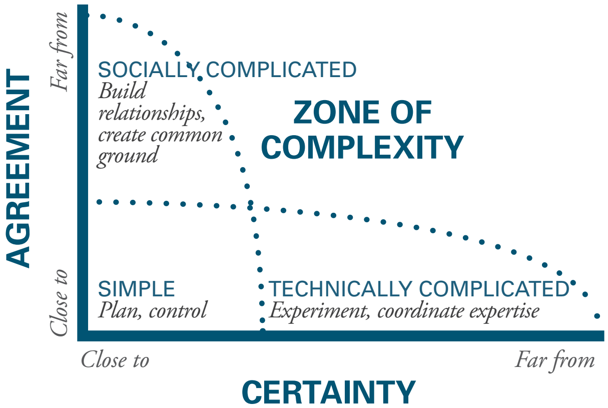
Patient safety experts are strongly advocating a way of thinking that views human error as a symptom of broader issues within a poorly designed system, such as an adverse physical or organizational environment. Dekker[28] refers to an old and new view of human error. In the old view the objective is 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.

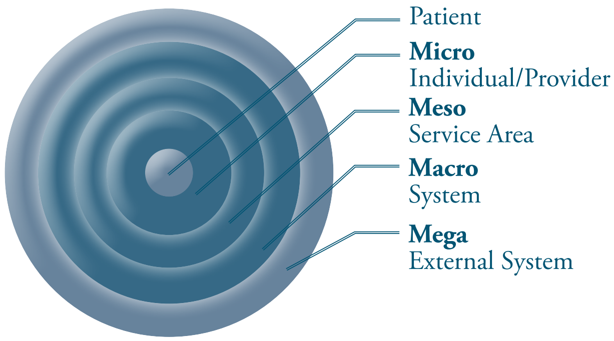
System Levels

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.