

ABOVE BOARD:ISSUES IN MEDICAL ACCIDENT INVESTIGATION AND ANALYSIS

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Thorough, objective investigation of medical adverse events rarely happens due to the complexity of the environment, litigation, risk, and socio-political implications. Investigations of healthcare adverse events by in-house panels that lack sufficient training and expertise do not produce results that educate their own, or other, institutions. Clinicians lack sufficient training in how to report events or assist their investigation. Effective healthcare adverse event investigation relies on impartial, qualified experts who have detailed domain knowledge, use diverse investigation methods, and remain impartial in the face of stakeholder interests. It also depends on the resolution of issues that span clinical practice, healthcare organization management, and regulatory and governmental agencies. Collaboration among these interested parties will open the way to the scientific collection of data that can serve as a foundation for effective measures to improve patient safety.

INTRODUCTION

Healthcare is unique by comparison with other high hazard sectors such as transportation and nuclear power generation. Stakes are always high in healthcare because outcomes routinely have a significant effect on patient health. While other sectors strive to minimize variability through uniform, consistent operations, healthcare cannot. Healthcare operations are necessarily complex, highly variable and comprised of densely concentrated professional knowledge in order to meet the complexity, variability and uncertainty of patient care needs. These traits make information difficult to know ahead of time. Emergencies, cancellations, unprepared or absent patients create conditions that change continually. Multiple conflicting agendas result in ill-defined team goals that can be in conflict. Information must be pooled and shared because no individual can have all of the knowledge that is necessary to coordinate activities that are distributed across so many departments. In sectors such as aviation, physical evidence is a major source of forensic information. As a service sector, the circumstances and activities of healthcare play a more significant role in understanding the circumstances of an accident. This paper describes the current state of medical accident reporting and analysis, obstacles to understanding such accidents, strategies to overcome those obstacles, and a possible approach investigation and analysis.

CURRENT APPROACH

Adverse events, or accidents, in healthcare can have significant clinical outcomes including loss of property, health (morbidity), and life (mortality). Organizations such as state governments, the Joint Committee on the Accreditation of Healthcare Organizations (JCAHO) and the U.S. Food and Drug Administration (US FDA) have mandated reporting of adverse, or “sentinel,” events. The investigation and analysis of medical accidents is intended to discover information that explains the nature and cause of what occurred in the interest of preventing or minimizing future loss. However, healthcare accidents have features that make post-event investigations particularly difficult. Thorough, objective investigation of medical adverse events rarely happens due to the complexity of the environment, litigation, risk, and socio-political implications. (Nemeth, *et.al.* 2004)

No impartial external resource is available to assist healthcare organizations with their response to regulator mandates. Each institution, then, is responsible to develop its own accident investigation and analysis program using resources that are available locally. The safety programs that healthcare organizations create are designed to meet the approval of their accrediting organization when it conducts a review. This arrangement amounts to a social contract (Tasca, 1990) that works well until an event occurs that draws attention of the public and regulatory organizations such as state medical boards.

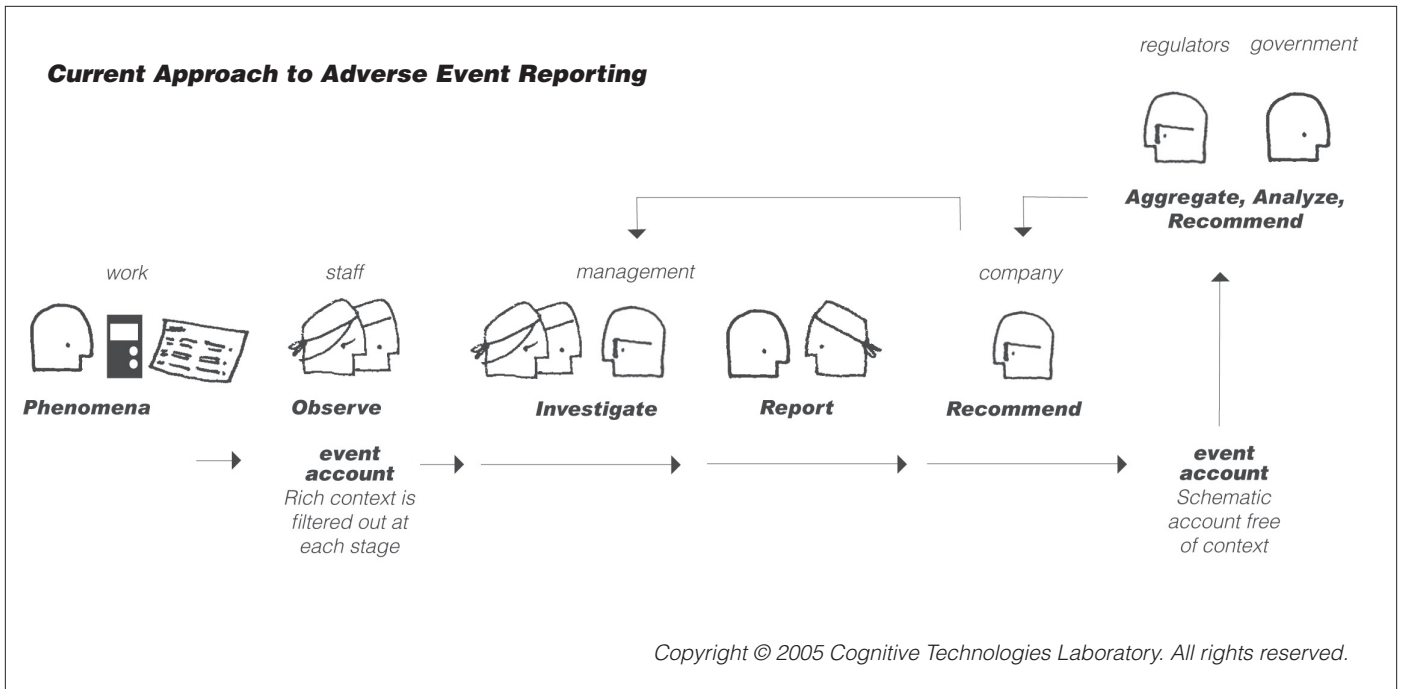


Figure 1: The current approach to adverse event reporting filters context information through summary accounts, providing regulators and government agencies with managed, schematic constructions with little resemblance to the event.

Investigation

Each healthcare organization’s safety committee tends to be comprised of administrative and medical staff members who have little to no experience in systems analysis or accident investigation. The local committee approach sheds more light on why institutions cannot deal with adverse outcomes than on the nature of the events they seek to understand.

Members of safety committees do not have the benefit of the same level of education, training and insight as the practitioners who are involved in an incident. Committee members typically lack insight into clinical procedures or underlying principles of medical devices. This leaves safety committees unaware of complexity, modifications, or interactions among procedures that make up the bulk of issues in such an investigation. Information on device performance or pertinent design and human factors considerations are overlooked.

Lack of familiarity with accident theory tends to result in safety committees that conduct accident investigations using a single method such as root cause analysis. Workers and managers within a system tend to view almost everything about that system as unchangeable except for the most superficial local factors. Locally conducted analyses seem to focus on what is described as “operator error” because the panel’s scope of action is largely limited to influencing local conditions instead of broader agendas such as device design or regulatory policy.

Because members of accident inquiry panels are employed by the institution they are investigating, it is difficult to be impartial. Investigations by such panels tend to discover information that is limited to an individual event. Information that is gathered is not shared with other medical institutions, which prevents the improvement of safe practices among hospitals.

Reporting

Figure 1 depicts the activity and flow of information that occurs in response to regulator mandates. Clinicians and technicians at the sharp (operator) end are immersed in the minute-by-minute phenomena of patients, equipment, facilities and procedures that comprise the healthcare setting. By reporting an adverse event, they bring it to the attention of hospital management, which determines how to proceed. The investigation process relies on a hospital staff member to manage the collection of information, have medical devices and equipment tested, and produce a report. The report is passed to senior hospital management, for further transmittal.

Woodward (2005) cautions that sanctions related to reporting systems ranging from disciplinary measures to suspension and censure have significant implications. Efforts to comply with reporting requirements, yet avoid sanctions, result in behaviors such as delaying, modifying, even skipping reports. Each of these erode the value that reports have to understand the nature of

adverse events. Individuals who call attention to safety matters may run afoul of organizational interests and suffer consequences. A recent real life example demonstrates how organizational pressure plays out at the local level. An emergency department (ED) director reported in a letter to hospital management that a death had occurred in the ED. In the report, the physician indicated that a shortage in nursing staff had resulted in the adverse event. The report was not taken as an opportunity for improvement but rather as an unwelcome criticism of conditions at the hospital that was inappropriate and unnecessary. Within a short time after submitting the report, reports heard “through the grapevine” that hospital management was looking for a way to remove the physician from the hospital staff. While the final outcome is unknown, the implications are clear. In this and other cases, social and political pressure on those who report can be substantial and adverse.

Organizational influence can result from narrow mission focus or the need to protect interests. Organizations view reports according to their mission. This can force a certain point of view by identifying one item as the cause, such as a device. Typically, multiple factors contribute to an adverse event. The presumption that a single item, such as a device, was the cause collapses the inquiry and encourages other factors to be ignored or underreported. Equipment-related incidents are forwarded to manufacturers for comment, then on to US FDA for inclusion in their Center for Devices and Radiological Health (CDRH) Manufacturer and User Device Experience (MAUDE) database. The focus can be narrowed within a regulator as well. For example, FDA components other than Devices and Radiological Health will field reports of events that may involve biologics, or contagious disease. Incidents that fit the description of “sentinel event” are forwarded to the JCAHO.

Organizational interpretation of an event also affects its reporting. Each step in the reporting process is further removed from the detail-rich context in which the event occurred. With no method to ensure these critical details are accounted for, the incident report becomes less and less of an account and more of a creation that is shaped by the organization’s need to protect its own interests and comply with mandate requirements. Social and organizational pressure at each level tends to filter out crucial details of the context in which the event occurred. By the time the account arrives at the level of the regulators or agencies that mandated them, meaningful details have been expunged. As a result, the accounts that reach the regulatory organization and governmental level bear a pale resemblance to what actually happened.

STRUCTURE AND PROCESS

Special concerns such as organizational embarrassment and fears over the potential loss of funding can undermine investigation depth, breadth, and quality. Sociopolitical concerns can pre-empt even the most effective data collection effort. In order to be effective, measures to improve the safety of healthcare must be based on accurate, reliable data. For that reason, healthcare adverse event investigation must be *above board* and conducted in an objective, impartial manner.

Other high hazard sectors have already addressed the issue of how large scale organizations can deal with adverse events. For example, the National Transportation Safety Board (NTSB) exists to examine accidents and provide findings to the benefit of all concerned with transportation. While opinions may vary regarding their methods, NTSB investigators are considered to be technically competent and have developed an organization and procedures that serve accident investigation well.

Reason (1997:18) has described a process of accident analysis for any complex system: start with a bad outcome, consider how and when defenses failed, establish what active failures and latent conditions were involved (for each defense that was bypassed or breached), consider what local conditions could have shaped or provoked each unsafe act, and ask what upstream factors could have contributed to each local condition. Cook, Woods, and Miller, (1998) have demonstrated the use of a parallel approach to understand the role that practitioners play in operating demand-driven complex technical systems such as healthcare. Beyond process, though, it takes deliberate effort to create the kind of environment that makes effective adverse event investigations possible. The nature of risk management encompasses a much greater range of elements than a single field of practice or even a single hospital. Failure to account for those elements ignores many of the aspects that influence how each facility operates. Insights into adverse events flow from diverse, not uniform, points of view. Rasmussen (1998) described the relationships among various disciplines that are involved in risk management. Professionals in engineering, human performance, organization and management, and the social sciences can, and should, be available in order to bring insight to the accident investigation. Each of these disciplines understands the nature of action, judgment and plans at the work and staff levels. Professionals in law, economics, sociology and political science have insight into the activities of regulators, associations and the government.

The composition of an investigative team should ultimately be a function of which parties add technical expertise and value to the investigation.

Inquiry should follow consistent procedures to obtain data that build a thorough description of what occurred. Investigators should be impartial in the face of stakeholder interests. The organization that would be able to accomplish such a role would be based on a model that is similar to the NTSB.

Investigation timing

A window of opportunity exists for about a week after an adverse event. During that time, the memory of what occurred remains fresh and has not yet been reinterpreted to expunge potentially embarrassing details. Participants have not combined and hardened their accounts of the event. With time, those who have witnessed a mishap can be affected by what Walters and Sumwalt (2000:xxx) term *closure theory*, in which an individual tries to reconcile the traumatic event by “filling in the blanks.” The quality of verbal accounts depends on debriefing those who were involved before they have had the time to exchange reports of what occurred. On-site investigation teams should include professional expertise in medicine, human performance, and systems forensics. The complexity of these events requires a cadre of experts in critical areas to assist the investigation team. These include hospital management, equipment, surgery, anesthesia, infection control, nursing, and intensive care. The consultants can also serve as a resource in case the size of the investigation team needs to be increased.

In order to be effective, the team of expert investigators will need to be available 24/7 and able to be dispatched to the site of an accident within hours of decision to investigate. Facilities will need to identify suitable events, request investigation within hours of occurrence, and cooperate in the conduct of an investigation. Consultants will need to be available to assist the investigation team with in-depth technical background. The final report will assemble all pertinent data into a cohesive account of the mishap including all contributing factors.

Role of the board

A small group of senior experts in patient safety will serve as board members. One board member will be assigned to participate in each case by being included in the investigation. This will provide the on-site investigation team with an informed, objective perspective. It will provide the board with direct exposure to investigations, ensure that the board is invested in the investigation team’s work, and make it possible for the board to meet and assess the experience of investigation. When the report is completed, the board will review and comment on it, endorse it, and forward it to appropriate regulatory and governmental agencies.

The investigation team’s report, after review and approval by the board, will be submitted to appropriate government and regulatory agencies. The findings will be a resource to all healthcare organizations, manufacturers, and members of the public.

Training and education

Investigation team staff should also develop training programs for healthcare organizations. The training would enable staff members to better understand the nature of adverse events and to obtain closure around the trauma that they must now endure with little assistance. The results would enable clinicians and managers alike to improve their ability to recognize, report, and assist the investigation of adverse events. This would complement the US FDA’s MeDSuN program to identify, understand and share information about problems with the use of medical devices. (US FDA, 2005)

ISSUES

Healthcare’s transition from closed, in-house inquiry to investigation by an external resource such as an independent board raises issues that will need to be addressed before the approach can be successfully implemented. Further inquiry in this area must address questions such as:

- How will the wide variety of healthcare organizations respond to the role of an independent investigation?
- How will such inquiries be protected from discovery in litigation?
- How will issues of patient information privacy square with the need to understand the specifics of what occurred?
- Who has the professional expertise that is necessary to get at the nature of what actually occurred?
- How will the results of the investigation be used outside the institution where the event occurred?
- How would an independent investigation team be funded?
- Under what authority or agency (state, federal, independent) does the team operate?

Views among the law, government, and healthcare each have an effect on the answers to these issues. A pilot program could be used to model the investigation organization and process in order to determine how to respond to these sensitive issues that currently stand in the way of investigation and analysis. This new model promises to investigate events using a consistent methodology

across healthcare settings and sharing relevant lessons that result in order to make learning possible across a wider audience, as Woodward (2005) recommends.

STRENGTHS AND SHORTCOMINGS

The approach to healthcare accident investigation and analysis we propose promises significant improvements to the current procedure. Findings will be grounded in data collected using reliable methods that have been proven effective by years of experience across the social sciences and engineering. Sharing results of the investigation will broaden the learning opportunity across the entire healthcare sector. Objective inquiry by qualified external investigators will demonstrate good faith effort to engage and resolve threats to patient safety resulting in increased public confidence in healthcare.

The obstacles to implementation are substantial. Participants in the process are subject to fear about litigation, that funding will be withdrawn, that managers and practitioners will be censured by their peers, and that regulators and healthcare organizations will impose sanctions. Organizations may suspect that there are other agendas hidden in the investigation process that may result in their institution being treated unfairly.

The steps that are necessary to overcome obstacles to implementing this new approach are feasible and will require cooperation among government, regulatory and healthcare organizations. Government protection may be necessary to create a "neutral ground" in which fair and impartial inquiry can take place free from legal, social and political pressure. Healthcare management will need to endorse the inquiry process, making their organization's resources available to assist the investigation. Staff members will need to offer their knowledge of what occurred so that an authentic base of data can be collected. A qualified board and team of investigators and consultants will need to be assembled, trained, and available to establish the organization, procedures, training, and education.

CONCLUSION

Over time, the consistent, validated, independent approach to accident investigation should produce a large body of reports with thorough data that stakeholders can trust. Public confidence will grow in both healthcare processes and the healthcare community's response to accidents.

The knowledge that is gained from qualified, impartial, scientific investigation and analysis can be used as the basis for effective measures to avert or minimize future mishaps. Healthcare forensics exists to both improve healthcare practice and to remedy loss. Short-term

progress in both areas relies on the evolution beyond 'blame the operator' to understanding health care uncertainty, complexity and scope. Long-term progress relies on the development of institutions, resources and values that collaborate to the benefit of those who seek care.

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