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Using simulation to improve root cause analysis of adverse surgical outcomes

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Abstract

Objective. The purpose of this study was to develop and test a simulation method of conducting investigation of the causality of adverse surgical outcomes.

Design. Six hundred and thirty-one closed claims of a major medical malpractice insurance company were reviewed. Each case had undergone conventional root cause analysis (RCA). Claims were categorized by comparing the predominant underlying cause documented in the case files. Three cases were selected for simulation.

Setting. All records (medical and legal) were analyzed. Simulation scenarios were developed by abstracting data from the records and then developing paper and electronic medical records, choosing appropriate study participants including test subjects and confederates, scripting the simulation and choosing the appropriate simulated environment.

Intervention. In a simulation center, each case simulation was run 6–7 times and recorded, with participants debriefed at the conclusion.

Main Outcome Measures. Sources of error identified during simulation were compared with those noted in the closed claims. Test subject decision-making was assessed qualitatively.

Results. Simulation of adverse outcomes (SAOs) identified more system errors and revealed the way complex decisions were made by test subjects. Compared with conventional RCA, SAO identified root causes less focused on errors by individuals and more on systems-based error.

Conclusions. The use of simulation for investigation of adverse surgical outcomes is feasible and identifies causes that may be more amenable to effective systems changes than conventional RCA. The information that SAO provides may facilitate the implementation of corrective measures, decreasing the risk of recurrence and improving patient safety.

Keywords: root cause analysis, simulation, adverse outcome, accident investigation

Introduction

Root cause analysis (RCA) in healthcare can help identify aspects of a system that may lead to errors occurring [1–3]. The Joint Commission has established a methodology to analyze the root causes of adverse events in healthcare that is retrospective and relies upon details in the medical record and the memory of participants. Several authors have written about the use of RCA in healthcare, but to date no definitive evaluation of effectiveness has been completed [4–7].

Conventional RCA has several limitations [2, 3, 8]. Healthcare professionals are trained to traditionally think in a deterministic manner (If A, then B). Therefore, conventional RCA in hospitals tends to follow this logic, working backward linearly to find the root cause, often human error. Identifying human error as the root cause is made more likely due to hindsight bias and the tendency to judge a process by its outcome [9, 10]. Because traditional retrospective methods of accident investigation have limitations and inescapable bias, other high reliability industries have incorporated accident reconstruction into their methodology for the analysis of adverse events [11–13]. Simulation allows accident investigators to put adverse events into the context of environment, time, people and place. By reconstructing accidents, investigators are able to more accurately determine how people react to events occurring in real time. Using simulation for the analysis of adverse events in healthcare may enhance the detection of causes of error, particularly systems-based errors that may not be recognized in a retrospective analysis.

Our group published a preliminary study evaluating the addition of simulation to the investigation of healthcare

adverse events [14]. In that study, we determined that the original outcome could not be consistently reproduced during simulations despite efforts at recreating the original environment. The pilot study did demonstrate that adverse event simulation could identify deficiencies that were not apparent in conventional RCA. We termed the methodology 'simulation, RCA'.

This study was designed to further refine and test the simulation—RCA methodology (renamed 'simulation of adverse outcome', SAO) to determine what new insight the technique brings to understand healthcare safety.

Methods

Selection and review of synopses of closed surgical claims

The synopses of 631 closed surgical claims of a medical malpractice insurance company (The Doctors Company) were reviewed. In each case, root causes had been identified during the process of closing the claim. Claims were categorized using the Eindhoven Classification Model (ECM; Table 1), according to the predominant root causes documented in the files [15–17]. The classifications were: technical error, organizational error, human error and miscellaneous/other factors. One hundred and seventy-one cases in which the predominant error appeared to be a surgical technique were eliminated from this study because intraoperative technical error was not the focus of this study.

Of the remaining 460 cases, 3 were randomly selected for simulation. The cases chosen were: (A) the delayed recognition of an operative complication (intestinal perforation) following laparoscopic cholecystectomy that resulted in death, (B) a missed post-operative bleed, resulting in death and (C) a patient receiving unnecessary surgery (laparoscopy for intended cholecystectomy), who was discovered to have had her gallbladder removed several years prior during a bariatric procedure.

Identification of conventional RCA findings

To recreate the factors leading up to the adverse outcomes in a realistic manner, essential patient data were abstracted from the closed claim documents. In each case, an RCA using conventional methodology had been performed. The conventional RCA root causes became the expected outcome for each simulation. In the first simulation series (A), the conventional RCA root cause was determined to be miscommunication of a critical laboratory value (markedly elevated amylase), resulting in delayed recognition and treatment of an iatrogenic duodenal perforation. For cases (B) and (C), the presumed root causes were: miscommunication of/inattention to the physical signs and symptoms of bleeding post-operatively and inappropriate/inadequate assessment of non-biliary abdominal pain, respectively.

Simulation of adverse outcome

Development of scenarios. Paper and electronic medical records were created for the involved 'patients', and scripts detailing the cases were developed for the simulation participants (confederates) to follow. Care was taken to ensure that the timing of information available during the original events was replicated. Necessary props were assembled, and appropriate environments within the simulation center were created.

Selection of participants. There were two types of participants. First, 'confederates' were chosen to represent key healthcare personnel and the patient. Their training and experience were similar to the people in the actual event. They were informed of necessary details, such as history and healthcare status at the time of the adverse outcomes, but not the ultimate outcome or the presumed root causes. Second, there were no more than two 'test subjects' per simulation. Cases A and C had one General Surgery test subject per simulation. Case B had one General Surgery test subject and one Anesthesiology test subject per simulation. Each case simulation was repeated 6 or 7 times using different volunteer test subjects and different confederates. A dry run of each simulation was performed, using the authors as test subjects, as a readiness assessment of the confederates and of the overall simulation design.

Performance of simulations. The simulations were performed in a standardized manner. To make the simulations practical, we compressed the time of the recreation, using a technique we termed 'simulation time'. For example, using simulation time, a complete blood count (CBC) ordered at 8:00 AM would result immediately, but the 'simulation clock' would be advanced 45 min representing the actual time for laboratory turn around. Results of tests were not given unless ordered by the test subjects.

Observation and debriefing. The simulations were monitored by the investigators hidden from view and were recorded for review and analysis. Test subjects were asked to dictate the details of their clinical judgment in an appropriate format (e.g. a history and physical dictation, a progress note etc.), and these dictations were recorded and transcribed. After completing each simulation, the test subjects and confederates were debriefed, meaning that they were informed of the details and outcome of the actual case, and were asked a series of questions about their decision-making processes during the simulation. Debriefing sessions followed the critical incident technique as first described by Flanagan [18]. They were also asked to provide their perceptions of the simulation, a description of the adverse outcome and changes they would make to reduce the risk of the adverse outcome being repeated in the future. They were asked for feedback regarding portions of the simulation that they felt were confusing or unrealistic and any logistical problems encountered during the simulation. Lastly, they were asked to fill out standardized debriefing forms to define the critical components of simulation (Fig. 1).

Results

Time

An average of 171.1 person-hours was used in the development of each simulation, including the initial review of all 631 cases and the in-depth review for final case selection. The development and performance of each simulation series required an average of 37.6 person-hours (Table 2).

Table I The ECM (medical version) [15–17]

Level	Category	Definition
Technical	External	Technical failures beyond the control and responsibility of the investigating organization
	Design	Failures due to the poor design of equipment, software, labels or forms
	Construction	Correct design, which was not constructed properly or was set up in inaccessible areas
	Materials	Material defects not classified under TD or TC
Organizational	External	Failures at an organizational level beyond the control and responsibility of the investigating organization, such as in another department or area (address by collaborative systems)
	Transfer of knowledge	Failures resulting from inadequate measures taken to ensure that situational or domain-specific knowledge or information are transferred to all new or inexperienced staff
	Protocols	Failures relating to the quality and availability of the protocols within the department (too complicated, inaccurate, unrealistic, absent or poorly presented)
	Management priorities	Internal management decisions in which safety is relegated to an inferior position when faced with conflicting demands or objectives. This is a conflict between production needs and safety. An example of this category is decisions that are made about staffing levels
	Culture	Failures resulting from collective approach and its attendant modes of behavior to risks in the investigating organization
Human	External	Human failures originating beyond the control and responsibility of the investigating organization. This could apply to individuals in another department
	Knowledge-based behavior	The inability of an individual to apply their existing knowledge to a novel situation. Example: a trained neonatologist who is unable to calculate the right infusion rate of a drug when changes in concentration have been made
	Qualifications	The incorrect fit between an individual training or education and a particular task. Example: expecting an intern to solve the same type of difficult problems as a neonatologist
	Coordination	A lack of task coordination within a healthcare team in an organization. Example: the patient did not receive essential medication because one nurse thought that another nurse had already administered the drug
	Verification	The correct and complete assessment of a situation including related conditions of the patient and materials to be used before starting the intervention. Example: failure to correctly identify the patient before administering a drug
	Intervention	Failures that result from faulty task planning and execution. Example: unsterile insertion of an arterial line
	Monitoring	Monitoring a process or patient status. Example: a trained nurse administering nutrition via a nasogastric tube and not realizing that the tube is clogged
	Slips	Failures in the performance of highly developed skills. Example: a doctor adding patient weight to a computerized order entry system and then missing a computer entry error
	Tripping	Failures in whole body movements. These errors are often referred to as 'slipping, tripping or falling'. Example: accidental disconnection of an intravascular lines while kangarooing
Patient-related	Patient-related factor	Failures related to patient characteristics or conditions, which are beyond the control of staff and influence treatment
Unclassifiable	Unclassifiable	Failures that cannot be classified in any other category

Simulation Participant Follow-up Questionnaire

Date: Time: Series#: Simulation#:

Name: Dept: Level of Training/years in practice:

1.) Please describe your plan for the management of your "patient's" care in this simulation.

2.) Please describe your principle considerations for your patient care decisions. What events altered your management?

3.) Did your plan change during the simulation? Why?

4.) Did you contact other "physicians" or "health care professionals" during the simulation? Why?

5.) Were there any aspects of the simulation that were confusing or made decision-making difficult?

6.) Were there any aspects of the simulation that were unrealistic or made the simulation difficult to "navigate?"

7.) Please provide any suggestions on how to improve these simulations.

Figure 1 Standardized debriefing questionnaire.

Simulation results

All test subjects deemed the simulations realistic, meaning they felt as though they were in a patient care environment.

Case A. In this case, a patient had developed an unrecognized duodenal perforation during a laparoscopic cholecystectomy. In the original case, the patient was discharged to home by a covering surgeon and inadequate follow-up instructions were provided. The patient died. In the SAO, we chose to simulate the morning of discharge. The test subject (covering surgeon) was provided a hand-off at the start of the simulation. All test subjects discovered the most critical laboratory value, elevated amylase (865 units/l), despite it not being communicated directly to them. Nonetheless, in two of the six simulations (33.3%), the adverse event (making the decision to 'discharge' the patient) was duplicated. In four of the six simulations (66.7%), test subjects responded in a way that could have avoided the adverse outcome, by postponing discharge to obtain additional laboratory data and perform serial physical exams. Review of the simulation revealed that in addition to the conventional RCA root cause of lack of communication of the abnormal laboratory value, there was marked variation in the judgment of the test subjects regarding the significance of the abnormal amylase value and their response to it.

During debriefing, the two test subjects who 'discharged' the patient each stated they had intended to arrange 'early follow-up' with the patient, demonstrating that the abnormal lab value was not overlooked or miscommunicated, but rather discounted. All test subjects expressed concern that if the patient was discharged, adequate follow-up may not be available or reliable (a systems failure). This reasoning was consistent with the facts of the original case.

Case B. This simulation was of a patient in the post-operative recovery unit, who was tachycardic and anxious but

Table 2 Person-hours by research phase

Phase	Person-hours per phase
Initial review	24
In-depth review	15
Simulation development	25.3[a]
Simulation performance	12.3[a]
Additional hours	94.5[a]
Total	171.1[b]

[a]The value averaged from data for three simulation series.
[b]The value includes averaged and non-averaged data.

with normal blood pressure at first. In the original case, decreased post-operative hemoglobin and hematocrit (H&H) of more than 30% were noted but no action was taken until the patient arrested and died. Conventional RCA determined human error was the root cause. In the simulation test, subjects were provided a brief description of the patient and the procedure that was done, as well as current status, vital signs and recent medications by the nurse.

During simulation, all test subjects (both general surgeons and anesthesiologists, separately or in collaboration) ordered a CBC and noted that the H&H values were well below the normal range. Each test subject repeatedly checked vital signs and asked about pain. In two of the six simulations (33.3%), test subjects did not respond to the low H&H, replicating the adverse event. In four simulations (66.7%), the test subjects avoided replication of the adverse event by recognizing the post-operative hemorrhage early, and ordering the patient back to the operating room for exploration.

Critical review of the simulation demonstrated that those test subjects who compared the post-operative H&H to the preoperative values and determined that the intraoperative blood loss and intravenous fluid administration could not explain the drop in H&H concluded that the patient was bleeding and avoided the adverse event. The test subjects who viewed the post-operative H&H without comparing with the preoperative values did not recognize the changing values as indicating hemorrhage and replicated the adverse event.

During the debriefing, the four test subjects who did not replicate the adverse event stated that they knew that the patient was bleeding, due to decrease in the H&H and physical signs. The two test subjects who replicated the adverse event stated that they likely would have recognized the hemorrhage if they had a different (graphically represented) interface for the laboratory data. Analysis of this simulation revealed aspects of systems that could be improved including collaborative training to recognize deviations from expected post-operative course, and perhaps graphic representation of lab values to emphasize changes.

Case C. This simulation evaluated the decision-making of surgeons presented with a patient who had right upper quadrant pain. In the original case, the patient was taken to surgery to perform a cholecystectomy only to discover the gallbladder had been removed during a prior surgery. In the simulation, test subjects were presented the patient history by the attending internist and then had the opportunity to review the chart and examine the patient.

In this series of simulations, six of the seven test subjects (85.7%) did not replicate the adverse event. These test subjects either requested a CT scan to workup the pain or alternatively stated that they wanted to obtain the operative record. The timing was variable but generally occurred as they were discussing their findings and differential diagnosis with the patient.

During the debriefing, all the test subjects stated that they knew that the patient's pain was not typical for a biliary etiology. Most stated that this was their rationale for not operating, except for the test subject who replicated the adverse event, stating that they 'did not think it was cholecystitis, but [they] wanted to give the patient the option just in case it was.'

This simulation demonstrated the complexity of medical decision-making. The cues that each test subject used were slightly different. The debriefing portion of the SAO was crucial in evaluating the thought process involved in medical decision-making. Interestingly, the rapidity by which the correct decision was made did not correlate directly with years of test subject experience; however, due to small sample size and the exploratory nature of this research, it is not possible to draw clear conclusions.

Discussion

This study evaluated a method of SAO designed to improve the understanding of root causes of error in healthcare. Understanding what factors influence the occurrence of an adverse outcome is essential if patient safety is to be improved. Compared with conventional RCA, SAO identified more potential causes of error and, perhaps most importantly, revealed how the complexity of the healthcare environment and organizational factors affected decision-making.

During SAO, the investigators were able to evaluate probabilistic and naturalistic decision-making [19, 20]. The test subjects used cues, past experience and information available to them during simulation in the context of their understanding of the system (environment) to determine the probability of success of decisions. SAO allowed an assessment of why people made decisions in real time and what limitations they faced. In Case A, for example, SAO determined that the greatest limitation faced by test subjects was not the decision to discharge the patient, but rather the uncertainty of follow-up, and this created variability in deciding what to do. This points to a system deficiency and not an individual education deficiency or rule violation. For each decision test subjects made, there were various possible outcomes, each with some probability of achieving a desired outcome. SAO allowed for the observation of naturalistic decision-making, models of which help researchers to understand how people make decisions in the environment, context and under the various pressures in which they actually work [21, 22]. The conventional RCA finding of human error in each of the three cases focused on the 'sharp end' of the organization. SAO, in contrast, allowed the investigators to have a greater understanding of why decisions were made, by converting retrospective RCA to a witnessed event.

The focus on individual errors ('why people did things incorrectly') is described as the 'old view' of understanding human error, which determines why people failed [8]. From a safety perspective, it is essential to understand what the event participants knew and perceived during an event, and how systems deficiencies allowed these perceptions to result in error. Conventional RCA rarely achieves this type of analysis and understanding [6]. SAO, by recreating events step-wise, allows observers to evaluate actions, perceptions and understanding of test subjects, not solely their actions, so that systems deficiencies are revealed.

Another advantage of SAO is the ability to assess team dynamics, including patients and families. Conventional RCA methodologies do not typically include patients or the families of patients [23, 24]. In this study, the interaction between the test subject and the confederate patient was an important component of the analysis of decision-making. This reinforces the concern that conventional RCA may miss important aspects of context and behavior that impact outcomes.

The SAO method has the potential benefit of being able to access situational awareness [25]. Although we did not include situational awareness in our study design, review of simulation recordings and the debriefing sessions provided an unanticipated opportunity to evaluate test subject perception of environment and understanding of cues presented during the simulation.

There are several additional limitations to the use of SAO. One limitation is that some specific details of the original environment are not knowable. Significant time investment and an environment that allows simulations to be conducted in a realistic manner are required for SAO and this adds expense. The effect of our use of 'simulation time' is unknown and will need to be evaluated. Another limitation is that only one portion of the event chain was simulated. The time chosen was the time identified in the claim files as being most important, but whether that is in fact the case is difficult to prove. Finally, simulation itself, whether recorded or observed, lends itself to attention bias and may not seem real to the participants. Refinement of SAO in the future will require evaluation of these limitations.

The use of closed malpractices case files in this study allowed for in-depth review of conventional RCA interpretations of error, providing a detailed context by which SAO could be measured. Van Noord *et al.* published their evaluation of the application of RCA on malpractice claims, also using the ECM [15, 17]. They demonstrated that the method had only moderate validity in defining root causes because the lack of context. Other authors studying retrospective RCA evaluation of error have concluded that cognitive factors and system-related problems were leading causes [26, 27]. These studies illustrate how RCA of closed cases can provide insight into the causes of error or adverse outcomes, but also reveal that conventional RCA method is limited. This is in contrast to the SAO method that primarily seeks to understand why things happen and why decisions are made in the complex healthcare environment.

To date, no studies have demonstrated that conventional RCA techniques as applied in healthcare reduce recurrence of errors [24, 28, 29]. RCA assumes deterministic (linearity) cause and effect, and that systems can be broken down into components that are understandable independently [30]. In the cases in this study conventionally determined root causes emphasized errors made by individuals. We do not know what if any interventions were made in the original cases to improve safety.

If errors and serious adverse outcomes are to be prevented, the personnel performing the analyses of safety in healthcare need to be equipped with the most effective means of recognizing all the causes leading to errors. Error investigation should seek to discover causes that are amenable to intervention, behavioral and/or systems change and should also allow for testing recommended interventions to assure that the correct systems changes are being implemented and desired outcomes result.

One of the potential applications of SAO is testing methods designed to improve patient safety before implementation. Commonly patient safety initiatives are in the form of policies and procedures [6, 22]. Implementing untested policies and procedures has several drawbacks. First, even if well intentioned, there is typically little evidence that the changes will actually result in improved patient care [31]. It is well established that there is often a difference between policy, what is reported and what actually happens [22]. To be effective, safety initiatives should have a systems approach to encourage compliance and behavioral change, but those goals can be elusive in the complex healthcare environment [31–33]. These types of system changes differ from those that focus on individual error. Effective system changes assume that error is inherent but can be reduced by improving human performance, a process recognized as a strong action with a high probability of reducing harm [6].

Conclusions

This study demonstrates that simulation can be used to perform analysis of adverse medical events. SAO is an adjunct to RCA methods not merely because it identifies root causes that may go unrecognized in conventional RCAs, but also because it uncovers aspects of root causes that may be more amenable to system intervention. With further refinement, SAO could be used to help establish best practices and create interactive training scenarios.

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