Root-Cause Analysis and Health Failure Mode and Effect Analysis: Two Leading Techniques in Health Care Quality Assessment

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In this review article, the authors provide a detailed series of guidelines for effectively performing root-cause analysis (RCA) and health failure mode and effect analysis (HFMEA). RCA is a retrospective approach used to ascertain the "root cause" of a problem that has already occurred, whereas HFMEA is a prospective risk assessment tool whose aim is to recognize risks to patient safety. RCA and HFMEA are used for the prevention of errors or recurring errors to create a safer workplace, maintain high standards in health care quality, and incorporate time-saving and cost-saving modifications to favorably affect the patient care environment. The principles and techniques provided here should allow reviewers to better understand the features of RCA and HFMEA and how to apply these processes appropriately. These principles include how to organize a team, identify root causes, seed out proximate causes, graphically describe the process, conduct a hazard analysis, and develop and implement potential action plans.

Key Words: Quality, errors, root-cause analysis, RCA, health failure mode effect analysis, HFMEA

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INTRODUCTION

John Smith (a pseudonym) is a 70-year-old man admitted to the hospital for cerebral angiography. The day after that procedure, he mistakenly underwent an invasive cardiac electrophysiologic study. Mr Smith had been well and active until several months earlier, when a ball hit his head. MRI showed a large cerebral aneurysm, after which he was admitted for cerebral angiography. The day after admission, cerebral angiography was performed, and the aneurysm could not be embolized. It was decided that he required surgical therapy, and subsequent admission was planned. After angiography, the patient was transferred to the respiratory unit rather than being returned to his bed for continuous electronic monitoring (blood pressure, electrocardiography, etc). Discharge was planned for the following day. The next day, however, the patient was taken for an invasive cardiac electrophysiologic study. Approximately 1 hour into the study, it was realized that Mr Smith was the wrong patient. The procedure was immediately stopped, and he was taken to his room in stable condition.

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When such a medical error arises, an in-depth investigation into its causes is typically the first step within the corrective action process. Hence, it is beneficial to use tools that can systematically analyze these events to prevent them from ever occurring and to reduce the possibility of recurrence for events that have already happened [1].

Defenses, barriers, and safeguards are often put in place at key positions that may seem intact at the theoretical level. However, in practice, they have many holes or deficiencies that can allow potential hazards and accidents to occur. This concept of vulnerabilities in an organization's defenses against failure is known as the Swiss-cheese model [2]. In the case of John Smith, a traditional analysis, for instance, might have focused on the most visible causal factor, such as the nurse sending the wrong patient to the procedure room without a proper consent form. In contrast, root-cause analysis (RCA) could reveal multiple distinct errors, ranging from work environment factors (a resident who suspected the mistake but was reluctant to confront his superiors) to organizational factors (a program system that identifies patients by name instead of medical record number) [1]. Medical errors are typically the result of a combination of contributing factors, and rarely is there just one causal factor [3]. The combined errors of many individuals interact with system weaknesses, raising the likelihood that individual errors will do harm. In the case of

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Mr Smith, not only did the nurse fail to recognize him as the wrong patient, but so did the physician who had already started the procedure. The whole situation could have been avoided had the program system identified patients by number instead of name. When only one obvious causal factor is scrutinized, the list of recommendations will likely be incomplete, and future occurrences of the same event are highly likely because the organization failed to properly analyze the situation [3].

RCA has been popularized in the US health care system by The Joint Commission (JC) and the Veterans Health Administration as a systematic analytic approach to health care improvement since the 1990s [4,5]. The JC requires organizations to perform an RCA for every sentinel event, which it defines as "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof" [6]. The limitations of RCA have been addressed by using it in combination with other analytic methods, such as health care failure mode and effect analysis (HFMEA) [7].

The US Department of Veterans Affairs National Center for Patient Safety designed the HFMEA process for the purpose of preemptively detecting high-risk situations to patients in order to implement certain measures that would prevent such situations from happening in the first place [3]. In accordance with the JC, "At least every 18 months, the hospital selects one high risk process and conducts a proactive risk assessment" [8]. Proactive identification of risks and prevention of errors are pertinent and supportive of health care systems [7]. The JC also indicates the importance of HFMEA, stating that health care institutions should ensure that "an ongoing, proactive program for identifying risks to patient safety and reducing medical/healthcare errors is defined and implemented" [8]. The goal of this article is to introduce these two quality assessment techniques so that the readers can understand and perform the processes on their own.

METHODS

Defining RCA

RCA is a retrospective approach used to get to the "root cause" of a problem, which when identified and resolved prevents recurrence of the problem [4]. RCA is designed to help identify not only what and how an event occurred but, more important, why it happened [3]. If analysts stop after obtaining an accurate description of what happened and how the error happened, the investigation is insufficient to recognize the reasons for the problem [3]. Therefore, analysts will not be able to make useful recommendations to avoid the error from happening again. Only by determining why an event or failure occurred will analysts be able to create effective corrective measures that can prevent recurrence of future similar events [3].

For a causal factor to be labeled as the root cause, it must be the originating, most underlying cause of a problem. The root cause should be reasonably identified and managed, and effective recommendations aimed at preventing recurrences from this cause should be feasible [4]. Time should not be exhausted in dealing with and eliminating other causes, as this will only temporarily relieve the problem [2]. The earlier the root cause is identified, the quicker the problem can be resolved.

Some investigators have described their use of RCA to evaluate whether emerging mortality risk assessment tools sufficiently help reduce mortality after major pancreatectomy [9]. Other articles have described using RCA as a way of analyzing system failures to enhance patient safety in surgical residency [10] and identifying how falls on psychiatric units occur to create effective action plans to reduce falls and injuries [11].

How to Perform RCA. RCA is most effective when equipped with adequate resources and carried out by trained personnel. There are 11 steps (Tables 1 and 2 [2,3,12-18]), which serve as a detailed guide to perform the most effective RCA [2]. Transparency of information among all members involved in the process is critical throughout all stages of the RCA to ensure an environment in which all members feel equally involved and acknowledged during the process [19].

Typically, RCA is performed by a small team, with members selected from all levels associated with the event [2]. The team should consist of a minimum of 4 to a maximum of 10 members, from all levels of the staff, who have fundamental knowledge of the specific area involved [9]. Recruiting noninvolved staff members for the team can help maintain objectivity in the process [19]. Once the team is formed, analysis of the problem includes defining the event, verifying the root cause(s), and creating solutions [2]. The event can be adequately defined by asking 5 simple yet key questions: What happened? When did it happen? Who is involved? How did it happen? and Why did it happen? Without comprehensive information and knowledge of the event, the causal factors and root causes related to the event cannot be identified [3]. A complete RCA entails interviews with every staff member directly involved in the incident, as well as a review of related clinical documentation from records, charts, and online databases [19]. Once causal factors are identified, they are organized in a chart to help investigators organize and analyze the information gathered. This way the team can find any gaps or deficiencies in knowledge as the investigation progresses [3].

Events in a process are usually the result of several combined factors, and these factors can be grouped into several categories: institutional, organizational, work environment, team environment, staffing, task related, and patient characteristics. When the entire occurrence

Table 1. Eleven-step process of RCA

Step 1: Organize a team

- A typical team should consist of 4–10 members from all levels of staff who have fundamental knowledge of the specific area involved [9].
  - Area supervisor with decision-making authority
  - Quality improvement experts
  - Physicians
  - Credible and respected leaders with extensive knowledge
- Despite the team consisting of staff members with different levels of authority, they should all see and treat one another as equals [8].
- A facilitator should be appointed to gather facts and put together a team that is trustworthy and beneficial to the task at hand [8].
- The facilitator should not be directly implicated in the incident, nor should the facilitator have predetermined ideas of possible causal factors.
- It is best to create a team of <10 members so that the RCA process can be carried out efficiently [8].
- It is also important to keep the team at a minimum of 4 members, as this will likely provide a broader knowledge base, a more creative thinking process, and adequate experience to solve the problem and create a plan of action [8].
- Credible representatives, most closely involved in the process under review, should be appointed by the team [8].
- Physicians' involvement in the RCA process is crucial, as their knowledge and experience are vital to help recognize possible root causes [8].
- In fact, if no physician has participated in the team, The Joint Commission's accreditation committee will not accept an RCA of a medical care process [10].

Step 2: Define what happened (the event)

- It is crucial that the problem (event) be adequately defined, and this is done by asking 5 simple yet key questions:
  - What happened?
  - When did it happen?
  - Who is involved?
  - How did it happen?
  - Why did it happen?
- Once these questions have been answered, a framework can be created for exploring the probable issues that underlie the problem.

Step 3: Identify and define the processes related to the event

- Using a flowchart to graphically describe the processes while brainstorming possible causes is an effective technique that can help identify the various possibilities leading to the event [8].
- Organizing the information in a diagram can help the team reach a mutual understanding of the problem and lessen subjective decision making [4].
- Other methods include fishbone diagrams, histograms, and tree diagrams [8].

Step 4: Identify proximate causes

- Proximate causes are immediate, obvious, or superficial causes relating to the event, which are usually found during the beginnings of the RCA process [11].
- The most critical cause can be determined by weighing all the causal factors' importance and relevance to the actual process [4].
- An acceptable RCA focuses on system-related problems, not people or groups.
- If the team comes to the conclusion that a certain individual had some part of blame or cause in the problem, the team should refer the relevant information to the appropriate department dealing with individual performance assessment [19].

Step 5: Design and implement necessary "quick fix" interim changes

- Because health care errors can lead to potentially serious outcomes that can endanger patient care, a quick solution may be required to temporarily alleviate the problem, meanwhile "buying" the team more time to find the root cause [8].
- Quick fix interim changes are usually designed on the basis of the proximate cause and should not be considered long-term solutions [8].
- Therefore, it is necessary that the organization respond quickly to prevent a similar problem from recurring while the team is going through the RCA process [8].

Step 6: Identify root causes

- Events in a process are usually the result of several combined factors and to reach a conclusion all other presumptive and contributing causes should be removed.
- These causes can be grouped into several categories:
  - Institutional
  - Organizational
  - Work environment
  - Team environment
  - Staffing
  - Task related
  - Patient characteristics
- These categories should address communication problems; rules, policies, and procedures; human errors (fatigue, overwork); and overall information management, among others.

(continued)

Table 1. Continued

- Contributing causes are factors that are significant enough to result in future unwanted events but, if corrected or eliminated, do not prevent future occurrences [8].
- Presumptive causes are those that initially appeared as possible factors in the process, but after beginning and collecting data for the RCA process, there is no relevant evidence to support them [8].
- To identify the root cause, the team needs to dig deep into the problem and exhume all possible causes until the true root cause can be established.
- The five rules of causation (Table 2) are a tool developed to help create minimum standards for searching out root causes in the RCA process [20].

Step 7: Identify potential risk reduction strategies

- After identifying the root causes of the event, attempts are made to identify corrective measures and risk reduction strategies [8].
- The team may use various techniques to reach a potential action plan.
- One approach is to breakdown the root causes into smaller recognizable portions with known solutions [8]. This way, a potential fix may be devised for the more complex root cause.
- Another example is the "six thinking hats" technique, whereby each member is forced to think on the basis of roles that differ from their usual ones [8].
- It is essential that that some sort of action plan or strategy be reached before moving on to the final stages.

Step 8: Formulate and evaluate proposed improvement actions

- Once a risk reduction strategy has been created, a trial test is highly recommended to identify its measure of success.
- If good results are achieved, the team can be reassured before committing significant organizational resources [8].
- However, should there be any unintended consequences, the team can go back and adjust accordingly [8].
- A scientific method, such as the plan-do-study-act cycle, can be used to decide what changes or improvements need to be made [18].
- Using this method allows the team to test how successful the changes made were and whether or not they need to rehypothesize and conduct another experiment in case no good results were achieved [18].

Step 9: Develop and implement an improvement action plan

- Before significant organizational resources are used to develop and implement the improvement action plan, all relevant staff members, hospitals, departments, and stakeholders involved with the process must reach a consensus [8].

Step 10: Evaluate and fine-tune improvement efforts

- To appropriately evaluate improvement efforts, clear quantifiable data must be obtained showing the impact of actions on the root causes and, if applicable, demonstrate change over time [18].
- Comparing the data against internal references, practice guidelines, and practice and external standards helps in fine-tuning the final action plan.
- If the data show that all objectives have been accomplished, the team will focus on organizing successful improvement initiatives [18].

Step 11: Communicate the results

- Communicating the results of the RCA to all staff members involved, including management, is essential to build trust and show appreciation of the team's effort in this process [8].
- A table can be created listing the causal factors, root-cause identifications, and recommendations and handed out to all personnel. This way, all the information can be interpreted in an organized fashion, and each person can analyze the information at his or her own pace [21].
- This step is critical to the success of improvement initiatives [18].

Note: RCA = root-cause analysis.

has been charted out and the major causal factors are identified, the investigators are in a good position to decide the major root causes(s) of the incident and begin creating achievable solutions [3]. To identify the root cause, the team needs to dig deep into the problem and exhume all possible causes until the true root cause can be established. After identifying the root cause of the event, attempts are made to identify corrective measures and risk reduction strategies [2]. The team may use various techniques in order to reach a potential action plan. One approach would be to breakdown the root causes into smaller recognizable portions with known solutions [2]. It is important that some sort of action plan or strategy be reached before moving on to the final stages.

Once a risk reduction strategy has been created, a trial test is highly recommended to identify its measure of success. If good results are achieved, the team can be reassured before committing significant organizational resources [2]. Once solutions have been finalized, the decision to implement these solutions may take days to months to complete [1].

Limitations and Difficulties. RCA is one of the most widely used methods to improving patient safety, but few data exist that uphold its effectiveness [1]. The quality of RCA varies across facilities, and its effectiveness in lowering risk or improving medical safety has not been systematically established [7,20]. The quality of RCA is dependent on the accuracy of the input data as

well as the capability of the RCA team to appropriately use these data to create an action plan [2]. In some cases, only one source of error or a few sources of error are emphasized, when in reality the situation might be more complex [7].

The thoughts, conversations, and relationships of members play an important role in determining the effectiveness of an RCA team [2]. People tend to select and interpret data to support their prior opinions. An atmosphere of trust, openness, and honesty is critical to encourage members to share what they know without fear of being criticized or unacknowledged [18]. In addition, RCA lacks the ability to allow one to determine the probability, criticality, and severity of events, which can be useful for prioritizing management and preventing future undesirable events [7].

RCA can be very time-consuming because of all the time required for data gathering, as the accuracy of the research is crucial [2]. Organizations should ensure that adequate resources, time, and feedback are sufficiently provided during the RCA process so that the team will be able to carry out its task effectively.

Defining HFMEA

Failure mode and effect analysis is a prospective risk assessment tool originally developed in the manufacturing industry that is now being used in health care to proactively recognize risks to patient safety and lessen medical and health care errors [3]. Usually, a process in a high-risk area is categorized as one that has great potential for compromising patient safety. Through HFMEA, the ways in which the process can fail can be identified, the parts of the process that are most in need of change prioritized, and corrective action taken before failures occur. An emphasis on prevention will reduce the risk for harm or injury to both patients and staff members [21].

In a radiology department, HFMEA can be a useful approach for a number of common sources of error, including patient identification, preparation, and consent; radiation exposure; monitoring during an examination; and maintenance of a safe working environment [7,22]. Published examples of topics in radiology failure mode and effect analysis include screening of patients with diabetes before interventional procedures [7], ordering of radiologic studies, and misadministration of intravenous contrast medium in outpatient radiology settings [23].

How HFMEA Is Performed. The core of the HFMEA approach includes constructing a multidisciplinary team and diagramming process, identifying failure mode and causes, and the prioritization of potential risks by determining the severity and probability of a failure mode (Tables 3 and 4 [3,8,23]). There are 5 steps listed in Table 3, which serve as a detailed guide to performing the most effective HFMEA. Given the resource and time investments of the HFMEA team, the department or institution must pick the most optimal topic appropriate for its needs [7]. Any weakness or vulnerability in a process that hinders it from accomplishing its intended purpose or meeting desired requirements or standards is known as a failure mode [21]. Asking questions such as "What could go wrong if this process failed?" "Why would the failure happen?" and "What would be the consequences of each failure?" is essential when prioritizing and assessing parts of a high-risk process that are most in need of change.

Once a topic that has high severity, high probability, or both is chosen, a multidisciplinary team is assembled that should be committed to identifying opportunities for improvement and to creating effective changes [7]. The HFMEA team consists of personnel from different backgrounds with expertise in the subject matter and is led by a team leader, who should be familiar and skilled with the group process [7]. It may also include patient representatives and team members with other roles to provide different viewpoints, helping the team identify vulnerabilities that others may miss [7]. A recorder is appointed to document assigned roles to ensure that each person's role on the team is clearly outlined [19]. Additionally, the recorder

Table 2. Five rules of causation

Rule 1:	Causal statements must clearly show the "cause-and-effect" relationship. This is the simplest of the rules. When describing why an event has occurred, you should show the link between your root cause and the bad outcome, and each link should be clear to the RCA team and others.
Rule 2:	Negative descriptors (eg, *poorly*, *inadequate*) are not used in causal statement. To force clear cause-and-effect descriptions, the use of any negative descriptor such as *carelessness* or *complacency are not recommended* because they are broad. Negative judgments do little to describe the actual conditions or behaviors that led to the mishap.
Rule 3:	Each human error must have a preceding cause. Most of our mishaps involve at least one human error. Unfortunately, the discovery that a human has erred does little to aid the prevention process. You must investigate to determine why the human error occurred.
Rule 4:	Each procedural deviation must have a preceding cause. Procedural violations are like errors in that they are not directly manageable. Instead, it is the cause of the procedural violation that we can manage.
Rule 5:	Failure to act is causal only when there was a preexisting duty to act. We can all find ways in which our investigated mishap would not have occurred, but this is not the purpose of causal investigation. Instead, we need to find out why this mishap occurred in our system as it is designed today.

Source: Wu et al [20].

Table 3. HFMEA steps

Step 1: Define the topic
- The topic is usually a process in a high-risk area or has great potential for compromising patient safety.
- It is important in an HFMEA analysis to outline boundaries to focus on one or two topics annually per department, as this process entails great time and effort to complete [8].

Step 2: Assemble a team
- The team should include multidisciplinary members from all levels who are involved in the topic being analyzed [8].
- This can range from 7 to 9 members, including leaders to help start the project and quality improvement experts to provide support [8].
- Additionally, recruiting a person without knowledge of the topic can be useful in providing different viewpoints on the matter [8].
- Having someone who is unfamiliar with the topic of interest can help encourage a critical review of practices and standards and the detection of potential weaknesses that others may miss [3].

Step 3: Graphically describe the process
- A detailed chart of the process should be constructed by the team to help enable complete understanding of the individual steps involved in the process [12].
- This understanding can be accomplished by creating a process map that visually illustrates the sequence of related events in the process [12].
- The process map is a hierarchical means for depicting complex processes and includes further aspects, such as cycle time and delays amid stages, the cost or value added at each step, inventory, responsible persons, and wastage [12].
- The details of each process and sub process should be precise and extensive, but keeping in mind that narrowing the scope of the analysis is important because too comprehensive an approach will result in an inappropriately drawn out process [12].
- The team should focus on the steps that are most susceptible to intervention and improvement in order to create an environment for a successful outcome [12].

Step 4: Conduct a hazard analysis
- After all the processes and subprocesses have been identified, the team should create a list of all the potential failure modes that may occur and number them consecutively [23].
- These failure modes can be thought of through brainstorming possible scenarios by simple cause-and-effect diagramming ("What might happen?" "What could happen to the patient?" etc) [23].
- Information from FDA databases, Institute for Safe Medication Practices, and Joint Commission sentinel event alerts can also be used to obtain failure modes [23].
- Once the failure modes have been laid out, the next step should be to assign the probability ("How likely is this to happen?") and severity ("What would be the impact on the patient?") for each mode [8].
- A score is calculated for the both the severity and probability, and a hazard scoring matrix (Table 4) is then used to determine whether the specific failure mode requires further action [8].
- Potential areas on which the team should focus include modes with high criticality (single-point weaknesses that would result in adverse events should they fail), high detectability (very obvious hazards that could result in adverse events), or lack of sufficient and effective control measures [8].

Step 5: Define actions and outcome measures
- At this step, the team will determine whether to control, eliminate, or accept the failure mode cause.
- A description of the process of action for each failure mode should be identified if it is to be controlled or eliminated.
- Once the measures are identified, the team should appoint an individual to be responsible for the ensuring the completion of the proposed action [3].
- It is critical to indicate whether top management agrees with the recommended action before the process has begun.

Note: HFMEA = health care failure mode and effect analysis.

will document the progress made throughout the HFMEA process [19].

Once the team is formed, a process map is then developed that graphically describes and verifies the process in detail [7]. In contrast to a flowchart (which displays the process flow graphically), a process map is different by showing inputs, outputs, decision or action points, and units of activity [19]. The team should focus on the steps that are most susceptible to intervention and improvement to create an environment for a successful outcome [19]. The details of each process and subprocess should be precise and extensive, keeping in mind that narrowing the scope of the analysis is important because too comprehensive an approach will result in an inappropriately drawn-out process [19]. The process and subprocesses are identified and numbered (1, 2, 3, etc, for processes; 1A, 1B, 1C, etc, for subprocesses), and a hazard analysis is done to identify failure modes and their causes and effects [7].

The team determines the severity and probability of each failure mode and assigns scores to help prioritize which failure modes warrant further action using a decision tree analysis [7]. This decision tree analysis can be done by asking 3 questions: First, is there one single-point weakness in the particular subprocess at which failure would be critical (criticality)? Second, is there an existing effective control measure for the failure mode? Third, is the failure obvious enough to be noticed before the adverse event occurs (detectability) [7]? Effective control measures are then devised and implemented to greatly reduce the possibility of such hazardous events from ever occurring [7].

Table 4. Guide to performing hazard scoring for all failure modes

Severity
1 = No harm to patient or process
2 = Mildly harmful to patient or process
3 = Moderately harmful to patient or process
4 = Severely harmful to patient or process
Probability
1 = Rare (1 time/month)
2 = Uncommon (1 time/wk)
3 = Occasional (<2 times/d but >1/time/week)
4 = Frequent (>2 times/day)
Criticality
Ask the question "Is there redundancy?"
Detectability
Ask the question "Is this totally obvious?"

Source: Quality and Safety Network [8].

Limitations and Difficulties. Although HFMEA proves to be very useful in proactively recognizing and preventing potential problems, it is very costly and time consuming because of the complex processes involved [2]. For example, developing a flow diagram for the topic and numbering each step and substep of that process (step 3, Table 3) can be confusing and perhaps frustrating as team members work together to define the sequential steps [24]. Time and diligence are required to accurately identify the key processes, so that the next step of conducting a hazard analysis will yield more precise and reliable results.

HFMEA also lacks a thorough and systematic human error identification technique [25]. HFMEA fails to provide any specialized method for the identification of human errors and their causes; instead, it depends on the subjective recall (severity, occurrence, and detectability) of the team performing the analysis [25]. Inadequate human error identification technique hinders the ability to accurately estimate the significance of the identified human errors [25]. Also, it might be challenging to measure the outcomes of recommendations because of low error reporting rates [19].

Careful attention to the selection process is critical (step 3, Table 3). For example, an institution that might pick high criticality as its priority could lose the value of detection ratings, which constitute an integral part of the HFMEA methodology, resulting in a loss of robustness in the decision-making process [25]. Criticality is a single-point weakness that would result in system failure or an adverse event should it fail [2]. Focusing on a single point lets us disregard other obvious problems that could be addressed and weaken the decision-making process. In contrast, high detectability focuses on multiple problems in a product or process design [2]. High detectability can add more strength and value to the decision-making process and detection ratings, as multiple issues are addressed and prioritized according to significance for corrective action.

Another drawback is that departmental leaders can initially determine the scope of each HFMEA topic on the basis of the amount of resources available to support their analysis [2]. Therefore, institutions are limited to selectively picking only one or two high-risk HFMEA topics per year [2].

CONCLUSIONS

Although conventional RCA tools provide good retrospective investigations, they are imperfect and often work by chance, not by design [26]. HFMEA uses a different approach and prospectively aims to avoid potential failures by systematically identifying and preventing process failures before they happen [26].

Together, RCA and HFMEA help prevent errors so that we can reduce possible injuries to patient or personnel, promote a safer workplace, and maintain acceptable health care satisfaction. RCA investigates a case or single incident, whereas HFMEA investigates a whole process or system design [26]. HFMEA focuses on systems and processes, and the changes implemented are likely to affect and benefit a large number of people potentially affected by that process [26]. Although RCA may not benefit the patient who was harmed, the implementation of changes as a result of the investigation may be beneficial by preventing the occurrence of future similar events [26].

Leadership support of RCA and HMFEA is essential in the success of such programs. Both systems require significant resources and personnel. Support of the outcomes of these investigations is pivotal to improving quality. Eventually, with continued support, adoption of these processes into the culture would be achieved, and this is necessary for long-term success. A thorough understanding of the steps, principles, and techniques discussed in this article will help provide an understanding of how to perform both RCA and HFMEA more effectively.

TAKE-HOME POINTS

- RCA is a retrospective approach used to get to the highest level underlying cause of problem that has occurred so that when the cause is resolved this will prevent the problem from recurring.
- RCA investigates a case or single incident and can be very time-consuming. Although, RCA may not benefit the patient that was harmed, implementation of changes as a result of the investigation may benefit and prevent the occurrence of other future similar events.
- HFMEA is a prospective approach used to analyze high risk processes and focuses on systems, and the changes implemented are likely to impact and benefit a large number of people potentially affected by that process.
- HFMEA is very costly and labor-intensive; therefore hospitals should spend time thinking about which high risk process to investigate.

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