

Chapter 10. Human Factors Informed Root Cause Analysis

Section 10.1. Setting the Stage

Root Cause Analysis (RCA) is a retrospective incident investigation framework, initially developed as a quality management engineering tool, that is now widely used in many industries to support the improved safety of systems following an accident or incident. In healthcare, regulators such as The [Joint Commission](#) have mandated immediate investigation and response following a sentinel event, which is “an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof” [44]. RCA is a means by which this type of investigation and response can be accomplished.

Like the other human factors methods presented in this handbook, a central tenet of RCA is that in healthcare, inherently people do not want to cause harm. Consequently, this method focuses on identifying the system factors and issues contributing to an incident, rather than what a person might have done wrong. The root causes inherent to the system, and not the people, are the factors that will need to be addressed to improve overall system safety. When individuals are blamed for an incident, remedial action tends to focus on the person or people involved, but this represents a missed opportunity to make wider reaching changes to the system, aimed at preventing future occurrences of the same, or a similar error. Unfortunately, there are many examples of healthcare professionals who have unintentionally made errors as a result of a poor system design, and who have received harsh punishments such as losing their professional license, or being criminally charged [45, 46]. These punishments are in addition to the guilt, mental anguish, and loss of self-confidence experienced as a “second victim” of the incident [47, 48]. In the case of one such second victim blamed for an accidental calcium chloride overdose that led to the death of an eight month old patient, the emotional stress of the aftermath of the incident led her to commit suicide [49].

These types of tragic outcomes for staff involved in an incident are not inevitable. Rather than assigning blame, if one instead applies systems thinking and views an incident as a series of system failures ultimately contributing to a sentinel event, identifying and addressing those system failures will serve to strengthen the system and improve the likelihood that future similar incidents will be eliminated.

To support the completion of an RCA several quality and safety organizations, such as The [Joint Commission](#), the [VA National Centre for Patient Safety](#), [ISMP Canada](#), the [Canadian Patient Safety Institute](#), and the NHS (UK) have developed different RCA frameworks and tools. For example, the [Joint Commission offers an online RCA framework](#), along with publications about specific sentinel events that have been investigated using RCA[50]. Additionally, the VA has online tools and triage cards[51], ISMP Canada has

published several high profile RCA investigations[52], ISMP Canada and CPSI have jointly authored the comprehensive Canadian Incident Analysis Framework [53] and the NHS (UK) has an online Root Cause Analysis Toolkit and eLearning Programme [54].

For the purposes of this handbook, portions of these RCA frameworks will be combined and various human factors methods will be incorporated to create an ^{HF}RCA framework.

Section 10.2. What is ^{HF}RCA

^{HF}RCA is a human factors analysis method used to retrospectively identify root causes and contributing factors leading to a incident. A *root cause* can be considered an initiating factor leading to a particular effect or outcome and a *contributing factor* can be considered a condition that influences a particular effect or outcome. Ideally, a multidisciplinary team works together to collect information, document the incident, identify the root causes and contributing factors, and identify mitigating strategies targeted at improving the system in order to prevent similar incidents from happening again.

The ^{HF}RCA aims to improve on the more traditional RCA method by incorporating a range of human factors methods during the analysis to:

- Determine whether an ^{HF}RCA should be completed at all
- Promote the collection of accurate and quality data and artefacts from the field in a tactful manner
- Document the events leading up to the sentinel event
- Enable the identification of root causes from a human factors perspective by taking our natural human strengths and limitations into account
- Identify human factors informed mitigating strategies and set expectations about how much risk is likely to be mitigated given the proposed solutions

Section 10.3. Why use ^{HF}RCA

After a sentinel event, or a near miss that could have negatively impacted patient safety, an ^{HF}RCA should be conducted to examine and identify the root causes that contributed to the event. Completing an ^{HF}RCA is strongly recommended because this method allows the biomedical technology professional to go beyond the surface level contributing factors, to the true underlying root causes of the issue. It is only when the true root causes are addressed, that a reliable improvement to safety can be realized. These more surface level contributing factors, called *active failures*, tend to be focused on a person's actions and are highly dependent on the context of the specific incident. When an investigation stops here, it means that when other people find themselves in the same or a similar situation, the sentinel event is likely to recur because the system factors that were in place during the incident, still exist. In contrast, when the underlying root causes, also

called *latent failures*, can be identified and addressed, the design of the system is inherently improved to support staff in performing safely, making the occurrence of a similar sentinel event unlikely.

When done well, an ^{HF}RCA can unite staff from across the organization who have been touched by a patient safety incident. Organizational culture can be strengthened when staff work together to identify the root causes that contributed to an incident, which can lead to a strong resolve among staff members to improve the system in order to promote patient safety.

From the biomedical technology professional's perspective, completing an ^{HF}RCA will be helpful for:

- Preventing similar sentinel events from recurring
- Retrospectively examining and managing the root causes contributing to a sentinel event
- Retrospectively examining and managing the root causes contributing to a near miss
- Meeting accreditation requirements following an incident

Section 10.4. When to use ^{HF}RCA

An ^{HF}RCA should be conducted following a sentinel event, an incident that resulted in serious harm or death, or a near miss that could have resulted in serious patient harm. Completing an ^{HF}RCA on a serious near miss that was caught can be an excellent opportunity to proactively prevent other similar events from occurring.

Prior to conducting an ^{HF}RCA, the biomedical technology professional should ensure they have the support and buy-in of management to increase the chance for uptake and positive changes stemming from the analysis. In the case of a near miss, although an ^{HF}RCA may not be required from a regulatory body perspective, a strong case can still be made based on the liability associated with a possible future sentinel event with a history of near misses.

Completing an ^{HF}RCA following an incident can be a cathartic experience for those involved, providing an opportunity to strengthen workplace culture and unite staff in the face of a tragedy.

Section 10.5. In Preparation for an ^{HF}RCA

There is little that can be done in preparation for an ^{HF}RCA. Often sentinel events seem to occur suddenly, and so just being familiar with the ^{HF}RCA framework and being prepared to work with senior leaders and act quickly once an incident has occurred, is the best approach.

Section 10.6. Completing an ^{HF}RCA

The ^{HF}RCA process comprises six steps, outlined in [Figure 25](#). Each step will be outlined and described in this section.

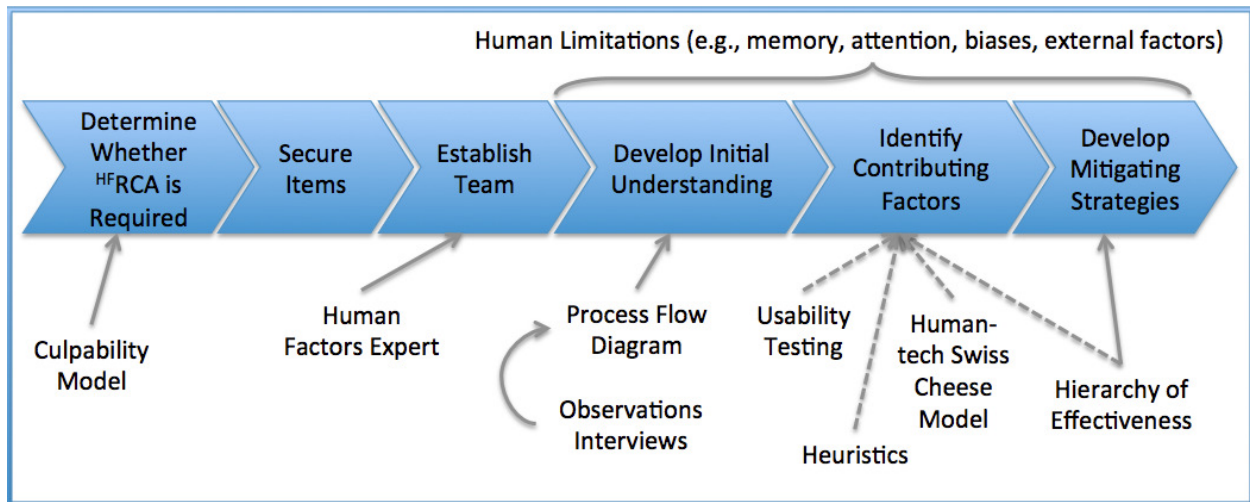


Figure 25. The six steps and opportunities to incorporate human factors as part of an ^{HF}RCA

Section 10.6.1. Determine Whether an ^{HF}RCA is Required

Following a sentinel event, the first step is to determine whether an ^{HF}RCA is required. This should be done as quickly as possible to increase the chance of collecting all equipment, supplies, and as much information as possible from the location of the incident before anything is adjusted or removed by others.

As noted previously, a determination of whether the incident is considered unintentional will have to be made. To assist with this determination, an Incident Decision Tree developed by the NHS (UK) [55] and adapted for this text ([Figure 26](#)) should be used. The decision tree is a tool that guides the process of determining whether an individual or the system is culpable for a sentinel event.

To apply the incident decision tree, each of the four tests from [Figure 26](#) should be applied sequentially. If the actions were as intended and/or there is evidence of ill health or substance abuse, the incident may have stemmed from a wilful action, and is not a good candidate for analysis using ^{HF}RCA. In these cases, consult with the appropriate regulatory bodies and union representatives, if applicable, and consider how the situation will be handled by the healthcare organization.

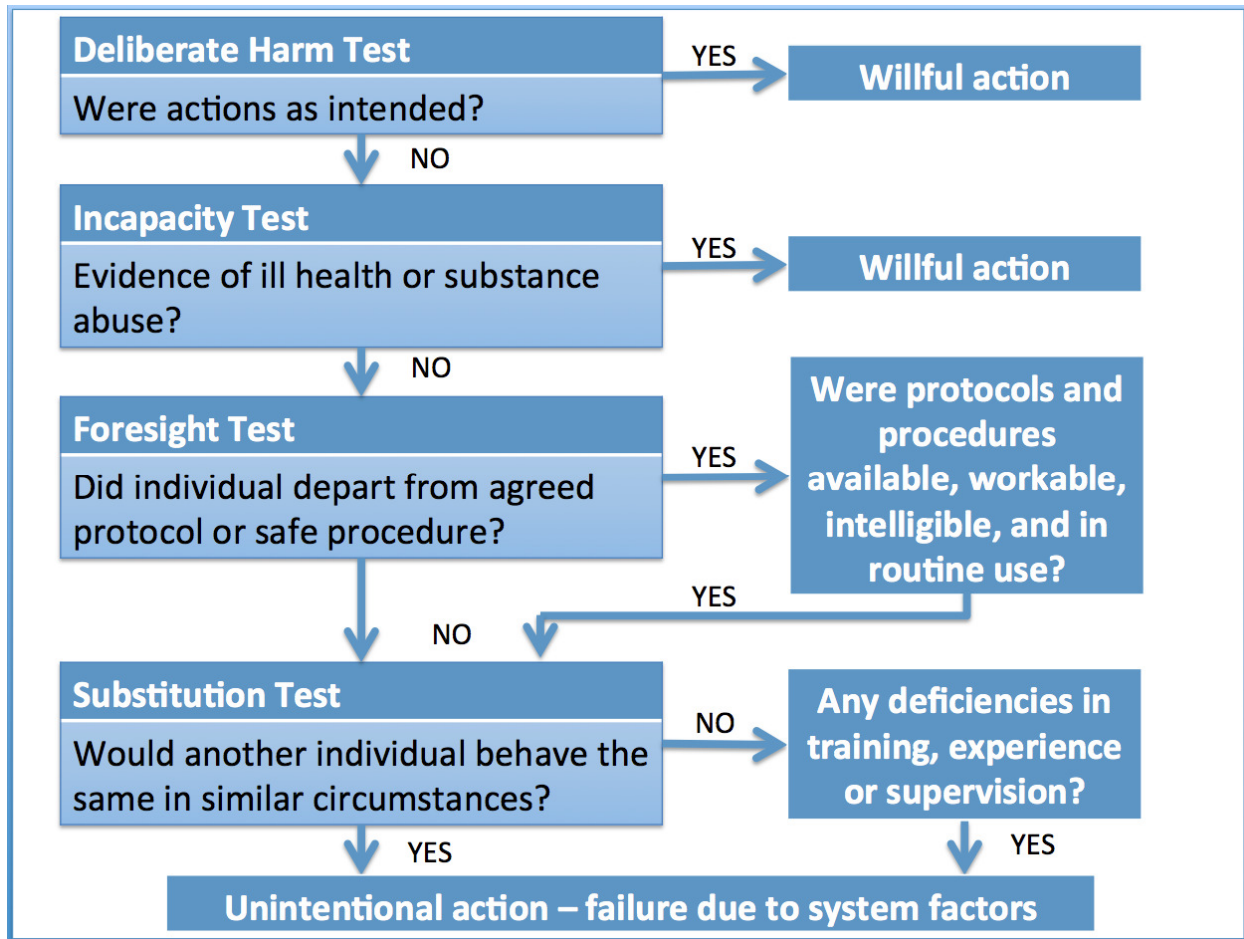


Figure 26. Incident Decision Tree For Responding to Patient Safety Events. Reprinted with permission (adapted from the UK National Health Service).

If the individual's actions were not as intended and there is no evidence of ill health or substance abuse, the foresight test is applied. In cases where an individual departed from an agreed upon protocol or safe procedure, it is important to consider whether (1) the protocols and procedures make sense, (2) they were readily used, and (3) they were readily available to staff. Remember that given what we know about inherent human limitations, trying to influence behaviour by writing expected actions in a protocol is not a very robust strategy to prevent errors.

The final test requires the biomedical technology professional to consider whether another individual in similar circumstances is likely to behave in the same way. It is important to approach this final question from a human factors perspective, that is, to consider the system factors that may have led someone to behave in a certain way. Keep in mind our inherent human limitations ([Chapter 3](#)) and consider whether there might be any deficiencies in training, experience, or supervision. In most cases, the biomedical

technology professional will find that sentinel events are a result of unintentional actions leading to system failures, rather than from wilfully harmful actions.

When the incident decision tree points to an unintentional action resulting in a failure, it indicates it is the system that has failed. These types of events are good candidates for analysis using an ^{HF}RCA. In these cases, the healthcare institution will have to determine whether the sentinel event will move forward for investigation using an ^{HF}RCA. This decision will likely be based on many factors including legislative requirements, accreditation standards, hospital policies, and resources. Since conducting an ^{HF}RCA can be resource intensive, this kind of undertaking is more likely to be supported when the organization is required to perform this type of analysis.

Section 10.6.2. Secure Items

As soon as the decision has been made to move forward with an ^{HF}RCA, it is critical that all items used at the time of the incident, and any used shortly beforehand, be collected and secured. If a technology is involved, the device must immediately be taken out of use and the logs retained to ensure this information is available to the team going forward. Other things to collect might include, but are not limited to:

- All medications and fluids, including packaging and sharps
- Copies of medication orders
- Medication labels
- Scrap paper used for calculations
- Any other supplies and packaging
- Photographs of the environment
- Photographs of the technology set up
- Screen shots from any electronic systems
- The patient's health record

If the patient's health record is obtained, make a copy for the unit to continue using if the patient is receiving ongoing care and be sure to follow all privacy regulations when handling the health record. Information about the unit such as a schedule, any shift changes, new procedures, changes to equipment or supplies, organizational practices, and policies can also be quite valuable if they are available.

Once these things have been collected from the field, a photograph should be taken of each item and all lot numbers, serial numbers, and expiration dates should be recorded. The items should be reviewed, and the biomedical technology professional should consider whether there is any evidence of items that are inherently confusing, complicated, or seem to be outside of what would be considered normal procedure (e.g., handwritten changes to

an order, look alike sound alike medications). Any of these types of observations should be noted for future reference.

It is important to collect and document this information (e.g., through photographs and written records) in a timely manner to ensure it is as accurate as possible because in stressful situations especially, humans have inherent limitations in memory.

Section 10.6.3. Establish the Team

Once items have been secured from the field, a core analysis team must be established to conduct the ^{HF}RCA. Team members should be knowledgeable about one or more topics related to the sentinel event, be analytical, and have a mindset that supports a just culture where health care organizations are accountable for the systems they have designed and staff are accountable for their behavioural choices and reporting errors and system vulnerabilities [56, 57]. Core team members should participate over the course of the entire analysis but others may be involved as team members on an as needed basis to support certain aspects of the analysis. For example, patients and family members, and some subject matter experts, may only be involved while an initial understanding of the incident is being developed. Thus, the size of the larger team will vary not only depending on the context of the incident, but also the stage of the analysis.

Generally, teams should be multidisciplinary, including both clinical and non-clinical staff, to represent a broad range of perspectives, and to provide valuable insight and leadership to support the analysis.

Section 10.6.3.1 Complete a Confidentiality Agreement

Depending on the policies of your healthcare organization, team members may have to sign a confidentiality agreement prior to participating as part of an ^{HF}RCA team. Signing this kind of agreement can serve as a reminder of team members' responsibility to protect any information obtained as part of the ^{HF}RCA. [The Canadian Incident Analysis Framework](#) [53] provides a sample confidentiality agreement in the event your healthcare organization does not have a template prepared.

Section 10.6.3.2 Team Member Roles

Individual team members will need to fulfill a number of roles to ensure a successful ^{HF}RCA. These roles include a *leader*, a *facilitator*, and a *senior leadership representative*. In addition, you will need *subject matter experts* who are knowledgeable and can provide information and think critically about the system factors that may have led to the sentinel event such as technologies, processes, environmental factors, policies, training programs, organizational changes, etc. One team member should take on the role of *scribe*, and ideally, a *human factors expert* should also be included as part of the ^{HF}RCA team.

Finally, depending on your institution, you may want to reach out to the *patient and family* to see if they are willing to participate as part of the ^{HF}RCA team. Patients and family members can provide an essential perspective that will be unique from that of any of the clinical team members. In addition, involving patients and family members can provide a needed sense of closure and contribution in some cases. It is essential to note, however, that including those who were directly involved in the incident, whether they are patients and family members or staff, can be difficult, and will have to be approached with extreme sensitivity to ensure the experience is positive and not defensive or punitive.

Team Leader

According to the [Canadian Incident Analysis Framework](#) [53] a leader is someone who has a general understanding of the incident that occurred, and has the authority to undertake an investigation. An individual in a senior clinical management role who possesses strong clinical and analytical skills would be a good candidate. The leader will be responsible for:

- Keeping the team focused
- Supporting cultural change
- Supporting other team members in their analysis
- Removing barriers encountered by other team members

Facilitator

A facilitator is someone who can manage group dynamics, delegate tasks, and facilitate group consensus building. An individual that is a specialist in quality or risk management, who possesses confidence and has expertise in analytical methods, would be a strong candidate. The facilitator will be responsible for:

- Coordinating team meetings
- Ensuring the team stays focused
- Facilitating constructive discussion among team members
- Monitoring timelines
- Ensuring the analysis process follows the healthcare organization's protocol and policies
- Ensuring the completion of a final report, if applicable

Senior Leadership Representative

A senior leadership representative is someone who has the authority for decision-making, and helps to drive a culture of safety. An individual who is a senior manager for the

organization will be a strong candidate. The senior leadership representative will be responsible for:

- Ensuring any actions and mitigating strategies are implemented
- Authorizing scheduled time away from staff member's regular duties to participate in the analysis
- Encouraging and supporting the broad communication of the results and mitigating strategies
- Ensuring those involved in the sentinel event, including patients and families, and staff, are supported so the experience is as positive as possible

Subject Matter Experts

Subject matter experts are individuals who are knowledgeable about one or more topics related to the sentinel event. They should have a detailed understanding of any technologies, processes, environments, policies, training, and organizational structures or changes that may have contributed to the incident. Subject matter experts should be critical thinkers, capable of providing feedback and input over the course of the ^{HF}RCA. These team members will carry out the bulk of the hands-on analysis including developing an initial understanding of the incident, identifying root causes and contributing factors, and developing mitigating strategies.

Scribe

The scribe is responsible for capturing any discussion or decisions made whenever the team convenes. The scribe should circulate meeting minutes to the entire team and an agenda of what the team hopes to accomplish prior to each meeting.

Human Factors Expert

Ideally, the ^{HF}RCA team will include at least one human factors expert. The human factors perspective is important for an ^{HF}RCA because this will facilitate the inclusion of various human factors methods, and ensure the analysis takes our inherent human limitations into account, especially when thinking through the root causes and contributing factors to the sentinel event. If it is not possible to include a human factors expert, the health technology professional can apply their newfound human factors knowledge (supported by this book and the additional resources highlighted in this book) during the ^{HF}RCA in order to fulfill this role. Another more cost effective option to consider is to bring in a graduate student of human factors and their advisor to help provide this insight, if available.

Patient and Family

If the patient and family are included as part of the ^HFRCA team, they will be able to provide invaluable information about the sentinel event from a unique perspective that no other team member will have. They will serve as subject matter experts from the perspective of the ones receiving care.

Section 10.6.4. Develop Initial Understanding of Incident

Developing a thorough and accurate initial understanding of the incident will be key in supporting the identification of the actual root causes and contributing factors, and the development of robust and effective mitigating strategies.

Section 10.6.4.1 Create an Initial Process Flow Diagram

To start, create a process flow diagram ([Chapter 6](#)) based on your preliminary understanding of the incident. This initial understanding should be informed with any information collected from the staff who were involved, information from any incident reports, a chart review, history logs of any devices, any information that can be acquired from hospital systems, and artefacts. The defined goal for this task analysis should match that of the individual(s) at the time of the sentinel event. The scope for this task analysis should also match the conditions and context present at the time of the sentinel event. The initial process flow diagram should describe the *actual*, rather than the ideal or prescribed process and sequence of events.

As the diagram is being created, keep track of any questions that arise or areas of uncertainty, as these will have to be addressed as the diagram is updated iteratively.

Section 10.6.4.2 Iteratively Update the Process Flow Diagram

Once this initial diagram has been created to describe the sequence of events, it is essential the diagram be shared with the ^HFRCA team to get any feedback. As with any task analysis, the creation of a process flow diagram is an iterative one, requiring multiple rounds of sharing, incorporating feedback, and review. To support the ^HFRCA method, in addition to sharing the diagram with the ^HFRCA team for feedback, observations ([Chapter 4](#)), and interviews ([Chapter 5](#)) should also be done to further improve the process flow diagram. Once several rounds of iteration have been completed and the diagram reflects the actual workflow during the sentinel event as closely as possible, the diagram can be considered complete; in the event new information comes to light, however, this diagram should be updated no matter what point of the ^HFRCA the team is at to ensure the diagram reflects the most accurate information possible.

Section 10.6.4.3 Layer Other Contextual Information on to the Process Flow Diagram

This process flow diagram can be used as the backbone for developing an initial understanding of the incident. In addition to an overview of the tasks leading up to the sentinel event, this diagram can also be used to document the timing of various tasks and

events, and as a legend or key to link to artefacts, policies, procedures, and other contextual information that was collected as items were secured.

The biomedical technology professional may also find it helpful to indicate not only the actual events leading to the sentinel event, but also the “expected working process” and the “typical working process” so that any deviations can be highlighted. The expected working process is the series of steps that should be performed by staff as outlined by a healthcare organization’s policies and procedures. The typical working process is the series of steps most staff carry out as a result of the reality of daily operations including factors such as work, time, and cost pressures. Expected and typical working processes are likely to differ, as typical working processes will include things like workarounds and shortcuts that most staff use to try to get their work done as efficiently and safely as possible. Adding information about the expected and typical working processes to the diagram of the actual events leading to the sentinel event can be extremely helpful because any points at which there are deviations serve as clues that the system as designed is failing to support the people working within it. The policies and procedures that have been developed may look right on paper, but when the context and reality of the front lines are taken into account, policies and procedures can be cumbersome to follow.

Section 10.6.4.4 Finalize the Process Flow Diagram

Once the diagram has been created, updated iteratively, and used as a basis for linking artefacts and other contextual information, including any deviations from expected and typical workflows, it should be circulated to the core ^{HF}RCA team for any additional feedback. This diagram will be used as the basis for identifying the root causes and contributing factors leading to the sentinel event.

Section 10.6.4.5 Create a Factual Description of the Events Leading to the Incident

Based on the finalized process flow diagram, a written, factual description of the events that led up to the sentinel event should be created. This description will be more accessible for staff who are outside of the core and extended ^{HF}RCA teams when it is time to share information about the incident with them.

Section 10.6.5. Identify Contributing Factors

Once the team has a clear initial understanding of what happened leading up to the incident, the next and most important step of an ^{HF}RCA is to understand the root causes and contributing factors leading to *why* the incident happened. It is critical to note that a sentinel event is almost always caused by multiple factors, rather than just a single root cause. The root cause is typically considered to be only the first in a chain of contributing factors leading to the incident. The contributing factors can be considered circumstances, actions, or other influential factors that are likely to have played a role, or increased the chance of, the incident occurring [53].

A helpful starting point when identifying causes can be to write down the task or action that went wrong, and then to keep asking *why* it went wrong using the process flow diagram and any artefacts as you go. This approach will allow the team to build an understanding of the system context that surrounded the incident. At this point it will already have been established that the individuals involved in the sentinel event did not intend to cause harm, so as is the case for ^{HF}FMEA, it is important to avoid focusing only on the human centric causes, and failures of individuals to comply with established protocols and procedures ([Section 13.2.6](#)). If an individual makes a mistake or fails to comply with an established protocol or procedure, the job of the ^{HF}RCA team is to ask why that might have been. The systems we work within should not require us to be superhuman, but rather, systems should be designed to take our human limitations into account. Features of a system that do not support us in our inherent strengths and limitations have the potential to lead us to make mistakes, and thus should be thought of as contributing factors.

Section 10.6.5.1 Human-tech/Swiss Cheese Model Framework

To help in identifying the system features contributing to a sentinel event, several human factors methods, such as observations ([Chapter 4](#)), interviews ([Chapter 5](#)), heuristics ([Chapter 7](#)), or usability testing ([Chapter 8](#)) can be used. In addition, a combination of the Human-tech ladder ([Section 3.2](#)), and Reason's Swiss Cheese Model of Error ([Section 3.4](#)) is highly recommended as a guiding tool ([Figure 27](#)).

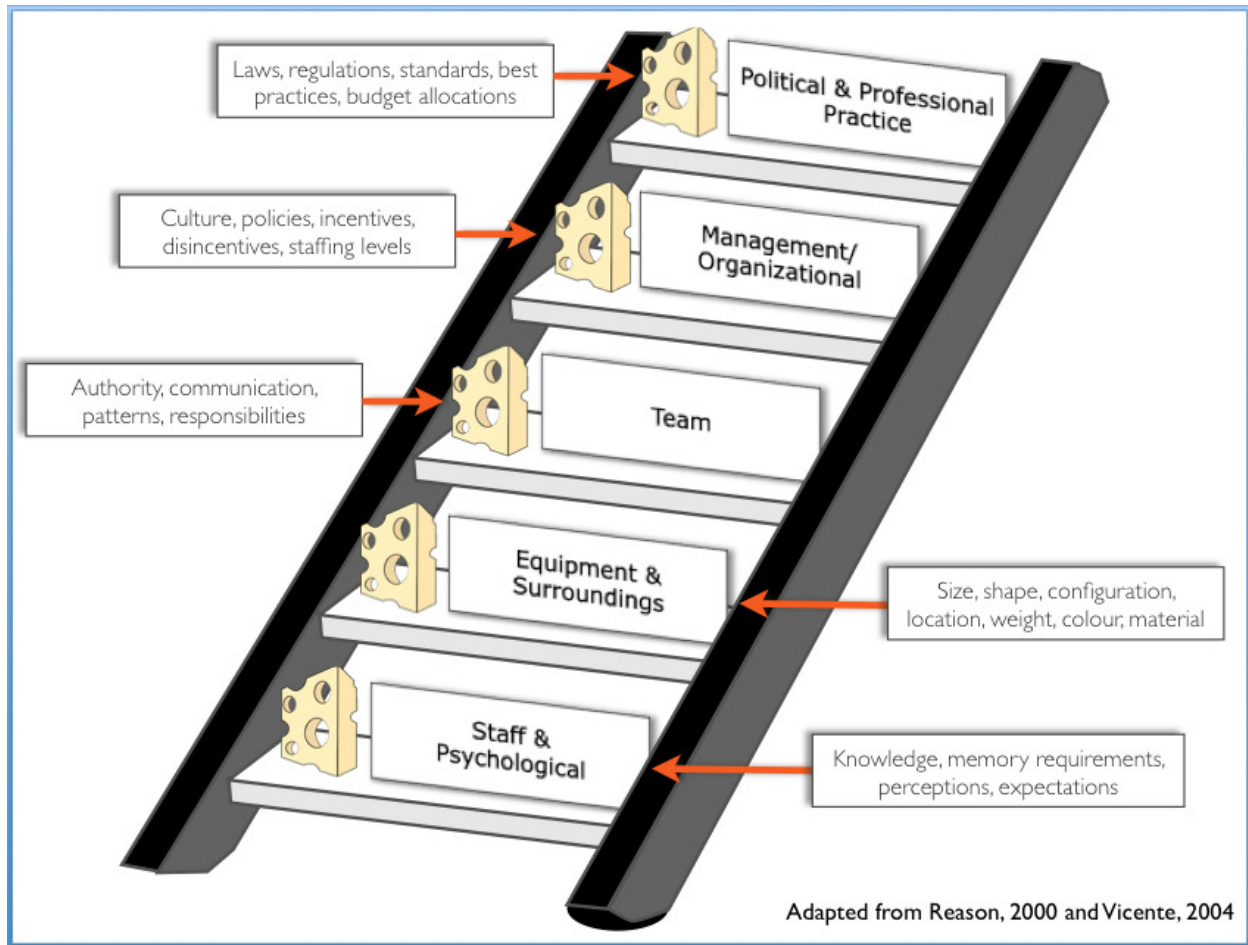


Figure 27. Human factors framework adapted from Reason's Swiss Cheese Model, 2000 and Vicente's Human-tech ladder, 2004

This human factors framework illustrates the importance of thinking beyond the human centric causes, to thinking about contributing factors related to the physical, psychological, team, organizational, and political levels of the system. Latent factors at each of these levels typically translate into system weaknesses that can combine to allow a sentinel event to occur. For example, if an ^{HF}RCA team is trying to identify contributing factors leading to an incident where a calculation error was made leading to a patient overdose, the adapted human factors framework could be used as follows ([Figure 28](#)).

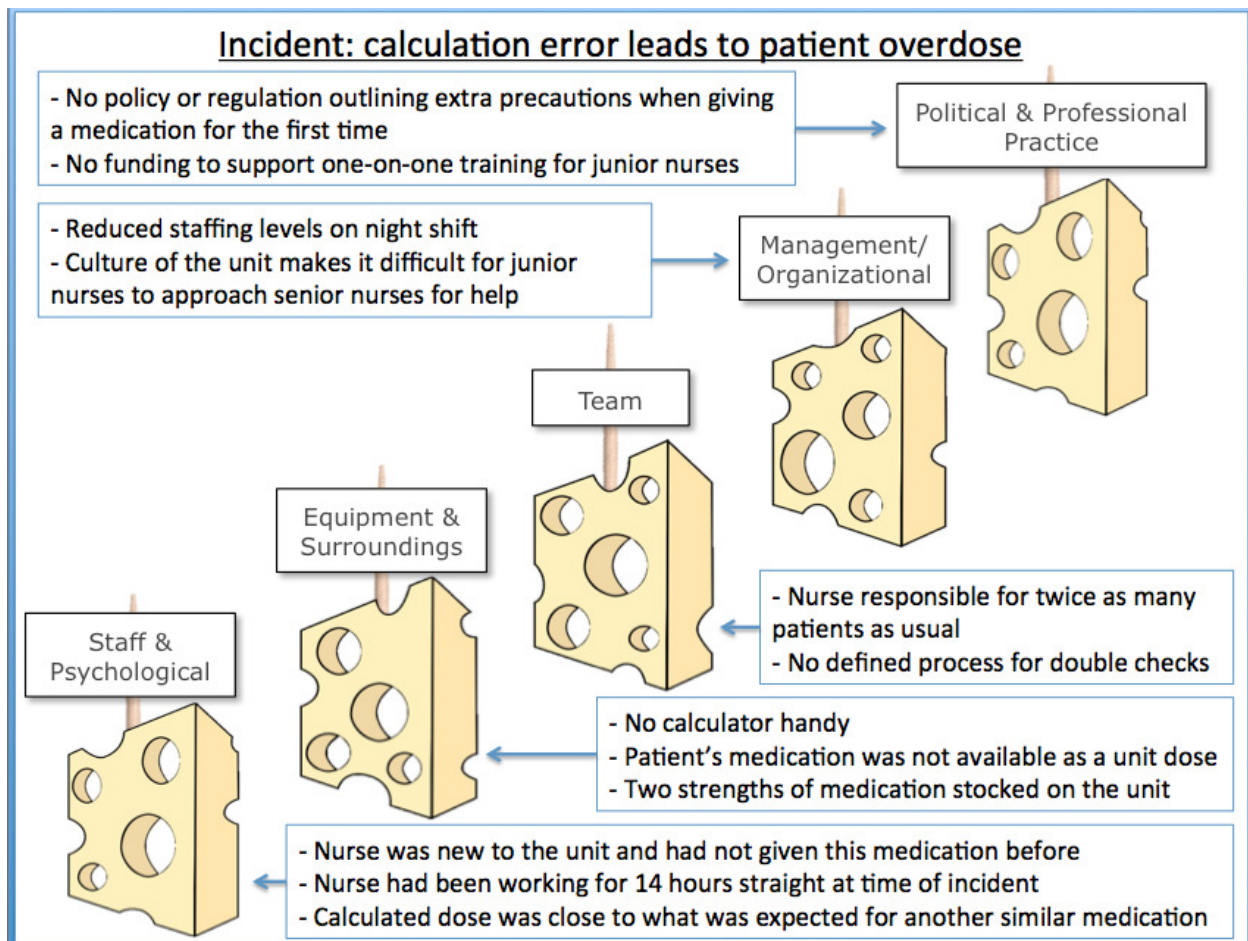


Figure 28. Using Reason's Swiss Cheese Model and Vicente's Human-tech ladder to identify contributing factors to a sentinel event

In addition to this human factors framework, and the other human factors methods mentioned above (i.e., observations, interviews, heuristics, usability testing), The [Joint Commission's RCA Framework](#) [50], [Table 18](#), provides a series of helpful prompts to encourage the ^{HF}RCA team to think through a wide range of potential contributing factors.

Table 18. RCA Action Plan Tool (© The Joint Commission, 2013. Reprinted with permission.)

	Analysis Question	Prompts
1	What was the intended process flow?	List the relevant process steps as defined by the policy, procedure, protocol, or guidelines in effect at the time of the event. You may need to include multiple processes. Note: The process steps <i>as they occurred in the event</i> will be entered in the next question. Examples of defined process steps may include, but are not limited to: • Site verification protocol • Instrument, sponge, sharps count procedures • Patient identification protocol • Assessment (pain, suicide risk, physical, and psychological) procedures • Fall risk/fall prevention guidelines
2	Were there any steps in the process that did not occur as intended?	Explain in detail any deviation from the intended processes listed in Analysis Item #1 above.
3	What human factors were relevant to the outcome?	Discuss staff-related human performance factors that contributed to the event. Examples may include, but are not limited to: • Boredom • Failure to follow established policies/procedures • Fatigue • Inability to focus on task • Inattentional blindness/ confirmation bias • Personal problems • Lack of complex critical thinking skills • Rushing to complete task • Substance abuse • Trust
4	How did the equipment performance affect the outcome?	Consider all medical equipment and devices used in the course of patient care, including AED devices, crash carts, suction, oxygen, instruments, monitors,

		infusion equipment, etc. In your discussion, provide information on the following, as applicable: • Descriptions of biomedical checks • Availability and condition of equipment • Descriptions of equipment with multiple or removable pieces • Location of equipment and its accessibility to staff and patients • Staff knowledge of or education on equipment, including applicable competencies • Correct calibration, setting, operation of alarms, displays, and controls
5	What controllable environmental factors directly affected this outcome?	What environmental factors within the organization's control affected the outcome? Examples may include, but are not limited to: • Overhead paging that cannot be heard • Safety or security risks • Risks involving activities of visitors • Lighting or space issues
6	What uncontrollable external factors influenced this outcome?	The response to this question may be addressed more globally in Question #17. This response should be specific to this event. Identify any factors the organization cannot change that contributed to a breakdown in the internal process, for example natural disasters.
7	Were there any other factors that directly influenced this outcome?	List any other factors not yet discussed.
8	What are the other areas in the organization where this could happen?	List all other areas in which the potential exists for similar circumstances. For example: • Inpatient surgery/outpatient surgery • Inpatient psychiatric care/outpatient psychiatric care Identification of other areas within the organization

		that have the potential to impact patient safety in a similar manner. This information will help drive the scope of your action plan.
9	[Were]... staff properly qualified and currently competent for their responsibilities at the time of the event?	Include information on the following for all staff and providers involved in the event. Comment on the processes in place to ensure staff is competent and qualified. Examples may include but are not limited to: • Orientation/training • Competency assessment (What competencies do the staff have and how do you evaluate them?) • Provider and/or staff scope of practice concerns • Whether the provider was credentialed and privileged for the care and services he or she rendered • The credentialing and privileging policy and procedures • Provider and/or staff performance issues
10	How did actual staffing compare with ideal levels?	Include ideal staffing ratios and actual staffing ratios along with unit census at the time of the event. Note any unusual circumstance that occurred at this time. What process is used to determine the care area's staffing ratio, experience level and skill mix?
11	What is the plan for dealing with staffing contingencies?	Include information on what the organization does during a staffing crisis, such as call-ins, bad weather or increased patient acuity. Describe the organization's use of alternative staffing. Examples may include, but are not limited to: • Agency nurses • Cross training • Float pool • Mandatory overtime • PRN pool
	Were such contingencies a	If alternative staff were used, describe their orientation to the area, verification of competency

12	factor in this event?	and environmental familiarity.
13	Did staff performance during the event meet expectations?	Describe whether staff performed as expected within or outside of the processes. To what extent was leadership aware of any performance deviations at the time? What proactive surveillance processes are in place for leadership to identify deviations from expected processes? Include omissions in critical thinking and/or performance variance(s) from defined policy, procedure, protocol and guidelines in effect at the time.
14	To what degree was all the necessary information available when needed? Accurate? Complete? Unambiguous?	Discuss whether patient assessments were completed, shared and accessed by members of the treatment team, to include providers, according to the organizational processes. Identify the information systems used during patient care. Discuss to what extent the available patient information (e.g. radiology studies, lab results or medical record) was clear and sufficient to provide an adequate summary of the patient's condition, treatment and response to treatment.
15	To what degree was the communication among participants adequate for this situation?	Describe staff utilization and adequacy of policy, procedure, protocol and guidelines specific to the patient care provided. Analysis of factors related to communication should include evaluation of verbal, written, electronic communication or the lack thereof. Consider the following in your response, as appropriate: • The timing of communication of key information • Misunderstandings related to language/cultural barriers, abbreviations, terminology, etc. • Proper completion of internal and external hand-off communication • Involvement of patient, family and/or significant other
	Was this the appropriate	Consider processes that proactively manage the

16	physical environment for the processes being carried out for this situation?	patient care environment. This response may correlate to the response in question 6 on a more global scale. What evaluation tool or method is in place to evaluate process needs and mitigate physical and patient care environmental risks? How are these process needs addressed organization-wide? Examples may include, but are not limited to: • alarm audibility testing • evaluation of egress points • patient acuity level and setting of care managed across the continuum, • preparation of medication outside of pharmacy
17	What systems are in place to identify environmental risks?	Identify environmental risk assessments. • Does the current environment meet codes, specifications, regulations? • Does staff know how to report environmental risks? • Was there an environmental risk involved in the event that was not previously identified?
18	What emergency and failure-mode responses have been planned and tested?	Describe variances in expected process due to an actual emergency or failure mode response in connection to the event. Related to this event, what safety evaluations and drills have been conducted and at what frequency (e.g. mock code blue, rapid response, behavioural emergencies, patient abduction or patient elopement)? Emergency responses may include, but are not limited to: • Fire • External disaster • Mass casualty

		• Medical emergency Failure mode responses may include, but are not limited to: • Computer down time • Diversion planning • Facility construction • Power loss • Utility issues
19	How does the organization's culture support risk reduction?	How does the overall culture encourage change, suggestions and warnings from staff regarding risky situations or problematic areas?
20	What are the barriers to communication of potential risk factors?	• How does leadership demonstrate the organization's culture and safety values? • How does the organization measure culture and safety? • How does leadership establish methods to identify areas of risk or access employee suggestions for change? • How are changes implemented? Describe specific barriers to effective communication among caregivers that have been identified by the organization. For example, residual intimidation or reluctance to report co-worker activity. Identify the measures being taken to break down barriers (e.g. use of SBAR). If there are no barriers to communication discuss how this is known.
21	How is the prevention of adverse outcomes communicated as a high priority?	Describe the organization's adverse outcome procedures and how leadership plays a role within those procedures.
22	How can orientation and in-service training be revised to reduce the risk of such events in the future?	Describe how orientation and ongoing education needs of the staff are evaluated and discuss its relevance to event. (e.g. competencies, critical thinking skills, use of simulation labs, evidence based practice, etc.)

23	Was available technology used as intended?	Examples may include, but are not limited to: • CT scanning equipment • Electronic charting • Medication delivery system • Tele-radiology services
24	How might technology be introduced or redesigned to reduce risk in the future?	Describe any future plans for implementation or redesign. Describe the ideal technology system that can help mitigate potential adverse events in the future.

In addition to the Human-tech/Swiss Cheese Model Framework ([Figure 27](#)) and The [Joint Commission's action plan tool](#), the [Canadian Incident Analysis Framework](#) outlines a set of guiding questions that can encourage the ^{HF}RCA team to identify potential contributing factors at various levels of the system ([Table 19](#)).

Table 19. Guiding questions to support identifying contributing factors²

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?

² Reprinted from the Canadian Incident Analysis Framework. Copyright (2012) with permission from the Canadian Patient Safety Institute.

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?

Care team: 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 workarounds 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?

Organization: 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?

Organization: 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?

Section 10.6.5.2 Traditional RCA Tools for Documenting Contributing Factors

The ^{HF}RCA team may also find other types of diagrams useful for documenting contributing factors identified at different levels of the system. Many documentation tools and approaches may be used, but three examples often used as part of a traditional RCA method are included here: the Ishikawa Diagram, the Tree Diagram, and the Constellation Diagram. Further detail about these diagrams is available as part of the [Canadian Incident Analysis Framework](#).

Ishikawa Diagram⁴

An Ishikawa diagram, named for its' creator, is also known as a fishbone diagram. To create this type of diagram a straight line that ends in a box containing the incident is drawn ([Figure 29](#)). Next categories representing contributing factors are indicated and connected to the straight line leading to the incident ([Figure 30](#)). Finally, more detailed information about the contributing factors is noted under each category of contributing factor ([Figure 31](#)). Ishikawa diagrams do not generally allow for a clear understanding of the order in which contributing factors occur, but rather, they provide a means of categorizing and summarizing contributing factors at a glance.



Figure 29. Ishikawa Diagram: Straight line ending in a box containing the incident

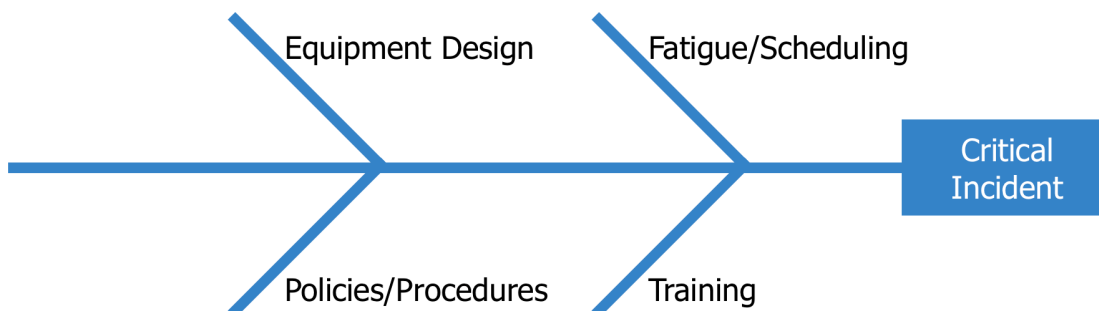


Figure 30. Ishikawa Diagram: Categories of contributing factors

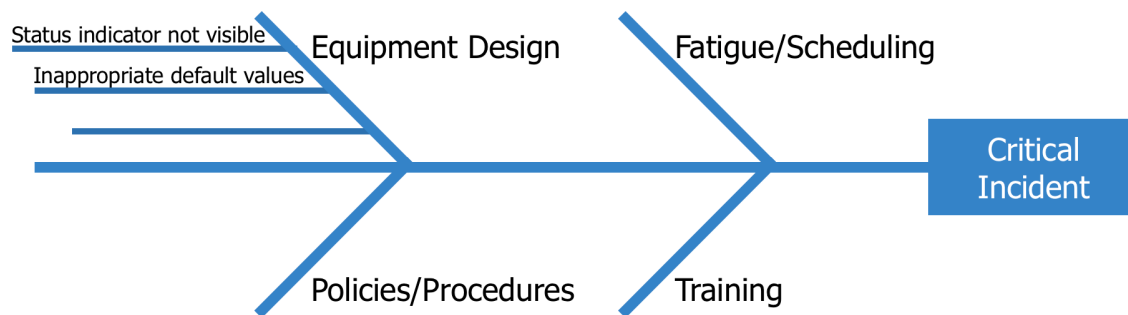


Figure 31. Ishikawa Diagram: Detailed information about contributing factors by category

Tree Diagram⁴

A tree diagram ([Figure 32](#)) is a linear cause-consequence diagram that starts with the incident and grows backwards as the actions or conditions leading to the preceding action are documented. Unlike Ishikawa Diagrams, tree diagrams allow causal chains to be denoted, where the respective causes and effects of a series of actions can be traced from root cause to incident. In most cases however, tree diagrams will be too simplistic as a documentation tool because in reality, incidents result from multiple contributing factors, rather than a one-to-one cause and effect relationship.

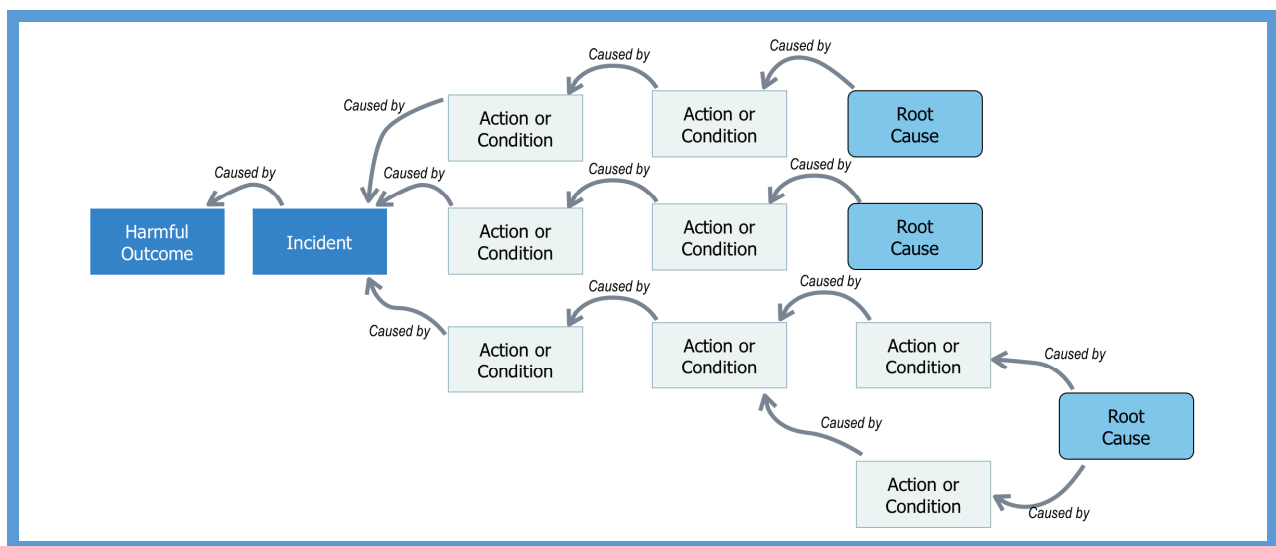


Figure 32. Tree diagram⁴

Constellation Diagram⁴

A constellation diagram ([Figure 33](#)) is a more versatile documentation tool than either the Ishikawa diagram or tree diagram that allows one to categorize and illustrate the causal relationships between all the identified contributing factors.

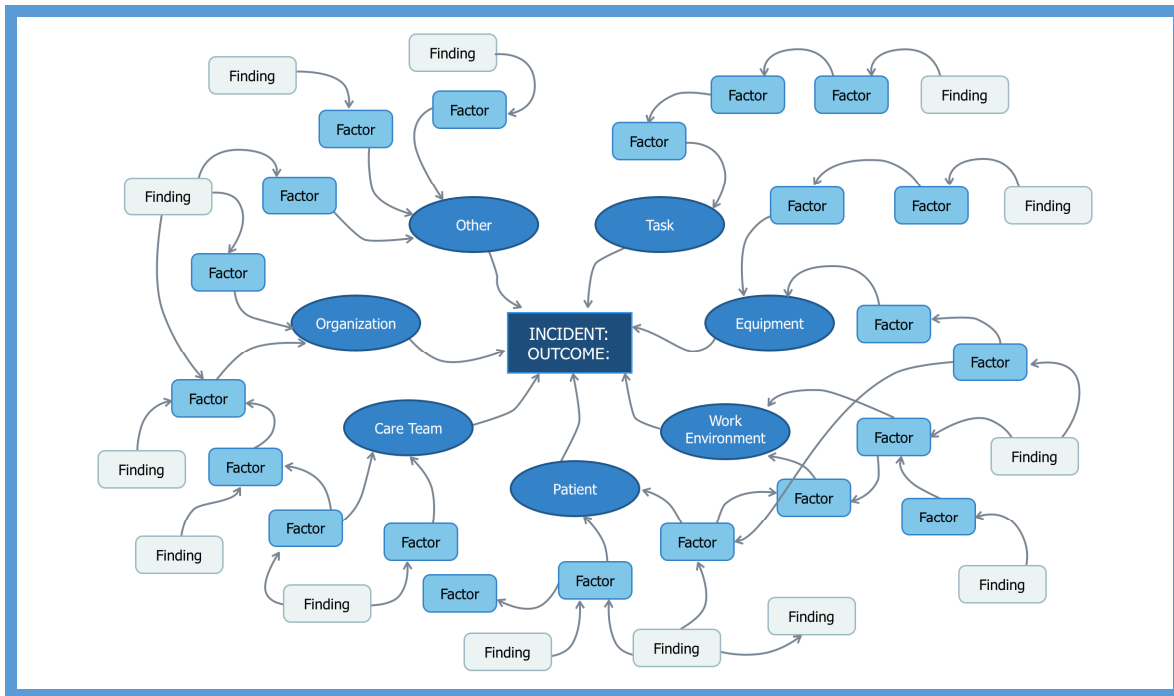


Figure 33. Constellation Diagram⁵

This type of diagram will likely be the most useful to the biomedical technology professional once the Human-tech/Swiss Cheese Model framework ([Figure 27](#)) has been applied, as the levels of the Human-tech ladder can be used as categories, and the causal relationships between contributing factors can be indicated in a flexible way ([Figure 33](#)). With a constellation diagram, every contributing factor should be connected to at least one other factor, or a category of factors. If a contributing factor does not connect to either another factor or a category, a new category will have to be created, or the factor does not belong in the analysis.

Section 10.6.5.3 Finalize Documentation of Contributing Factors

Once the root causes and contributing factors have been identified and documented, the analysis should be shared with the ^{HF}RCA team to gather any feedback. As the analysis is reviewed, the ^{HF}RCA team should consider three main questions:

What are the factors that:

1. If corrected, would have prevented the incident or mitigated the harm?
2. If corrected, would NOT have prevented the incident or mitigated the harm, but are still important to enhance patient and/or staff safety in general?
3. Prevented the incident from having more serious consequences, and thus, represent safeguards that should remain in place?

Regardless of the approach to documenting contributing factors, these three questions should be used as the basis for prioritizing which factors warrant the further consideration and development of recommendations and mitigating strategies.

Section 10.6.6. Develop Mitigating Strategies

After the root causes and contributing factors leading to the incident have been identified, documented, and prioritized using the three questions from [Section 10.6.5.3](#), mitigating strategies will have to be developed. Since most healthcare organizations have limited resources, a selection, rather than every root cause and contributing factor, will end up being addressed. The number and types of mitigating strategies implemented will depend on the context of the incident, your healthcare organization, and the resources available. To help guide the ^HFRCA team in figuring out which root causes and contributing factors to address, a number of tips are included below.

Section 10.6.6.1 Use the Hierarchy of Effectiveness to Develop System-Focused Strategies

Focus on system-level mitigating strategies rather than person-centered solutions. Use the Hierarchy of Effectiveness ([Section 3.5](#)) to determine whether a proposed solution is system focused. Person-centered solutions will not result in system improvements, and when person-centered solutions are implemented without addressing the system issues, the same, or a similar incident is likely to happen again.

Section 10.6.6.2 Quality Over Quantity

Rather than trying to implement many, lower impact mitigating strategies, aim to implement a few, well thought out recommendations that target system change. A well planned and carefully executed mitigating strategy that targets system improvement will be a more robust and long-term solution to prevent similar incidents from occurring again.

Section 10.6.6.3 Use the SMART framework

When drafting recommendations ensure they are SMART [58] ([Table 20](#)):

Table 20. SMART framework[58] [101]

Specific	Target a clearly defined issue with known scope
Measurable	Demonstrate an impact on outcomes through an indicator or progress
Attainable	Can be achieved given the available resources
Realistic	Results are possible given the available resources
Timely	Achievable in the defined implementation timeframe

As part of the SMART framework, try to ensure any primary mitigating strategies fall within the locus of control of the healthcare organization, rather than an outside group,

such as a manufacturer or vendor. Although it may be necessary to work closely with a manufacturer to implement a mitigating strategy, solutions that originate outside of the healthcare organization will naturally be much harder to advance and control. When it is necessary to implement a solution that originates outside the healthcare organization, working closely with regulators, policy makers, and other healthcare organizations experiencing similar challenges, can help sustain momentum for a change to be realized.

Section 10.6.6.4 Validate Potential Mitigating Strategies

Prior to implementing a mitigating strategy, it should be validated to ensure it will have the intended effect without introducing other unintended consequences into the system. Gathering evidence from the literature, experiences from other healthcare organizations, and recommendations from professional and safety organizations can be a useful exercise to get a baseline understanding of potential implications. When little evidence exists, or there are features or factors that make your healthcare institution unique, applying human factors methods such as observations ([Chapter 4](#)), interviews, focus groups and surveys ([Chapter 5](#)), heuristics ([Chapter 7](#)), usability testing ([Chapter 8](#)), or a ^{HF}FMEA ([Chapter 9](#)), are recommended.

The [Canadian Incident Analysis Framework](#) provides templates both for assessing potential mitigating strategies while taking these considerations into account ([Table 21](#)), and tracking progress during the implementation of mitigating strategies ([Table 22](#)). The individual responsible for implementing each strategy that is agreed upon by the ^{HF}RCA team should put a plan together that outlines a project plan, timelines, required resources, and measures of success. The individual or team that implements each mitigating strategy does not have to be the same as the ^{HF}RCA team; however, depending on the incident and mitigating strategy, it may be helpful to keep the ^{HF}RCA team involved as an advisory group to maintain some consistency and oversight.

Table 21. Prioritized list of RCA actions [99]

Recommended Action (category)	Risk (severity assessment)	Hierarchy of Effectiveness (high, medium, low leverage)	Predictors of Success (alignment, existing mechanisms, quick wins)	System Level Targeted	Evidence Available? What Type?	Confirm Validity, Feasibility	Order of Priority or Time Frame

Table 22. Follow through actions from a RCA [99]

#	Recommendation	Source and ID #	Date Entered	Progress Status	Timeframe (end date)	Target Area	Risk Level	Individual Responsible

Section 10.7. What to do with a Completed ^{HF}RCA

Section 10.7.1. Create a Draft Report

Once the ^{HF}RCA has been completed and a decision made about which mitigating strategies the healthcare organization will move forward with, a report should be created that summarizes the incident and ^{HF}RCA process. Remove as much identifying information about the patient and staff involved in the incident as possible for privacy purposes.

Once drafted, the report should be labeled “Draft” and “Confidential” and then shared with any key stakeholders for review. Preparing a report following an incident that includes information about the information gathering, documentation, analysis, and mitigating strategy development process can contribute to organizational learning and memory when another sentinel event occurs. When shared with staff, this type of report can provide helpful context so those responsible for and affected by mitigating strategies understand the rationale driving any changes.

Consider sharing de-identified information about the incident, analysis, and planned mitigating strategies, beyond your healthcare institution if senior management supports this type of dissemination. If this type of sharing is supported, it can be an invaluable opportunity for other organizations to learn from the incident so similar events can be avoided in other institutions.

Section 10.7.2. Conduct an ^{HF}FMEA

Depending on the context of the incident and findings from the ^{HF}RCA, the ^{HF}RCA team may want to consider conducting an ^{HF}FMEA to identify more general risk factors not

immediately implicated in the sentinel event, but that could contribute to a future incident. See Chapter 12 for information about how to conduct an ^{HF}FMEA.

Section 10.8. Limitations of ^{HF}RCA

Although ^{HF}RCA can be an excellent means of understanding the root causes that contributed to a sentinel event, there are also some challenges and limitations to consider.

Section 10.8.1. The Resources Required

Properly carrying out an ^{HF}RCA is resource intensive, as it can be time consuming for a multi-disciplinary team to identify the root causes of a sentinel event. For an ^{HF}RCA to have impact, the multi-disciplinary team will also have to dedicate time to identifying and implementing mitigating strategies to address the identified root causes. Although ^{HF}RCA can be resource intensive, the benefits to successfully completing this type of analysis are substantial. Preventing future patients from being harmed as a result of a similar event is an invaluable opportunity.

Section 10.8.2. ^{HF}RCA is not Appropriate for Every Incident

Given that ^{HF}RCA is intended to identify system level root causes and contributing factors, incidents where a person wilfully causes harm are not appropriate for analysis using ^{HF}RCA. Examples of such circumstances include criminal acts, purposely unsafe acts, substance abuse by staff, and patient abuse of any kind. To determine whether an incident falls into the category of unintended harm caused by system factors or wilful harm, the Incident Decision Tree ([Figure 26](#)) is recommended.

Section 10.8.3. Completing an ^{HF}RCA Requires Tact

Following a sentinel event, it is normal for staff involved in the incident to be upset and scared about potential punitive actions towards them, or towards their colleagues, particularly if this approach was used historically. Consequently, it is of the utmost importance that those conducting the investigation are sensitive, and recognize that any interactions should leave staff feeling supported, rather than perpetuating any feelings of fear or paranoia. Follow the guidance provided for conducting observations ([Chapter 4](#)) and interviews ([Chapter 5](#)) such that staff do not feel they are being audited or judged, but rather that you are there to learn from them to make the system around them safer.

Section 10.9. Additional Resources

Reports

1. Incident Analysis Collaborating Parties. Canadian Incident Analysis Framework. Edmonton, AB: Canadian Patient Safety Institute; 2012. Incident Analysis Collaborating Parties are Canadian Patient Safety Institute (CPSI), Institute for Safe Medication Practices Canada, Saskatchewan Health, Patients for Patient Safety

Canada (a patient-led program of CPSI), Paula Beard, Carolyn E. Hoffman and Micheline Ste-Marie. Available at www.patientsafetyinstitute.ca

Tools and Frameworks Available Online

1. Veterans Affairs National Centre for Patient Safety Root Cause Analysis Tools
<http://www.patientsafety.va.gov/CogAids/RCA/index.html#page-4>
2. Veterans Affairs National Centre for Patient Safety Root Cause Analysis Triage and Triggering Questions
<http://www.patientsafety.va.gov/CogAids/Triage/index.html>
3. The Joint Commission Framework for Conducting a Root Cause Analysis and Action Plan
[http://www.jointcommission.org/Framework for Conducting a Root Cause Analysis and Action Plan/](http://www.jointcommission.org/Framework%20for%20Conducting%20a%20Root%20Cause%20Analysis%20and%20Action%20Plan/)
4. National Health Services (UK) Root Cause Analysis Toolkit
<http://www.nrls.npsa.nhs.uk/resources/rca-conditions/>

Examples of Root Cause Analyses

1. ISMP Canada published RCA's:
 - Fluorouracil Incident Root Cause Analysis
<http://www.ismp-canada.org/download/reports/FluorouracilIncidentMay2007.pdf>
 - Hydromorphone/Morphine Event
http://www.ismp-canada.org/download/Hydromorphone_Morphine_RCA_Report_final12.pdf
 - The Joint Commission - Sentinel Event Data: Root Causes by Event Type
http://www.jointcommission.org/sentinel_event.aspx
 - The Joint Commission - Sentinel Event Data: Root Causes by Event Type