

LEARNING FROM INVESTIGATION: EXPERIENCE WITH UNDERSTANDING HEALTHCARE ADVERSE EVENTS

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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. Special concerns can, and do, undermine investigation depth, breadth, and quality. Healthcare's distinct difference from other high hazard sectors requires a unique approach to adverse event investigation. We report on the initial results of a 15-month pilot program now underway to model a national healthcare investigation team. An example of adverse event investigation and organizational response illustrates these issues.

INTRODUCTION

Mandatory adverse event reporting has resulted in much data but little insight as to why adverse events occur. Concern over possible discovery during litigation and the effects of formal or informal sanctions have imposed a chilling effect on learning from adverse events. Clinicians at the sharp (operator) end of healthcare need assistance to understand the nature of accidents and how to investigate them. 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. Effective adverse event investigation requires qualified experts who have detailed domain knowledge, use diverse investigation methods, and are separate from the interests of those who are responsible for daily operations. 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.

We have previously addressed issues that are related to adverse events in healthcare (Nemeth, *et.al.*, 2004) and the social and political influences that make learning from such adverse events particularly challenging (Nemeth, *et.al.*, 2005). This paper provides some of the insights that we have learned during the first

portion of the current Medical Event Data Collection and Analysis Service (MEDCAS) project. It also presents a case study of an adverse event investigation that demonstrates how the use of forensic methods and expertise assisted a healthcare organization.

BACKGROUND

MEDCAS is a nation-wide fifteen-month pilot program among the pediatric intensive care unit (PICU) at as many as ten acute care facilities in the U.S. and abroad. Participants have been recruited from the US Food and Drug Administration (FDA) MedSun project as well as the VHA hospital network. The project's main goals are to validate the methods and procedures to investigate, analyze, and report adverse health care events, as well as to provide a model for the creation of a safe reporting environment. The MEDCAS project team consists of acute care clinicians, human factors professionals, and specialists such as pediatric intensivists. Following completion of each hospital's institutional review board approval process (which can be extensive), the team conducts a monthly live web-based videoconference with two to three clinicians from each participating PICU. The sessions are used to develop a sense of what "normal" is for these units, what issues concern the teams, and offer answers to questions that have been raised in previous sessions. The team is available to provide on-demand guidance on incident reporting, or analysis by phone or videoconference, as well as to visit the unit to assist with investigation of an incident if a unit requests it.

CASE STUDY

The MEDCAS team approach lends itself to investigation of many care areas. A recent event that the team was asked to investigate illustrates the process and poses issues of broader import.

Overview

In April of 2006, a patient was being prepared for spinal surgery. After preparation, members of the surgical team placed the anesthetized patient onto a modular table. One member noticed that there was a slight tilt to the table and began to correct the table's position. The table swung loose. The patient fell from the table to the floor but sustained no injury.

Details

The postural support device involved in this event consists of two products: a base and frame that are used to support the patient during the performance of orthopedic surgery. The base is a U-shaped structure on casters, which holds the frame. The frame includes support cushions to position the patient and is radiolucent so it does not appear in X-rays that are taken during the procedure. The frame can rotate 360-degrees around its centerline to improve visualization when taking images (such as X-rays) and to make the surgical site more easily accessible. Controls to operate the base and frame are in a housing at the head end of the base. A hand-held remote control allows one person to stand apart from the unit and change the frame position in a number of different ways: up /down, trendelenburg/ reverse trendelenburg, left/ right lateral tilt.

The patient was brought into the OR on a gurney where the procedure was to be performed, placed under anesthesia, lifted onto the unit by the OR Nurse (ON), resident Anesthesiologist (RA), and resident Surgeon (RS), and was prepared for surgery. The team placed the patient face down on the frame, then positioned arms to either side to be as symmetrical as possible. The patient was not strapped onto the table. The ON left the room, leaving the RS and RA with the patient. The RA was standing at the head of the table.

The RS took a position near the foot of the table to look straight down the patient's body to ensure it was symmetrically positioned. Looking toward the patient from the foot of the unit, the RS noticed after the patient had been transferred that the frame was slightly tilted. With the remote control in hand, the RS momentarily pressed the "Right Lateral Tilt" button. The frame tilted slowly after the control had been pressed, then suddenly swung loose and swivelled around its

centerline. The patient fell from the frame head first to the floor. The team immediately ensured the patient was stable, carefully lifted the patient onto the gurney, took the patient for a CT scan and confirmed that no injury had been sustained in the fall.

Investigation

The MEDCAS team was notified and four team members arrived on scene soon after the event. The team invited the RS to describe what happened, using the table and its controls as he did. The team recorded the description on audio tape, then asked a number of probe questions in order to fill in context details. When the RS had finished, the team continued by examining the table to learn what might make it possible for the event to occur. During the MEDCAS team's analysis, it became clear that a number of factors had a bearing on the outcome. We account for a few of them here:

- The table's ability to swivel around a centerline is a feature that is essential to positioning a patient for spinal surgery. It also presents a hazard, as the table's ability to freely rotate makes it possible for an anesthetized patient to fall.
- The team collectively handled patient preparation and positioning. However, no single individual had explicit responsibility for the table's operation.
- The head end of the table has a lever to tighten and loosen the table clutch, a control switch to lock the foot end of the table, and indicator lights. The head end housing is covered with labels that indicate how to operate the device and warning what not to do. The team spent a good deal of time during the first and follow-up sessions to understand how the table is operated and discovered a number of conflicting cues. The control/display design's complexity and ambiguity made it impractical for any clinician to understand it.
- The clutch control lever, which is located at the side of the base end housing, requires a substantial amount of force to be exerted before the table is locked. The control may have required more strength than operators were willing or able to exert.

The team's response soon after the event made it possible to account for the context in which the event occurred. It brought forensic skills to understand the nature of the table and its performance that medical professionals do not have. It was also able to embody the nature of what occurred in a well-grounded account to assist the hospital organization.

Organization response

In the following days, the hospital's risk manager convened a "root cause analysis" meeting, that was

intended to discover the event's underlying cause(s). The inquiry included members of the patient care team that was involved, as well as OR equipment technicians, lawyers, risk managers, operations managers, and administrators. Members of the MEDCAS team were invited to attend and played a significant role in the discussion.

Discussion during the meeting centered on both what the participants could account for and what they could influence. After a discussion of contributing factors, the focus of the discussion quickly swung to proposals for solutions. The surgical team found the unit's features made it desirable to continue using it, despite its safety-related issues. Warranty and US FDA certification concerns precluded the hospital from modifying the equipment. The attending surgeon had called and spoken to the president of the unit's manufacturer who expressed surprise about the event, despite reports in the US FDA's Manufacturer and User Device Experience (MAUDE) database that confirmed this kind of event has occurred at other locations using this unit.

The unit would not be removed, as no other product offered the features this one did. Changing the unit is up to the manufacturer, not the hospital. Options that remained available to the hospital would necessarily be less effective. These options included the addition of warning signs or labels, training members of the staff, protocols restricting use of the machine to certain extensively trained individuals, checklists, and using a buddy system to check the unit's status.

The hospital developed a report of the event including MEDCAS team input to forward to the manufacturer. It also produced a brief improvement plan that included training surgical care team members and a warning sign that the MEDCAS team developed to hang from the lever on the side of the head end housing.

DISCUSSION

In the case that this paper describes, the hospital's locally-bounded view of the event is efficient and satisfying. This is partly because the rate of occurrence is so low. Countermeasures seem successful, even if they are weak. The hospital's approach is also efficient, because spending time deliberating options is not productive when only a few options are available.

Grounding the discussion of adverse events in data significantly changes their investigation. The MEDCAS team's evaluation of the base and frame brought information to the analysis meeting that would not have been available otherwise. This expanded the focus of

attention from members of the surgical team to include contributing factors such as the unit's control/display issues. Beyond immediate investigations, other issues have proven important to the MEDCAS process.

Regular conferences between the team and participating sites invite further interaction. Issues that are part of daily work in each PICU lead to discussion of other topics that PICU teams have pondered but have not yet solved. The conferences also enable the team to determine what is "normal" for the participants. This forms the denominator of daily work, making it possible to understand the context in which "abnormal" events occur. Regular contact also develops the trust relationships that are essential to candidly discuss matters related to sharp end practice.

Broader Issues

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, health-care 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, a defensive approach to litigation, risk, and socio-political implications. Special concerns can, and do, undermine investigation depth, breadth, and quality.

Technical. The medical domain's complexity is substantially higher than others in which accident investigation is conducted. This makes the assembly and validation of the precise sequence of the accident and its surrounding context more difficult than in other fields. The variety of technical knowledge in this domain is exceptionally high. Investigation necessarily requires a cadre of investigators who have the necessary technical knowledge as well as specialists whom they can consult for deeper expertise.

Social. Reports are molded by incentives and sanctions. Any regime that includes sanctions for those who are involved in reported events influences their behavior. Sanctions create a structure of incentives for people to consider in what they report, when they report it, and how they report it. Automatic sanctions can be particularly inhibiting because they create significant incentives to risk not reporting an incident, or to misrepresent the incident. Reporters may attempt to submit reports that misrepresent what happened. They may also deliberately misclassify the incident as a way to decrease the sanctions that they might ultimately face. The shape of the reports that are generated in this

environment reflects the structure of the sanctions, as much as the events they are reporting. Regimes that mandate reporting as a prelude to disciplinary actions create further political, professional, and organizational problems for those who submit reports.

Political. Those who are closest to the sharp (operator) end of the healthcare organization understand the difficulty and uncertainty that underlies their daily activities. Those who are closest to the blunt (management) end are most remote from sharp end operations and are concerned with maintaining the organization. Threats to the organization are minimized by casting adverse events as anomalies. Identifying and removing the event's proximate cause gives the appearance of restoring the organization to "normal" conditions.

Legal. The potential for possible legal proceedings compels organizations to manage information that is related to an adverse event. This occurs even through the investigation does not expose the organization any further.

CONCLUSION

Expertise, tools, and experience with forensic investigation of adverse events provides a basis for solutions that are grounded in reality. In the case study, the MEDCAS investigation helped to broaden, deepen and enrich the hospital organization's review. This difference between scientific data and organizational behavior shows the important linkage and interplay between understanding and solutions.

The MEDCAS team analysis and solutions went beyond what the hospital organization would normally find. This is not because the hospital is unwilling but because the organizational frame that bounds those who perform the daily work of the organization makes it difficult to see other related connecting factors.

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