

Investigating the Causes of Adverse Events



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If I had an hour to solve a problem and my life depended on the solution, I would spend the first 55 minutes determining the proper question to ask, for once I know the proper question, I could solve the problem in less than five minutes.—attributed to Albert Einstein

Despite remarkable advances in surgical care, unintentional harm and suboptimal outcomes persist in the health care environment [1–7]. Many serious events are not attributable to the natural course of the patient's underlying condition or illness but, rather, to system and process failures, many of which share common characteristics. Organizational learning and continuous improvements resulting from the thoughtful and systematic analysis of such events are of vital importance in preventing their recurrence and keeping in patients safe.

Organizations and their cardiothoracic surgical teams must determine the causes of errors and develop solutions that address the inherent systems problems that lie at the root of these events. When they occur, however, the causes are not readily apparent to front-line staff because of the affective and cognitive distortions these failures engender as well as the complexity of the environment. Several analytic tools and methods are available for this purpose that have been widely used in other industries to learn from mistakes and mitigate identifiable hazards [8]. Many health care systems and regulatory agencies have embraced these methods to complement other strategies aimed at reducing events that can be “reasonably prevented” [9]. The Joint Commission (TJC), for example, maintains that meaningful improvements in patient safety are dependent on each organization's ability to identify errors and analyze their contributing factors to prevent similar errors from occurring again at the same institution [10]. Furthermore, the information learned about error frequency, type, and root causes support continuous improvement efforts as organizations redesign systems of care to improve outcomes and enhance patient safety. The purpose of this paper is to highlight the utility of event investigation and analysis to identify the causes and prevent the occurrence of adverse events.

Identifying Causal Factors

The conceptual model for evaluating the quality of medical care, proposed by Donabedian in 1966, contains three components of medical care from which to derive information regarding quality: structure, process, and outcomes [11]. The structure of care involves the settings and context of medical care delivery. Individual processes of care—the actions and activities of delivering medical care—can be examined and compared with best known standards of practice. The processes that can readily be examined, however, are not always those that have the most direct impact on outcomes. For example, the timing of preoperative antibiotic administration can more easily be measured than the performance of a surgeon. Although many other factors (antecedent conditions), such as a patient's comorbidities, influence the result of health care, it is ultimately the outcomes that are the most important indicators of quality [9]. In this framework, undesirable outcomes are a consequence of defects in either the structure (ie, system design) or the incorrect application of processes. The root causes of poor quality can be found by exploring the gap between optimal and suboptimal results. This gap is the object of root cause analysis (RCA) methods.

Individual behavior is influenced by an organization's structure, set of processes, and values [12]. Understanding human performance is critical to identifying causal factors. Error-prone conditions are usually predictable and preventable. Errors, accidents, and adverse events can only be avoided by understanding the reasons they occur and by applying lessons learned from similar past events. Unfortunately and too often, human error is the conclusion of a poorly performed accident investigation. Errors are usually a symptom of deeper (systemic or “latent”) conditions. To understand the basic, root causes of events, human error must be the starting point rather than the end of an investigation to truly understand causation, systemic hazards, and gaps in organizational performance.

Organizational learning in health care is a necessary characteristic for teams to improve [13]. An organization must be skilled at extracting “learning,” not only from major errors, but from all available growth opportunities such as minor events, real or perceived safety risks, near misses, and precursor events. For learning to occur, however, organizations must also be able to systematically aggregate and widely disseminate the results of all its problem-solving activities. Because most adverse

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events rarely have a single cause, the ability to identify a number of contributing conditions can yield a number of possible solutions for correcting system flaws and process failures. Identifying causal factors should follow certain rules (Table 1) so that investigations do not fall short of reaching true causal factors.

Monitoring

The ideal safety-conscious clinical environment has systems in place to monitor for potential problems so that, when they occur, a prompt response can be mounted, data collected, and hazards neutralized. Protocols and procedures should be implemented to immediately respond to critical events. Crisis management algorithms and simulation exercises with frequent training are important components of risk management for a safety-focused clinical team. When accidents happen, however, this heightened predisposition to action may not lead to capturing critical information. The use of incident reporting systems, although widely available in hospitals and ambulatory settings, have had a poor track record of capturing safety events due to several factors such as a poor reporting culture, poorly designed reporting tools, inadequate feedback to those who report, and persistent lack of evidence for the application of learning from investigations [14].

Although the immediate causes of patient safety events may be evident to those frontline clinicians at the “sharp end,” root causes may be tied to decisions made remotely in the past or elsewhere. The complexity of modern health care organizations may obscure causal and contributing factors that are far removed from frontline operations. Among these are such factors as educational and training requirements, staffing ratios, level of support services, workflow design, and composition of work teams.

Root Cause Analysis

An RCA is a formalized, indepth process for investigating an incident with the goal of identifying the most basic factors contributing to error or poor performance. It is an

impartial, interdisciplinary approach involving both individual persons uninvolved with the event as well as those who are the most familiar with the situation. By digging deeper at each level of cause and effect using an iterative and systematic approach, basic and contributing causes are surfaced with the ultimate goal of preventing recurrence and supporting human performance by the judicious application of “human factors engineering” methods. Excellent resources are available for conducting an RCA, such as “Root cause analysis in health care: tools and techniques from Joint Commission Resources” [10] and “VA National Center for Patient Safety: root cause analysis (RCA) step-by-step guide” [15].

Although relatively new in the health care context, RCAs were developed by industrial psychology and systems engineering to identify causal factors underlying variations in performance [8]. They have been used in many other industries successfully in uncovering latent errors, particularly in high-reliability organizations such as aviation and nuclear power [16, 17]. This approach may identify causes of a problem in either processes or structure, and the findings can aid in developing strategies to prevent its recurrence.

There are three fundamental components of an RCA: (1) identification of causal and contributory factors associated with the event (including upstream and downstream factors and individual persons); (2) causal analysis and prioritizing corrective actions; and (3) development of preventive strategies and effective countermeasures. The overarching goal is to find out what happened, why it happened, and how it can be prevented in the future. Once causal and contributory factors have been identified, their root causes can be elucidated so that teams can generate effective responses.

To identify possible process flaws and potentially unsafe conditions, highly reliable organizations and teams also examine near misses and conduct forward-looking exercises such as “failure mode and effects analysis” (FMEA) [18]. Unlike the retrospective analysis done through an RCA, the FMEA technique is a systematic way to analyze potential failures [19]. It is often the initial method used to study a system’s reliability and involves reviewing all components and subsystems to identify potential failure points and their consequences on the rest of the system (ie, the causes and effects).

Fundamentally, an RCA attempts to correctly frame each problem and identify all contributory factors. Once the chronology of events is established, information is gathered directly from the persons involved. Given the complexity of multidisciplinary surgical care, it is important that information and narratives are collected while it is fresh in everyone’s mind. Asking key questions in a structured format assists in analyzing the situational factors surrounding the event.

The “5 whys” approach, developed and used extensively by Toyota Motor Corporation during the early evolution of their manufacturing processes, is able to outline the causal chain in which one event or set of conditions causes the next [20]. The technique of asking “why?” for each subsequent response allows the

Table 1. The Five Rules of Causation

Rule 1. Clearly show the “cause and effect” relationship to each contributing factor.
Rule 2. Use specific and accurate descriptors for each action rather than vague, negative words. Avoid descriptors such as poor, inadequate, wrong, bad, failed, careless.
Rule 3. Human errors must have a preceding cause.
Rule 4. Violations of procedure are not root causes but must have a preceding cause.
Rule 5. Failure to act is only causal when there is a preexisting duty to act.

When these rules are used, causal statements resulting from a properly conducted root cause analysis focus on correcting actual system issues and will increase the likelihood that those corrective actions will be supported and sustained. (Modified from National Patient Safety Foundation [21].)

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