Strengthening Med Safety in Long-Term Care

Concise Incident Analysis Workbook

Institute for Safe Medication Practices Canada

ISMP CANADA

The Institute for Safe Medication Practices Canada (ISMP Canada) is a national, independent, and not-for-profit organization that purposefully partners with organizations, practitioners, consumers, and caregivers to advance medication safety in all healthcare settings. Our team of experts analyze reports of medication errors from across the country and provide resources, education, and consulting services to improve medication safety. guide

We analyze reports of medication errors and other issues so we can learn about the risks related to medications and collaboratively develop strategies to address them. We share lessons learned, including compelling actionable, evidence-informed recommendations that organizations, practitioners, consumers, and caregivers can use to reduce the risks related to medications. We partner to implement, sustain, and evaluate medication safety improvements in practice.

Additional information about ISMP Canada, and its products and services, is available at www.ismpcanada.ca

Acknowledgements

The need for a Concise Incident Analysis Workbook was identified as an important tool for long-term care homes participating in the *Strengthening Medication Safety in Long-Term Care* initiative* led by ISMP Canada. Through reviewing academic and grey literature, it was determined that building upon the Concise Incident Analysis Tool, released by the Canadian Patient Safety Institute in 2014, would address this need. The Workbook is designed to be used in all sectors of the healthcare system as the methodology is applicable regardless of clinical setting.

In this Workbook, there is an increased emphasis on the nature of human factors in the analysis process and a more structured approach to quality improvement strategies.

Thank you to Dr. Julius Pham, Carolyn Hoffman, Ioana Popescu and O. Mayowa Ijagbemi, co-authors of the Concise Incident Analysis Tool, 2014, and to the Canadian Patient Safety Institute for sponsoring the development of the tool.

Special thanks to Raymond Obed and the Daphne Cockwell School of Nursing, Toronto Metropolitan University. Raymond completed the literature search and prepared the initial version of the Workbook as part of his Master of Nursing practicum placement with ISMP Canada.

**The Strengthening Medication Safety in LTC Initiative is funded by the Ontario Ministry of Long-Term Care. Views expressed are the views of ISMP Canada and do not necessarily reflect those of the province.*

Institute for Safe Medication Practices Canada
4711 Yonge Street
Suite 706
Toronto, ON
M2N 6K8

Telephone: 416-733-3131 or toll free 1-866-544-7672
Fax: 416-733-1146
www.ismpcanada.ca
LTC@ismpcanada.ca

A Key Partner in the Canadian Medication Incident Reporting and Prevention System
Un partenaire clé du Système canadien de déclaration et de prévention des incidents médicamenteux

Table of Contents

SECTION 1 – Background

Incident management and analysis in the healthcare system started with the use of root cause analysis (RCA), primarily using the five whys to get to the root cause of an incident.[1,2] The use of this approach emerged as healthcare professionals and system leaders began to recognize the significant number of patient safety incidents[i] that happen in healthcare settings.[3] The term patient is used throughout the workbook and is intended to encompass everyone who receives health services across the continuum of care (e.g., patient, client, resident, consumer and their caregiver if applicable).

In 2012, the Canadian Patient Safety Institute collaboratively developed and disseminated the Canadian Incident Analysis Framework.[4] The Framework introduced a systems approach, including the integration of human factors science, to incident analysis. Through the use of this methodology, the process of incident analysis is more effective in identifying contributing factors that impact the safety and reliability of care delivered by healthcare professionals. In addition, there are tools and techniques for designing more effective improvement strategies.

Principles of incident analysis:

- Begins as soon as possible;
- Includes all involved in the incident (including patient/family) and leadership of the organization;
- Is objective and impartial;
- Is thorough; and,
- Considers reporting systems and alerts, relevant literature and expert evidence.

There are three types of incident analysis: comprehensive, concise and multi-incident. This workbook is designed to support a rigorous but concise approach that can be used more often to complete meaningful analyses of patient safety incidents, incorporating a greater emphasis on the role of human factors and more impactful quality improvement strategies. See Table 3.1 below for how a concise analysis is completed and how it differs from a comprehensive analysis.

[i] A patient safety incident is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient.

Table 3.1 Characteristics of Concise and Comprehensive Incident Analysis

Characteristic	Concise	Comprehensive
Should include person(s) with knowledge of incident analysis, human factors, systems approach, and effective solutions development	Yes	Yes
Often facilitated by an individual with input gathered from a few other individuals, such as the patient, family members, staff, and/or prescribers local to the incident as well as organizational or external experts	Yes	No
Conducted by an interdisciplinary medium-to-large ad hoc group (may include patients, family members, staff, and prescribers local to the incident as well as operational/medical leadership and recognized independent internal or external experts/consultants not involved in the incident)	No	Yes
Time taken for analysis	Short timeframe (hours to days)	Long timeframe (up to 90 days)
Identifies contributing factors as well as remedial action(s) taken (if any)	Focus on key factors	Yes
Recommendations for improvement	Yes (if applicable)	Yes
Principles of incident analysis	Reflects the intent, but may not address all principles. May not be as thorough, or incorporate expert evidence	Incorporates all principles
Evaluation strategy to determine what impact was achieved	Yes (if applicable)	Yes

Why use the concise method?

Comprehensive incident analysis, described in the Canadian Incident Analysis Framework, is an in-depth process for identifying all potential contributing factors related to an incident. Concise analysis, on the other hand, is a less resource intensive approach to incident analysis that can contribute important knowledge regarding a larger number of incidents. This analysis method involves a conscious and deliberate decision to focus primarily on four aspects of the comprehensive methodology:

- the agreed upon facts,
- key contributing factors and findings,
- actions for improvement (if any), and
- evaluation.

Learning at the local level can then flow into the higher organizational level for prioritization of risks and integration into a systematic quality improvement approach to improve patient safety. A concise incident analysis uses a systems approach and considers human factors.

Who should the concise incident analysis tool be used?

This tool should be used by a facilitator with knowledge and skills in incident analysis, human factors, systems approach (explained in Section 3C), and effective solution development. The facilitator usually gains this expertise through a formal education program, and/or mentored experience. Several resources for incident analysis training are available online.[4,5,6] The facilitator may be a health care provider or other professional, such as a process improvement expert; this individual does not have to be a risk manager or quality improvement consultant.

Note: *Incident analysis should comply with all local policies and legislation. Legal advice is recommended when establishing any incident analysis policies or processes. A concise analysis approach is not suitable for all types of reviews. It is possible to transition from a concise approach to another type of analysis as new information is obtained and reviewed.*

SECTION 2 - Overview of Concise Incident Analysis Method

1. Case Selection

a. Determine if incident analysis is appropriate.
b. Determine if concise incident analysis is appropriate.

2. Understand What Happened

Obtain enough information to understand the incident.

a. Identify a facilitator to conduct analysis.
b. Gather facts
    i. From records and other applicable documents.
    ii. If applicable, gather and examine the equipment, product, or environment.
    iii. Have a limited number of informal discussions (interviews) with patient/family, provider(s), manager(s), attending physician, and/or expert(s) in the specific circumstance, equipment, and/or product.
c. Develop a high-level timeline or narrative description.
d. If applicable, transition to comprehensive analysis

3. Determine How and Why It Happened

Analyze information to identify key contributing factors and the relationships among them. Use a systems approach and human factors.

a. Identify key contributing factors
    i. BRIEFLY explore all the domains of contributing factors.
    ii. Select the one or two key contributing factors that are relevant to the incident to further focus the analysis.
b. Identify any relationships between contributing factors
c. Prioritize and summarize findings
d. Develop statement of findings.

4. Develop Recommended Actions for Improvement

If there is enough evidence, formulate actions for improvement to reduce the risk of recurrence and make care safer.

a. Selecting the most effective actions from a list of possible recommendations
    i. The Hierarchy of Effectiveness
    ii. Impact-Effort Matrix
b. Setting SMART goals for each action selected for implementation
c. Testing the actions on a smaller scale before full implementation
    i. Plan-Do-Study-Act cycle
d. Sustaining the improvements
e. Share learning

A. Case Selection

Determine if incident analysis is appropriate

A systems-based approach is looking beyond the contribution of individuals to consider how complex interacting elements of the entire healthcare system positively or negatively influence care. It uses a standardized methodology to minimize hindsight bias and ensure that applicable contributing factors are objectively determined.

Because the concise analysis method is not suitable for all incident types, the first step is to determine if a systems-based incident analysis is appropriate (see Section 4A). The following types of incidents are not recommended for a systems-based analysis:[7]

1. Events thought to result from a criminal act.
2. Purposefully unsafe acts (an act where care providers intended to cause harm by their actions).
3. Acts related to substance abuse by provider or staff.
4. Events involving suspected patient abuse of any kind.

These situations should be referred to the appropriate police, administrative, professional, or regulatory bodies for investigation and resolution.

Determine if concise incident analysis is appropriate

If a systems-based incident analysis is suitable, the second step is to determine if a concise incident analysis is appropriate for that case. The following attributes can guide this decision (see Section 4A):

- Incidents that resulted in no or low harm to the patient.
- Incidents primarily limited to one work area, division, or department.
- New incidents for which a comprehensive analysis was recently completed.
- Initial review to determine whether a comprehensive incident analysis is appropriate.

Note: not all information regarding the incident may be available during the case selection process; therefore, the facilitator selects the optimal method and anticipates the potential for changing the method as new information emerges.

B. Understand What Happened

Identify a facilitator

A facilitator (analyst/reviewer) with knowledge and skills in incident analysis, human factors, systems approach, and effective solution development performs the concise analysis.[4,5,6] The individual may be a health care provider or other professional, such as a process improvement expert; this individual does not necessarily have to be a risk manager or quality improvement consultant. A single facilitator can perform a concise incident analysis; however, some organizations may find benefit in using a team.

Gather facts

The facilitator should gather facts from different sources to understand what happened and to develop a high-level timeline or narrative of the incident from:

- Records (e.g., health record, incident report) and other documents;
- Discussions (interviews) with a few selected individuals directly involved in the incident.[7] These individuals may include healthcare providers, managers, experts, patients, and/or family members directly involved in the incident.[7] Patients and/or family members bring a unique perspective; therefore their input is important. Expert(s) in the specific circumstance, equipment, and/or product may also be consulted. See Section 4C;
- Equipment/ products/ environment examination (if applicable); and,
- Other techniques that might be employed include direct observation of practice, recreating the events by "walking the process," and group meetings with involved members.

Interview principles

- Interviews should be conducted as soon as reasonably possible after the incident for two reasons: (1) Memories fade quickly, and important details may be lost over time, and (2) 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.
- Informal interviews should be conducted one person at a time so that individual perspectives about the incident are well understood.
- A supportive interview approach is encouraged, using open-ended questions.
- Sincerely thank people for helping and ensure that their questions about the process are answered.

Gathering equipment, products, and other items

Gather materials used during or close to the time of the incident that may have directly or indirectly contributed to the circumstances (such as the equipment and any product/care items). These materials can be secured for testing and review. Materials may include, but are not limited to, biomedical equipment, IV solutions, medications, packaging, and garments. Photographs of the items and workspace are often helpful.

Develop a timeline or narrative description

Document key information in the form of a high-level timeline or narrative description. It is common to provide this information in a narrative chronological descriptive format. This understanding will collate information from various sources, including the health record and informal interviews with key individuals. It is important that the timeline include only the actual events or processes as they occurred, and not what was supposed to happen. For a template of the timeline, see Section 4D. An example of a completed timeline is shown in Appendix B.

C. Determine How and Why It Happened

Concepts

Systems

There are two key concepts to consider for ensuring the analysis reflects the complexities of the health care system while remaining practical: the systems approach (as illustrated by the Swiss Cheese Model in Figure 1) and the domain of human factors. These concepts support a deeper understanding of how and why incidents occur in health care, including the identification of specific contributing factors.

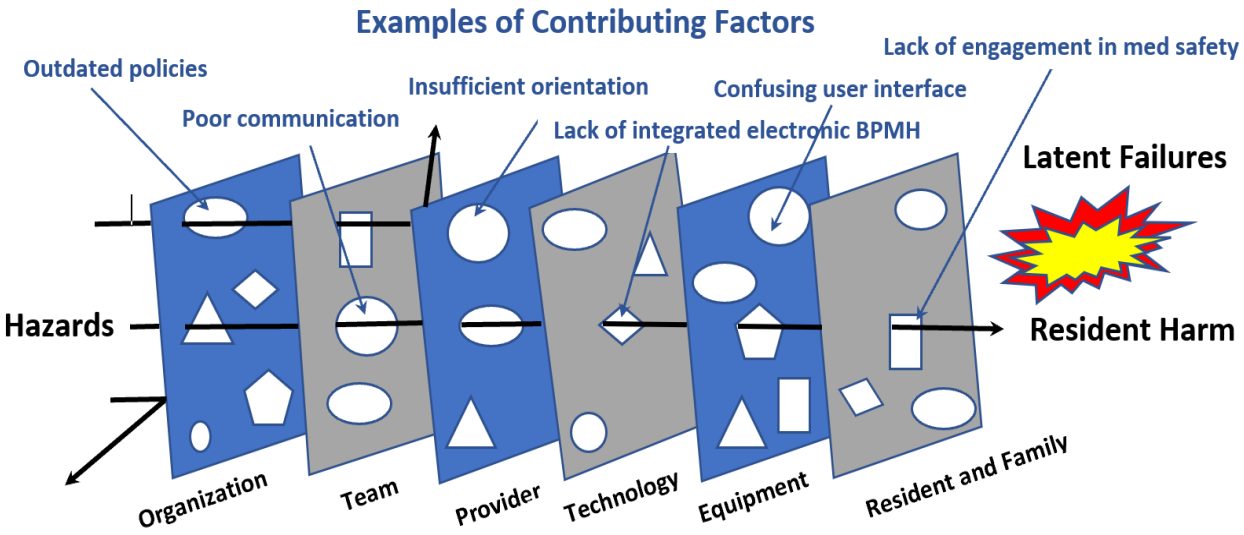


Figure 1. Reason's Swiss Cheese Model[8]

James Reason's Swiss Cheese Model[8] provides a framework for understanding and analyzing the complex and dynamic nature of patient care from a systems perspective. The model explains how the defenses, barriers, and safeguards that exist in a system are not impermeable and can be penetrated. This occurs when active failures (unsafe acts; e.g., inappropriate procedures being followed[9,10]) and latent conditions (dormant system conditions; e.g., poor lighting when reviewing medication[9,10]) align and create the opportunity for an incident. Latent conditions can be identified and corrected. Targeted strategies can also mitigate the frequency and severity of unsafe acts. It also points to the fact that humans are fallible, and errors will occur even in the best organizations because people are incapable of perfect performance every time.

Human Factors

Moving through the different layers of an incident can be daunting and so having a systematic approach that incorporates human factors to guide reasoning though an incident is beneficial. Human factors engineering focuses on designing systems, tools, and processes that recognize human capabilities, limitations, and characteristics. It helps create environments that support people in doing their work safely and effectively[9,10,11]. Some examples to consider are what is seen in a person's field of view or the amount of noise present that affects attention[10]. Human cognition is important for making the workplace efficient and user friendly. By recognizing all factors that exist in the workplace, it becomes easier to find where necessary changes are needed.

Through the guided approach, it becomes easier to determine contributing factors to an incident and make appropriate recommendations. Recommended actions for improvement will vary significantly and may range from physically changing the design of a software interface, sign, form, or medical device to redesigning a room (for example, operating suite) in a facility to optimize safety and efficiency. Change at various levels of the system are supported through human factors and human factors engineering.

Identify key contributing factors

Use the information gathered to identify key factors that contributed to the incident. Use the guiding questions (Section 4E) to briefly explore each domain (task, equipment, work environment, patient characteristics, care team, organization, other) of factors that may have contributed to this incident. For domains that are relevant to the incident, further explore each specific question. Questions to ask throughout the process include "how did this happen?", "are their supports in place to prevent this from happening?", and "what else influenced the circumstances?"

Table 3.3: Domains of Factors in Guiding Questions

Patient(s) characteristics: (Considered in the context of how well the system identified, understood, and acted upon these factors. It should not be the only factor considered.)
Task (care/work process)
Care team – Caregiver(s)
Care team – Supporting team (all involved in care process)
Equipment (including materials, fixtures, information, and communication systems)
Work environment
Organization – Policies and priorities
Organization – Culture
Organization – Capacity (resources)
Other (including Mitigating or Preventative Factors or Actions)

Identify the relationship between contributing factors using a diagram

Diagramming is a helpful exercise in understanding the relationship between contributing factors. The Constellation Diagram (Figure 2) is a useful tool for diagramming.

A constellation diagram visually shows the non-linear relationships between factors contributing to an incident. Collected incident information is used to identify actions or conditions related to the seven domains. These factors form chains that may interact and create clusters. The diagram illustrates relationships between contributing factors and helps identify areas where actions can address multiple issues. See Section 4F for instructions on developing a Constellation Diagram. See Appendix C for a sample of a completed constellation diagram.

Following completion of the Constellation Diagram, formalize the findings in writing. These findings are most often the basis for recommended actions. The overall goal is to determine if an action or a small number of actions can be taken to address all key contributing factors identified.

Prioritize and Summarize Findings

Once the team has completed the analysis, the contributing factors should be prioritized by importance (Section 4G). Several attributes could help in prioritizing: [12]

Factors that, if corrected, would likely have prevented the incident or mitigate the harm that occurs.[5]
Factors that are important for patient/staff safety or safe patient care in general.
Factors that represent solid safeguards that should be kept in place.

Statement of Findings

Prepare a summary of the findings to clearly articulate the contributing factors related to the incident and/or outcome. This summary should be formatted as a series of statements of findings (referred to as causal statements). The statement of findings should have the following characteristics:[13]

- Clearly shows the relationship between the contributing factor (actions / conditions) and the outcome.
- Use specific and accurate descriptions of what occurred rather than negative and vague words.
- Identifies the preceding system contributing factor of the error and NOT the human error.
- Identifies the preceding cause of procedure violations (if applicable).

The suggested statement has three parts and uses the following format:

A= Antecedent
B= Behaviour/Bridge
C= Consequences

This set of circumstances increased/decreased the likelihood that these consequences would occur.

Examples of Causal Statements:

"Lack of an explicit and formalized hand over communication protocol between the daytime and nighttime on-call physicians increased the likelihood that key patient care information would not be effectively transferred and that follow up medical assessments would not occur."

"Lack of an electronic prescriber order entry system increased the likelihood of medication transcribing errors related to the illegibility of prescriber handwriting."

"Lack of pharmacy support on the weekend resulted in a lack of specialized pharmaceutical expertise for medical and nursing questions at these times and increased the likelihood that a drug interaction could occur and/or be perpetuated."

"Medication reconciliation without using at least two independent sources of medication information decreased the likelihood of detecting and addressing errors related to inaccurate and/or incomplete best possible medication histories."

D. Develop Recommended Actions

Selecting the most effective actions from a list of possible recommendations:
Identifying possible recommendations after an incident analysis could generate many actions. It is possible for teams to come up with numerous changes that could be implemented to reduce the risks of recurrence. However, teams do not have the time to implement all the changes. Furthermore, teams tend to start with the easiest actions and even after completing most of the actions, they may not see a noticeable change in their safety metrics.

TIP: Focus on the "critical few" actions that will have the most impact or be the most effective. Use the hierarchy of effectiveness (shown below) to rate the actions as having high, medium or low impact.

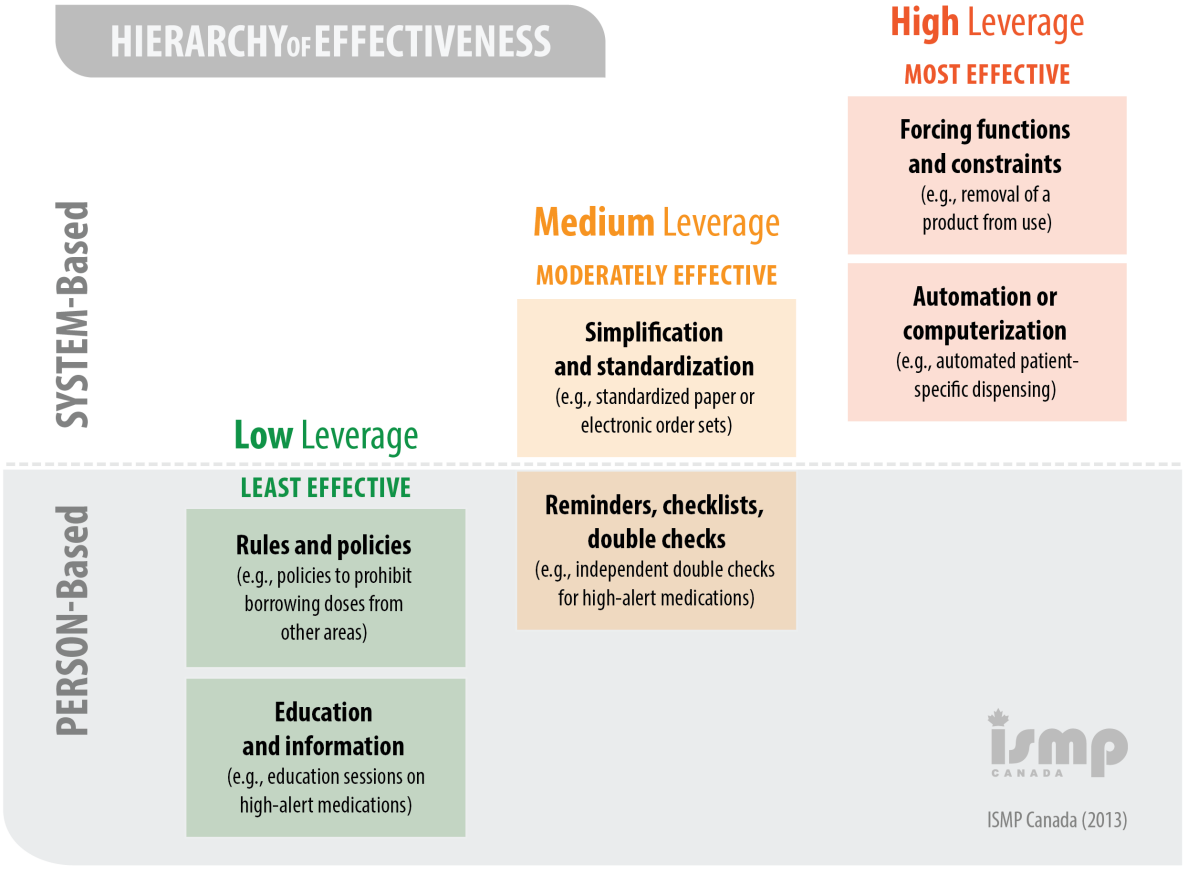


Figure 2. ISMP Canada Hierarchy of Effectiveness[14]

- Next, rate the effort required to implement the actions. Once the team is reasonably comfortable with rating the impact and the effort for each action, plot the actions on an Impact-Effort Matrix as shown below in Figure 4. The Impact-Effort Matrix is a decision tool that will ensure teams select the fewest possible actions that would achieve the objectives. This matrix includes:
    - **Gems** represent actions that yield significant impact with a low level of effort, and should therefore be prioritized;
    - **Major projects** may also have a significant impact, though resource constraints (e.g., limited budget, low staffing) may be prevent them from being prioritized;
    - **Fillers** are actions that demand a low level of effort but generate minimal impact;
    - **"Don't do"** are actions that should generally be avoided because they require significant effort to implement but have little to no impact.

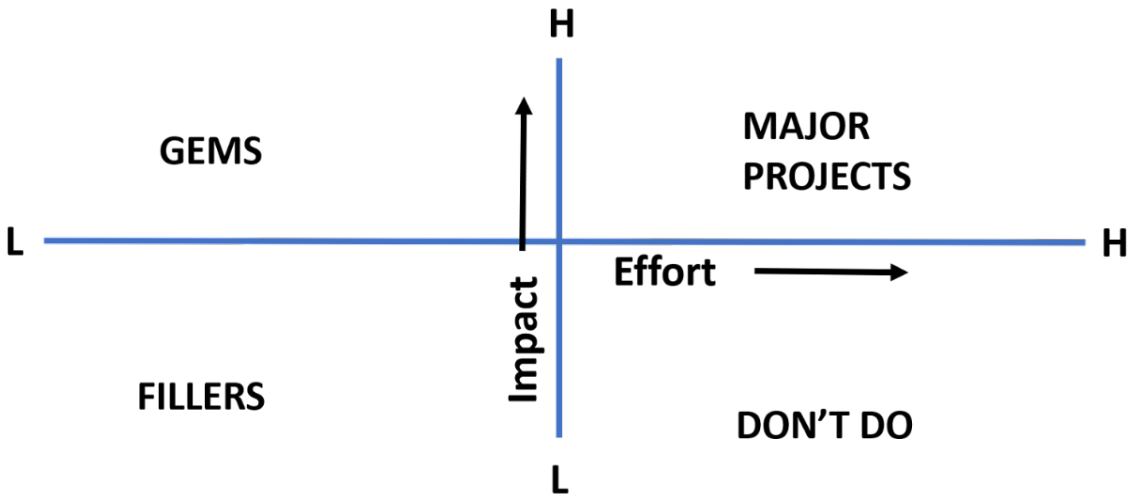


Figure 3. Impact-Effort Matrix

Setting SMART goals for each action selected for implementation:
Writing down goals for each action increases the chances that the action will get implemented. It also provides a quick documentation of what changes were made, what the impact of the changes were and builds the organizational capability for change. The goals should be:

- **Specific** – tackle a clearly defined issue and have a clear scope;
- **Measurable** – can demonstrate impact on process and outcomes;
- **Achievable** – Is the action attainable with available resources and support by a defined date;
- **Relevant** – ensure that the action is appropriate to the situation and possible; and,
- **Timely** – have a timeframe for implementation.

SMART Goal Examples:

- "In 6 months, 80% of prescribers will input all of their medication orders on the computerized prescriber order entry" or

- "In 12 weeks, at least 2 independent sources of medication information will be used for 90% of best possible medication histories".

An example of a completed action plan is shown in Appendix D.

Testing the actions on a smaller scale before full implementation:

After the team has selected the actions and has put measurable goals (predictions) for each, it's time to test the ideas on a small scale before full-scale implementation. This has a few advantages – one, the team gets to see if the idea works in practice and if the predicted improvement happened, and second, it is a way to provide some comfort to team members or other staff members who might otherwise be reluctant to take the risk of trying something new.

The tests of change are called Plan-Do-Study-Act (PDSA) cycles and are also a component of IHI's Model for Improvement shown below.

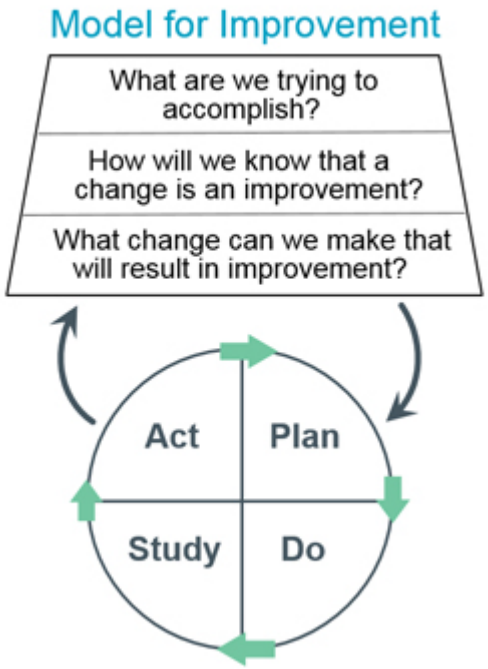


Figure 4. Developed by Associates in Process Improvement Model for Improvement[15]

Some important principles for conducting effective PDSA cycles are listed below:

- Document each component of the PDSA cycle (preferably on one page);
- Write down an explicit prediction for the test (from the SMART goals written earlier);
- In multiple iterations, incrementally increase the scale of the test; and,
- Use regular data collection over time (run charts) throughout all the iterative tests of change.

Sustaining the improvements:

After the improvements have been tested and the most effective actions have been selected for full-scale implementation, it's critical that the new processes are embedded into how work happens. Some of the steps that improvement facilitators and teams can perform to achieve sustainability are listed below.

- Involve the process owner (this is typically the manager or supervisor of the department where the new process is being implemented) in the planning for full-scale implementation.
- Create a new process map for the changed process (this enables staff to be easily educated in the new process).
- Educate staff in the new process.
- Demonstrate how the run charts are used to keep the process in control, so that backsliding is prevented.
- Create templates for auditing the process frequently so that the process owner is comfortable in compliance to the new process.

Share learning

This is the final objective of the analysis. Without learning and sharing, the organization and/or external organizations, remain vulnerable because the same or similar incidents could happen again in another area.

The general lessons and findings should be disseminated within, and where applicable, outside the organizations to prevent harm recurrence. Possibilities for sharing the lessons learned include:

- local staff/team members;
- local quality and patient safety committees;
- senior leadership; and
- other units with similar patient populations, and affiliated organizations.

SECTION 4 - The Workbook

(All elements of the workbook can be adapted to fit the incident and the organization to ensure ease of use and remove duplication of effort.)

A. Checklist

Use this checklist to keep track of your progress with completing a concise incident analysis.

	Review incident report
	Determine if an incident analysis framework is appropriate. a. Is the event thought to be the result of a criminal act? b. Was the event a purposefully unsafe act? c. Was the event related to substance abuse by any provider/staff? d. Did the event involve suspected patient abuse? If the answer to any of these is clearly yes, do not proceed with an incident analysis framework. Instead, refer the case to the suitable police, administrative, professional, and/or regulatory bodies for resolution.
	Determine if a concise incident analysis is appropriate. a. Did the incident result in no or low harm to the patient? b. Is the incident primarily limited to one work area, division, or department? c. Is this a new incident for which a comprehensive analysis was recently completed? d. Is this an incident where you have insufficient information to decide whether to perform a comprehensive or concise incident analysis? If the answer to one or more of these questions is yes, consider using the concise incident analysis tool.
	Complete informal interviews with key individuals
	Write up timeline
	Review guiding questions for relevance
	Develop constellation diagram
	Write summary of findings
	Develop recommended actions (if appropriate)
	Evaluate effectiveness of actions (if implemented)

B. Interview Sheet

Interviewee	Date of Interview
What happened?	
Factors that may have contributed to the incident	
Factors that may have mitigated severity of the incident	
How might an incident like this be prevented in the future?	

C. Timeline

Date/Time	**Information Item**	**Information Source**

D. Guiding Questions

Adapted from the Canadian Incident Analysis Framework. Read each guiding question to determine relevance to the incident.

Domain/category of contributing factors	Relevant?
Patient(s) characteristics: (Considered in the context of how well the system identified, understood, and acted upon these factors. It should not be the only factor considered.)	
Did the patient(s) have the information to assist in avoiding the incident?	
Did factors like age, medications, allergies, diagnosis, other medical conditions, contribute to the incident? How did they contribute?	
Did any social or cultural factors contribute to the incident?	
Was language a barrier?	
Other?	
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)? If so, was it followed?	
Were there constraints or pressures (e.g., time, resources) when performing the task?	
Was the information required to make decisions available and up-to-date (e.g., test results, documentation, patient identification)?	
Are there too many tasks for the individual or team to safely complete?[10]	
Other?	
Care team – Caregiver(s)	
Were the education, experience, training and skill level appropriate?	
Were fatigue, stressors, health or other factors an issue?	
Was the workload appropriate?	
Was appropriate and timely help or supervision available?	
Other?	

Domain/category of contributing factors	Relevant?
Care team – Supporting team (all involved in care process - includes family)	
Was there a clear understanding of roles and responsibilities?	
Were 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?	
Other?	
Equipment (including materials, fixtures, information, and communication systems)	
Were the displays and controls understandable?	
In what and how many ways is information conveyed?[10]	
Did the equipment automatically detect and display problems?	
Were the warning labels, reference guide, and safety mechanism functional and readily visible/accessible?	
Were the maintenance and upgrades up-to-date?	
Was the equipment standardized?	
Is the equipment located appropriately for reaching, viewing, and/or hearing? Are they located appropriately for several people to perform their tasks?[10]	
Other?	
Work environment	
Did noise levels interfere with the alarms?	
Was 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)?	
Are people aware of possible risks and hazards in their workplace?[10]	
Other?	
Organization – Policies and priorities	
Were the relevant policies and procedures available, known, and accessible, and did they meet the needs of users?	
Were there workarounds to the documented policy/procedure?	
Was there a mechanism in place to identify and resolve gaps between policy and practice?	
Other?	

Domain/category of contributing factors	Relevant?
Organization – Culture	
Was everyone (patients, family, clinicians, other staff) comfortable to speak-up about safety concerns?	
Is there leadership? Who is/are the leaders? How did they become leaders?[10]	
Was there visible support from leadership and the board for safe patient care?	
Was communication between staff and management supportive of day-to-day safe patient care?	
How is information transferred within the organization?[10]	
Does the organization have positive culture with respect to safety and quality?[10]	
Other?	
Organization – Capacity (resources)	
Did scheduling influence the staffing level, or cause stress, or fatigue?	
Was there sufficient capacity in the system to perform effectively (e.g., access to resources)?	
Were formal directives and/or incentives appropriate?	
Other?	
Other (including mitigating or preventative factors or actions)	
Are there any factors that prevented this event from happening on a more regular basis?	
Were there any factors or actions taken that mitigated the severity of the event?	
Were there any local conditions or circumstances that may have influenced the incident and/or an outcome?	
Were there any other contextual conditions or circumstances that may have influenced the incident and/or outcome?	
How do other external governing bodies contribute to the current situation?[10,11]	
Other?	

E. Diagramming Contributing Factors and Their Interconnections Around Domains (Categories of contributing factors)

Instructions[7,16]

Describe the incident. Briefly summarize the incident and harm/potential harm in the centre of the diagram (typically fewer than 10 words).

1. **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.
   b. Use the guiding questions provided to identify potential contributing factors.
   c. Place each potential contributing factor on a sticky note and group the factors near the category title.

2. **Define inter-relationships between and among 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". Some contributing factors may be directly linked with each other, within the same category to create a chain. 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.

3. **Identify the key findings that are central to the incident.** The team should expect to identify the one or two key findings – there is seldom, if ever, only a single reason why an incident occurred.

   Findings will be identified in three categories.
   a. **Preventive** – 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).
   b. **Incidental** – 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 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 constellation diagram is illustrated in the figure below.

4. Confirm the findings with the team. The team should agree on the findings before moving forward to develop recommended actions.

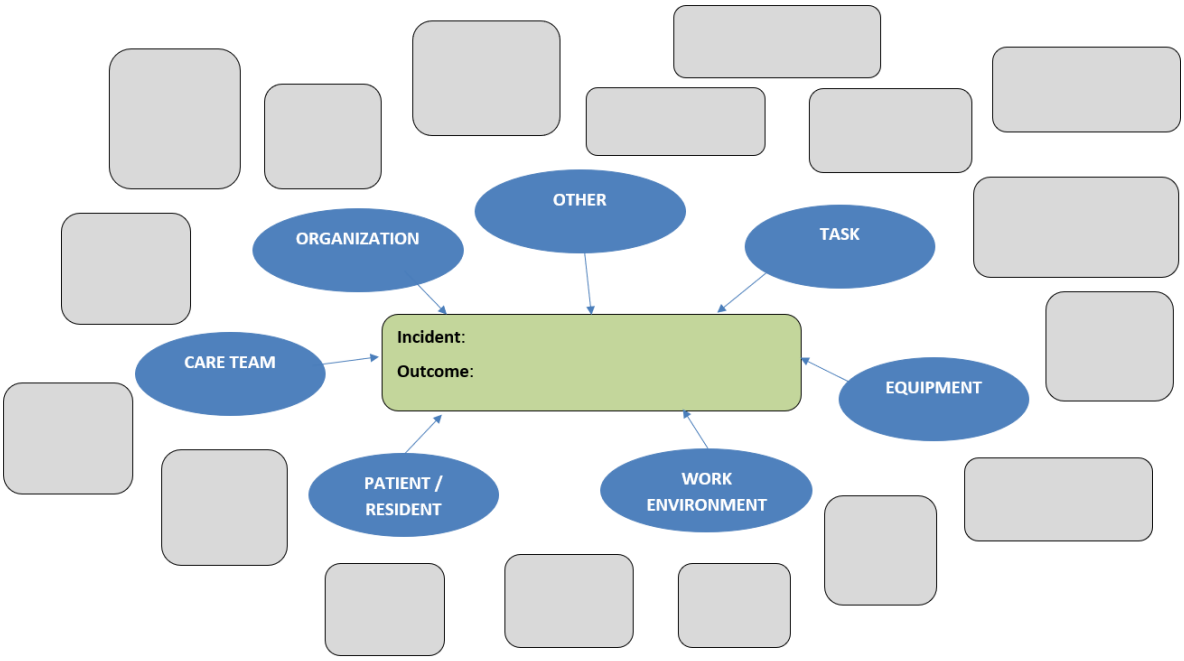


Figure 5. Constellation Diagram template

F. If Applicable, Develop an Action Plan

Summary Statement: ***Suggested format:*** ***This set of circumstances increased/decreased the likelihood that these consequences would occur***						
Recommendations/ Actions *(What are you planning to do?)* *Actions should be specific, measurable, achievable, and relevant to the issue addressed in the summary statement.*	**Priority** *(order of implementation)*	**Timeframe** *(What is the timeframe for implementation?)*	**Rank Hierarchy of Effectiveness** *(high, medium, low)*	**Accountability** *(Who, or what department is accountable for the implementation?)*	**Measure of Implementation** *(How would you assess the level of implementation and impact of actions?)*	**Status** *(C = complete; IP = in progress; NS = not started)*

References

1. Cuong, J., Hoffman C., Popescu I.C., & Ijagbemi, O.M. (2014). Concise incident analysis tool. Canadian Patient Safety Institute. Available from: https://ualberta.scholaris.ca/server/api/core/bitstreams/15be3a9c-1072-4cc0-967e-3062809a01a9/content

2. Isherwood, P., & Waterson, P. (2021). To err is system; A comparison of methodologies for the investigation of adverse outcomes in healthcare. *Journal of Patient Safety and Risk Management, 26*(2), 64-73. Available from: https://doi.org/10.1177/2516043521990261

3. World Health Organization (2009). *The conceptual framework for the international classification for patient safety (v.1.1)*. Available from: https://www.who.int/patientsafety/taxonomy/icps_full_report.pdf

4. Canadian Patient Safety Institute (2013). *Session recordings and documents.* Available from: http://www.patientsafetyinstitute.ca/English/news/IncidentAnalysisLearningProgram/Pages/SessionRecordings-and-Documents.aspx

5. JHSPH Open Courseware (2013). *Patient safety and medical errors lecture materials.* Available from: https://ocw.jhsph.edu/index.cfm/go/viewCourse/course/PatientSafety/coursePage/lectureNotes/

6. ISMP Canada (2021). *Incident analysis workshops (in person and live interactive online).* Available from: https://www.ismp-canada.org/education/

7. Canadian Patient Safety Institute (2012). *Canadian incident analysis framework.* Available from: https://www.patientsafetyinstitute.ca/en/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF

8. Reason, J. (2000). Human error: Models and management. *BMJ, 320,* 768-770. Available from: https://doi.org/10.1136/bmj.320.7237.768

9. Wiegmann, D. A., Wood, L. J., Solomon, D. B., & Shappell, S. A. (2020). Implementing a human factors approach to RCA2: Tools, processes and strategies. American Society for Healthcare Risk Management, 41(1), 31-46. Available from: https://doi.org/10.1002/jhrm.21454

10. Parush, A., Parush, D., & Ilan, R. (2017). Human factors in healthcare: A field guide to continuous improvement. Morgan & Claypool.

11. Holden, R. J., Carayon, P., Gurses, A. P., Hoonakker, P., Hundt, A. S., Ozok, A. A., & Rivera-Rodriguez, A. J. (2013). SEIPS 2.0: A human factors framework for studying and improving the work of healthcare professionals and patients. *Ergonomics, 56*(11), 1-30. Available from: https://doi.org/10.1080/00140139.2013.838643

12. Pham, J. C., Kim, G. R., Natterman, J. P., Cover, R. M., Goeschel, C. A., Wu, A. W., & Pronovost, P. J. (2010). ReCASTing the RCA: An improved model for performing root cause analyses. *American Journal of Medical Quality, 25*(3), 186-191. Available from: https://doi.org/10.1177/1062860609359533

13. University of Nebraska Medical Center (n.d.). *Causal statement summary*. Available from: https://www.unmc.edu/patient-safety/_documents/sample-generic-causal-statement.pdf

14. ISMP Canada (2013). *Designing effective recommendations.* Available from: https://www.ismp-canada.org/download/ocil/ISMPCONCIL2013-4_EffectiveRecommendations.pdf

15. Institute for Healthcare Improvement (2021). *How to improve*. Available from: http://www.ihi.org/resources/Pages/HowtoImprove/default.aspx

16. Clinical Excellence Commission (2020). *Concise incident analysis – workbook for teams.* Available from: https://www.patientsafetyinstitute.ca/en/NewsAlerts/Alerts/Pages/default.aspx

Appendix A: Human Factors Literature

Given the nature of RCAs and implementing effective change, the Canadian Incident Analysis Framework was updated in 2012 to include concepts related to human factors and human factors engineering. The idea is to incorporate higher levels of the system for changes to be implemented, moving away from the individual level. Isherwood and Waterson[2] compare three different methods of incident analysis against the same case study and use six criteria to determine effectiveness for the healthcare system. The three methodologies are root cause analysis (RCA) following the NHS guidelines, human factors analysis classification system (HFACS), and Accimap analysis. The six criteria are the ability to build graphical data, data requirements for analysis, usability, validity in healthcare, reliability, and ability to identify system-level factors.

Root cause analysis has high usability with the five whys requiring minimal training; however, this method scores low because it does not offer guidance on system-level thinking, show effectiveness in the healthcare system, or offer a meaningful diagram.

The HFACS falls under intermediate and high for all six criteria (i.e., intermediate score) with the shortcomings as requiring an understanding of human factors and systems for use, not guiding the user to offer regulatory changes, and including a diagram that shows layers of the healthcare system, but not the complexity. Of note, the HFACS has demonstrated validity in the healthcare system.

Finally, Accimap analysis is a strong methodology that shows the complexity of healthcare systems and identifies factors at all levels in the healthcare system. The weakness of Accimap analysis (i.e., low score) relates to the high starting point for use, requiring extensive training and time constraints.

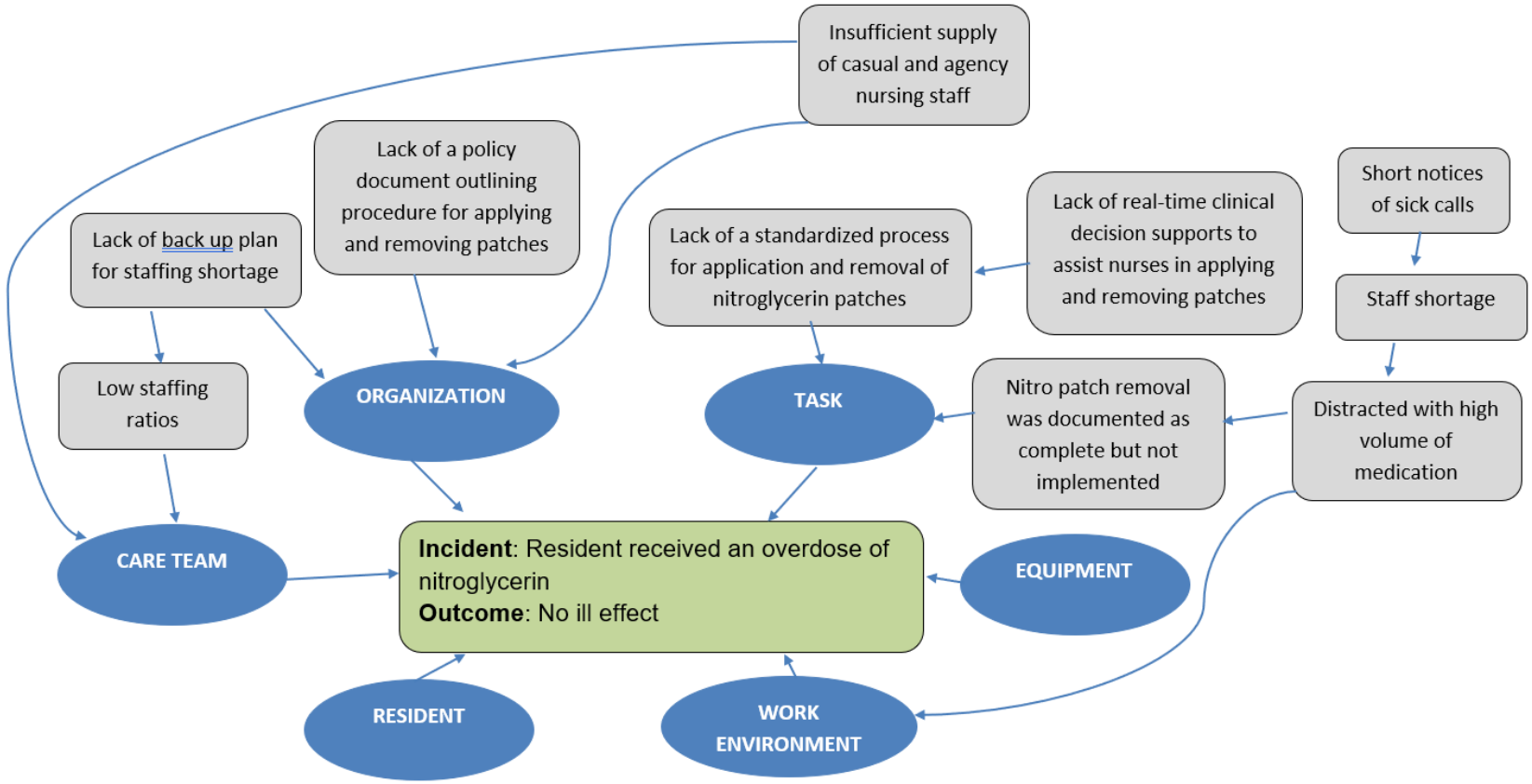
The overall suggestion is to use HFACS on two sides. First, it is shown in the literature to be valid for use in the healthcare system. Second, a human factors analysis examines the work environment and how human capabilities conform to the environment.

Appendix B: Sample of a Timeline

Time	Information Item	Information Source
January 5, 2022	An 86-year-old female is admitted to the LTC Home. She was previously living alone in the community and was experiencing challenges with performing activities of daily living. She experienced a fall in December 2021. Medical History: Osteoporosis, Angina secondary to history of cardiovascular disease, Mild cognitive impairment, Hypertension. Medications on admission to the LTC Home: • ASA 81 mg po daily • Metoprolol 100 mg po twice daily • Nitroglycerin 0.4 mg patch applied topically daily (**applied in the morning and removed at bedtime**) • Prolia 60 mg injected subcutaneously every 6 months • Ramipril 5 mg po twice daily • Vitamin B12 1200 mcg daily • Vitamin D 1000 units po daily The LTC Home had fewer staff to support their residents, after two of the staff members called in sick.	**LTC Home Record**
June 2, 2022 0600	Nitroglycerin patch was applied to the resident's upper back.	**eMAR**
June 2, 2022 2100	Nitroglycerin patch was documented as being removed from the resident's upper back.	**eMAR**
June 3, 2022 0600	RN1 was going to apply the new nitroglycerin patch onto resident for the day and found that resident's nitroglycerin patch from the previous day was not removed. RN1 notified and assessed resident and checked vital signs. No adverse impact to the resident was noted.	**RN1 Interview**
June 3, 2022 0600	Resident was made aware that the patch was still in place. The resident reported feeling fine but expressed concern about the error.	**Resident Interview**
June 3, 2022	Attending physician was notified of the medication incident and asked if the new patch should be applied.	**RN2 Interview**

0930		
June 3, 2022 0930	Attending physician responded that new patch should be applied at noon and then normal administration schedule should be resumed.	**RN2 Interview**
June 3, 2022 1100	Resident's POA was notified of the medication incident. They were "concerned about their mom's well-being" and indicated that they wanted to be notified of any changes.	**Progress notes**
June 3, 2022 1200	RN2 assessed the status of the resident and found no change in vital signs or condition. A new patch was applied on the resident.	**Progress notes**
June 3, 2022 2100	Nitroglycerin patch was removed as per regular schedule. No ill effects to resident were documented.	**Progress notes**

Appendix C: Sample of a Constellation Diagram



Appendix D: Sample of an Action Plan

Summary Statement # 1: Lack of real-time clinical decision supports to assist nurses with patch administration decreased the likelihood of timely patch removal, leading to the resident receiving an overdose of nitroglycerin which resulted in no ill effect.						
Recommendations/ Actions *(What are you planning to do?)* *Actions should be specific, measurable, achievable, and relevant to the issue addressed in the summary statement.*	**Priority** *(order of implementation)*	**Timeframe** *(What is the timeframe for implementation?)*	**Rank Hierarchy of Effectiveness** *(high, medium, low)*	**Accountability** *(Who, or what department is accountable for the implementation?)*	**Measure of Implementation** *(How would you assess the level of implementation and impact of actions?)*	**Status** *(C = complete; IP = in progress; NS = not started)*
1A: Institute a double check of patch removal by a second staff member (e.g., RN, PSW) that is to be documented on the electronic resident chart with the time of removal	1	2 weeks	Medium	DOC	Perform chart audit to determine if PSWs are documenting in the health record	NS
1B: Develop a patch calendar to manage patch removal	2	1 month	Medium	DOC	Audit use of the patch calendar	NS
1C: Implement alerts in the electronic medication administration record (eMAR) to notify staff when patches must be removed.	3	1 month	High	DOC	Audit documentation of patch removal in the eMAR	NS

Summary Statement # 2:
Insufficient staffing at the long-term care home, including a low supply of casual and agency nursing staff, increased the likelihood of a discrepancy between patch removal on the resident and documentation of patch removal, leading to an overdose of nitroglycerin with no ill effect.

Recommendations/ Actions *(What are you planning to do?)* *Actions should be specific, measurable, achievable, and relevant to the issue addressed in the summary statement.*	**Priority** *(order of implementation)*	**Timeframe** *(What is the timeframe for implementation?)*	**Rank Hierarchy of Effectiveness** *(high, medium, low)*	**Accountability** *(Who, or what department is accountable for the implementation?)*	**Measure of Implementation** *(How would you assess the level of implementation and impact of actions?)*	**Status** *(C = complete; IP = in progress; NS = not started)*
2A: Seek out other agencies to provide nursing staff on short notices (e.g., due to sick calls).	1	2 weeks	Low	Administrative staff, HR contact/ department	Two more agencies identified to provide nursing staff on short notice.	NS
2B: Hire two more casual nursing staff to cover absences.	2	2 months	Low	Administrative staff, HR contact/ department	Two more casual nursing staff added to the team.	NS