Human factors engineering design demonstrations can enlighten your RCA team

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A case study is presented, based on the experience of the US Veterans Affairs health system, which shows the benefits of healthcare personnel understanding human factors engineering (HFE) and how it relates to patient safety. After HFE training, personnel are better able to use a systems-oriented approach during adverse event analysis. Without some appreciation of HFE, the focus of adverse event analyses (e.g. root cause analysis (RCA)) is often misguided towards policies or an individual’s shortcomings, leading to ineffective solutions. The case study followed the investigation by an RCA team of a retained sponge following cardiac surgery. The team began with a focus on the specific failings of the surgical nurse and outdated policies. HFE design demonstrations were used to redirect the team’s focus to more systems-oriented issues, which could be uncovered even when events appeared to be related to policy or training, and to point them towards examining the design of systems that contributed to the event. The team was thus able to identify design flaws and make improvements to the design of the forms and computer systems that were key to preventing such events from recurring.

Root cause analysis (RCA) is the name given to the investigation of adverse events and “close calls” in health care and other settings in the US and other countries. In the healthcare setting it usually involves a team of clinicians, managers, and technicians who are assigned to answer at least three questions: what happened; why did it happen; and what can be done to prevent it in the future? The case study presented below and the following discussion show how some RCA teams have a tendency to focus on policy violation issues and personal shortcomings rather than on underlying design related factors. We also illustrate how human factors engineering (HFE) design demonstrations can be used to quickly redirect RCA teams to improve their development of root causes and actions.

CASE STUDY*

The problem

The patient in operating room (OR) number 6 was having coronary artery bypass graft (CABG) surgery. The operation was nearly complete and had been without surgical or anesthesia complications. As the patient’s sternum was being closed the nurse notified the surgeon that the first sponge count revealed a missing “lap” sponge. After a second count of sponges confirmed the initial count, a radiograph was ordered to look for a suspected retained sponge. The radiograph was taken while the patient was still in the OR. The information listed on the radiograph order form was “line placement CABG” with a “routine” status. The surgeon read the chest radiograph in the OR and it did not reveal a retained sponge in the chest cavity. Since the order form indicated this was a “routine” radiograph, a radiologist would not read the film for nearly 15 hours. The patient’s chest cavity was visually examined but, since the radiograph was negative, the surgeon did not palpate the chest cavity again for a sponge.

The patient was transferred to the coronary care unit (CCU). However, the surgeon was still slightly uneasy so another chest radiograph was taken in the CCU. Since this order designated the radiography as an emergency to rule out a retained sponge, its parameters were adjusted and the film was read within an hour by a radiologist. In this radiograph a sponge was detected in the chest cavity. The patient underwent urgent re-exploration and removal of the sponge. After an uneventful recovery from CABG surgery the patient was discharged home days later.

Root cause analysis

To understand what occurred in this case and what steps should be taken to prevent recurrence, a root cause analysis (RCA) team was formed. Members of the team had expertise in the various aspects of CABG surgery and radiology but none was directly involved with the case.

The hospital’s patient safety manager (PSM) guided the RCA team to develop a chronological flow chart of events. A number of relevant facts were noted: (1) operative CABG radiographs are not usually requested or entered as stat (urgent); (2) the cardiothoracic (CT) team relied on certain intraoperative radiographs in the prevention of retained instruments; (3) the radiology department was unaware of this reliance on radiographs; (4) the CT team was not aware that the settings of the radiographic equipment could be adjusted to detect sponges in the case of an inaccurate sponge count.

*The main points of this event come from a real case, but it is not necessarily a case from within the VA healthcare system. The details are taken from many cases in many healthcare systems.
The team began developing certain thoughts about suspected root causes and identified a number of possible causes for the event. Specifically, they believed that the CT team should have known about the capabilities and different settings of the radiographic equipment, and they also believed that failure to follow the official “retained sponge” policy and procedure was responsible for the event. Having identified these personnel shortcomings and policy inadequacies, the team reverted to a “blame” mind set. They enquired whether anyone in this particular surgical team had been involved in other policy deviations or violations; they proposed analysing the male versus female members of the surgery team as they believed one gender was more diligent about sponge counts than the other; and they wanted to make sure that the nurses involved were placed on non-surgery duties.

**HFE demonstrations**

The PSM recognized the “blame” mind set into which the RCA team had fallen. Having some existing knowledge of the field of human factors, she decided that some timely instruction on human factors engineering (HFE) was needed. To demonstrate HFE design she collected items from her readings and from her experience in training and leading previous RCA teams; some of the items were poorly designed from an HFE standpoint and thus were difficult to use or prone to error, while others were well designed with features that might act as safeguards and/or promote ease of use and efficiency. The set of demonstration items was varied as no single item or example resonated with everyone. The PSM chose four items to demonstrate to the team. The demonstrations and discussion which followed took approximately 30 minutes.

The PSM’s first demonstration to the team was of a bone replacement product used for orthopedic applications. This so-called bone void filler is labeled at the end of the package with product, product size, catalogue number, and expiration date. Unfortunately the label is too large to fit the end of the package and, as a result, the portion of the label with the expiration date is folded and cannot be seen when the packages are stacked flat on top of each other in the storage room. The inventory staff could not see the expiration date of the bone filler when rotating and pulling expired products. This case illustrated to the team how an otherwise readable label became unreadable in a working environment. It underscores the importance of considering environmental influences and the typical work environment when designing anything from labels to computer systems. Following an RCA on a close call where an expired product was almost used, the hospital added expiration dates to the bar coding within the hospital inventory system. The bar codes were placed in an easily accessible location on the packaging and mobile bar code readers, which did not restrict the reach of inventory staff, were used to read the bar codes.

The second demonstration was an electrosurgical unit (ESU) knife and a disabled ESU machine connected together with a three-prong plug. The RCA team members were asked to try and plug the knife in all possible outlets. Although they tried, it was impossible to plug the ESU knife into an 110 V wall outlet. They also could not plug it into any other slot on the ESU except where it was supposed to go. This is an example of a well designed forcing function—that is, a design that forces a user to operate or manipulate the machine in the way that was intended. This avoids leaving it up to the user to remember or, even worse, to guess at where the connector is supposed to go. To demonstrate how a lack of forcing functions could lead to disaster, the PSM then summarized incidents from two hospitals in which nursing staff inadvertently connected patient ECG lead wires to a 110 V electrical outlet. In both cases, lead wire pins were plugged into the female connector of an energized line cord that was detached from an infusion device. One incident resulted in death by electrocution; the other produced severe third degree burns that required plastic surgery.

The third demonstration was an oral syringe supplied with a liquid psychotropic medication. The graduated markings on the “pipette” were unlike the markings on the syringes commonly used in the USA. Therefore, when using a “pipette” the dose has to be measured in the opposite way from the normal procedure. The graduated markings are on the plunger of the 3 ml “pipette” and start at 3 ml on the tip end with intervals of negative (−) 0.05 ml per division. On the standard USA syringe the markings are on the barrel and start with 0 c/ml on the tip end with intervals of positive (+) 0.1 ml per divisions. The demonstration of this “reverse design” helped the team to think about potential hazards in seemingly minor changes in appearance or labeling. It also showed how a design incompatibility between system and end user could easily lead to problems.

Finally, the team was shown a potential error that could occur with the use of the American Heart Association 2000 *Handbook of Emergency Cardiovascular Care*. The PSM referred the team to page 55 of the book and asked them to note that “amiodarone” was listed on the lower half of the page with the name appearing in the crease of the book spine. It was very easy to miss the name amiodarone and to assume that the text was a continuation of “adenosine”. On the top of page 56 the drug “amrinone” was listed. The team was shown how a carefully placed sticker alerting the reader helps to prevent the potential error. Two copies of the book were provided to the team one with the label enhancement and one without. It illustrated to the teams the problems that can occur when the formatting of information (in this case, compounded by the book binding) can obscure or even mislead the intended meaning. It also demonstrates the importance of testing a design under realistic situations and typical usage to uncover these flaws. Under time pressure one would be more susceptible to misreading such text.

**Application of HFE to case study**

After this informative break from analysing their case of the retained sponge the team resumed their discussion about root causes and potential remedies. They abandoned efforts to focus on people or policy as root causes but, instead, they directed their attention to the computer methods and default procedures for ordering radiographs in the ORs. Understanding the issues with the design of the computer tool and lack of procedural forcing functions were now seen as more important and useful in avoiding future occurrences of the problem. Beyond an apparently obvious oversight by the surgeon and violation by OR personnel were vulnerabilities that would affect all ORs. Previously thought to be details, the RCA team now understood that software and procedures were the more remedial contributing factors.

Given these contributing factors, the RCA team made several recommendations. In the software they recommended that all intraoperative radiographs should be automatically considered “stat” so the radiologist will read them within 50 minutes. All incorrect sponge counts are now automatically listed on the OR request for radiographs so that the radiology department can adjust settings and “find” radio-opaque ribbons in the retained sponge. Nurses should inform attending physicians of incorrect sponge counts before the patient leaves the OR, and the attending physicians must review the radiographs on patients with an incorrect sponge count before they leave the OR.

**DISCUSSION**

**RCA team problems and solutions**

By focusing on individual competency and policy violations, the RCA team was left with no other alternative but to develop punitive remedies for individuals. What was unknown to
these team members was that HFE design issues often underlie policy violation or personal miscues. It is difficult to identify these issues even with some basic knowledge of HFE. The reason is that a shift in one’s mind set is often necessary in order to grasp and apply HFE. This shift entails adopting a systems-oriented perspective, and understanding that a system is made up of many interdependent components and that properties of one component can influence, both positively and negatively, many other components. With this view it is more readily apparent how HFE design impacts on the performance of clinicians. An effective way of bringing about such a shift in mind set is through “hands on” examples and demonstrations of a broad spectrum of HFE issues.

**More than just medical device related events**
In experiences with other RCA teams, three surprising things have held true in relation to the demonstrations:

1. it is not necessary for the demonstrations be closely related to the event or close call;
2. as in this case, even if the case is apparently about procedural, organizational, or other “big picture” issues, the HFE demonstrations still help the team to develop better root causes and more effective actions;
3. if the team gets off track later in the process, repeating the demonstrations is useful.

**Comments**
Many have explored the problem of teaching people to recognize the safety implications of human factors design issues. To address this, some introductory courses in HFE have many interactive exercises with tangible items. In addition, HFE experts have proposed that demonstrations and exercises are crucial to introducing the theory and practice of HFE. Finally, biomedical engineers and healthcare providers have documented the importance of HFE practice and learning in healthcare organizations and medical schools.

Understanding how to think about systems and design issues during RCA is neither an innate talent nor one usually acquired during medical training. It is an understanding gained through training in the field of HFE and interactive demonstration of key design concepts. Without some training in HFE concepts, many patient safety activities are not going to identify systemic design issues. It is important to heed the growing cynicism from healthcare providers as they become overloaded with more training and policies that are minimally effective in addressing patient safety.

**Key messages**
- Many evaluations of adverse events in healthcare settings such as root cause analysis (RCA) are inadequate.
- Well intentioned RCA teams have a tendency to focus on policy violation issues and personal shortcomings and not to look for underlying design related factors.
- The case study presented in this paper illustrates how human factors engineering design demonstrations can be used to train RCA teams and improve the development of root causes and actions.

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**REFERENCES**