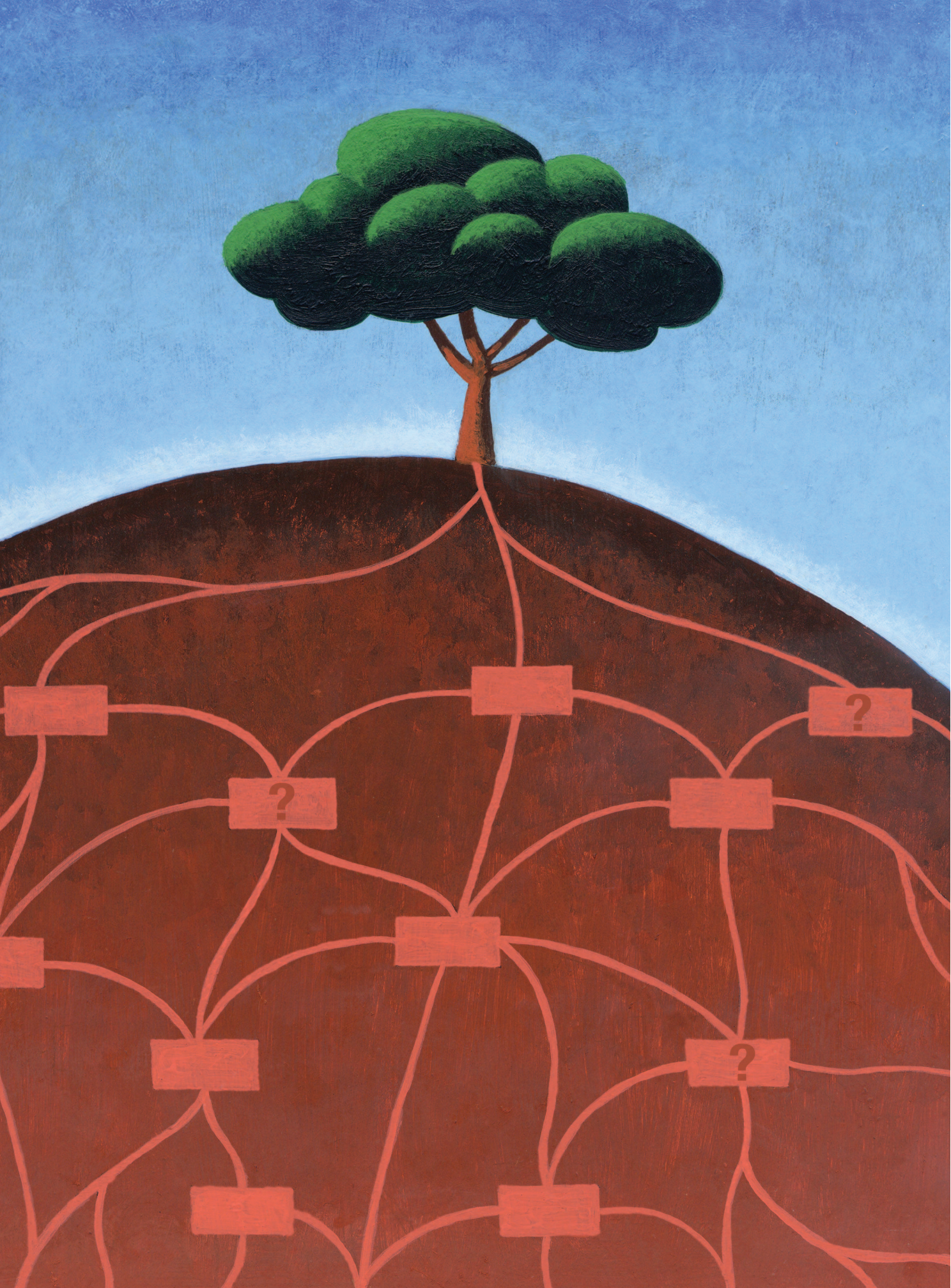

CE 2.5 CONTACT HOURS

Drill down with root cause analysis

Know the source of the spark while protecting yourself from the fire.

By **Ann McDonald**, RN, MN, and **Thomas Leyhane**, JD

Abstract: Review the structure of an effective critical event analysis and suggestions for completing documentation and maximizing knowledge while protecting your organization from litigation.
[Nurs Manage 2005:36(10):26-32]

Healthcare facilities have lived with event reporting for many years, although formats have varied. The genesis of the more recent flurry of activity in the realm of event reporting occurred in the wake of the Institute of Medicine (IOM) report *To Err Is Human* in November 1999.[1] Now, we're all very aware of the findings: Nearly 100,000 Americans die each year from preventable medical errors, many of which are related to systemic flaws rather than individual fault.

The general structure of an effective critical event analysis (CEA) consists of data collection, investigation, determination and reporting of root causes, implementation of corrective actions, and monitoring for sustainability.[2] The goal of the entire process is to ensure that a preventable adverse event or risky chronic problem never recurs. For staff to fully participate in the process, it's critical to present an atmosphere of learning, one that avoids blame or perception of negligence.

Structuring your investigation around "What could we do to prevent this in the future?" creates a very different environment than "What should we have done to prevent this from having occurred?" Staff willingness to report events may serve as an indirect measure of staff belief about the punitiveness of the environment. Physicians are often the most distrusting of a nonpunitive approach and need to be reassured that the documentation and patient and family communication support them, as well.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recently published a summary of the type, number, and distribution of the more than 3,000 sentinel events in its database.[3] The four leading types of events include patient suicide (14%), wrong-site surgery (12.5%), operative and post-op complication (12.3%), and medication error (11%). Sixty-five percent of the events occurred in general hospitals, while 12% took place in psychiatric hospitals. Deaths generally occurred in 74% of the events reported to JCAHO by facilities, and in 64% of those reported by members of the media, CMS, or the medical or public community. The value of this report lies in the information it yields specific to root causes and the percentage of cases to which they're applied. Individual cases may count root causes in several categories.[4] (See "Causes and percentages.")

Investigating and categorizing

Critical event or root cause analysis (RCA) is a six-step process designed for use in investigating and categorizing the root causes of events that impact patient or staff safety, health, quality, or environment. Most commonly, the resources for an RCA are chartered when a preventable adverse or sentinel event has occurred or a near miss and its potential consequence are truly understood.

An RCA is a set of tools to help you identify not only *what* and *how* an event occurred, but *why* it happened. The steps are event definition, team chartering, data collection and investigation, identification of preventive mechanisms, organizational reporting, and implementation with monitoring. The analysis focuses on systems and processes, *not* individual performance during the investigation, cause determination, and implementation processes.

The authors disclose that they have no significant relationship with or financial interest in any commercial companies that pertain to this educational activity.

First step: Determine if an immediate risk to patients or providers exists, and act accordingly. In most organizations, this is accomplished through a team effort and may include stopping processes, taking equipment out of service, or other actions to ensure a safe environment. Many organizations use JCAHO's definition of a sentinel event or another definition legislated through their state's reporting system. JCAHO's definition is "an unexpected occurrence involving death or serious physical or psychological injury or the risk thereof." The term "sentinel" derives from the idea that it's casting a signal or sounding a warning that requires immediate attention.

Administrators must discuss the definition and specific appropriateness to a current event. Each organization has different responsibilities to report to regulatory and healthcare safety organizations if an event is classified a sentinel or preventable serious adverse event. Knowing individual state laws, processes, and expectations of timeliness is critical for senior leaders.

Second step: Clearly define the role of leaders and facilitators, because an effective RCA requires involvement of a multidisciplinary team of staff at all levels closest to the event and those with decision-making authority. The team must have the flexibility to meet as often as necessary and be provided with the resources and dedicated time. Also, the team must be empowered to complete its assessment and make recommendations for change while working with policy-driven established tools, structure, and timeliness. Ideally, the core team should stay as consistent as possible, though physicians and ad-hoc team members may be necessary when exploring foundational areas such as medication processes.

Just-in-time training for quality tools, the global processes, specific forms, and work plan development may be necessary to ensure consistent application of the RCA process across the organization. Process standardization with forms for each step will increase staff vigor and ease readability by senior leaders. The policy and work plan should contain target dates to maintain compliance with regulatory and accreditation standards.

The policy should include the administrative or committee structure to which the RCA will be reported when complete. It's also important to understand if the process for monitoring and reporting effectiveness and implementation data occurs at the departmental process improvement plan level or an organizational committee level. A lack of implementation monitoring with in-process and outcome measures will prevent sustainability of the recommended changes and increase the likelihood of the event recurring.

Third step: Determine the sequence of events, contributing conditions, and assumptions related to the critical event. Given that most of the information will come from involved staff and supervising staff that may be able to critically assess the contributing factors, the interviews should begin immediately once the patient receives care and the planning for communication to the patient and family is completed. The analyzed time frame should predate the event by long enough to add confidence that all the environmental and contributing factors are described.

Data gathering is a time-intensive step, as it involves analyzing the event or pattern of events.[5] In the case of a sentinel event, the proximate cause is almost always a special cause variation. The analysis progresses from proximate special causes in clinical processes to common causes in organizational processes. In many analyses, the most visible cause is given all the attention, to the detriment of the staff, patients, and facility. Consider using a flow chart or simple table to document and summarize the sequence of contributing factors. (See "Event analysis.")

Fourth step: Analyze causal factors, those that if eliminated would have prevented the occurrence or reduced its severity. Try to gain an understanding of what mechanisms normally prevented problems from occurring in the past. Encourage brainstorming of all possible contributing causes. Some organizations set a goal number of possible contributors to stretch the staff's tendency to resort to the special cause answer. Rarely is there only one causal factor; events are usually the result of a combination of circumstances.

If only one factor is addressed, the list of recommendations will be inadequate to prevent similar events. In healthcare, it's advisable to complete a fishbone diagram, cause and effect diagram, or causal factor chart to provide structure for investigators to organize and identify related and unrelated gaps and deficiencies in knowledge, along with the conditions surrounding these events.

Causes and percentages

Root causes	Percentages of sentinel events
Communication	66%
Orientation and training	57%
Patient assessment processes	42%
Staffing levels	22%
Information availability	20%
Competency/credentialing	20%

Source: JCAHO, http://www.jcaho.org.

Event analysis

Date	Time	Event sequence Describe step-by-step what occurred leading up to the event, including interruptions and assumptions.	System/process issues Did something go wrong or cause a delay at this step?

Fishbone diagrams drive data collection by identifying data needs. Think of them as a pictorial strategy for drilling down into root causes and determining the redesign and change implementation.

It's vital for team members to understand active and latent error taxonomies, as well as JCAHO's requirements for category analysis of specific types of events. The analysis digs deeper by asking "why" questions until no other logical answer can be identified. A level of confidence can be achieved when "why" has been asked five times, backing up any perceived cause in time. You should be able to view the "why's" in your fishbone diagram.

Drilling down to the root cause of performance variation is difficult and uncomfortable, though long-term benefits to patient care, outcomes, and staff education outweigh the discomfort. Analysts should avoid using general causal classification such as human error, equipment failure, or external factor, as these don't happen in isolation of potentially preventive measures. Lasting change can only come about when the root cause of variation in performance is discovered and changed. Once you've completed the brainstorming, diagramming, and intensive questioning (the "why's"), sort, rank, and analyze the cause list, placing the root cause high on the summary table. (See "Summarizing issues.")

Fifth step: Identify changes and develop action plans for rollout across disciplines and employee levels. Implement changes through either redesign or development of new systems or processes that improve the level of performance at all employee levels and reduce the risk of a particular serious adverse event occurring in the future. Some of the most difficult areas to improve are the contributions of human factor theory: attention, memory, or the impact of interruptions.

High-risk procedures can be examined prospectively using the failure mode and effects analysis (FMEA)—a team-based, systematic proactive technique used to prevent process and product problems before they occur.[6] In addition to determining the steps in the process, with a goal of identifying the greatest risk of failure, the FMEA also helps project the severity of the outcome. FMEA assumes failures will occur no matter how careful or knowledgeable the staff. The process attaches a numeric value to the frequency of step failure, degree of severity for the effects of the failure, and the chance of detection of the failure by multiplying these numbers at each step. This allows the process leader to prioritize future improvements in high-risk areas.

Sixth step: Present the recommended improvements to senior leaders for review and approval of implementation. Included in the presentation would be timelines for implementation and monitoring strategies. The monitoring strategies should include in-process measures (what percentage of time the change was implemented) and outcome measures. Outcome measures shouldn't be the lack of the critical event but an inclusion of the completion of the product for a process. With optimal performance, frequency or sample size of the monitoring can decrease with time.

Describe the reporting structure in the CEA policy and include senior leaders on the reporting committee. To further align physicians with the medical center, the medical executive committee should receive a summary report of critical events—with a severity ranking—the root causes, and the recommended process changes that you've implemented. This report should be provided once or twice a year with comparisons through JCAHO or other organizations.

Large organizations or health systems should categorize and track events across facilities, which allows senior leaders to understand critical events occurring at each location. Within an industry or organization, an additional benefit of categorizing CEAs over time is that the root causes identified across the population of occurrences can be used to target major opportunities for improvement across nursing units and medical centers within a system. The National Quality Forum and JCAHO have recently endorsed a standardized integrative classification system for healthcare errors and other patient safety problems.[7]

Currently, many states have optional or mandatory reporting systems, which are generally untrusted by practitioners. Unfortunately, most of these systems don't talk to each other, so the ability to learn from them is limited. To reverse this disturbing trend, the Patient Safety Event Taxonomy (PSET) was developed. PSET enables interoperability of reporting systems and comparability of information across systems, thus furthering the ability to implement preventive actions similar to those distributed in JCAHO's *Sentinel Event Alert*. All healthcare organizations are encouraged to map their existing classifications to this system of standardized definitions and categories.

Summarizing issues

Additional issue	Normal preventive barrier	Why did the normal barrier not work?	What may have contributed to this step?	Recommended action plan to prevent future occurrences, and monitoring strategies
What went wrong? What was the active error?	What policy/ procedure/ safety measures should be used here?	Why did it go wrong? Why was the policy not followed?	Did anything else contribute?	
Behavioral				
Assessment				
Patient identification				
Issues				
Care planning				
Process				

RCA and the law

By its very nature, RCA requires the participation of individuals from different disciplines and a clear understanding that the qualitative evaluation can't be fault based. The development of RCA protocols and, more importantly, an appreciation of the quality improvement goal at the heart of the process have occurred within a legal system that emphasizes fault-based liability. The inherent conflict threatens the effectiveness of RCA.

Federal initiatives in the wake of the IOM report triggered a variety of responses from state legislatures throughout the country, seeking both to implement reporting requirements and afford levels of disclosure protection, particularly in the context of malpractice litigation. The result has been a patchwork of differing levels of protection in different states and a persistent concern among healthcare providers whether their RCA efforts will be used against them or their facility in litigation. Obviously, an effective RCA process mandates a level of disclosure protection to foster its very purpose.

For those in key RCA roles, knowledge of the particular protective framework existing in their state is critical. Process participants need to know that there are legitimate disclosure safeguards and the limits of those protections. Since states vary in their response to the issue, this discussion focuses on some general legal principles governing privileges and protections. Legal counsel for a facility can advise regarding unique requirements of particular jurisdictions.

Litigation involves a discovery process in which each side is permitted to gather information. By legislation or court decision, states may recognize privileges with respect to certain types of disclosures. Examples include the attorney-client, physician-patient, and cleric-penitent privileges. Legislative enactment of a privilege against disclosure of RCA or sentinel event data is the strongest protection available. In the vast majority of instances, the privilege will hold against a demand for disclosure in litigation. Legislative creation of a privilege is particularly vital because it's an expression of the public policy of the jurisdiction; courts will generally defer to the pronouncements of the legislature.

States that have enacted privileges covering reporting, sentinel event, or RCA data have, for the most part, made such protections against disclosure unequivocal. However, since privileges are interpreted narrowly, an understanding of exceptions—whether carved out by the legislature itself or by court decision—is also important. Thus, if a claimant in malpractice litigation can demonstrate an inability to obtain factual data regarding an event by any other method, a court may well order disclosure of at least the factual data assembled in the RCA or sentinel event reporting process.

Legislatively or judicially created privileges may not afford protection to aggregate reporting data, which in most instances is de-identified and statistical in nature. Purely statistical data regarding, for example, the number of medication errors reported for a specific facility may well be discoverable. Unfortunately, the use of the term "privileged" or "confidential" in a statute may not be an accurate reflection of the level of protection afforded. A close reading of the applicable statute is essential.

Other states have declined to create a privilege against disclosure. Where a legislature hasn't acted or has declined to create an outright privilege, reporting and RCA data may be subject to disclosure in litigation. Essentially, disclosure is determined on a case-by-case basis with the potential for conflicting rulings within the same jurisdiction. Accomplishing the fundamental purpose of the RCA process can be hampered by the natural fear of courtroom disclosure. It's in this framework that the task of key RCA participants becomes most difficult and, presumably, underreporting most prevalent. A few practical pointers may be helpful.

It may well be that disclosure fears are overrated. In one survey conducted by the National Academy for State Health Policy, no identifiable connection could be made between mandatory or "open" reporting systems and an increase in malpractice suits.[8] The result suggests that malpractice

claims aren't necessarily generated by public reporting requirements.

When malpractice litigation commences, plaintiffs generally have already assembled enough data to satisfy an expert that negligence occurred. Moreover, much of the information necessary to support a claim is assembled during the discovery process without the need to probe internal processes. Finally, even in those jurisdictions without a privilege, courts remain mindful of the need for internal analyses as a component of quality medical care and require a showing that the information is critical to the plaintiff's case and can't be obtained through regular discovery methods.

Within this context, how can RCA processes be designed so as to enhance the quality of medical care through improved systems while at the same time affording disclosure protection? Although they seem to be conflicting goals, they're not. To the extent that candid analysis and discussion are fostered by a reasonable assurance of disclosure protection, the goals of RCA are advanced. RCA participants must remain constantly mindful of the fact that it's a process designed to identify systemic concerns, not individual fault. The ultimate documentation involved should be segregated into sections that simply identify the facts of an event, not inferences, speculation, or opinion, followed by sections that contain analytical, deliberative, or opinion information. The latter is most critical to the integrity of any RCA procedure and, of course, most desired by an adverse litigant.

When permitting disclosure, courts are far more likely to exclude analytic, deliberative, or opinion documentation. Why? Because if the facts are known, plaintiffs can obtain the opinions they need from their retained experts without the need to invade a facility's analytic and opinion data. Moreover, it's precisely the analytic or deliberative material most deserving of protection as a matter of public policy.

Teasing apart fact from opinion or analysis can be a difficult process but an essential one if RCA is to succeed in our litigation environment. While no level of statutory protection or judicial protection is absolute, reasonable steps can be taken that serve the integrity of the RCA function to both enhance quality and protect healthcare providers and facilities. NM

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CE 2.5 CONTACT HOURS

Drill down with root cause analysis

GENERAL PURPOSE: This article provides the registered nurse with the general structure of an effective critical event analysis.

LEARNING OBJECTIVES: After reading the preceding article and taking this test, the reader should be able to: **1.** Define critical event or root cause analysis. **2.** Discuss the six-step process used in investigating the root causes of an event. **3.** Identify legal aspects of root cause analysis.

1. The root cause analysis (RCA) investigation should focus on which of the following questions?
a. What should we have done to prevent this from occurring?
b. What did we do wrong?
c. Who's at fault?
d. What could we do to prevent this in the future?

2. According to JCAHO, what's the leading type of sentinel event?
a. suicide
b. wrong-site surgery
c. post-op complication
d. medication error

3. Deaths occur in what percentage of the events reported to JCAHO?
a. 100%
b. 74%
c. 50%
d. 25%

4. What's the most common root cause of sentinel events?
a. education
b. staffing
c. communication
d. competency

5. Which statement is true about the focus of RCA?
a. RCA looks only at what and how an event occurred.
b. The primary concern of RCA is individual performance.
c. The analysis focuses on systems and processes.
d. RCA consists of five essential steps.

6. JCAHO defines a sentinel event as
a. any unexpected occurrence.
b. an unexpected occurrence involving death or serious injury or risk thereof.
c. any death.
d. any serious physical injury or death.

7. The first step in the process of RCA is to
a. charter the team.
b. investigate the event.
c. define the event.
d. conduct RCA.

8. Which of the following is true about determining the sequence of events?
a. The time frame should predate the event long enough to describe all environmental and contributing factors.
b. The time frame being analyzed should begin at the time of the event.
c. Most of the information will come from the patient.
d. The interview should begin as soon as the patient is discharged.

9. Which of the following is true about causal factors?
a. Analyzing causal factors is the first step in the RCA.
b. There's usually only one causal factor.
c. Causal factors are those factors that, if eliminated, would have prevented the occurrence or reduced its severity.
d. Only the primary causal factor should be addressed to prevent similar events.

10. The most critical question to ask during the analysis of an event is
a. "What?"
b. "Who?"
c. "How?"
d. "Why?"

11. An example of a general causal classification is
a. communication.
b. human error.
c. medication error.
d. orientation and training.

12. Which of the following *isn't* true about the failure mode and effects analysis (FMEA)?
a. FMEA uses a team-based and systematic approach.
b. FMEA is used to prevent process and product problems before they occur.
c. FMEA helps project the severity of the problem.
d. FMEA stops failures from occurring.

13. The sixth step in the RCA process is
a. implementation and monitoring.
b. identification of preventive measures.
c. making recommendations.
d. the final analysis.

14. Which of the following is true regarding disclosure protection related to RCA?
a. There's federal regulation to facilitate effective RCA.
b. This regulation varies from state to state.
c. RCA shields healthcare facilities and practitioners from malpractice litigation.
d. Disclosure protection isn't needed for an effective RCA.

15. In states that have disclosure protection, a court may order disclosure of which part of the process?
a. event definition
b. identification of team members
c. data collection
d. prevention implementation and monitoring

16. The potential for underreporting sentinel events exists because of
a. fear of courtroom disclosure.
b. lack of knowledge of the need to report.
c. lack of effective reporting mechanisms.
d. conflicting rulings within jurisdictions.

17. The RCA documentation should be
a. segregated into sections that identify facts, followed by an opinion section.
b. integrated with facts and associated opinions.
c. inclusive of speculation about event details.
d. inclusive of individuals believed to be at fault.

18. When permitting disclosure, courts are far more likely to include only
a. analytic documentation.
b. opinion documentation.
c. inferences.
d. facts of the event.

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2.	❍	❍	❍	❍	6.	❍	❍	❍	❍	10.	❍	❍	❍	❍	14.	❍	❍	❍	❍	18.	❍	❍	❍	❍
3.	❍	❍	❍	❍	7.	❍	❍	❍	❍	11.	❍	❍	❍	❍	15.	❍	❍	❍	❍					
4.	❍	❍	❍	❍	8.	❍	❍	❍	❍	12.	❍	❍	❍	❍	16.	❍	❍	❍	❍					

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