A Systems Approach to Analyzing and Preventing Hospital Adverse Events

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Objective: This study aimed to demonstrate the use of a systems theory-based accident analysis technique in health care applications as a more powerful alternative to the chain-of-event accident models currently underpinning root cause analysis methods.

Method: A new accident analysis technique, CAST [Causal Analysis based on Systems Theory], is described and illustrated on a set of adverse cardiovascular surgery events at a large medical center. The lessons that can be learned from the analysis are compared with those that can be derived from the typical root cause analysis techniques used today.

Results: The analysis of the 30 cardiovascular surgery adverse events using CAST revealed the reasons behind unsafe individual behavior, which were related to the design of the system involved and not negligence or incompetence on the part of individuals. With the use of the system-theoretic analysis results, recommendations can be generated to change the context in which decisions are made and thus improve decision making and reduce the risk of an accident.

Conclusions: The use of a systems-theoretic accident analysis technique can assist in identifying causal factors at all levels of the system without simply assigning blame to either the frontline clinicians or technicians involved. Identification of these causal factors in accidents will help health care systems learn from mistakes and design system-level changes to prevent them in the future.

Key Words: patient safety, systems theory, cardiac surgical procedures, adverse event causal analysis

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Despite much well-intended effort, patient safety has been resistant to significant improvement. In recent Congressional testimony,[1] Jha and others, who have been strong advocates for patient safety, conceded that little improvement had been made in reducing adverse events (AEs) since the 1999 Institute of Medicine report, *To Err Is Human*.[2] A U.S. Department of Health and Human Services report in May 2014 was more optimistic, however, and suggested that in some targeted areas, much improvement has been found. One of the interesting aspects of this report is that most of the successful interventions cited were attributed to changes in the overall health care system, such as changing incentives and payment structures and improvements in sharing information and transitioning patients.

Industries with very low accident rates, such as commercial aviation and nuclear submarines, in fact use a systems approach to safety.[3] Basically, the systems approach to safety argues that a flawed system, rather than flawed individuals, is responsible for accidents and AEs and improving safety requires system changes.

All medicine is practiced within a system. A hospital is a dynamic and complex system, interacting as a structured functional unit to achieve its goals (e.g., treating patients). One system may be nested within another; for example, a hospital is nested within a larger health care system, and an intensive care unit exists inside a hospital. The behavior of a system reflects the linkages and interactions among the components or entities that make up the entire system. The behavior of the components or entities that exist within that system is influenced by the system design and structure. Changing that system design and structure can result in changing safety and other system properties by changing the behavior of the entities within the system.[3]

One important aspect of the systems approach is engineering against human fallibility. In some cases, this approach has been interpreted as giving people a procedure to follow or a checklist, but as argued by Dekker and Leveson in a recent *BMJ Viewpoint*, these steps do not constitute a systems approach.[4] Aviation, for example, like health care, is a complex system with many interacting components, including manufacturers of aircraft, airlines, airports, the Federal Aviation Administration, and so on. Each plays a role in maintaining the low accident rates. Safety control is not concentrated only at the manufacturer or the airlines or the pilots but instead starts at the governmental level with policies, standards, oversight, and accident investigation, and it continues down to the aircraft manufacturers, airlines, and airports, with each level and component in this complex system playing a role and having specific responsibilities for ensuring safety. A very important component of aviation safety is that all accidents and serious incidents are thoroughly investigated and the entire industry is informed about the causes so that extensive changes can be designed into the whole system to prevent reoccurrences.

Even if one agrees that a systems approach is necessary, the question remains of how to identify changes in the system, which will reduce losses. One way to do this is to use the information that is available after AEs. Learning from AEs is an important part of implementing an effective systems approach to safety. When we blame losses on mistakes or poor training of frontline health care workers without understanding the role of the system in which they were operating on their behavior, we lose the opportunity to make important improvements in safety. Simply replacing one fallible human with another one inside a system design that inadvertently contributes to human mistakes and poor decision making is akin to moving around the deck chairs on the Titanic.

Root cause analyses in health care currently are heterogeneous in methodology and quality, with little evidence of efficacy in preventing future incidents.[5,6] Procedures range from haphazardly

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investigating accidents to rigorously following protocols for identifying root causes of accidents.[7–9] All of these are based on a traditional understanding of accidents as resulting from the failure of system components cascading in a linear fashion to result in a loss. For example, a mistake is made in entering data in the electronic health record (EHR) system, which leads the caretaker to provide incorrect treatment, which leads to patient injury.

In contrast to root cause analysis, system-theoretic accident analysis neither identifies a root cause or causes nor assumes that the loss involves linear causality. In fact, the "root cause" of all accidents is the same in this approach, that is, the system design did not prevent or control the behavior of the system components so as to avert an AE.[3,10] Instead, the goal is to identify the flaws in the system structure that contributed to the AE to determine how to redesign the safety control structure (safety management system) to be more effective.

METHODS

In this article, we demonstrate how a systems approach to investigating AEs in hospitals can provide the information necessary to make lasting and widely effective changes to prevent their reoccurrence. The approach was applied to 30 AEs that occurred during cardiac surgery on 380 consecutive patients during a 24-month period in a large American academic medical center. A time-out was conducted in a standard fashion for all patients in accordance with the World Health Organization surgical checklist protocol but the checklist clearly did not prevent the adverse results even though compliance in performing the time-out was established by direct observation during the surgeries. The systems approach to investigating these events identifies how the system design, that is, the hospital safety control structure, can be changed to eliminate or reduce such events in the future.

Systems theory was developed beginning in the 1940s and 1950s to understand the behavior of complex systems in biology and in engineering.[11,12] It can be used to identify and prevent AEs in the complex systems involved in health care today.

To identify the systemic causal factors in the 30 AEs, we used a new causal analysis technique called CAST [Causal Analysis based on Systems Theory].[3] Our goal was to demonstrate what a systems-theoretic causal analysis involves. A different causal analysis approach could be used if it is based on the same theoretical systems theory principles.

CAST (and systems theory in general) is based on the system-theoretic principle that accidents are not just the result of individual system component failures or errors but more generally result from inadequate enforcement of constraints on the behavior of the system components. Examples of safety constraints are that preemptive immunosuppression must be administered to patients before receiving a heart transplant or that all required equipment must be available during cardiac surgery.

The safety constraints are enforced by controls. Controls include such things as physical and logical design to reduce or eliminate common errors, checklists, performance audits, altering the order of steps in a procedure to reduce the risk of skipping some, and changing incentive structures (i.e., aligning individual incentives with system-level goals). In general, controls may be physical, procedural, or social. Losses result when the controls are inadequate and flaws in the overall system design and in the interactions among the system components violate the safety constraints. Safety is treated not as a human reliability problem but as a control problem where the system design should prevent (control) unsafe behavior.

The basic philosophy in CAST is that identifying the mistakes people make and going no further, which is often the result of root cause analysis performed on AEs in hospitals, does not provide the information needed to prevent future losses. Most people want to do a good job. Although in hindsight, their behavior may seem to involve "mistakes," at the time, they were trying to do the right thing.[13] To get the information necessary to change the work context to one that increases safe behavior, we must understand *why* it made sense to those involved to act the way they did when the behavior, in hindsight, turns out to be unsafe.

People's behavior is affected by the context in which it occurs. Therefore, the first step in identifying why particular behavior occurred is to identify the contextual influences that determined or influenced it. Then, to change behavior, we change the context. That is the "systems" approach to accident reduction.

Behavior is also affected by our mental models of the state of the process being controlled. Figure 1 shows a simple feedback control loop. At the top is the controller, the control loop element responsible for constraining the behavior of the process immediately below; it is typically either a software or a human. The controller, perhaps the surgeon or nurse, executes control actions that may be instructions or actual physical actions on the controlled process. Decisions about what to do are affected by the model the controller has of the current state of the controlled process. If the model of the controlled process becomes inconsistent with the real state of the process (perhaps because of missing or incorrect feedback), then mistaken and perhaps unsafe behavior will result. For example, the nurse or physician believes that an immunosuppressant has already been given when it actually has not and therefore does not administer it themselves.

The individual feedback control loops are part of a larger hierarchical control structure. Figure 2 shows a model of the control system (feedback and communication loops) used to control surgical medication errors at the hospital where the AEs occurred. The model shows the system as it is assumed to work under ideal conditions. It will differ for each hospital, depending on the particular processes used. Accidents and incidents occur when the control structure (i.e., the designed controls) does not enforce the safety constraints on the system operation, assuming that the controller did not intentionally harm the patient.

Each "controller" in the system has specific responsibilities with respect to safety. Each also has a model of the process being controlled (not all shown in Fig. 2) that will impact how well the safety-related responsibilities are performed. Note that the attending cardiac surgeon and the surgery fellow both have the responsibility for ordering medications, which could potentially lead to confusion and omission of required actions.

Accidents occur as a result of (1) a poorly defined safety control structure where individual responsibilities do not combine to enforce the overall system safety constraints or (2) individual controllers not performing their responsibilities for some reason. Identifying these reasons and/or the flaws in the overall safety

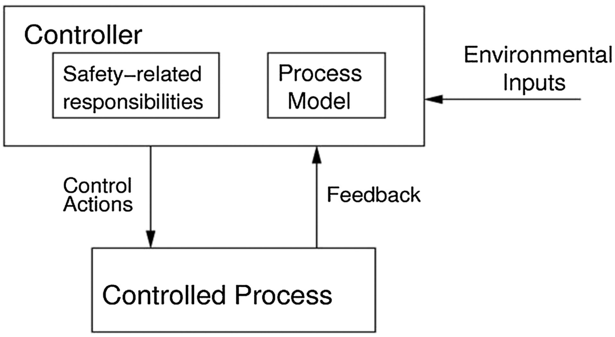

FIGURE 1. A general safety control structure.

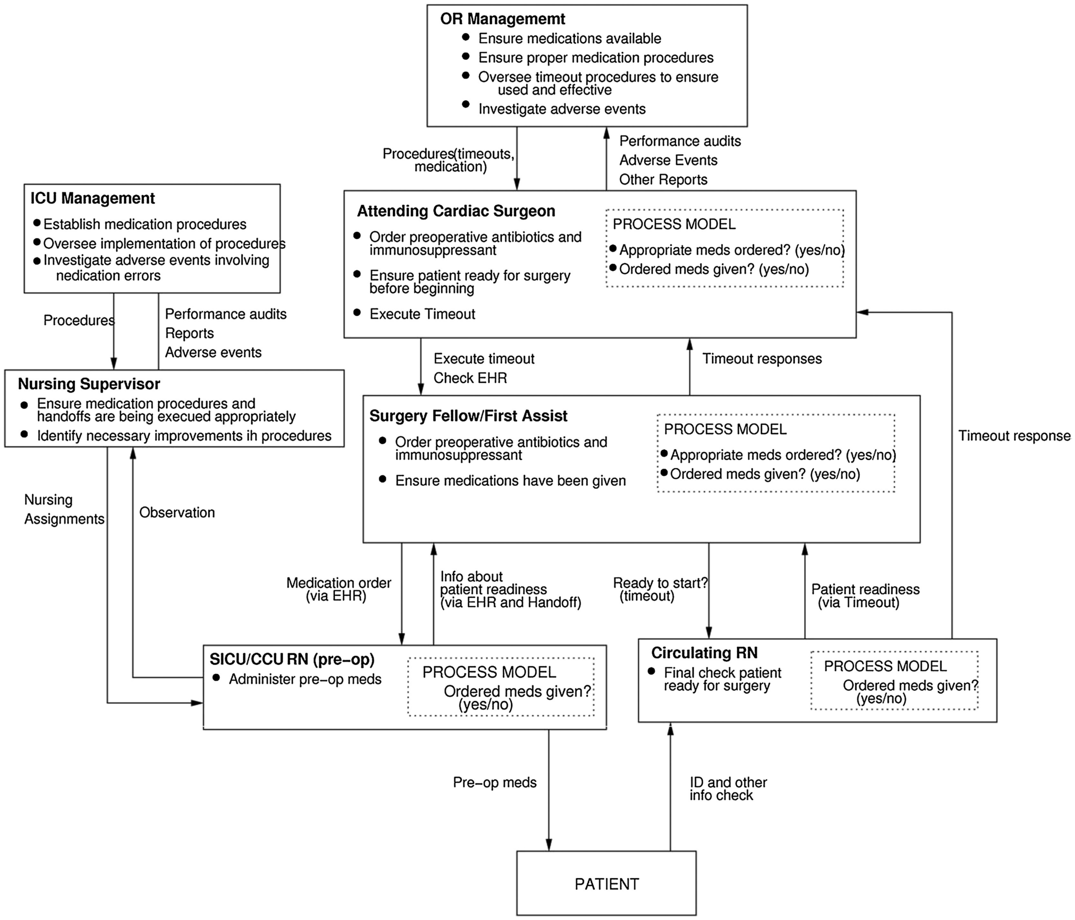

FIGURE 2. The safety control structure to protect against preoperative medication errors.

control structure provides the information necessary to redesign the system to prevent future losses.

When analyzing incidents and accidents, CAST starts at the events and the "local actors," and then the analyst tries first just to understand *what* happened. The next step is to find out *why* it happened by examining the local control loops and working upward in the control structure to understand the impact of the entire system design on the AEs. For example, the analysis may start with cardiac surgery, but missing or malfunctioning equipment problems are probably related to more general surgical equipment processing at the hospital and that may be related to factors in the process for ordering hospital supplies in general, which may have financial influences. The goal is to understand why the controls were ineffective in enforcing the safety constraints and then to use that information for continuous improvement, not just in the behavior of individuals, but in the processes and structures used to treat patients and the controls to prevent AEs.

CASE STUDY RESULTS

All 30 AEs were analyzed using CAST. We illustrate the process using a case where preoperative immunosuppression was not provided to a patient receiving a cardiac transplant. We then summarize the results for all 30 AEs and describe how to apply this process to improve patient safety.

The patient had been admitted to the cardiac care unit (CCU) where he was being supported with a left ventricular assist device to bridge to transplant. When a heart became available, the patient was taken to the operating room, and an uncomplicated cardiac transplantation was completed. Shortly after surgery, the patient showed worsening left ventricular function. The patient was placed on extracorporeal membrane oxygenation and treated for presumed transplant rejection. Careful analysis of the patient's chart revealed that immunosuppression had been ordered but never given preoperatively.

Figure 2 shows the safety controls for ensuring that proper preoperative medication is administered. In most situations, as in this case, there are multiple controls for safety-critical requirements and therefore usually more than 1 inadequate control involved in every AE. With the use of the normal root cause analysis performed in hospitals, it would seem that several people did not fulfill their responsibility and would likely be "blamed" for the events. For example, the surgeons started surgery without the patient receiving prophylactic immunosuppression, and the nurses did not give the medication and did not tell the surgical team that the medication had not been administered. The problem with this approach is that placing blame on individuals does not solve the problems or prevent them from occurring again if the unsafe control resulted from flaws in the design and operation of the safety controls, which in almost all cases it does. (Although there are, of course, individuals who are incompetent or negligent and need to be identified so that remedial measures can be taken, even in that case an effective identification and remediation system needs to exist and have appropriate controls.[14,15])

CAST starts from the assumption that everyone was trying to perform their responsibilities and do not want patients to be harmed. Therefore, there must be some explanation for their behavior. The goal is to understand why. In the hospital in which these AEs occurred, there are multiple controls to ensure that proper medication is given, including a time-out before surgery in case all the other controls, such as handoffs and written orders, are not effective. In this example case study, none of these controls was effective, and the medication was not given. To understand why, 2 general categories of factors must be considered: individual behavior and the operation of the structural controls. To do this, we analyzed the controllers looking at their safety responsibilities, unsafe control actions in the incident, process model flaws, and context of their actions. Sample analyses are shown in Table 1.

Individual Behavior Analysis

Individual behavior is impacted by both process model flaws and the context in which the behavior occurs, as defined previously. In these AEs, the actors directly involved in the events all had incorrect process models. The surgeons and circulating nurse thought that immunosuppression medication had been administered, while the CCU nurse was not aware she needed to give an immunosuppressant. How could all these process models be dangerously wrong?

TABLE 1. Analysis of Controllers

Controller	Analysis
CCU RN	Safety responsibilities • Administer preoperative medications • Report concerns about patient to the surgical team Unsafe control actions • Did not give preoperative immunosuppression • Did not tell surgical team that the patient had not received the medication **Why?** Process model flaws • Not aware that they needed to give the immunosuppression Contextual factors • New leadership in cardiac surgery pushing cardiac transplantations after several years of doing very few, so they were not very familiar with that particular operation • Antibiotics are ordered as part of the preoperative order set, but the floor nurses do not give them; they are instead given in the operating room. This could have caused confusion about who was responsible for giving the immunosuppression. • The order in the EHR does not specify who is responsible for carrying out the order
Surgery attending	Safety responsibilities • Order preoperative antibiotics and immunosuppression • Ensure that patient is ready for surgery before beginning • Supervise surgical fellow Unsafe control actions • Began surgery without patient having received prophylactic immunosuppression **Why?** Process model flaws • Ordered the immunosuppression and so believed that the patient had received it Contextual factors • On the order screen of the EHR, there is no record of whether an order has been acknowledged and carried out • Patients all came from CCU where the surgical team knows and trusts the nurses so do not feel the need to check up on their work. These nurses also specialize in cardiac patients, so (in the mind of the surgical team) they should be very familiar with the preoperative medications

One reason a process model may be incorrect is that the person gives an order to do something and assumes it was accomplished and no feedback is provided in the system design to correct that misimpression. Alternatively, there may be feedback designed into the system, but that feedback is inadequate, for example, it may be incorrect, ambiguous, or missing. To understand the reason for the behavior of the surgical team and nursing staff, more information is needed about feedback and other communication links in the safety control structure.

One important communication and feedback source is the EHR. This patient was very sick and had been admitted to the hospital preoperatively. This meant that all preoperative medications and testing were ordered by the surgical team the night before to be given by the nurses the morning before the procedure. However, the EHR has a poor layout in terms of giving clear orders from the physician to the nursing staff and providing feedback regarding the carrying out of those orders.

Orders for preoperative care are given as an order set to decrease the chance of the surgical team forgetting to place important orders. In fact, investigation after the AE showed that all orders were placed as intended. However, the order sets introduce a different source of confusion because they contain both orders that should be filled by the CCU nurses as well as orders that are to be carried out by the surgical or anesthetic team in the operating room. A time is assigned to each order, but there is no mention of who is responsible. In the case of common surgeries, the division of labor is clearly known and understood by all parties. However, in the case of a less common surgery, such as a cardiac transplantation, which includes less common orders such as immunosuppression, confusion about who is expected to give the medication and when it is given is more likely and, in fact, occurred in this case.

A second source of feedback to the surgical team from the CCU nurses about the patient's readiness for surgery occurs in the handoff when the surgical team picks up the patient for transport to the operating room. The handoff is a time when the nursing staff can communicate any concerns and the surgical team can ask any questions about the patient. However, there is no formal structure in the handoff, so important information may not be shared. In this case, the nurses had no concerns as they were unaware they were supposed to provide immunosuppressant medication.

A third opportunity for feedback on the patient's readiness for the operation is the preoperative time-out. The time-out, however, has no question about preoperative immunosuppression. The only medication-related question explicitly asked is about preoperative antibiotics along with a general question asking about any other concerns, neither of which could be expected to prompt staff to think about preoperative immunosuppression.

Creating a long and detailed checklist is not a good solution. A long checklist is unlikely to be fully completed. In fact, airlines often try to do everything they can to keep the "before take-off" checklist (the final one before barreling down the runway) as short as possible, with only the most critical or "killer" items left on it. Compliance rates are much more likely to be high with short checklists.[16] One recommendation that might come from this CAST causal analysis is to tailor the checklist to make it more specific to cardiac surgery rather than using one that is designed to be useful in every operation. Some of the questions, such as the site of the surgery, are not relevant to cardiac surgery, whereas some specific to this type of surgery are omitted.

Additional factors influenced the events here and help explain why the people involved behaved the way they did. For example, the surgical team did not receive any information that would lead them to believe immunosuppression had not been administered. The EHR design does not provide clear feedback regarding the status of the medications ordered. To see if the orders are completed requires leaving the EHR order screen and going to an entirely separate screen, the electronic medication administration record. The electronic medication administration record lists the medications and the time they were given to the patient, but there is nothing in the EHR that clearly shows an order was given and not carried out. One has to be looking specifically for it to pick up on this scenario, and there was no reason for the surgical team or the circulating nurse to suspect that the medication had not been given. In fact, these nurses specialize in cardiac patients, so (in the mind of the surgical team) they should be familiar with the preoperative medications.

Why was the CCU nurse unaware that she needed to give an immunosuppressant? New leadership in cardiac surgery in the hospital was pushing cardiac transplantations after several years of doing very few, so the nursing staff were not very familiar with that particular operation. In fact, accidents often occur after changes. Sophisticated companies use *management of change* procedures to identify and evaluate any new or increased hazards that may result from a planned change. The same principles should be used in surgery (and other hospital procedures). A checklist will have little impact on preventing AEs resulting from new or significantly changed surgical practices.

Another factor in the CCU nurse not being aware of her responsibility is that antibiotics are ordered as part of the preoperative order set, but the nurses on the CCU do not give them. They are instead administered in the operating room, which could have caused confusion about who was responsible for giving the immunosuppression. Unfortunately, these CAST analyses were performed long after the incident, so direct questioning of the actors involved was impossible.

Finally, the order in the EHR does not specify who is responsible for carrying out the order, for example, the antibiotic order is written the same as the remainder of the preoperative orders but is meant to be carried out differently.

The other main participant in the events was the circulating nurse, who is responsible for a final check to ensure the patient is ready for surgery. Like the surgeons, her process model was negatively impacted by the lack of mention of immunosuppression in the time-out and the poor design of the medication administration record in the EHR.

Looking at the results of the CAST analysis even at this lower level of the control structure provides a great deal of useful information to improve practices, including changes in the checklist, in the EHR, in the handoff, and in the order sets. Considering only the direct actors in the events will, however, limit the opportunity to prevent future accidents. Extending the analysis to the higher-level safety controls can potentially have a much greater effect.

Analysis of the Higher Control Levels

Figure 2 shows that the nursing supervisor, the intensive care unit administration, and the operating room administration have broad responsibilities for preventing AEs involving medication (and other) errors. Understanding why these controls were not effective is an important source of information about how the system can be redesigned to prevent them. For example, several of the AEs involved medication errors and had the same or very similar causal factors. If the first ones had been thoroughly investigated in terms of determining why the safety controls did not prevent them (instead of just stopping with blaming the medical staff), the later events might have been prevented.

Limited space precludes describing the causality behind all 30 AEs. When looking at the causes behind these events identified in the CAST analysis, there were recurring themes at these higher levels of control. There is a constant compromise between safety and cost, which permeates every decision in the hospital. This tension impacts staffing levels, equipment inventory, personnel training, and more. A culture of safety trickles down from the upper-level management, so until safety trumps cost at these higher levels, accidents will continue to happen. In addition, a lack of communication between departments played out in many scenarios leading to false assumptions and inconsistent processes, which created delays and misunderstandings. How can staff make the correct decisions regarding patient care if they are not communicating fully and clearly about the patient's status? Ways to address these problems in design are beyond the scope of this article. They are covered by Leveson.[3]

DISCUSSION

There is always a temptation to identify individual human errors as the cause or major contributor behind the 30 AEs discussed. The CAST analysis reported here aimed, instead, to identify why the people involved behaved the way they did—why indeed their assessments and actions made sense given the contextual factors surrounding them at the time. As a result, the CAST analysis was able to point to general weaknesses in the controls used at this hospital to prevent such events. A CAST analysis leaves a well-articulated analytic trace behind, which can be assessed and checked by other stakeholders. In addition, it is able to generate the kinds of systemic recommendations that current root cause analysis techniques might sometimes overlook. These can be implemented not only to reduce highly similar events but also to address a larger class of related events. A CAST analysis, in other words, might greatly enhance learning and safety improvements in a hospital.

Many evaluations of chain-of-event safety approaches to systems-theoretic approaches have been performed, which show the superiority of the systems approaches. Perhaps, the most relevant is one that compared CAST with the root cause analysis method used in the Veterans Administration hospitals.[17]

CONCLUSIONS

Using a systems approach to safety has been very effective in reducing accidents in commercial aviation and other industries. However, to be effective, the entire system and potential safety controls must be considered, not just a few controls such as checklists plucked out of their context. Checklists, protocols, and other devices that aim to streamline and reduce variation play a role in a number of safety-critical fields. The goal of a systems approach, however, is not to reduce human behavior to rule following but to design a system in which individual responsibility and competence can effectively help create desired outcomes.[4] Achieving this goal includes the design of the system to reduce human errors.

One way to move toward a systems approach is to analyze the AEs that occur to determine what changes in the system are required to prevent them. An example of how to accomplish this goal is provided in this article. More information about how to perform such an analysis can be found in Leveson.[3]

From a longer-term perspective, we need to design safety control structures to prevent AEs before they happen. The type of prospective analysis required is called *hazard analysis* in engineering. Most traditional hazard analysis techniques (such as FMEA or Fault Trees) are based on a component reliability model and do not provide the information necessary to identify the systemic changes required for preventing accidents in complex sociotechnical systems such as health care.[3] The next steps in this research should be to adapt a systems-theoretic prospective hazard analysis to the health care setting to identify scenarios leading to AEs so they can be designed out of the system before losses occur.

As shown in many other domains, adopting a system-theoretic risk management approach that combines both prospective hazard analysis and retrospective AE analysis could have a major impact on health care safety.

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