

Acute Decompensation after Removing a Central Line: Practical Approaches to Increasing Safety in the Intensive Care Unit

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Intensive care is one of the largest, most expensive, and complex components of U.S. health care. Errors and the resulting adverse events are, however, common in intensive care units (ICUs). Theories about errors in high-risk environments, developed by aviation and other industries, provide insight into why ICUs are prone to errors. Complex systems—of which ICUs are certainly an example—are breeding grounds for errors because interdependent components interact in unexpected ways. To achieve favorable outcomes, ICUs require that many processes occur in sequence. For example, patients are cared for by many providers with vary-

ing levels of expertise across several disciplines, and these providers use highly sensitive and potentially dangerous technologies and medications. Such complex systems require careful planning, excellent teamwork and communication, and designed redundancies to recheck for proper care processes. This paper provides a practical framework for improving patient safety.

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For a list of questions and answers from the Quality Grand Rounds conference, see the Appendix, available at www.annals.org.

“Quality Grand Rounds” is a series of articles and companion conferences designed to explore a range of quality issues and medical errors. Presenting actual cases drawn from institutions around the United States, the articles integrate traditional medical case histories with results of root-cause analyses and, where appropriate, anonymous interviews with the involved patients, physicians, nurses, and risk managers. Cases do not come from the discussants’ home institutions.

SUMMARY OF THE CASE

A woman with metastatic cancer was hospitalized in the intensive care unit (ICU) for management of congestive heart failure and acute-on-chronic renal failure. The nephrology service initiated continuous venovenous hemodialysis through a large-bore catheter inserted in the right internal jugular vein. Two weeks later, a first-year renal fellow removed the catheter while the patient was seated upright in a chair. The patient became acutely hypoxemic and appeared to seize. Head imaging revealed global central nervous system ischemia suspicious for hypoperfusion.

THE CASE

Mrs. L., a 64-year-old woman with a history of metastatic colon cancer and chronic renal insufficiency, presented to a large university hospital with acute shortness of breath and fever. She was found to have jugular venous distention, bilateral pulmonary crackles, peripheral edema, and irregular tachycardia that progressed in the emergency department from atrial fibrillation to ventricular tachycardia. She underwent cardioversion and received intravenous amiodarone and lidocaine. Laboratory tests showed hyperkalemia (potassium level, 5.7 nmol/L), acidemia (HCO_3^- level, 12 nmol/L), a creatinine level of 707.25 $\mu\text{mol/L}$ (8 mg/dL) (baseline level, 176.8 $\mu\text{mol/L}$ [2 mg/dL]), and a markedly elevated troponin T level (>50 $\mu\text{g/L}$). An echocardiogram showed severe left ventricu-

lar dysfunction. Chest film showed diffuse patchy infiltrates. Despite the patient’s poor prognosis, her family chose to proceed with aggressive curative care.

Mrs. L. was intubated and hospitalized in the ICU for management of congestive heart failure after anterior myocardial infarction and acute-on-chronic renal failure. The renal service was consulted and initiated continuous venovenous hemodialysis through a temporary catheter inserted in the right internal jugular vein. The patient also had a left radial artery line and left femoral venous line through which she received vasopressor medications, antiarrhythmic agents, and empirical antibiotics.

One week into her ICU stay, Mrs. L. remained intubated and continued to require continuous venovenous hemodialysis because of hypotension. Several days later, her respiratory status improved and she was weaned off the ventilator. Her blood pressure had stabilized sufficiently to permit intermittent hemodialysis.

By week 2, Mrs. L.’s condition had improved and ICU discharge was anticipated. Her cancer prognosis was regarded as poor, but her quality of life had been relatively good, so the patient and her family elected to continue aggressive treatment, including hemodialysis. Plans were made to place another catheter, tunneled under the skin and intended for long-term use, while awaiting definitive vascular access. In preparing for this procedure, the first-year renal fellow came to the ICU to remove the large-bore catheter from the right internal jugular vein.

When the fellow arrived, Mrs. L. had just been helped into a chair by the nurse and was visiting with her family. Rather than force the patient to return to bed, the fellow undertook the procedure with Mrs. L. in the chair. He gave her no specific instructions and simply pulled the line, placing a plain piece of gauze over the exit site. The patient’s nurse witnessed the procedure from just outside the room.

Table 1. Risk Factors for Venous Air Embolism from Central Venous Catheters*

Procedure	Risk Factor
Catheter insertion or removal	Patient sitting during procedure Low central venous pressure Deep inspiration by patient Failure to occlude needle hub or catheter during insertion Disconnection of catheter from tubing Fracture or laceration of catheter Failure to use occlusive dressing Presence of persistent catheter tract after removal (related to large catheters that have been in place for several days)
Catheter maintenance	Disconnection of catheter from tubing Fracture or laceration of catheter Failure to use occlusive dressing

* Data from Phifer TJ (42).

COMPLEX ENVIRONMENTS ARE COMMON SITES OF ERRORS

Intensive care is one of the largest and most expensive components of U.S. health care. Approximately 6000 ICUs in the United States (1) care for about 55 000 patients on any given day, totaling 31 million patient-days per year and accounting for approximately 30% of acute care costs (2). Intensive care units account for approximately 10% of inpatient acute care beds, a percentage that is expected to increase as the population ages (3). Aggregate mortality in ICUs in the United States is between 8% and 10%, equal to 400 000 to 500 000 deaths annually (4).

Errors and resulting adverse events are common in ICUs (5–13). In one investigation, observers attending ICU rounds and meetings found that staff reported a serious adverse event in 17% of patients (11). An evaluation of errors that combined self-reports and direct observations in a medical–surgical ICU found 1.7 errors per patient per day (9). Of these errors, 29% could have caused clinically significant harm or death. Given that the average ICU length of stay is 3 days, these data suggest that nearly all patients hospitalized in the ICU sustain a potentially life-threatening mistake at some point during their stay. Extrapolation of these results to all ICUs in the United States suggests that approximately 85 000 errors occur every day, of which 24 650 are potentially life-threatening.

Of note, these observed mistakes are generally errors of commission—things we actively do to patients. By adding in errors of omission—things we should do but fail to, including not using evidence-based therapies—the estimates of preventable harm increase dramatically (14, 15). A recent study involving patients both in ICUs and regular wards suggests that U.S. patients receive, on average, only half of the recommended care they should receive (15).

THE CASE, CONTINUED

Immediately after the catheter was removed, the patient became extremely hypoxemic and appeared to seize. Code Blue was called, and the patient was reintubated. On examination, she was unresponsive with sluggish pupils. She had left-sided paralysis and left-sided extensor plantar reflex. Emergency computed tomography of the head showed no acute events, but a follow-up examination the next day revealed changes consistent with global ischemia suspicious for hypoperfusion. The patient had recurrent seizures and persistent left-sided paralysis, presumably due to air embolus or embolic clot, but the temporal association with removing the central line made air embolism the most likely diagnosis.

IDENTIFYING RECURRENT ERRORS

The incidence of venous air embolism resulting from removal of a central venous catheter is unknown. In our surgical ICU, this event is reported approximately 6 to 10 times per year. With the high prevalence of underreporting in most systems (16), this complication may be even more common. In fact, many of the “idiopathic” arrhythmias and episodes of hypoxemia and hypotension that occur when changing or removing central venous catheters could be caused by venous air embolism.

Venous air embolism occurs when there is communication between the atmosphere and the intravascular space, and intravascular pressure is less than atmospheric pressure. As such, risk factors for venous air embolism include low central venous pressure (which may result from the sitting position) and use of large catheters. Prolonged use of large catheters or dialysis catheters creates a communication with the intravascular space that may persist after the catheter is removed, and this poses particular risk.

The degree of harm from venous air embolism is related to the volume of gas entrained, the rate of entrainment, and the patient’s position at the time of the event (17) (Table 1). Entrained air generally embolizes to the pulmonary arteries; this can result in elevated pulmonary artery pressure, right heart failure, hypoxia, hypocarbia, arrhythmia, and electrocardiographic evidence of right ventricular strain. With massive venous air embolism, the right ventricular outflow tract becomes obstructed, leading to cardiovascular collapse and death.

Venous air embolism can be diagnosed in several ways. Transesophageal echocardiography and precordial Doppler ultrasonography have high sensitivity, end tidal carbon dioxide and pulmonary artery pressure measurement have moderate sensitivity, and pulse oximetry and physical examination have low sensitivity (17). Treatments of venous air embolism have limited effectiveness, emphasizing the importance of prevention.

Venous air embolism can be prevented by ensuring that central venous pressure remains greater than atmospheric pressure during catheter insertion and removal. This can be accomplished by placing the patient in the

Trendelenburg position, having the patient perform the Valsalva maneuver (18), increasing central venous pressure with intravenous fluids, occluding the needle hub, and covering the catheter site with an occlusive dressing after catheter removal. However, most physicians do not appreciate the risk factors for venous air embolism (19) or the importance of prevention strategies. In a survey at an academic medical center, only 26% of physicians reported concern about venous air embolism during central venous pressure catheter removal and 9% (incorrectly) elevated the head of the bed during catheter removal. Although an education program improved these knowledge deficits, the effects were ephemeral—lasting less than 6 months—demonstrating the need for system redesign to supplement education (19).

These findings suggest that the fellow's actions in this case, if not the norm, are certainly not exceptional. No one had advised the fellow that pulling a large central venous catheter with a patient in the sitting position predisposes to venous air embolism, the fellow's appreciation of the possible risk associated with this technique was not systematically reinforced, or both.

THE CASE, CONTINUED

A magnetic resonance imaging scan obtained 3 days after the event revealed evidence of global anoxia with several ischemic infarctions in the right middle cerebral artery, bilateral occipital arteries, bilateral middle cerebral artery watershed areas, anterior communicating artery, and inferior temporal and cerebellar regions. Echocardiography with bubble study was negative for right-to-left shunt, and ultrasonography of the upper and lower extremities revealed no sources of clot.

Ultimately, Mrs. L.'s neurologic status improved. She could open her eyes to a voice and weakly move her left side but had difficulty sitting in a chair. She had recurrent seizures and required around-the-clock attendant care at home. She died 6 months later.

ESTABLISHING A FRAMEWORK

This adverse event, like most, was not caused by an incompetent physician or irresponsible nurse. Rather, it resulted from several coincident factors and mistakes that occurred at several levels of the organization. Factors that can lead to patient harm can occur at the level of the patient, task, individual provider, team, work environment, department, hospital, and larger institution (20). **Table 2** shows a framework for conceptualizing the different levels. This framework provides a guide for evaluating all types of events and areas in health care, including patient floors, procedure areas, and outpatient clinics. Although the details vary, the application of this framework to unearthing hazardous systems is similar. Using the framework, we will discuss approaches to improving ICU safety and then return to the specifics of this case.

ORGANIZATION OF ICU CARE

Although we know little about how the ICU is organized in this case, ICU organization is correlated with patient outcomes. Intensive care unit physician staffing models in which intensivists provide most or all of the care are associated with a 30% relative reduction in hospital mortality and length of stay (7); an effect as large as the most effective therapies to reduce mortality in critically ill patients, including tight control of blood glucose levels, activated protein C for sepsis, and low tidal volume ventilation (21–23). Yet, intensivist staffing is invisible to most patients. Currently, intensivists staff only 10% to 20% of ICUs in the United States (1, 10). This contrasts sharply with Europe and Australia, where intensivists staff nearly all ICUs (11).

THE ROLE OF TEAMWORK

Teamwork failures figured prominently in this case. The aviation industry, with its well-defined hierarchy, redundant processes, complex tasks and technology, and industry-wide focus on safety, provides an important starting point for medicine's efforts to design systems to prevent errors. In medicine, we must allow ourselves to be human and accept that we will make mistakes—a bitter pill for some physicians to swallow. Aviation offers a model in which several lines of defense are used. First, active attempts are made to prevent mistakes from occurring. Second, mistakes are made visible before harm occurs. Finally, if the mistake still reaches the patient, efforts focus on mitigating the potential harm (24).

Preventing mistakes is a particularly robust solution but is infrequently applied in health care. For example, each year in nearly every ICU, at least 1 patient is estimated to have a pulmonary artery rupture from a pulmonary artery catheter being introduced too far. Despite our knowledge that introduction beyond 60 cm is a risk factor, we lack a forcing function or constraint, such as a removable hub at 60 cm, that would induce the physician to pause. Alternatively, labeling epidural catheters with a bright color sticker stating “epidural only” would make a mistake visible. Even if one of these catheters was mistakenly connected intravenously, the mistake could still be identified before harm occurred. In a similar way, removing concentrated electrolytes from care areas should mitigate harm from potassium overdoses.

Emerging evidence suggests that much work is needed to improve teamwork in health care. In a recent study (25), perceptions of collaboration and communication differed strikingly between physicians and nurses working in the same critical care unit. We found a similar disconnect in perceptions of teamwork between critical care nurses and staff physicians in our survey of safety attitudes for 11 Intensive Care Unit Safety Reporting System (ICUSRS) pilot sites. Most physicians (90%) are pleased with nurse

Table 2. System Factors that May Contribute to an Incident*

Factor Type	Definition	Example
Patient factors Condition (complexity, seriousness, agitation) Language/communication Personality and social factors	Clinical or social characteristics of a patient that contribute to an adverse event	Patient does not speak English. Patient declines therapy.
Task factors Availability of protocols Availability of test results Accuracy of test results	Characteristics of a specific task that contribute to an adverse event	Lack of protocol to guide therapy Test results not available for provider to make an informed care decision
Provider factors Fatigue Motivation or attitude Physical or mental health	Characteristics or state of an individual provider that contribute to an adverse event	Fatigue at the end of a double shift causes provider to forget to give a medication. Provider does not think he or she needs help or advice with a complicated procedure.
Team factors Verbal or written communication during hand-off Verbal or written communication during care Verbal or written communication during crisis Team structure and leadership	Characteristics of the work team that contribute to an adverse event	Lack of standard procedure during hand-offs at shift change Perceived barrier to speaking up
Training and education Knowledge, skills, and competence Supervision and seeking help Following established protocol	Aspects of a provider's training or education that limit their ability to care for a patient or that contribute to an incident	Lack of skill in performing procedure Inexperienced nurse not supervised while mixing a medication concentration
ICU environment Staffing levels Skills mix Workload Availability or maintenance of equipment Administrative and managerial support Physical environment (e.g., lack of space, noise)	Characteristics of the work environment that contribute to an adverse event	Overworked ICU residents Broken ventilator alarm
Institutional environment Financial resources Time pressures	Decisions or lack thereof by management that contribute to an adverse event	Limited financial resources Pressure to treat more patients

* ICU = intensive care unit.

collaboration, whereas only half of the nurses reciprocate that attitude (26).

Even in the same ICU, physicians largely evaluate teamwork much more favorably than the nurses. This may be because physicians' mental models of teamwork (physicians give orders and nurses take them) may need to be recalibrated. Critical care nurses and physicians are clearly interdependent in that one cannot function without the other; however, they are not necessarily integrated (that is, actively and consistently engaging one another). In the reported case, Mrs. L.'s nurse witnessed

the procedure from just outside the room but did not intervene. Perhaps not surprisingly, in several ICUs from the ICUSRS survey of safety attitudes, more than 1 of 3 nurses reported that it is difficult to speak up when a problem with patient care is detected. This is a symptom of interdependence without integration and is an important area to improve.

Team training teaches staff to speak up when they have concerns, listen when others express concerns, and acknowledge personal and organizational vulnerabilities. Although medical care is increasingly being delivered by multidisci-

plinary teams of clinicians, teamwork is not adequately emphasized in medical schools and training programs.

TRAINING, EDUCATION, AND SUPERVISION

Although competency is a characteristic of individuals, adequate supervision is a property of the system. Trainee supervision has much room for improvement. Sexton and colleagues implemented a Safety Attitudes Questionnaire that collects data on frontline staff attitudes about their organizations' strengths and weaknesses (Sexton JB, Helmreich R, Rowan K, Vella K, Boyden J, Neilands T, et al. The Safety Attitudes Questionnaire: A psychometric validation. Submitted for publication). In a survey of 10 843 caregivers from 203 hospitals in the United States, the United Kingdom, and New Zealand (response rate, 67%), only 58% of care providers reported that trainees in their discipline were adequately supervised. Ensuring safety in academic medical centers requires attention to the risks intrinsic to practitioners operating in a system of graduated responsibility and supervision. An important first step is to discuss the tension between production pressures and patient safety. In most institutions, the balance is tilted toward production.

ENSURING RELIABILITY OF TASKS: INDEPENDENT REDUNDANCIES

In addition to improving communication and teamwork and optimizing processes by reducing complexity, health care systems can create independent redundancies (such as checklists) for key processes. In the aviation industry, checklists provide consistent redundancy (2). In health care, some redundancy is provided by different providers who share care for the same patient, but too often this protection is insufficient or inconsistent. Checklists add redundancy by transforming complex diagnostic or therapeutic decisions into a series of simple yes-or-no tasks. In this case, a checklist could have included placing the patient in bed, placing the patient in the Trendelenburg position, having the patient perform the Valsalva maneuver, removing the catheter, and sealing the wound with an occlusive dressing. This kind of checklist can easily be used to monitor performance with each item, serving as a process measure of care quality (27, 28). Using checklists in this way creates a tool for performance improvement that is also a method for data collection of key processes.

By contrast, clinical practice guidelines or clinical pathways, where each decision node is a conditional probability statement ("if yes, then . . ."), are generally used to increase reliability for key processes in health care, such as the use of evidence-based therapies (www.guidelines.gov). However, guidelines are far more complex and unwieldy because they don't divide tasks into simple dichotomies. The evidence about the effect of guidelines is uncertain. Some evidence suggests that the way guidelines are written

or used does not comport with how caregivers actually make decisions (29–32). Under time pressure, caregivers recognize patterns or deviations from patterns rather than think in terms of conditional probabilities. For this reason, checklists are more practical than guidelines, especially for performing common procedures. Another problem is that most practice guidelines, especially those developed by professional societies, have been developed for physician use, ignoring other members of the health care team who could provide an independent check. Finally, because guidelines often lack specific details and have several decision nodes, monitoring adherence to them is difficult.

Obviously, checklists are beneficial only if they are used. Checklists that enlist both physicians and nurses to ensure adherence to evidence-based therapies are particularly helpful. For example, we developed a checklist for adherence to the guidelines by the Centers for Disease Control and Prevention (www.cdc.gov) for inserting central venous catheters (33). We asked the nurses who assist physicians inserting the lines to ensure physician adherence to each step. If physicians did not adhere, nurses could intercede, analogous to a flight engineer stopping take-off if events deviate from the prescribed sequence (Pronovost PJ. Personal communication).

When this intervention was announced, both nurses and physicians challenged it. Nurses said their role was not to police residents, while residents worried that public questioning by nurses would damage their credibility. However, in a joint meeting, nurses and residents agreed unanimously that harming patients was unacceptable. Reframed in terms of the jointly held professional obligation to prevent harm, a rubric was formulated that requires nurses to intervene when they see care that increases the probability for patient harm. We are now applying this concept to other situations.

DECONSTRUCTING THIS ERROR

The lack of a protocol (task factor), insufficient communication between physician and nurse (team factor), and possibly inadequate training and supervision (individual and team factors) all figure prominently in this case (Table 2). Although we cannot definitively identify all of the system factors that contributed to this error, several likely system failures fall squarely within our framework. First, the hospital could have had a checklist (independent redundancy) for removing central venous catheters. The checklist could have been attached to the patient's chart during rounds at the time the decision was made to remove the catheter. Second, during removal, the nurse could have expressed concern that removing the catheter with the patient sitting in a chair deviated from standard protocol. Third, the fellow could have admitted a lack of knowledge about the appropriate procedure for removing a catheter. The "see one, do one, teach one" model of training hinders this kind of admission. Fourth, a senior physician could

have supervised or provided previous training. Indeed, supervision until a trainee is deemed competent in a given procedure could be part of a checklist and the hospital's policy. Fifth, the ICU might have benefited by having more nursing staff (or perhaps a specialized "lifting team") to facilitate timely transfer of a patient back to bed.

In identifying and deconstructing the errors in this case, we review the evidence from health care and other complex industries and apply it to the framework presented in **Table 2** to broaden clinicians' understanding of incidents and to identify potential opportunities for improvement.

TRAINING AND SAFETY: THE INHERENT TENSION

Patients in the ICU are frequently subjected to invasive procedures, with almost half receiving central venous catheters at some time during their hospitalization (34). These procedures expose patients to risks for harm. In academic medical centers, ICU patients are often cared for by physicians-in-training who may not be experienced in performing all procedures. A challenge for any academic medical center is balancing its training mission with patient safety, which calls for graduated responsibility for trainees with limited experience. As described by surgeon and author Atul Gawande, "This is the uncomfortable truth about teaching. By traditional ethics and public insistence (not to mention court rulings), a patient's right to the best possible care must trump the objective of training novices. We want perfection without practice" (24, 35).

The process for determining competency to perform procedures is of interest to many stakeholders in medicine (36, 37). Patients, training programs, Accreditation Council for Graduate Medical Education requirements, hospital credentialing committees, and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) ask whether a physician is competent to perform procedures. The traditional approach is to assume competency "ex officio," that is, after completing a certain number of procedures or attaining a certain level of training, physicians are assumed to be competent. In fact, they may not be. For example, a program may allow residents to insert subclavian lines without supervision after they have completed 5 insertions or after they have finished their internship year. An alternative method to evaluate competency would be to anonymously ask peers, and perhaps nurses, whether they would recommend the caregiver to a family member or friend. Such an approach can narrow the confidence intervals with which we currently evaluate competency, allowing the creation of a structured improvement plan. It is hoped that such a plan would prevent the all-too-common experience of long-standing concerns about competency surfacing only after a patient is harmed. Simulation methods may provide another, although more costly, method to evaluate competency (36, 38, 39).

THE INSTITUTION'S RESPONSE TO THE CASE

The case was reported through the hospital's incident reporting system. A root-cause analysis revealed that the fellow did not know the proper technique for removing central lines, the patient's nurse was reluctant to correct the fellow during the procedure, and the institution had no mechanism to ensure competency in this and several other procedures. Several initiatives were launched, including an instructional video on central line safety, a new central line kit that includes warning labels about proper removal techniques, and training physicians and nurses to speak out when they see unsafe acts. Finally, since the prevailing view was that it would be easier to enforce safe central line practice in the ICU rather than on the floors, a policy was instituted to remove all central lines from ICU patients before they left the unit.

Several sources of data on mistakes, including peer review, morbidity and mortality conferences, liability claims, and error reporting, alert us to errors after they occur. However, incident reporting alone proactively identifies and helps us learn from both adverse events and, more important, near misses that do not lead to harm.

However, the potential of incident reporting has not been realized in health care, where reporting tends to be punitive and focused on people rather than systems. More effective reporting systems will evaluate how we organize our work and include expert analysis and feedback (12).

In the ICUSRS (<http://icusrs.org>), funded by the Agency for Healthcare Research and Quality, we created a Web-based, anonymous reporting system for researchers and caregivers that seeks to uncover the unsafe conditions that could or did lead to patient harm, using the framework outlined in **Table 2**. In partnership with the Society for Critical Care Medicine, ICUSRS panelists provide expert analysis and feedback to members on lessons learned about how to improve patient safety. Over the past 18 months, the ICUSRS has received 1500 reports of incidents from 22 ICUs across the United States. Nonetheless, more research is needed to learn how to code and analyze incidents and, most important, how best to use data from incident reports to improve patient safety.

In this case, the institution's responses were targeted to several levels of the hierarchy: task, provider, team, and institution. Both the culture that allowed the case to be reported and the organization's response are laudable. In many cases, although conducted to identify system problems, root-cause analysis (a detailed analysis of a mistake) fails to progress beyond provider factors or to delve into "undiscussable" cultural issues. The term *root-cause analysis* is misleading because it implies that there is a single root cause. This is not the case; a cascade of events is present in nearly all serious incidents. For example, in the ICUSRS, staff identified 2 or more system factors contributing to the event in 95% of incidents (Pronovost PJ. Personal communication).

Nonetheless, the institution's response could have

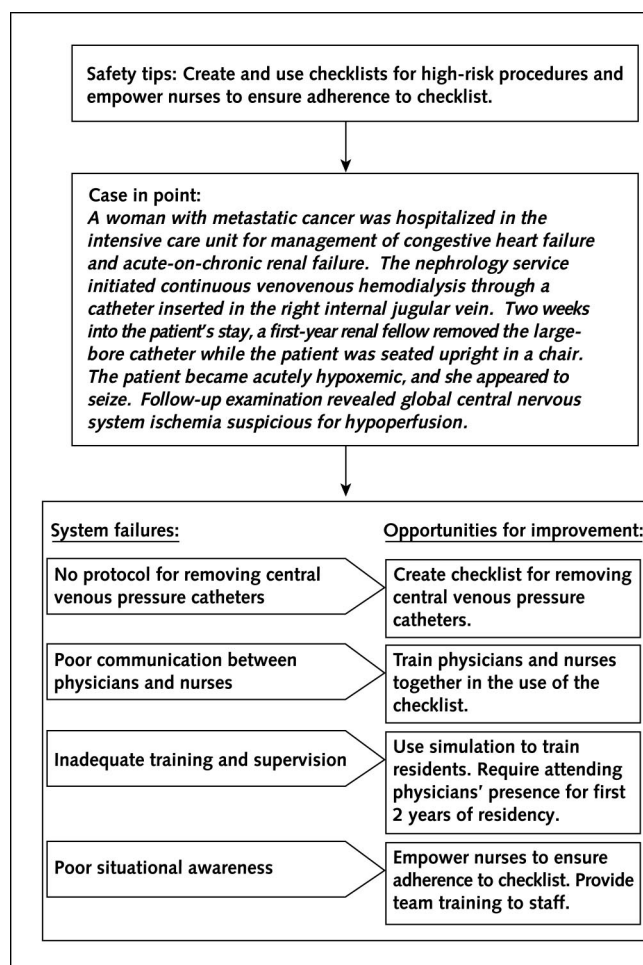
been more robust. Effective communication requires that a message is both sent and received. Training staff to speak up should be accompanied by training that enhances the ability of those with higher authority to listen when colleagues voice concerns. The ideal method to accomplish this has not been established for the health care setting. Checklists, such as the one to prevent bloodstream infections, or an interdisciplinary daily goals form can serve as a forcing function for teamwork and allow staff to model effective behaviors (40).

Formal training in teamwork is another alternative. Team training could be reinforced by tools such as the daily goals forms (40), multidisciplinary shift briefings, or an institutional code of conduct.

Another concern with root-cause analysis is that the lessons learned may never leave the risk management department. When a sentinel event occurs, the organization must ensure that the entire staff learns from the mistake. Few hospitals do this. How can hospitals learn from mistakes without exposing themselves to undue risk? First, they can recognize that failure to improve and the risks posed by recurrence of errors are far worse than managing the immediate risk after a specific incident has occurred. One possibility is to selectively discuss cases in which harm did not occur or in which a settlement, with or without litigation, occurred. The **Figure** presents an example of a summary of this case that could be widely disseminated. An important way to facilitate learning is to assure that personal performance will not be considered when discussing the incident. If needed, this should be emphasized separately with the clinician and his or her supervisor. A second tool is using a framework, such as that in **Table 2**, to help identify potential hazards and summarize this learning, as seen in the **Figure**. Third, when considering interventions to reduce the risk for recurrence, caregivers should be asked to consider how they could improve teamwork, reduce complexity, and create independent checks for key processes. Because many system factors are not apparent to staff, the root-cause analysis must be interdisciplinary, including caregivers from different areas and from all levels in the chain of command. In our institution, we now routinely include a finance person in our root-cause analyses to help administrators understand the hazards inherent in care delivery and to provide the team with a broader perspective.

One successful strategy used in our organization is to have senior executives adopt an ICU or other area of the hospital (41). This approach is part of an organizational effort to sequentially transform the culture of our organization. For example, the president of The Johns Hopkins University has adopted one of our ICUs. When the president asked why infection rates were so high, a senior cardiac surgeon showed pictures of dust-laden light fixtures in the operating room. The surgeon stated that poor cleaning was contributing to wound infections. The president then asked why he continued to operate under such hazardous

Figure. Adverse event summary report.



conditions and followed up by stating that each staff member is responsible for ensuring that patients are not exposed to undue risk.

Although staff members were frustrated by the dirty lights, they did not understand their responsibility to stop operating until this hazard was fixed. After the discussion, the balance of power shifted, resulting in safety empowerment of staff: The staff assumed responsibility for safety and then discussed their goal to reduce rates of wound infections to the fiftieth percentile. The university president challenged the group to strive for 0 defects—in other words, elimination of infection. If we practice patient-centered care, the question becomes: "What rate of infections would patients want?" After some discussion, staff agreed they could no longer accept the status quo and needed to assume responsibility by striving for 0 defects. This executive continues to meet monthly with staff to eliminate surgical site infections, bloodstream infections, and medication errors.

In many organizations, caregivers rarely talk to risk managers or performance improvement leaders. There is

scant evidence that patient safety actually improves because of a root-cause analysis. For example, many hospitals have repeated sentinel events in areas where they have had root-cause analysis. The lack of demonstrated benefit of root-cause analysis may result in part from the challenges in measuring “safety” and from the failure of organizations to actually eliminate the hazards identified in root-cause analysis.

Another technique used to improve safety and required by the JCAHO is failure mode and effect analysis (42, 43). A team prospectively dissects a process, examines where it can go wrong, and assigns priority areas for action by using a scoring system. In our experience, failure mode and effect analysis has not been adequately tested in health care, and in its current form is impractical for routine use, especially for frontline staff. For example, we conducted a failure mode and effect analysis after a patient-controlled analgesia incident. After nearly 100 staff hours to examine one step in the process, we independently asked a group of nurses where the defects were. Within 5 minutes, they reached essentially the same conclusion as did the failure mode and effect analysis. If the reliability of health care processes can be improved, failure mode and effect analysis may play an increasingly important role. For now, hazards are common and generally visible to caregivers.

AN IMPROVED RESPONSE

We recommend that hospitals 1) work to improve teamwork and communication, 2) optimize care processes by reducing complexity and creating independent checks, and 3) automate these processes to enhance reliability and monitor performance. Although many hospitals are investing heavily in information technology, few are attempting to improve communication and to redesign care processes. This can be hazardous. For example, in our ICUSRS project, 3 hospitals implemented computerized physician order entry. Overall, medication errors increased dramatically, comprising mistakes that staff attributed directly to computerized physician order entry (Pronovost PJ. Personal communication).

Although automation may be beneficial, automating broken processes may yield poor results. Moreover, although harm seems to result most often from teamwork or communication failures, few systematic efforts have been applied to improve this area. For example, we reviewed our sentinel events and rated each incident on a scale of 1 to 5, with 5 being “communication failure contributed greatly” and 1 being “communication failure contributed minimally.” All events were scored as a 4 or 5. Greater effort is needed to identify practical tools, such as the goals sheet, to improve communication. The goals sheet is a practical tool by which the care team establishes daily goals, identifies and eliminates hazards, and creates an explicit care plan for the patient and communication plan for the care team. In the long run, computerized physician order entry and

other information technology solutions should help improve patient safety, but only if they are applied to processes that are understood and optimized. We must not neglect efforts to improve our interpersonal skills and how we care for patients.

All health care institutions must recognize that fallibility is inevitable where humans practice, and so our objective must be to deliver care that is *harm-free* rather than *error-free*. Through enhanced training, supervision and independent checks to prevent mistakes, and improved recovery when mistakes occur, we can make the training environment a safer place to practice. The approach outlined in this paper, particularly in **Table 2**, provides a framework to broadly improve patient safety well beyond the walls of the ICU. Nevertheless, we will probably need to enhance caregivers’ capacity in the sciences of patient safety and quality improvement and provide time to lead improvement efforts. The looming question is: Who will fund the needed research for the optimal organizations of care to ensure that the best therapies are delivered safely and effectively and that trainees enjoy the needed balance of autonomy and supervision? Only when such research is supported and implemented will the public begin to realize the full potential of their investment in modern medicine.

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APPENDIX: QUESTIONS AND ANSWERS FROM THE CONFERENCE

A physician from Seattle: I appreciate the parallel to aviation, but in aviation, there is a proud history of working on simulators, and I don't see that same effort in medicine. It seems to me that the only way to see or look at errors is to create virtual patients, or fake patients in a real ICU, have people round on them, make orders, see what goes on.

Dr. Pronovost: Simulation use is really in its infancy. There are a few places that are beginning to use it, but, as with aviation, we don't want to focus just on the technical. What is not really that well developed is how we incorporate working as a team.

A hospitalist from San Diego: I couldn't agree more that people think that computerized solutions are a panacea and that sometimes all you do is automate a bad process. But I think that there is some role for trying to automate some processes because what you can't measure, you can't manage. I wonder if you could comment about how putting in some of these medication ordering systems at least allows you to understand the number of mistakes that are being made. The second problem I have is with the training issue. One thing that we battle with at my institution is how to balance resident autonomy. In other words, allowing them to at least make the initial decision but without sitting on their heads as attendings. If I did it, I would probably do it right and faster, but how do you balance the training mission with the need for safety and oversight?

Dr. Pronovost: We struggle with that issue daily, too. Let me address the first part of your question of monitoring. Absolutely we need a measurement system. What I see is that even when we automate, unless you understand your process and actually develop quality measures for those processes, what you're measuring tends to be garbage and so that there is no quick fix or substitute for rolling up your sleeves, digging into your processes, and understanding them. I'll give you a great example. We had an effort in our hospital to look at timely delivery of medications. We had all these automated tools that were driving the nurses crazy and compromising patient safety, and no one really knew the magnitude of the problem. So I suggested that we dissect the process. We couldn't look at timing of every medication. We decided we'd look at antibiotics because we agree that they ought to be given quickly. There is good evidence for that. And further, that we'd look at the first dose of antibiotics. So we developed a system to determine how long it took from writing an order of antibiotic to getting it into the vein? And we started with just a paper-based system. We uniformly start with paper, because we test a lot of things. Now once we recognize that that is a valid measure of performance, we know what the specifications are to measure for each step. We define very clearly: What's the numerator? What's the denominator? We then turn to our information technology folks and say, "Automate this." We still need to work to write the specifications. The training mission, that is a huge challenge because there are things that appear to be conflicting. I think the approach I am coming to realize is that perhaps we need to get a new mental model, that it shouldn't be an either/or, that we either have autonomy and errors, or that we don't have

autonomy but we have safety. The literature is not clear. If we recognize that training is a vulnerable period, can we put extra systems in place to potentially mitigate the harm. So it could be that we supervise residents in a more structured way, rather than "see one, do one, teach one," to ensure competency: by number of cases, PGY [postgraduate year], or simulation. The first part is recognizing that there is a vulnerability and that mistakes are going to occur, so how do we begin to put systems in place that are going to mitigate the harm?

Dr. Robert M. Wachter, Quality Grand Rounds Editor (Moderator): You've created a very clear culture in this fairly tight microenvironment of the ICU. These are fixed groups of attendings, nurses, administrators; you have your hospital president coming to the ICU. How generalizable is this paradigm to a lot of what we do that is less circumscribed and teams that are much more fluid?

Dr. Pronovost: You are absolutely right. The teams in the ICU are very clear. One of the definitions of a team is that you have to know who is on it. For hospitalists, many times it is a challenge because there are services all over the place. It is much more difficult. We've done this on our hospitalist service with the same results. We're doing it in the emergency department. I think they are a little more like the ICU in that there is a team. What we are doing right now, which seems to be working in the early stage, is to apply it to our transplant surgery program. They had cultural issues that I thought would be a hard nut to crack, but they actually came to us and asked us to apply our program to their area. For me, the greatest test of validity is if it works and people are asking for it. In other words, all the other safety initiatives had been pushed from the administration; this is one where staffers are saying the value is self-evident.

A hospitalist from Northern California: You indicate that it is better to concentrate on systems instead of people if you are going to try to fix something, but in the genesis of sentinel events, we have problems with both systems and people. You indicate that communication is a real issue in the delivery of health care, and it is, but one of the problems that we've got, and you alluded to it, is that nursing staff and the people who are not the captains of the ship have difficulty approaching the captains, and those are doctors. It was interesting in your first question, because you said that blame wasn't what should be assigned here, but two thirds of us wanted to blame the doctor [in a survey of conference attendees who were presented with this case]. Well, I would postulate that in cases where physicians are part of the problem, and where people are the problem in the genesis of sentinel events, there are probably two thirds of them responding with denial. In terms of the problem physician, how do you approach that person?

Dr. Pronovost: If there is a problem with personal performance, that needs to be dealt with in a disciplinary role, not in a safety investigation. They are very different issues. We're learning daily how to do this, and I won't pretend I have the answer. Let me give you a real case that I lived with. A patient was admitted to an ICU with a chest infection, had a known penicillin allergy, was prescribed Zosyn, and arrested and died 30 minutes later. One of the physicians wasn't coming to our sentinel event meet-

ings, and I went to him and asked him why. He replied that this was a case of a dumb doctor who wrote an order and a dumb nurse who gave the medicine. His idea was to go talk to them. I told him that what we have to recognize is that that approach isn't going to make care safer. I could have blamed the dumb doctor or the dumb nurse, but tomorrow it's going to be just as likely that it is going to happen again because the medication system is broken and memory and attention are the last step and least fixable links in the chain of a whole causal cascade that leads to harm. If that is where you are putting your emphasis, you have a really weak system. I think one of the powerful ways to do this is to make a statement, at the beginning of your discussions, that personal performance is off the table. When we have our M&M [morbidity and mortality] in the ICU, despite the change of culture, the conversation always goes back to, "Why did the fellow do that?" And it is really hard to step back and say, "But did we train them well? Are they well supervised? Did their culture allow them to say, 'I'm not certain'?"

Dr. Wachter: Final question, do you think residency work hours regulations will make care safer or less safe?

Dr. Pronovost: The residency hours question is fascinating. The literature is clear that fatigue hinders performance, and that is nothing new to any of us. The 80-hour workweek, nonetheless, is not necessarily based on empirical evidence of when that fatigue starts. The sleep literature is in its infancy. What we do know about fatigue is that probably, after 16 hours, and to a lesser extent after 12 hours, decrements in performance begin. Allowing a 24-hour work day is a change from where we were before, which was an exceedingly dangerous threshold, to moving toward something that is more rational. I think that the numbers got set more or less politically, really not based on what the science would support, because the science would suggest that we move to something that's more like shift work, much like what is

done in an emergency department. You have to be aware of spillover effects because any time you make a system change there are always vulnerabilities and you are potentially going to create harm. The best example is the JCAHO effort to improve pain treatment. It was a great initiative, but the tradeoff is that we have an awful lot of people who are having respiratory arrests from narcotics. We need a system to monitor it. The residency work hours changes happened in such an acute way that most hospitals, including my own, didn't have a system to deal with the increased handoffs. Any time you have a handoff in health care, it increases vulnerability to harm. So now in our hospitals, we're struggling with how to handle handoffs where the physicians who are cross-covering often know nothing about the patient. In some of our surgical subspecialties, to meet their hours, the chief has to be out of the house and can't come in. It is really acute in our pediatrics hospitals. The pediatricians call in with a sick neurosurgery kid. The neurosurgery resident says, "I can't come in because I'll violate our hours," and what do you do? Typically, that resident won't call the attending because of the cultural issues, and we have a mess. One of our strategies is that we are beginning to develop a standardized sign out that is going to have to be used throughout the hospital. It's going to have to be flexible enough to be configured for each area, but structured enough to make sure that key problems and key tasks are included and that nurses and respiratory therapists are aware of the potential problems. The goal is to avoid calling a resident blindly, who hasn't seen a patient, and who's been up all night.

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