6 What to Do When an Event Happens: Building Trust in Every Step

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Abbreviations

AHRQ	Agency for Healthcare Research and Quality
ETTO	Efficiency-thoroughness trade-off
FMEA	Failure mode and effects analysis
PSO	Patient safety organization
RCA	Root cause analysis
VA	Veteran's Administration
WAD	Work as done
WAI	Work as imagined

Chapter Objectives

- Clarify structures and methods to use when an event occurs.
- Highlight decision points and application of methods in varied situations.
- Demonstrate links between experience, learning, and improvement.
- Consider how decisions can affect trust and how application of methods used in event management, analysis, and follow-up can influence safety and improvement culture.

Opening Question/Problem

When a potentially serious harm event occurs, there is a duty to complete a thorough analysis to understand the cause of harm and the opportunity to prevent a similar, repeat occurrence. Historically, accidents are routinely followed by a public statement from a visible leader making the promise to find and fix the problem and assure accountability. The promise to find out what happened and fix the problem is a genuine commitment; however, the practical steps to fulfill this promise are intertwined with cultural nuances that shape the journey to prevent harm.

If errors were only a result of predictable patterns of broken parts, the promise of a certain fix could be made with confidence. The limits to confidence in the planned solution come from the realization that event occurrences are varied and often involve human performance in the context of complex and dynamic socio-technical systems. In this chapter we present a series of case vignettes that illustrate how the response to an

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event, including but not limited to an event investigation, is profoundly linked to culture. To examine the effectiveness of response in each situation, we have considered the Kirkpatrick framework which is a model suggested by Perry et al. to evaluate program effectiveness by assessing the impact on experience, learning, improvement, and outcomes [1]. The prevention of harm depends on reliable and resilient human performance in emergent situations that are not always predictable. Supporting resilient human performance is often not a quick find and fix but rather a journey through layers of culture that include accountability, leadership, learning, and improvement cultures. These are all critical components of the culture of safety needed for the prevention of harm and appropriate response to the occurrence of harm events. Said another way, the promise to investigate and ameliorate what went wrong is not a sufficient response to an event but rather, it is essential to consider event response in the broader context of building the culture of trust and continuous improvement.

The key takeaway from this chapter is to understand not only what to do but to also consider how each action, the conduct of those involved, and the communication in response to a serious event will have an impact on safety culture and outcomes with a particular focus on the impact on trust. As Berwick suggests:

> Because the improvement of health care is a team effort, the issue of trust comes to the foreground. Many forms of trust are relevant to improvement: trust that the future can be better than the present; trust in patients and families, allowing us to hear their needs as legitimate and reasonable; and trust in our own capacities to learn and change, even in a hostile environment. [2]

While the relationship between actions, decisions, and trust may vary based upon the culture of an organization, fostering trust should remain top of mind while carrying out responsibilities to respond when a harm event occurs.

In this chapter we highlight case vignettes that are noteworthy enough to warrant consideration for an investigation and response either through a root cause analysis (RCA), the most commonly used investigation approach, or an alternative response. Conducting an RCA has become a familiar standard in healthcare. The Joint Commission's Sentinel Event policy indicates:

> …appropriate response to a sentinel event includes the completion of an analysis of the causal and contributory factors. Root cause analysis, which focuses on systems and processes, is the most common form of comprehensive systematic analysis used for identifying the factors that underlie a sentinel event. A hospital may use other tools and methodologies to conduct its comprehensive systematic analysis. [3]

Expectations for conducting comprehensive systematic analysis and reporting findings are defined not only in accreditation standards but may also be defined by state law [4]. While specific rules defined in these laws may vary by state, the intent to utilize learning from harm occurrences for improvement is consistent. Approaches used for comprehensive analysis are based upon accident models that have evolved over time including those described in Fig. 6.1 that are considered throughout this chapter [5–8]. Each of these models represents an effort to understand causal relationships resulting in harm. The healthcare industry has adopted RCA methodology that was well established in other industries for accident investigation, and standard step-by-step approaches to conducting RCAs are well documented and easily accessible. It is important to note that available references on how to conduct an RCA have evolved and improved over the last two decades. Through experience and maturity in well-developed patient safety programs, we have learned to not only consider cause and effect but to also focus on the engagement of and impact on the people involved in the event occurrence. For example, both the step-by-step guide published by the Veteran's Administration [9] and the National Patient Safety Forum's root cause analysis and action approach (also referred to as RCA^2) [10] not only provide guidance on the steps needed for identifying a root cause but also provide consideration for those who need to be involved and how participants should be engaged to establish the basis for successful implementation of identified actions for

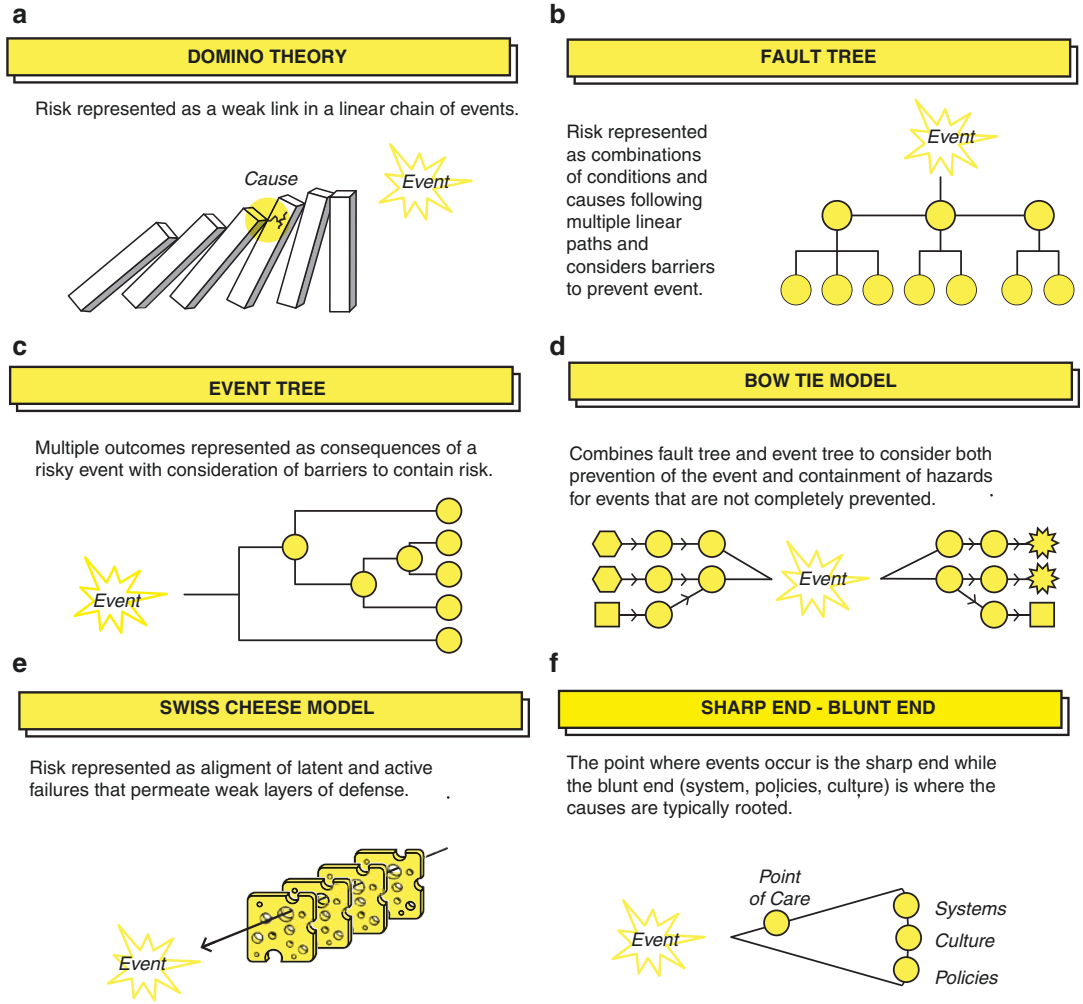

Fig. 6.1 Understanding events: accident models used to understand cause and effect relationships. **(a)** Domino theory; **(b)** fault tree; **(c)** event tree; **(d)** bow tie model; **(e)** Swiss cheese model; **(f)** sharp end-blunt end. Figures based upon descriptions of traditional accident models from several references including [5–8]

improvement (see Box 6.1 for websites). That is, the success of the analysis is not in just finding a root cause but rather in the engagement in learning from error, appreciating risk, and sustaining improvement. Both of these resources reflect the evolution of the RCA practices recognizing the value of methods that go beyond just asking "why." This is particularly important in healthcare where errors are very likely to involve human performance within complex systems. Additionally, the evolution of our understanding of how errors emerge from complexity warrants a new and broader lens described by Hollnagel and others as a new view of safety including a stronger emphasis on resilience:

> Simple linear models, such as Heinrich's (1931) Domino Model that is at the heart of Root Cause Analysis, later supplemented by composite linear models such as Reason's Swiss Cheese Model, were soon adopted as the basic safety tools in health care. Few people noticed that the very same models were being progressively challenged by industrial safety outside healthcare as inadequate to the newer, more complex working environments.
>
> During the second half of the 20th century the focus of industrial safety efforts shifted from technological problems to human factors problems

> and finally to problems with organisations and safety culture. Unfortunately, few of the models used to analyze and explain accidents and failures developed in a similar way. The result is that safety thinking and safety practices in many ways have reached an impasse. This was the primary driver for the development of resilience engineering in the first decade of this century (e.g., Hollnagel, Woods & Leveson, 2006). Resilience engineering acknowledges that the world has become more complex, and that explanations of unwanted outcomes of system performance therefore can no longer be limited to an understanding of cause-effect relations described by linear models. [11]

Since the absence of harm is likely dependent upon continued resilient human performance in complex environments and trying conditions, our mindset of how to respond when an event occurs must evolve beyond find and fix. The cases described in this chapter will consider how to respond when an event occurs but will also consider how we must take a broader lens and consider implications of the human experience before, during and after the event. The effort to understand what went wrong and how to fix it is not diminished in importance; however, the effect of event response decisions, behaviors, and communications on culture, trust, learning, and improvement must be elevated to the same level of importance to move the needle on prevention of harm (Key Points Box 6.1).

Key Points Box 6.1 Root Cause Analysis in Healthcare

Tools	Description	Website
Root cause analysis tools: VA National Center for patient safety's root cause analysis (RCA) step-by-step guide	Describes the step-by-step approach utilized by the Veteran's Administration	https://www.patientsafety.va.gov/docs/RCA_Step_By_Step_Guide_REV7_1_16_FINAL.pdf [9]
RCA^2: Improving root cause analyses and actions to prevent harm. National Patient Safety Foundation	Guidelines based upon examination of best practices designed to standardize and improve investigation of errors, adverse events, and near misses	http://www.ihi.org/resources/Pages/Tools/RCA2-Improving-Root-Cause-Analyses-and-Actions-to-Prevent-Harm.aspx [10]

As we contemplate the impact of decisions in the response to each case vignette below, we are anchoring to the following preconditions that are presumed likely given the regulatory requirements for event investigation:

1. There are existing norms within the organization for a response to an event.
2. There are structures, policies, and defined resources that define some responsibility within the organization for event investigation and response.
3. The current practice is generally aligned with recommended RCA approaches (see references and Internet resources in Key Points Box 6.1 and at the end of this chapter).

This chapter does not intend to declare a definitive best practice approach but rather recognizes that practices continue to evolve and are married to the culture within the organizations and sociopolitical environment where they emerge and are put into action. This chapter highlights the interconnectedness between culture and event response that calls into question looking for a best practice and instead calls for assessment of how to better understand the impact on culture along the way. To establish a baseline for consideration of the impact of key decisions and their impact on culture, we offer an event response roadmap in Fig. 6.2 as a framework for considering event investigation and response. It is presumed that the basic components of each of these responsibilities exist in some form in most healthcare organizations with varying degrees of maturity and reliability. As evidenced by the evolving body of literature on harm prevention, the event response approach

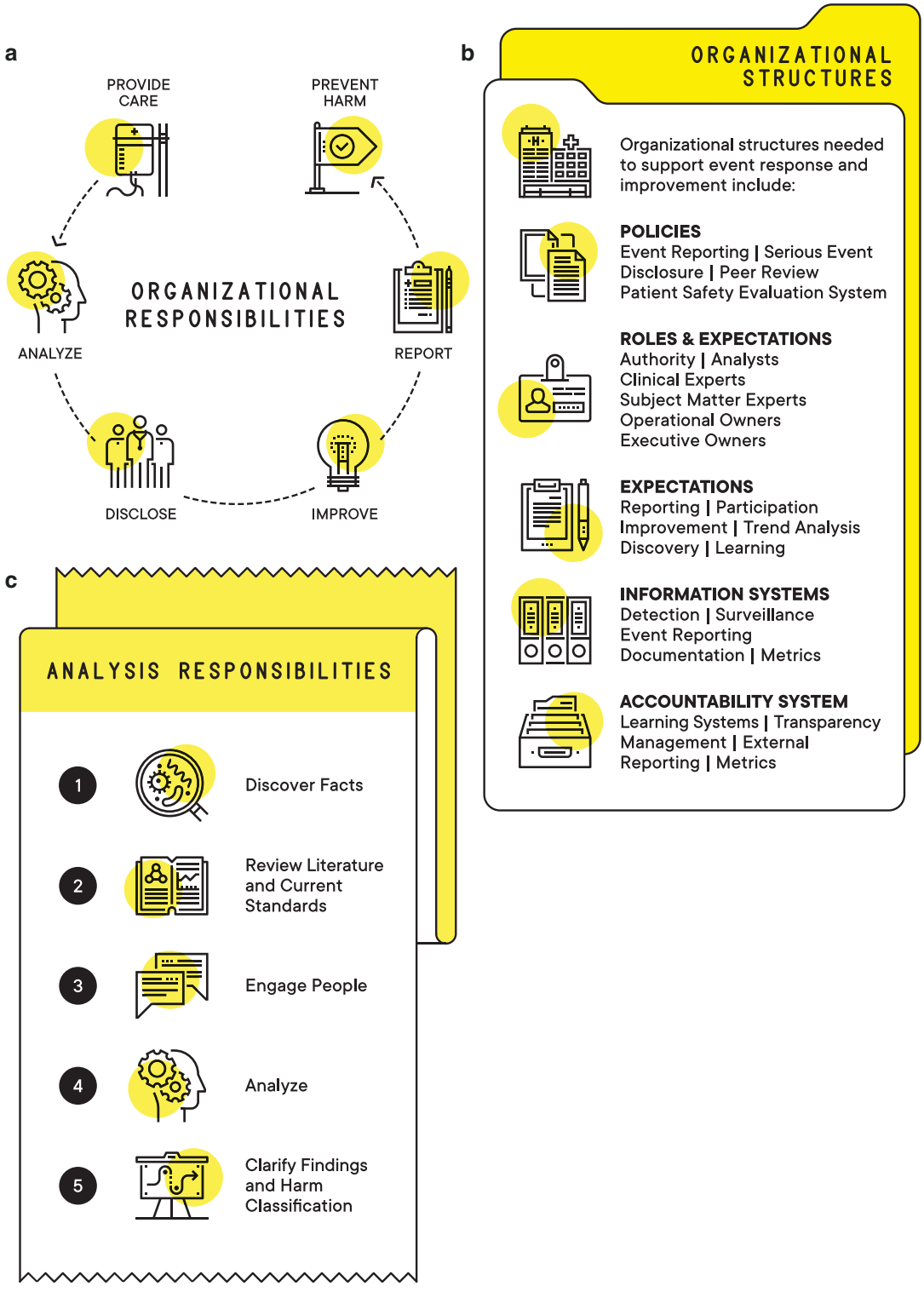

Fig. 6.2 Event response roadmap. **(a)** Organizational responsibilities; **(b)** organizational structures; **(c)** analysis responsibilities

will continue to evolve as long as harm events occur and as we broaden our lens in considering human performance within complex systems.

Understanding the Story

Vignette 6.1
Josea was admitted to the hospital for treatment of diabetic ketoacidosis (DKA). On the second day of admission, the plan was for the nurse to follow the titration protocol for fluids and insulin based upon glucose and bicarbonate levels that had been ordered. Josea's status began to deteriorate, so his nurse paged the physician who began to question the treatment plan and whether there was an additional cause of his DKA beyond the presumed viral infection. Rather than staying on the titration protocol, the physician changed the plan and ordered a consultation from infectious diseases colleagues. When Josea's bicarbonate levels continued to stay surprisingly low, a rapid response team was called. While the team was working through the diagnostic dilemma, uncertain of the cause of the surprisingly low bicarbonate levels despite the glucose levels normalizing, an intern noted that several of her patients had inexplicable changes in their electrolyte results. After calling the lab for clarification, it was discovered that a problem with an interface had resulted in errors in the lab result reporting for over 24 hours (correct lab results were reported with incorrect values). Once this was detected and the care plan was established based upon the correct results, Josea's fluids were slowed down to an appropriate level. The harm incurred included increased monitoring and lab work and he had to stay an additional day for extended monitoring.

We start by considering a case with detection of harm that is likely *preventable* but not *prevented* in this case. In fact, the situation described in this case could occur intermittently without detection, prevalent error, or harm. Historically, a response to this type of event would be to discipline the person with the closest proximity to the error as it was initially recognized. The application of accident models (described in Fig. 6.1) to understand cause and effect relationships has advanced our understanding of underlying systems, latent errors, and root causes. A first reaction, and perhaps the detail provided in an event report, may focus on why the clinical team did not question the inconsistent results sooner, complete a more thorough assessment, or recognize the pattern of abnormally low lab results. In this situation, a root cause analysis can be used for a more comprehensive analysis of the causal chain of events and an action plan that focuses on system-level improvements to address the cause and reduce the likelihood of recurrence.

This is a straightforward case that may be sufficiently understood using simple deductive reasoning to explore the causal chain of events to discover a root cause [12]. This approach is illustrated in Fig. 6.3 by asking why each step in the causal chain occurred and by considering weaknesses in layers of defense at both the sharp and blunt ends that, if strengthened, could have prevented the harm. This approach can be used to highlight a component failure in a causal chain of events, but the analysis is likely to only be effective with the engagement and candor of both the people involved in patient care and those that understand the underlying systems. Trust is essential to accurately clarify the chain of events through a review of data sources and interviews with staff involved. The patient experience should also be fully represented in the construction of the story. The value from an RCA often results from combined insights from a group that would otherwise never convene to collectively understand how parts of a complex system are causally related. Further value results from clarifying preventable actions in concert with system-level improvements. Sustained value comes when trust and collaborative approaches to understanding risks, detection opportunities, and harm prevention methods become pervasive through collaborative learning and improvement.

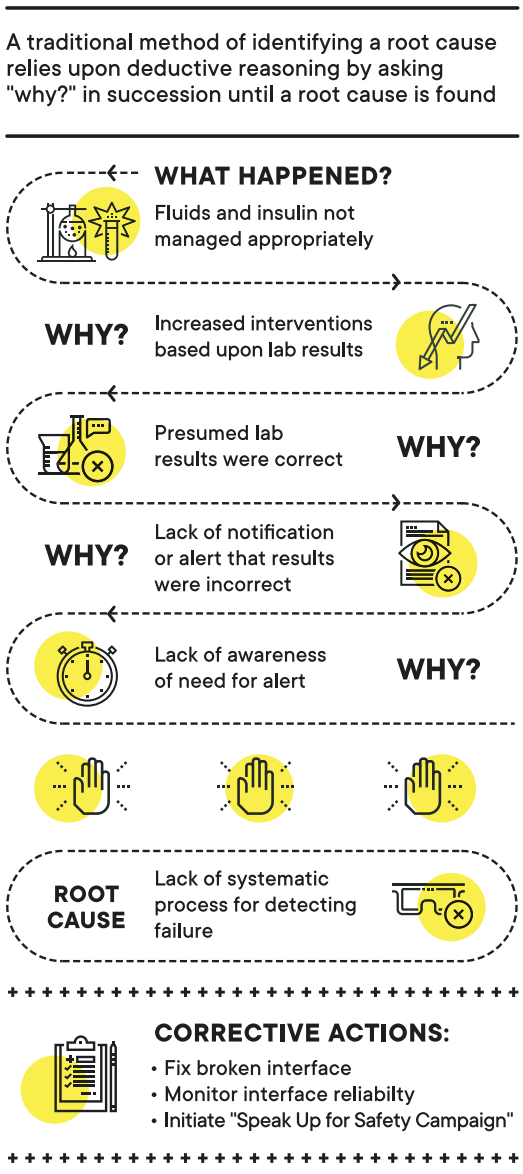

Fig. 6.3 Finding root cause by asking why

While this approach is likely to yield success in finding a system-level problem, sustaining success in fixing the problem is often not as simple as perceived when analyzing retrospectively. Further, generalized assessment of needed changes in behavior, such as encouraging staff to speak up, can be difficult to implement and may not address the underlying risks that contributed to the event occurrence. Fixing broken parts still makes sense, but preventing harm in complex and dynamic socio-technical systems is not limited to fixing broken parts but also requires attention to the longer efforts to change culture and build resilience. Braithwaite, Wears, and Hollnagel call attention to the need for a shift in approach:

> Even staunch health care supporters have gradually realized that real progress will require abandoning the Taylorist approach. Indeed, Berwick (2003) has indicated that: '… prevailing strategies rely largely on outmoded theories of control and standardization of work.' It seems to be a cornerstone of the human condition that people believe – or want to believe – that they will be able to solve today's problems, improve things, reduce errors, and ameliorate harm – all with just a few more resources, a bit more effort, another set of recommendations from a wise enquiry, a little more knowledge of the amount and rate of harm being delivered, increasingly precise measurements of system features, tightening up practices or a new whizz-bang IT system that is just around the corner. [13]

Traditional approaches of retrospective review often result in new policies and reeducation of staff. This type of response may result in some immediate risk mitigation, but the benefits are typically short-lived. The effort to engage front-line staff early in the investigation fosters trust and promotes open discussion and discovery of strategies to prevent harm, considering Dekker's insight that "the challenge is to create a culture of accountability that encourages learning. Every step toward accountability that your organization takes should serve that goal. Every step that doesn't serve that goal should be avoided" [14]. The trust is further developed and utilized when creating solutions that do not add additional complexity but rather improve usability and strengthen relationships to reduce risk in all situations and not only in situations involving the parties who otherwise would have been retrained or reprimanded. In this case, the reduction in risk relies not only on fixing the broken component but also on improving detection and awareness of this risk. With the complexity of caring for hospitalized patients, nearly all providers fail to challenge mundane things such as electrolyte reporting. In retrospect it might have been a clear cause, but the intensity of routine care does not make it plausible to challenge every result that

was not as the provider might have suspected. In fact, assuming all unexpected results are wrong can prompt trade-offs that could then further delay appropriate treatment or create distraction from important information needed for clinical decision-making.

A corrective action plan to address a root cause can be satisfying but carries a separate risk of hindsight bias, tunnel vision, and a tendency toward blame. These analysis pitfalls are illustrated in Fig. 6.4. In this case, the hindsight view may result in questioning why the lab was not called earlier because, with the benefit of hindsight, that action may have helped solve the problem more quickly. Efforts to mandate presumed solutions may result in adding complexity and burden that is ultimately not helpful in preventing the next event. Tunnel vision in the analysis of this case could be a result of focusing on the communications that did or did not happen and not recognizing some of the other factors in the socio-technical environment. The risk of blame is inherent in any event response that includes attributing an error to a specific cause. Even when there is no intention to blame, asking why they didn't know, didn't recognize, or didn't act is likely to result in at least a perception of blame.

In this case with a straightforward causal chain of events, the avoidance of blame can be a bit easier. That said, it is not uncommon for clinicians involved in the event to have already considered what they could or should have done to prevent harm from reaching the patient. This reflection is inherent in the culture of healthcare providers who have taken an oath to first do no harm. The effort to strengthen trust and limit the biases inherent in retrospective review calls for attention to the impact on second victims and the effort to ensure a just culture as emphasized by Dekker:

> Organizational justice does involve paying attention to second victims – practitioners involved in an incident that (potentially) harms or kills other people, and for which they feel personally responsible. There is a relationship between resilient individuals (who are supported in recovering from or even growing in the face of such inci-

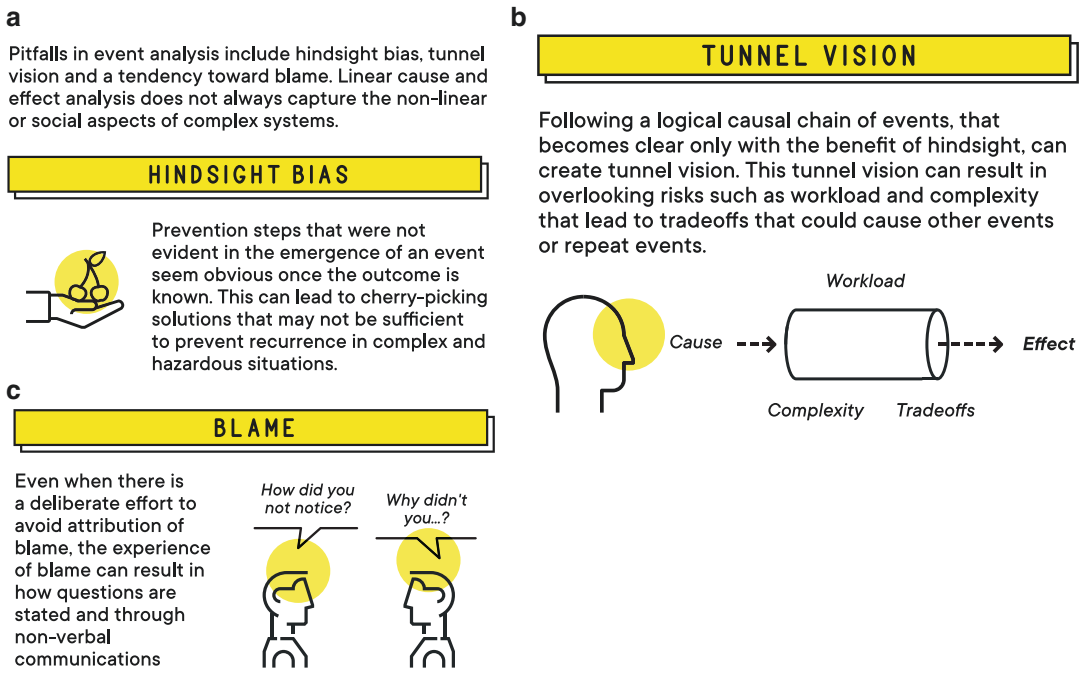

Fig. 6.4 Examples of analysis pitfalls: **(a)** hindsight bias, **(b)** tunnel vision, and **(c)** blame

> dents) and resilient organizations (which are able to face up to their vulnerabilities and learn from them). [15]

Awareness of the risks associated with second victims and just culture help shape inquiry that avoids asking staff why they did or didn't do something that is clear in hindsight but was not evident in the emergent situation. Questions that satisfy curiosity but do little to represent the realistic experience of those involved can further create defensiveness and limit candor. As Berwick describes, "Trust is central to this entire endeavour. Questions that are asked with distrust, jealousy, or defensiveness will not be authentic. Also, the answers will not be listened to" [2]. An understanding of how errors occur in complex systems and, in particular, how humans must adapt within complex and dynamic socio-technical systems helps to guide an effective inquiry process. In addition to authentically retelling the story of the event as it occurred, the safety analyst must be cognizant of the challenge of clarifying the causal relationship to harm while also showing the perspective that was experienced by those directly involved at the time of the event when the emergent problem was not evident.

Understanding the impact of the experience on patients and their families is paramount. The clinical team is often in immediate communications with patients and families that are trying to understand changes in the plan of care. While disclosure of errors is important, it can be challenging when the causes are not yet understood. In all cases, embracing reflective practice is important to clinician's evolution of practice; however, the participation in event investigation must foster reflective practice and trust rather than exacerbate a tendency toward blame including self-blame. It is also important that the avoidance of blame most proximate to the event does not just shift the blame elsewhere. For example, a finding that the clinical team is not at fault but shifting blame to staff in other roles stops short of finding a path to sustainable prevention of future harm. The evolution of thinking about accident models (Fig. 6.1) has helped illustrate the importance of not attributing blame at the point of care (the sharp end), but shifting blame elsewhere (the blunt end) is equally unproductive. Dekker goes even further to describe the risk of shifting blame to the system rather than the individual indicating that "at the sharp end, there is almost always a discretionary space into which no system improvement can completely reach. Rather than individuals versus systems, we should begin to understand the relationship and roles of individuals in the system" [16].

Increased attention to the experience of humans in the system has helped to improve the RCA approach keeping these analysis pitfalls in mind. As Dekker states, "of course we should look at the system in which people work, and improve it to the best of our ability. But safety-critical work is ultimately channeled through relationships between human beings (such as in healthcare), or direct contact of some people with the risky technology" [16]. Insufficient attention to perceptions of staff regarding both the authenticity and fairness of the analysis may limit improvement and learning opportunities and may also damage the trust relationship necessary for the prevention of future harm. Similarly, hindsight bias can further disrupt the learning and improvement journey and the effectiveness of the response. Hindsight bias can be so natural to the way humans respond once an outcome is known, that those involved with figuring out the find and fix may unwittingly predetermine the outcome of the analysis and event response. Dekker offers the reminder that "hindsight gets you to oversimplify history. You will see events as simpler, more linear and more predictable than they once were" [17]. That said, the goal is not to make the analysis more complicated or burdensome. The goal of the investigation process is to recreate the story of the event representing the authentic emergence of the event rather anchoring to a limited hindsight view.

The limitations of the effectiveness of RCA corrective action plans were highlighted by Wu et al. as they challenged the reliance on root cause analysis as the central method to learn from mistakes and mitigate hazards [18]. The commitment to learning and improvement must consider that a mindful approach to inquiry that extends beyond asking "why?" again and again can elucidate a far richer understanding of what happened and

why, while further promoting the trust relationship. For this, the involvement of people that can distinguish between work as imagined (WAI) and work as done (WAD) is essential. Hollnagel clarifies the risk overlooking the distinction between WAI and WAD:

> The difference between WAI and WAD may well be unavoidable, but it is not unmanageable. It can, however, only be managed if we recognize its existence and understand the reasons for it. The single most important reason is the human tendency to trade off thoroughness for efficiency. This is the reason why solutions often are incompletely thought through, and why we accept oversimplified descriptions as the basis for our plans and analyses. But we do so at our peril. [19]

This highlights the importance of involving frontline staff and diverse viewpoints. Also essential is a team with and knowledge in inquiry, investigation, and safety science and leaders willing to address conditions that limit human performance. Effective inquiry will yield more clarity than simply asking questions that begin with "why." Even with a goal to understand what has happened and why, in inquiry process must consider Hollnagel's clarification that "incidents and accidents do not only happen in a linear manner, but include emergent phenomena stemming from the complexity of the overall health system. Asking for 'why and because' does not suffice to explain the system in use and does not lead to an improvement in safety" [11].

The skills of effective inquiry are not easily explained and may need to be honed over a lifetime. At a minimum, effective inquiry involves listening and eliciting the story of an event from those that experienced it directly. That is, effective inquiry and analysis are not limited to illustrating a linear causal chain of events, but rather are an opportunity to recreate the story of an event as it emerged from the perspective of those involved and without the advantage of hindsight. The effort to elicit the story of the event, shown in Fig. 6.5, shows a nonlinear view that is not as tidy but may be a more realistic representation risk factors related to the emergent event. This approach also highlights the need for trade-offs at the time of care provision that may not be evident when focused only on the linear chain of events used to attribute cause and effect. Both the linear cause and effect relationships shown in Fig. 6.3 and the nonlinear relationships shown in Fig. 6.5 represent the story of this event, but the framing of the story can lead to different actions for improvement. The deductive reasoning used in Fig. 6.3 is used to identify a root cause to be addressed at the system level but overlooks some of the system complexities shown in Fig. 6.5.

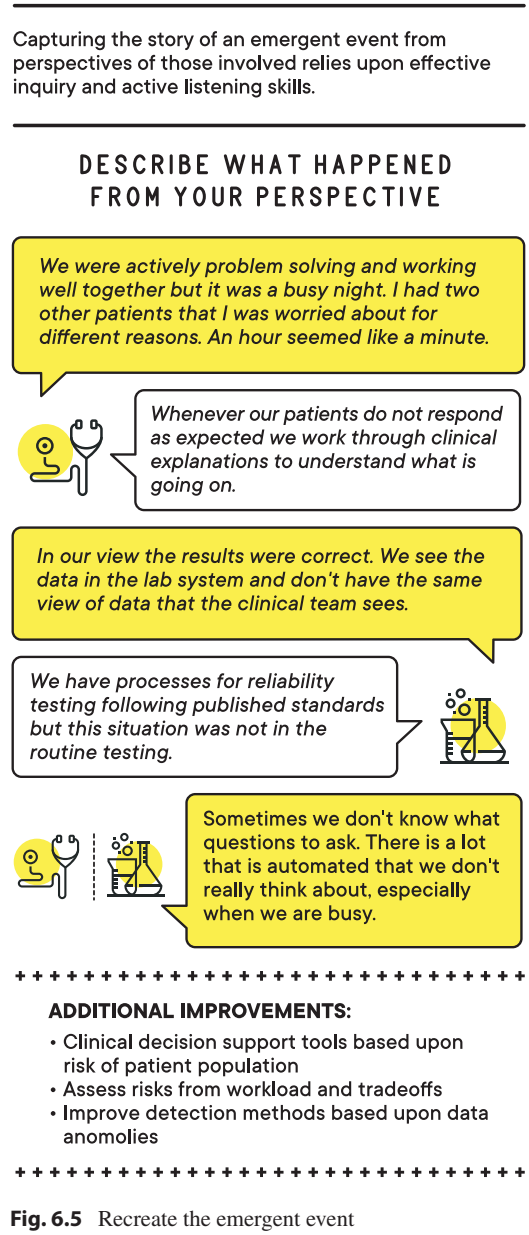

Fig. 6.5 Recreate the emergent event

To be sure, deductive reasoning is an intuitive way to think about error and has helped reduce harm events. In fact, deductive reasoning is a well-practiced skill used by humans to solve straightforward problems in everyday situations. According to Dekker, "Newton's and Descartes' ideas have pretty much set the agenda for how we, in the West, think about science, about truth, about cause and effect. And how we think about accidents, about their causes, and what we should do to prevent them" [20]. This explains our reliance upon reductionism to understand how systems work. That is, we can understand a complicated problem by taking apart the components and reduce to smaller components until the problem becomes understandable. In the case above, finding and fixing detected problems with the interface between information systems is important especially when this component failure could recur. This fix to this detected problem would prevent the same type of error that emerges in the same way. But is it also evident that issues excluded from this causal chain of events, including workload, user interface, and siloed workflows are factors that could cause additional errors that would not be addressed if we look only at the linear chain of events. The reductionist approach helps break down the system components along a specific causal path and is often easier to complete; however, it runs the risk of overlooking other critical aspects of system complexity that are necessary to fully appreciate the risk of other emergent errors and opportunities to ensure the safest care possible moving forward. While using reductionist thinking is a familiar approach for understanding complicated problems, it is not sufficient to understand complexity in adaptive systems [21] as clarified by Dekker in his examination of complexity and systems thinking. This suggests that we should go beyond the simple linear chain of events to consider how errors emerge and how they can be detected in the complex environments where healthcare is delivered. Attributing a cause to a system-level error is not a sufficient application of systems thinking. To understand how errors emerge from complexity, it is important to not just attribute a cause to a system component but instead to understand the risk represented in the emergent event experience as these risks are likely indicators of future errors if not fully addressed.

As we explore each additional case through this chapter, we will highlight both decisions and nuances that warrant some additional consideration while navigating how to respond to an event in varied situations. The emphasis on recreating the story from the emergent perspective is rooted in a recognition that trust will be lost if the story becomes infused with hindsight bias, tunnel vision, or blame. The emphasis on trust in this chapter also recognizes that that path of the next harm event may not follow the same causal chain of events. The event response and analysis experience of those involved will also have an impact on engagement in the detection of other risks that emerge from similar situations. By focusing not just on the component failure but also focusing also on the human experience, we can build a mindset of resilience regarding additional risks. Moreover, it is possible that the experience of those involved in the event analysis and response, either positive or negative, will have longer-lasting impact on the culture of safety and safe practices than the specific corrective actions identified (Key Points Box 6.2).

Key Points Box 6.2

- Recreate the story from the emergent perspective.
- Assess the entire situation including the effect on people rather than just cause and effect.
- Make trust and authenticity top priorities in event response.

Staying Ahead of Hubris

Vignette 6.2

In a busy primary care practice, the nurse called back a patient who coincidentally had a name very similar to another patient

in the waiting room. They shared last names and their first names differed by only one letter. Further complicating matters, these two young ladies were both 12 years old and were both there for well visits. Vanisha (the patient who was called back) had not completed her human papillomavirus (HPV) vaccination series, while Manisha had. Unfortunately, Manisha and her mother thought that it was Manisha who was called back, and the care team progressed with the visit of Manisha while charting in Vanisha's record. The physician discussed the need for HPV and influenza vaccination, the nurse drew up the vaccines, and just prior to inoculation, Manisha's mother pointed out that she had already received both doses of HPV vaccine. Initially, the nurse and physician challenged the mother's assertion, but eventually it became clear that there was confusion around the patient's identity. In discussing what happened in the office lounge over lunch, the physician was boasting that they got lucky that they didn't deliver an unwarranted vaccine. While the risk of side effects is low, there was no reason to accept any such risk. He was overheard by the practice's charge nurse stating, "I guess it's better to be lucky than good." While she agreed it was great that Manisha didn't have an unwarranted vaccine delivered, the wise words of Don Berwick, "Hope is not a Strategy," echoed in her head. She saw this as an opportunity to prevent a similar mishap in the future and recommended contacting the system's patient safety team who sanctioned further analysis.

It is often reported that the occurrence of harm events in healthcare is likely underestimated. One cause of this diminution of reported events occurs when the harm is prevented by mere chance or things that are out of the system's control. In this case vignette, there was no harm because a parent asked the right question at the right time to prompt the detection of this potential error. In the case of a no-harm or minimal harm event, there is no regulatory obligation to conduct an investigation or launch an improvement effort. Depending on the safety culture of the organization, this event may not be reported in a voluntary reporting system, or it may be reported, and the success of the avoidance of harm may be celebrated. While affirmation of positive safety behaviors contributes to building trust and resilience, the role of luck in this case should also be appreciated. When Weick and Sutcliffe describe characteristics of high-reliability organizations, they distinguish those that remain skeptical despite success indicating that "success narrows perceptions, changes attitudes, reinforces a single way of doing business, breeds overconfidence in the adequacy of current practices, and reduces acceptance of opposing points of view" [22]. Remaining wary despite a favorable outcome can mitigate the risk of overestimating reliability while underestimating the role of luck in preventing harm.

In this case the initial response to the event may be limited if the continued risk is not fully appreciated. The first reaction may focus on the atypical circumstances of the case and reassurance that the process works all the time, except of course, for this one unusual situation. Some may say that the error was caught because the system is working and speaking up just in time is an indicator of a strong safety culture. There may not be enough will to dedicate the time and resources to perform a timely and in-depth analysis in pursuit of reliability. Hollnagel considers the trade-offs in the resources spent digging deeper into causal chains:

> Since the purpose of an accident investigation is to find an adequate explanation for what happened, the analysis should clearly be as detailed as possible. This means it should not stop at the first cause it finds but continue to look for alternative explanations and contributing conditions, until no reasonable doubt about the outcome remains. The corresponding stop rule could be that the analysis should be continued until it is clear that a continuation will only marginally improve the outcome. [23]

When determining if a no-harm or minimal harm event warrants further investigation, it is

incumbent upon the organization to balance the potential lessons learned that prevent future harm against the effort and potential erosion of trust if the dedication of resources for an in-depth investigation does not make sense to those closest to the situation. In this case, the decisions regarding how to respond to the event are less about the determination of actual harm and more about understanding the complexity of the situation and likelihood of recurrence of the risk. The resistance to conducting an in-depth analysis could be overcome with persistence but the intended result of sustaining reliable changes in process and behavior may become even more elusive without the burning platform that is usually associated with harm events. The goal is not to analyze more but rather to engage staff in learning and improvement that includes remaining sensitive to the inherent risks. The decision on how to respond in this case is best informed by considering the approach that is most likely to garner the resources and commitment to improve.

Even with recognition of risk in this situation, the best path to learning and improvement may be found through less analysis and more attention to how clinical teams can partner with patients and families for better outcomes and experience for both staff and patients. A mature patient safety program has likely developed a portfolio of methods of event response that are not limited to root cause analysis. An alternative approach in this case is to consider is an apparent cause analysis to understand what happened. In cases where the causes or contributing factors are apparent, a decision to spend less effort digging into the causal chain of events and more effort on the improvement approach may be warranted. The North American Electric Reliability Corporation (NERC) suggests that the why staircase approach is typically a good fit for apparent cause analysis and further suggests different analysis approaches for different situations. Alignment of the right approach for the right situation considers both efficiency and effectiveness and recognizes that not all cases warrant the same approach used for more complex cases [24]. The use of apparent cause analysis is an option for judicious use of resources and can still lead to rigorous improvement by applying improvement science to the implementation as described by Crandall et al. [25].

The resistance to a full investigation for a near miss event does not have to be a barrier and can instead be used as leverage to focus on learning and improvement. If staff insist that the event is unlikely to recur because the process is usually reliable, there is also an opportunity to focus less on what went wrong and instead focus on understanding what happens when the process goes well and the importance of relationships and communication in assuring the best outcome. Dekker clarifies that the search for the root cause, or broken part, can be limiting. “If we want to understand why it ended up broken, analytic reduction doesn’t get us very far. Instead we need to go up and out, rather than down and in. We have to begin to probe the hugely intertwined web of relationships that spring out and away from the broken part, into the organizational, the institutional, the social” [26]. This suggests focusing on creating the culture and environment that supports human performance in risky situations. By shifting focus from the inquiry into what went wrong and instead considering the use of appreciative inquiry [27] as suggested by Trajkovski et al. as a way to understand what often goes right, there is a path to overcoming the resistance to both staff and patient and family involvement in the event response efforts. In some organizational cultures, this may yield better engagement in learning and improvement. Moreover, this process is likely to extend beyond fixing a process or technical component and, instead, extend further to consider relationships and how people adapt and collaborate for the prevention of harm.

A focus on the positive is often well received but must not overlook a realistic perception of risk. The effort to accurately assess risk can benefit from considering not only an internal assessment but participation in learning communities that foster greater transparency to better appreciate the risk. Events that are relatively rare occurrences are often perceived as unlikely to recur only because we lack perspective on occurrences elsewhere or lack appreciation for the severity of

potential consequences. This case vignette describes similarities to the confusion that led to the wrong procedure performed on a young child reported by the Associated Press in 2000. The report also described an overwhelming sense of devastation that the error had not been prevented [28]. Appreciation for risk and motivation to improve should not be limited because we lack frequent devastating events or publicity for close calls. This blind spot can be ameliorated by participation in a patient safety organization (PSO) or other learning communities that foster transparency of information about the pervasiveness of risk in healthcare environments. Greater transparent learning about harm and risk of harm can inform the assessment of rare events as they are detected more frequently when information is shared within a larger community with similar risky environments. To better understand the complexity, risk, and likelihood of recurrence, hazard assessment may be a more effective approach than cause analysis in this case. Again, the decision on how to respond considers the trade-off between a more detailed approach such as conducting a failure mode and effects analysis (FMEA) [29] or a simple hazard assessment matrix that highlights relationships between the probability of occurrence and severity of impact [5]. Both methods shown in Fig. 6.6 are similar in the factors considered in the assessment. The event response should consider the likely effect on the engagement of staff in sustainable improvement when choosing between the more thorough and detailed approach or the simple and efficient alternative. In this case the approach of using the simple matrix may be a sufficient first step to inspire the engagement in learning and improvement with continued sensitivity to the risk of harm.

As part of the event response process, it is common for events to be classified in terms of level of harm including near miss and minimal

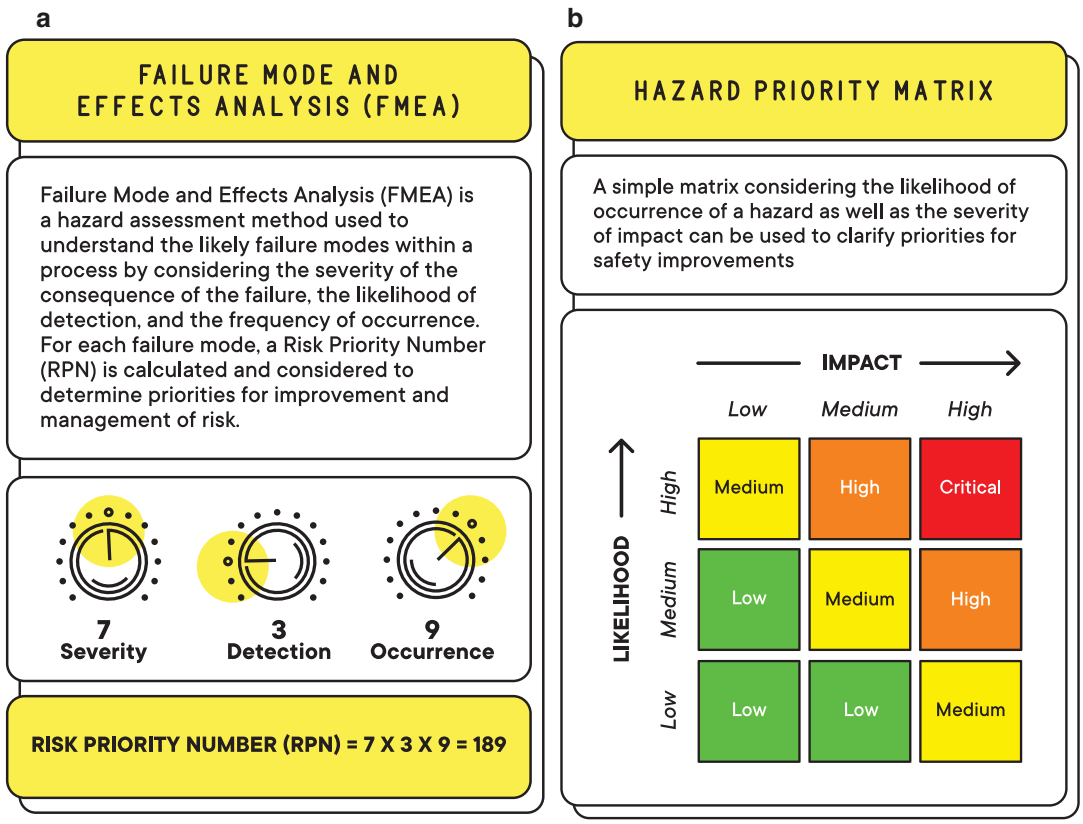

Fig. 6.6 Hazard assessment: **(a)** failure mode and effects analysis (FMEA); **(b)** hazard priority matrix

harm events. This event is not likely to be classified as a harm event because the patient did not experience actual harm. There could also be a debate on whether or not this event constitutes an error or if would be considered a near miss event. Hoppes and Mitchell summarize several harm classification systems in their white paper [30]. Regardless of what classification system or harm scale is applied, there could be some disagreement in how this event should be considered. While an effort is often made to assure consistency in classifying harm, consistency is elusive due to subjectivity in the classification process. Walsh et al. studied the reliability of harm classification and found that "Unfortunately, evidence to date suggests that clinician ratings of severity for adverse events are highly variable, with Cohen's Kappa coefficients ranging from 0.4 to 0.76. In spite of the importance of adverse event ratings, there has been little information on how to optimize the reliability of ratings" [31]. Williams et al. discovered similar challenges in reliability in assigning levels of harm [32]. Despite strategies to ensure inter-rater reliability, harm classification is often inconsistent. Pitfalls include distinguishing between potential harm and actual harm. There can also be subtle and subjective distinctions between levels of harm severity.

Does this matter? Application of harm scales is often used to clarify safety outcome data and to capture error rates to measure safety over time. Dekker challenges the usefulness of error rates as safety outcome measures indicating that "most organizations which have suffered big calamities over the past decades had exemplary performance on incidents and injuries" [33]. He further clarifies that an "organization does not have a great safety culture because it has a low number of incidents. In fact, the opposite is true" [33]. That is, robust detection and reporting may be a stronger indicator of safety than error rates that rely upon a subjective classification of harm. The Agency for Healthcare Research and Quality (AHRQ) also highlights the limitations to current data systems recognizing that event data cannot be translated to error rates without population data [34]. This specific case of a no-harm event illustrates that, regardless of harm classification method or outcome metric utilized, the risk in the environment identified will most likely not be reflected in the harm classification and therefore will not be reflected in an error rate. If harm classification data and error rates do not capture risks that show subtle changes in culture or gradual drift from safety-critical boundaries, they are unlikely to help with prediction or prevention of risks that are emergent from culture and complexity rather than a result of component failures.

What becomes more important is the engagement of staff in cultural aspects of learning and improvement. If the attention to error rates is the key to engagement in learning and improvement, then establishing trust in the reliability of those data becomes particularly important. Since harm classification has poor inter-rater reliability, understanding the impact of over-calling or under-calling the resultant harm is also important. Some organization cultures may find a better path to engagement by focusing on the positive outcomes and collaborative relationships. In some cases, it is perhaps better to give less attention to the harm classification and error rates and focus more on the collaborative culture needed to prevent a drift away from safety-critical behaviors and safety boundaries. The key point is again, focus on understanding how the decisions made throughout the event response will impact the experience of people involved. Each decision that enhances trust and improves culture is likely to benefit the longer-term goal of sustained improvement. A broader lens considering how to respond to an event can be realized by recognizing that focusing solely on finding and fixing a problem often does not result in reliable adoption of a change in practice. This is especially true when culture and behavior are part of the solution. The focus on trust, culture, and engagement of frontline staff in designing new ways to work is better aligned with improvement science methods that do not start with solutions, or corrective actions, but rather rely upon disciplined methods to engage frontline staff in designing improvements that are realistic and sustainable (Key Points Box 6.3).

Key Points Box 6.3

- Remain wary despite successful outcomes.
- Do not equate harm and hazard.
- Focus response to engagement in improvement.

Managing the Consequences

Vignette 6.3

Jason underwent the removal of a large lipoma that had appeared on his face. Prior to his to procedure, Jason's care team reviewed the procedure consent form with his parents. The procedure went as planned except the depth of the lipoma was greater than anticipated and closure was performed with unexpected difficulty. Jason was discharged after his outpatient procedure after the plastic surgeon chose to not disclose the unanticipated challenges as she thought there was an acceptable outcome despite the unexpected challenges. Notes in the outpatient chart indicated that Jason had a significant keloid development at the site. His parents expressed dissatisfaction with the results but stopped this part of the conversation when the surgeon stated that scarring was addressed in the consent form. Despite sensing the family was not pleased, the plastic surgeon discussed the plan for additional scar revision procedures. Jason's family agreed to the plan of care and left with the plan to return for a scheduled procedure. Prior to the procedure, an attorney contacted the hospital to request a copy of his records.

This case describes a situation that may not be identified for analysis or follow-up until medical malpractice activity raises concern about possible liability. Depending on reporting culture and surveillance systems, an unexpected outcome may be detected immediately; however, some complications may not be easily detected for further review or analysis. Once identified, if the outcome is not the expected or intended outcome, further consideration regarding preventability is warranted, but a presumption of error is not warranted. In this case, understanding cause and effect may not be as challenging as clarifying preventability and potential liability.

There is substantial improvement momentum in eliminating hospital-acquired conditions as shown in the results of the collaborative effort described by Lyren et al. [35]. This represents an important shift that many conditions that used to be accepted as known complications are now considered preventable. The shift in considering hospital-acquired conditions as preventable was made possible by collaborative work to develop the evidence base that clarifies how these conditions can be prevented with changes in practice. Yet there are still many complications where preventability is unclear. In their white paper, Hoppes and Mitchell offer a timeline that illustrates the shift in thinking about harm over several recent decades and further state that "Learning and improvement should also occur from events that are classified as known complications or no harm, as there is often opportunity for risk reduction in complications and no harm events and/or trends of events that may not be considered preventable at the time of occurrence. Learning from near misses is one of the tenets of patient safety" [30]. For many complications that occur in the course of care, clarifying preventability is not limited to understanding cause and effect but also understanding the current standard of care.

Determining deviation from the standard of care may not always require a comprehensive root cause analysis but does warrant some retrospective review. Hoppes and Mitchell emphasize the importance of understanding whether there was a deviation in practice standards and offer a decision tool that highlights both the reliance on evidence-based practice as well as assessing care decisions in the context of the situation when the outcome occurred [30]. Like the first case, the goal is to understand the story of the emergence of the outcome in the context in which it occurred. Response to this event should include a review of

the literature and current standards defined by policies or protocols. Many cases like this include decisions that include a trade-off of risk and benefit. Ideally, the risk and benefit relationship and consideration of a known complication would be clarified through communication and consent prior to the care episode; however, there may not be adequate anticipation or documentation to clarify risk-benefit trade-offs as they occur. There also should be an assessment of decisions made in managing uncertainty and reasonably unforeseen circumstances.

This is another situation that calls for caution regarding hindsight bias. Once an outcome is known it can be easy to cherry-pick a possible cause without looking at the complexity of managing the trade-off between multiple concurrent risks. Dekker suggests that it is important to "recognize that it is often compliance that explains people's behavior with norms that evolved over time – not deviance. What people were doing was reasonable in the eyes of those on the inside of the situation, given the pressures and priorities operating on them and others doing the same work every day" [36]. This highlights the importance of involving peers in the assessment of whether a deviation has occurred. The application of an algorithm such as the decision tree for unsafe acts [37] and applying the substitution test or a review of literature regarding management of known complications can be very helpful to assess if a decision was an error or a reasonable clinical judgment. The involvement of peers in the application of these tests is essential.

The response to this event should also include learning that is not limited to understanding the clinical decisions and processes. In some cases, the liability is created through breakdowns in trust rather than errors in care. Again, the analysis in this case may benefit from less emphasis on digging into the causal chain of events and more about understanding the communication and management of the trust relationship. Additional perspectives regarding patient-family experience and patient relationships can be valuable in this assessment. Focusing learning and improvement in detecting and containing the trust problem may offer a greater benefit than a determined effort to attribute the clinical outcome to a specific cause. In this case, the problem to be contained is the breakdown in communication resulting in the breakdown in trust.

This case also highlights the importance of disclosure as part of the event response. It is common for healthcare organizations to have policies that guide the communication of adverse outcomes. Policies may clarify the mechanics of the process but are likely insufficient support to those that must navigate these crucial conversations. The art of effective communication in disclosing adverse outcomes will be shaped by the organizational culture and will reflect both risk tolerance and approach to just culture within the organization. The skill and discipline in effective disclosure continue to evolve in healthcare organizations along with the understanding of the benefits and ethics associated with disclosure. Resources such as the Communication and Optimal Resolution (CANDOR) toolkit [38] can be a place to start. The effort to bolster or restore trust through disclosure of details of a complication, absent identification of an error, relies upon effective communication and a specific understanding of the trust relationship in question.

In this case, where the patient continues to seek care despite ongoing litigation, there is an urgency to restore the trust relationship. Regardless of the assessment of deviation or preventability, the priority is to manage the immediate needs of those involved. Dekker's explanation of just culture highlights the importance of restorative justice and suggests that "Restorative justice asks very different questions in the wake of an incident: who is hurt? What are their needs? Whose obligation is it to meet those needs?" [39] The consideration of these questions is not only applicable in considering communication and support for the patient but also for the others involved in the experience of the adverse outcome. Dekker succinctly describes reporting obligations and ethics for adverse outcome and disclosure:

> The ethical obligation to disclose your role in an adverse events comes from a unique, trust-based relationship with the ones who rely on you for a product or service. Disclosure can be seen as a marker of professionalism. Disclosure means making information known, especially information that was secret or that could be kept secret. Information

about incidents that only one or a few people were involved in, or that only professionals with inside knowledge can really understand, could qualify as such. [40]

In this case there is not an error to disclose but rather an opportunity to strengthen communication and understanding about the outcome and ongoing care. This case also reinforces the message that the event response is all about trust whether the focus is preservation of trust or restoration of trust. Both are important and the entire array of trust relationships, clinician to patient, patient to organization, and organization to clinician, should be considered when managing the response to this event.

Lastly, this case highlights the need to coordinate an array of resources to manage the event response. It is necessary to consider not only event investigation and improvement resources but also to assure a collaborative and aligned approach involving communication, patient relations, and disclosure processes. The alignment of these concurrent processes will help assure a cohesive experience for the people involved in all aspects of this event response (Key Points Box 6.4).

Key Points Box 6.4

- Event management is distinct from event analysis.
- Engage and leverage resources to manage and coordinate parallel processes (i.e., analysis, communication, patient relations).
- Attempt to restore trust through effective communication and disclosure.

Responding with Unanticipated Urgency

Vignette 6.4

Jackson was thrilled to hear that he was going to be discharged after being treated for congestive heart failure. He expressed his delight while reviewing his prescriptions and plan for follow-up visits at the time of his discharge. The timing was great as he was going to join his family on a trip the following week. Just before leaving for the airport, Jackson realized he did not feel well and went to the emergency department instead. During triage he asked if he could also visit the pharmacy to fill his prescriptions as he had not filled them after his discharge. Jackson was admitted, returned to baseline, and was then discharged late the next day. Two weeks later the hospital received a notification from the Department of Public Health that indicated that concerns were raised that Jackson did not receive adequate care prior to his first discharge which resulted in his readmission. Since the readmission occurred within 7 days, this case met the criteria for further review, and the hospital leadership expressed concern about financial penalties associated with readmissions. The care team indicated that they believed the readmission was related to nonadherence with his medication regimen.

This case is similar to the Vignette 6.3 in that it may not be detected until notification is received from an outside agency. Also like the case above, this could result from a patient complaint to a regulatory body, or it could result from external quality surveillance systems with different sensitivities than those used internally. For example, some external quality groups may prompt review based upon a readmission or the use of a billing code that may or may not be related to an error. In all events, the timeliness of the response is important, but in this case, the obligation to report findings externally may exert additional pressure on both the efficiency and thoroughness of the response.

To respond to this pressure, the initial investigation should consider the right type of analysis for the situation. It is important to recognize the

accreditation bodies share the goal of ensuring the response to the event advances understanding of how to identify hazards to be addressed to ensure safety and reliability in the system. For the case described here, there is less complexity in understanding the cause of the readmission and a need for greater attention on how to strengthen detection and containment. As Weick and Sutcliff indicated, while the unexpected is pervasive, "what is not pervasive are the well-developed skills to detect and contain errors at their early stages" [41]. While it is reasonable to assume that Jackson has culpability for having not obtained his prescriptions, stopping the review at this point will lead to missed opportunities to help future patients. Patients and families are often overwhelmed by the information at discharge and might not fully appreciate the importance of the timing of acquiring medications.

In this case an apparent cause analysis is likely sufficient to understand the factors that led to the readmission as long as it clarifies opportunities for better detection and containment of risk. McLeod and Bowie also highlight the usefulness of a bow tie analysis to understand both causal and contributing factors and safeguards necessary for detection, containment, and management of hazards [42]. As shown in Fig. 6.1, the bow tie analysis combines the concept of a fault tree and an event tree with the top hazard placed in the middle of the two sets of branching logic. While the branches of the fault tree consider potential causes similar to a root cause or apparent cause analysis, the addition of the event tree is utilized to understand consequences after the event occurs. This approach helps to expand the analysis to include not only consideration of how to prevent the hazard but also consideration of mechanisms needed to contain problems while they are small and steps that can still be taken to prevent harm. In this case, an improvement focused on containment may emphasize follow-up communication after discharge rather than focus only on what happens prior to discharge. Using the bow tie analysis method in this case may offer an efficient alternative to a root cause analysis and may also offer a broader lens to focus on the learning and improvement needed.

In this case, managing the event response requires a close partnership between resources that investigate events and resources that manage relationship and communication with the involved regulatory agency. This may be one in the same team or may include two groups working in alignment. The response to the event is not necessarily different than what would occur if the event had been detected internally; however, the learning and improvement opportunity may include attention to improving detection and surveillance systems and may also include opportunities to focus on proactive hazard assessment to better appreciate risks that are currently not sufficiently detected or contained.

This case also has similar challenges to the prior case in that the response to the event may highlight opportunities related to communication with patients and families. Subsequent care and communication rely upon restoring the trust relationship even though the regulatory agency may now be a participant in communications between the organization and the patient and family. While all parties have the shared goal of the best possible outcomes and experience going forward, the restoration of trust through all lenses will rely upon the effective coordination of communication and due diligence in responding to this event (Key Points Box 6.5).

Key Points Box 6.5

- Find balance between efficiency and thoroughness in response.
- Engage resources to manage and coordinate parallel processes (e.g., event response and communication with accreditation body).

Clarifying More than Causality

Vignette 6.5

Evelyn arrived at the emergency department via ambulance. She was stabilized at

an outside hospital, but given the complexity in Evelyn's condition, admission at the hospital with the team of specialists involved in her care was justified and a plan that comforted her parents. Although Evelyn was stable, there were many handoffs between hospitals, transport, and from the emergency department to the inpatient unit. During handoffs, it was unclear whether her antiepileptic medications had been administered, and at some point, it was assumed and reported that they had not. Subsequently, when she arrived at the unit where she was well-known, her nurse who endured several episodes of status epilepticus with her in the past and made sure she gave her medications as soon as she could get them on the floor. Unbeknownst to her, they had been given in the referring hospital, and this was a repeat and unnecessary dosing. She was noted to have increased somnolence, and the repeat dosing was identified. The levels drawn when the error was noted were found to be at the lower end of the range known to be at risk for toxicity. She remained somnolent well beyond the expected timeframe, and this led to a prolonged admission and further testing. While it was presumed that her change in level of alertness was due to the dosing error, her lack of improvement was not explained by this error, and this led to a delayed diagnosis of viral encephalitis. While this delay did not cause interventions to be withheld, it was realized that this could be a real risk in other situations when attributing symptoms to the wrong cause.

This is a case that presents unique challenges in understanding the best response. Traditionally, a potential error in diagnosis would only have been evaluated through a morbidity and mortality conference. This evaluation is still appropriate; however, with the increasing understanding of the complexity in healthcare, there is recognition of the benefit of understanding diagnostic errors through a systems view. The Society to Improve Diagnostics in Medicine highlights the National Academy of Medicine (formerly the Institute of Medicine) definition of diagnostic error "as the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient" and additionally emphasizes "diagnostic error stems from the complexity of the diagnostic process, complexities in how health care is delivered, and the same kinds of cognitive errors that we all make in our everyday lives" [43].

An event report resulting in an analysis of a diagnostic event is likely to be prompted by an unexpected outcome that may or may not be caused by an error. This case is similar to the known complication case above in that the initial challenge is to clarify whether there was a deviation in the standard of care. Again, this determination will likely rely upon the expertise of peers, a literature search, and application of tools such as the substitution test. In this case a comprehensive retrospective review through a root cause analysis can help assess not only potential errors in the diagnostic process but also contributing factors from the complexity of the system and environment. What can be particularly challenging is understanding the factors that may be causally related to the outcome when it is difficult to clearly distinguish whether the outcome resulted from these factors or progression of the disease.

While conducting a root cause analysis meets the expectation to conduct a comprehensive analysis of causal factors, the pitfalls of a root cause analysis, including the risk of hindsight bias and misattribution to a component failure, are particularly evident in this case. Our understanding of why diagnostic errors occur and how to prevent them is developing but is not as well established as our understanding of process errors and component failures and how they can be fixed [44]. There is notable attention to learning in the medical community about the risks of cognitive biases and some promising attention to the development of clinical decision support resources, but there is still only limited evidence on how to detect and prevent the array of diagnostic errors that occur but are largely unreported.

A starting point may be a recognition that the nature of a diagnostic error is fundamentally different than a process error or a component failure. That would suggest that our response to this type of event includes understanding the performance shaping factors present in the situation and environment and that may mean going *up and out*, as Dekker suggests, rather than going *down and in* to attribute the error to a single root cause [26]. Contributing factors may not be limited to linear cause-effect relationships but may also include dynamic coincidences of performance variability with humans performing within complex adaptive systems. The analysis should appreciate the complexity in the system and consider the suggestion from Braithwaite, Wears, and Hollnagel's that "adverse events increasingly needed to be explained as unfortunate combinations of a number of conditions, rather than as failures of single functions or components – including 'human error'" [13]. Once again, the goal of the retrospective review is to recreate the story as it emerged from the perspective of those involved rather than through a limited hindsight view.

Since humans are integral to the diagnostic process, an analysis to understand diagnostic error must be informed by knowledge of human performance, complexity, performance shaping factors that influence decision-making, medical knowledge, and understanding of the diagnostic process. This means that the mental model of understanding causal relationship to error must shift from linear thinking about resultant events caused by linear component failure to considering emergent events that occur in dynamic and evolving situations where humans are adapting to unknowns and problem solving in the moment. Hollnagel's description of the efficiency-thoroughness trade-off, or ETTO principle, is particularly helpful in understanding this case. The ETTO principle describes the balance between time to think and time to do in the context of time pressure and, at times, competing priorities. Hollnagel further clarifies:

> The ETTO principle refers to the fact that people (and organisations) as part of their activities frequently – or always – have to make a trade-off between the resources (time and effort) they spend on preparing an activity and the resources (time and effort) they spend on doing it. The trade-off may favor thoroughness over efficiency if safety and quality are the dominant concerns, and efficiency over thoroughness if throughput and output are the dominant concerns. It follows from the ETTO principle that it is never possible to maximize efficiency and thoroughness at the same time. Nor can an activity expect to succeed, if there is not a minimum of either. [45]

A tendency toward greater efficiency could result in the wrong action, and a tendency toward thoroughness could result in an action that occurs too late. In this case the correct diagnosis was in the differential but was not quickly identified as the correct cause of the symptoms seen. Thankfully, because her viral encephalitis only required supportive care, there was no intervention withheld; however, it is easy to think of situations where this delay could result in an adverse outcome. The concept of managing the risk associated with trade-offs is particularly relevant for diagnostic challenges. While generally, thoroughness is aligned with the caution that could benefit safety, there are some situations that the risk of delay of intervention outweighs the importance of using thoroughness to assure certainty of the diagnosis and plan of care. While the trade-offs in diagnostic decision-making may be evident in hindsight, increased reliability relies upon conditions that support the ability of clinical teams to assure timely interventions while making sense of uncertainty often in rapidly evolving situations. Weick and Sutcliff offer that "sensemaking is about updating plausible stories, often by means of action, while looking for data that question initial hunches" [46]. Safety in light of diagnostic dilemmas relies upon constantly finding the right balance between efficiency and thoroughness trade-off decisions that are needed for both the diagnosis and the delivery of timely interventions.

A corrective action plan resulting from the analysis of a diagnostic error is likely to consider how to predict and prevent similar errors in the future. The limitation in predicting diagnostic error is, in part, due to the likelihood that

diagnostic errors are more likely to be emergent from complexity rather than something that could be predicted by interpreting data on previous no-harm or low-harm events. The mental model that near miss event reporting data is predictive for this type of emergent error may not be realistic. The experience of a retrospective review of this event is likely to become integral to the reflective practice of the providers involved but difficult to spread. Transparent and broader learning from retrospective case review is valuable and important to increase awareness of risk. The challenge in error prevention is this case is the pervasiveness of the ETTO principle in action in the complex high-risk environments where care is delivered. A corrective action plan in this case is not likely to be limited to quick wins or easily assignable tasks but instead is likely to include strategies to change collaborative culture and practices, to enhance team behaviors, and to support human adaptation in complex changing environments filled with uncertainty and competing pressures.

This case also highlights challenges related to just culture and adverse impacts on second victims that were described in previous cases. However, in cases with resultant harm, the effects on people involved are likely to be felt more acutely and profoundly. This event presents similar disclosure challenges as discussed in the previous cases, but based upon the outcomes, restoring trust in this situation can be difficult. The questions associated with restorative justice mentioned above are relevant in both cases: *Who is hurt? What are their needs? Whose obligation is it to meet those needs?* The event response in any case should also consider how to provide appropriate support to the patient, the patient's family, and the care team (providers) in the aftermath of the event experience.

The attribution of a harm classification to this event can also be challenging especially if the causal relationships cannot be determined with certainty. This effort should rely upon peers with the medical knowledge to assess the plausibility and probability of the presumed causal relationships. The uncertainty regarding causality and preventability could result in a subjective classification decision ranging between considering the event a significant safety event or not a safety event at all. Considering the challenges with inter-rater reliability in the attribution of harm, it may be difficult to find a standard to establish which harm classification outcome is correct. As described throughout this chapter, each decision has an impact on trust relationships. Looking outside of the organization either for external event review or event reporting to a patient safety organization or similar learning organization can help to guide these decisions. Similarly, a better understanding of just culture and restorative justice can also help shape these difficult decisions. Like all the cases considered in this chapter, what may be most important is how these decisions help guide improvement in the learning, improvement, and safety culture (Key Points Box 6.6).

Key Points Box 6.6

- Consider plausibility and probability when the causal relationship to outcome is uncertain.
- Understand efficiency-thoroughness trade-off in a realistic context.
- Attend to the second victim and just culture risks.

Summary

In this chapter we have considered an array of situations that highlight the decisions encountered while navigating the response to events that occur in healthcare organizations. Through each situation we have emphasized the importance of trust and authenticity; tritely stated – no two situations will have the same response. Determining how to navigate event response requires understanding the culture that exists within an organization and the culture that is needed, and that the path to a better future is created through trust. This emphasis is rooted in the belief that experience with harm events has a notable impact on the people involved, and that the people are the key to safety in complex and dynamic sociotechnical systems.

Safer care is reliant upon human ability to work collaboratively and adapt to complexity, problem solve, manage the unforeseen, and appreciate safety boundaries while balancing trade-offs. Because of this, the response to events must emphasize social relationships as much as causal relationships. Perhaps the greatest learning from harm events comes from the appreciation that humans are uniquely able to adapt to complexity and do so more quickly and naturally than processes, protocols, or technology. The key takeaway from this chapter is to assess each decision made while responding to harm events when they occur. Start by listening and understanding the experience of all the people involved in the event and continue to understand how each person experiences the key steps in the event response. Lastly, to increase the likelihood of sustained improvement, understand how each experience will influence the relationships, trust, and culture that are needed to support human performance needed to adapt and manage the risk of harm in complex environments.

Internet Resources

- Agency for Healthcare Research and Quality: AHRQ.gov [47].
- Erik Hollnagel website: www.erikhollnagel.com [48].
- Institute for Healthcare Improvement: IHI.org [49].
- Society to Improve Diagnosis in Medicine: https://www.improvediagnosis.org [50].
- Safety Differently: The Movie: https://youtu.be/moh4QN4IAPg [51].
- Teaching and Assessing Critical Thinking: https://medicine.dal.ca/departments/core-units/cpd/faculty-development/programs/TACT.html [52].

Editors' Comments

Embracing high-reliability principles can drive hospitals toward unprecedented outcomes in quality and safety. Many chapters in this textbook speak of the five principles of high reliability from Weick and Sutcliffe. Broadly the principles are grouped into anticipatory and containment; highly reliable organizations focus on anticipating where, how, when, etc. problems can occur, and they also have systems in place to contain them once they inevitably occur. This chapter deals with the second grouping from Weick and Sutcliffe, containment. The title of this chapter summarizes the point of Green and Budin: "What to do When an Event Happens: Building Trust in Every Step." The chapter, through the series of vignettes, demonstrates how trust in one another, our colleagues, and the system is the keystone of being ready for how to respond when an event occurs.

The chapter thoroughly explains the role of root cause analyses (RCA) and how they can drive an understanding of an event as well as the response and action planning; our organizations complete approximately 12 RCAs a year between our 2 organizations (editors, RS-SG). We believe that for our organizations with 500+ beds and 30,000+ pediatric admissions with large emergency departments and many ambulatory settings between our facilities, this number of RCAs is "healthy" for our organizations; too many would be onerous and not value add, and doing less than this amount would not provide a robust safety and quality program. Each organization will ultimately decide on what healthy rhythm and amount of RCAs are best for their culture. Not all RCAs represent events that go poorly, but we also try to learn from events that go well and celebrate these moments.

As the authors indicate in the fourth vignette, it is important for an organization to align their resources and responses to an event in parallel. This includes the event response (e.g., root cause analysis), inter-

acting with the family (i.e., disclosure, involvement of the ombudsman, etc.), the risk management component (reporting to the institution's insurer), supporting the second victim if one exists, etc. There are myriad tasks that should occur in parallel once an event occurs; to wait and line them up to accomplish them one-by-one can perhaps be deleterious and result in worsening a culture and not properly addressing latent system defects.

Ultimately this chapter moves us past simply performing rote steps in response to an untoward or unexpected outcome; the chapter implores us to use the culture of the organization and the trust that has developed to deftly navigate an appropriate response.

Chapter Review Questions

1. Describe how hindsight bias can affect the attribution of root causes in a retrospective review of a harm event.

   Answer: When considering an event through retrospective review, those involved in the analysis have the benefit of already knowing the outcome. This can lead to a belief that the same error will occur in the same way and that prevention is simple. While this may be true for some errors that result from simple process breakdowns, this is often not true for errors that emerge in complex adaptive systems. This can lead to selecting seemingly straightforward solutions that are not sufficient because they do not consider the challenges of making inevitable trade-off decisions in complex environments where conditions include managing unknowns or emergent challenges.
2. Describe the differences in methods used for retrospective review.

   Answer: Most accident models used for cause analysis focus on understanding failures considering linear chains of events. The bow tie analysis method considers opportunities for containment as well as opportunities for prevention. Effective use of inquiry can broaden the perspective to consider the story of emergent events without reliance on hindsight.
3. What are alternative approaches to event response when a retrospective review is not required?

   Answer: Alternatives include the use of hazard assessment tools such as failure mode and effects analysis (FMEA) or a hazard assessment matrix (see Fig. 6.6). Appreciative inquiry is another alternative approach for engagement in the discovery of improvement ideas when a retrospective review is not required.
4. True/False – Effective inquiry means always asking why five times.

   Answer: False. While the approach of asking "why?" five times is a structured approach to deductive reasoning, the limitations of this approach should also be recognized. Hindsight bias, tunnel vision, and attribution of blame are risks associated with this approach. The risks of these analysis pitfalls should inform an inquiry process that also considers complexity, competing priorities, and other factors that influence trade-off decisions. The best use of inquiry is to authentically re-tell the story as it emerged. Is it important not only to go "down and in" to understand linear causal chains but just as important to go "up and out" to understand trade-offs that occur in the complex adaptive system.
5. Identify the impact of key decisions in other situations such including: error affecting many patients, exposure to staff and patients, or staff injury.

   Answer: Each of these scenarios should include consideration of what resources are needed for event management. Similar to some of the cases described in this chapter, it is often not sufficient to focus on analysis and corrective actions but important to also consider management of the entire situation. An error affecting multiple patients will require consideration of how to manage the opera-

tions tasks of communicating, evaluating, and providing subsequent care to multiple patients. A situation involving exposure to both staff and patients may require separate but coordinated resources to urgently evaluate and care for both staff and patients. Lastly, response to cases involving staff injury may require the involvement of additional expertise and may involve different policies and information systems that are not always aligned with resources used in response to patient events.

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