Toxic Tachycardia

The Case

A 66-year-old woman with a past medical history of hypertension and breast cancer was admitted with abdominal pain. She complained of 3 weeks of progressive severe right-sided abdominal pain associated with nausea, vomiting, diarrhea, and a few days of constipation. On physical examination, she was in distress secondary to pain and was afebrile but tachycardic. The abdominal exam was notable for diffuse tenderness on palpation without rebound or guarding. The pulmonary, cardiovascular, skin, and neurologic examinations were all unremarkable. All of her laboratory tests were normal. A computed tomography (CT) scan of the abdomen with iodinated contrast was done, which revealed a normal appendix and a colon filled with stool with no obvious explanation for her pain or tachycardia.

Her abdominal pain and tachycardia persisted with no clear etiology. On hospital day 3, a thyroid-stimulating hormone (TSH) level was ordered to determine the cause of the tachycardia. The level was undetectable at Table.)

The patient had no evidence of thyroid storm. The iodinated contrast given for the CT scan could have exacerbated her thyroid disease but fortunately did not. Therapy for her hyperthyroidism was initiated, and she was discharged without complications.

Code Blue—Where To?

The Case

An 80-year-old man with a history of coronary artery disease, hypertension, and schizophrenia was admitted to an inpatient psychiatry service for hallucinations and anxiety. On hospital day 2, he had sudden onset of confusion, bradycardia, and hypotension. He lost consciousness, and a "code blue" was called.

The inpatient psychiatry facility is adjacent to a major academic medical center. Thus, the "code team" (comprised of a senior medical resident, medical intern, anesthesia resident, anesthesia attending, and critical care nurse) within the main hospital was activated. The message blared through the overhead speaker system, "Code blue, fourth floor psychiatry. Code blue, fourth floor psychiatry."

The senior resident and intern had never been to the psychiatry facility. "How do we get to psych?" the senior resident asked a few other residents in a panic. "I don't know how to get there except to go outside and through the

front door," a colleague answered. So the senior resident and intern ran down numerous flights of stairs, outside the front of the hospital, down the block, into the psychiatry facility, and up four flights of stairs (the two buildings are actually connected on the fourth floor).

Upon arrival minutes later, they found the patient apneic and pulseless. The nurses on the inpatient psychiatry ward had placed an oxygen mask on the patient, but the patient was not receiving ventilatory support or chest compressions. The resident and intern began basic life support (CPR with chest compressions) with the bag-valve-mask. When the critical care nurse and the rest of the code team arrived, they attempted to hook the patient up to their portable monitor. Unfortunately, the leads on the monitor were incompatible with the stickers on the patient, which were from the psychiatry floor (the stickers were more than 10 years old). The team did not have appropriate leads to connect the monitor and sent a nurse back to the main hospital to obtain compatible stickers. In the meantime, the patient remained pulseless with an uncertain rhythm. Moreover, despite ventilation with the bag-valve-mask, the patient's saturations remained less than 80%. After minutes of trying to determine the cause, it was discovered that the mask had been attached to the oxygen nozzle on the wall, but the oxygen had not initially been turned on by the nursing staff. The oxygen was turned on, the patient's saturations started to rise, and the anesthesiologist prepared to intubate the patient. Chest compressions continued.

At this point, a staff nurse on the psychiatry floor came into the room, recognized the patient, and shouted, "Stop! Stop! He's a no code!" Confusion ensued—some team members stopped while others continued the resuscitation. Although a review of the chart showed no documentation of a "Do Not Resuscitate" order, the resuscitation continued. The intern on the team called the patient's son, who confirmed the patient's desire to not be resuscitated. The efforts were stopped, and the patient died moments later.

Do Not Disturb!

Case & Commentary: Part 1

A 55-year-old obese woman with a history of hypertension and severe obstructive sleep apnea requiring CPAP (continuous positive airway pressure) is placed on morphine PCA (patient-controlled anesthesia) pump for pain control following cholecystectomy. At approximately 1:00 AM, 5 hours after starting the morphine, the patient's respiratory rate decreased to 7 (while on CPAP). Physical examination revealed an oxygen saturation level of 98%, normal blood pressure, heart rate of 50, and pinpoint pupils. The patient was noted to be lethargic, opening her eyes and mumbling incoherently in response to vigorous shaking but quickly falling asleep when the stimulus ceased. Concerned, the RN

called the attending physician. The physician seemed annoyed by the call, barking, "What would you expect when you wake up a patient in the middle of the night from deep sleep—an excellent level of consciousness? Naturally, she would be drowsy!" He followed with, "Wake me up only on life and death issues!"

Professionalism—Does It Mean Always Being at the Top of the Game?

This case identifies intertwined failures in four physician competencies that affect patient safety: professionalism, patient care, communication and interpersonal skills, and systems-based practice. How a physician responds when disturbed from sleep to help a patient is arguably the best test of how well professionalism has been incorporated into a physician's personality. This case highlights how breaches in professionalism are often associated with cognitive or emotional impairment on the part of one member of the team, in this case the doctor, and corrective action often requires teamwork to ensure safe care.(1)

It is difficult to know whether this physician has sufficient knowledge to recognize the seriousness of the morphine overdose. Had there been no rude behavior, simple lack of knowledge could explain the judgment error. However, his dressing down of the RN suggests emotional impairment leading to cognitive dysfunction. Whether this is a single lapse in professionalism, a character trait, or acquired impairment can only be determined by comparing this event with his behavior in similar situations.

The phenomenon of *sleep inertia* (2) might be important in this case. Sleep inertia is confusion and dysfunction that occurs upon awakening from sleep during deep non-rapid eye movement (NREM) sleep. The disorientation may occur after 30 minutes of sleep and may last from 10 minutes up to 2 hours after arousal. The disorientation may also include periods of amnesia after awakening.

Most of us have experienced brief cognitive impairment when sleep is suddenly interrupted. It takes a few moments to awake sufficiently to process information after a call. Our first response may be automatic, but with a little reflection, we call back, ask for additional information, and revise our decisions. If our initial reaction lacked emotional attunement and was discourteous, we quickly apologize, admitting our lapse in professionalism. Such self-assessment and self-correcting behavior is central to competence in professionalism.

How Can We Predict Professionalism?

Screening applicants for medical school and dismissing a few students each year weed out some of those with character traits that are incompatible with

medical professionalism.(3) However, once students enter their training, we are not very successful in teaching medical professionalism or in identifying and preventing burnout, which leads to acquired professional incompetence.

Burnout is a syndrome of depersonalization in relationships with coworkers and patients, emotional exhaustion, cynicism, and ineffectiveness.(4) It results when physicians are under constant pressure, have little control over their schedules, and fail at self-care. Burnout is associated with impaired job performance and poor health and may contribute to alcoholism and drug addiction.(5) Three-quarters of the residents in one study were burned out. They reported unprofessional behavior in discharging patients early to make their work more manageable and admitted to making medical errors, not fully discussing treatment options with patients or answering their questions.(6)

Systems-Based Practice: On-Duty and On-Call Systems

One defining aspect of medical professionalism is responsibility for providing care throughout the course of a patient's illness, including nights and weekends. Failing to ensure that a competent physician is available in a timely manner is professional abandonment.(7) However, being available is not enough. The physician must be cognitively alert and emotionally attuned to respond compassionately to the needs of a caller or patient and motivated to take appropriate action regardless of the hour or physician sleepiness. In short, physicians must be at the top of their game when they are responsible for patient care.

That said, it is unreasonable to expect one human to be available 24 hours a day, 7 days a week, 365 days a year; therefore, physicians participate in systems that ensure availability of competent physicians as well as sufficient time off to restore physical and emotional stamina. When demands for care are nearly constant, limited "on-duty" shifts, with mandatory time off between shifts, ensures alert physician availability. When calls for service are infrequent, systems in which physicians are "on-call" for telephone contact from home, returning to duty if needed, are reasonable. Intermediate patient needs are provided by longer on-duty shifts, during which naps of uninterrupted sleep can be anticipated.

Systems, Teamwork, and Professionalism

Professionalism is an abstraction made concrete through acts of undeserved kindness and trust, and honest admission and correction of mistakes. Professionalism is challenged most when patient needs conflict with personal needs.(8) Therefore, professionalism includes self-assessment of one's own needs and self-care that ensures the physical and emotional well being of the health care team.

Team members share the goal of quality care, have specific roles, perform independent tasks, and adapt to circumstances as they arise. Moreover, good teamwork mitigates the risks of physician (or other staff) failures that disrupt team function and lead to unsafe outcomes. Since physicians have ultimate responsibility for diagnosis and treatment decisions, other team members (the nurse in this case) have responsibility for performance monitoring, backup, adaptability, and communication that ensures that a message sent was received.(9)

The physical and mental condition of every team member (including attending physicians) is important to a safe and patient-centered health care system. Although important, physician altruism is generally insufficient to overcome survival instincts when humans exceed emotional or physical limits. High-reliability health care systems must balance workload with time off to ensure the physical and emotional well being of their workers, including physicians.

The root cause for excessive sleep interruption is complex. Physicians may take on more patient responsibility than they can safely handle. There may be insufficient numbers of physicians to handle the patient care needs in the specialty, or the system may fail to design call or duty schedules that ensure accurate night-time decision-making and sufficient time for sleep and relaxation to rejuvenate emotional and cognitive functioning.

Whatever their cause, difficulties with professionalism, communication, and interpersonal skills identified during training are related to difficulties later in life. One study showed that disciplinary action by medical boards was strongly associated with irresponsibility such as unreliable attendance at clinic or failure to follow up on patient care assignments and diminished ability to improve behavior during medical school.(10) The American Board of Internal Medicine (ABIM) identified a relationship between low ratings by program directors of professionalism during residency and sanctions imposed by medical licensing boards years later (RS Lipner, PhD, oral communication, May 2007). Additionally, Levinson and colleagues reported that communication with patients that failed to express empathy created a sense of uncaring and abandonment in patients and was associated with increased malpractice claims.(11)

Case & Commentary: Part 2

Unsatisfied with this response, the RN, who had already stopped the PCA, called the surgeon to express her concern. The surgeon ordered naloxone (Narcan). The patient immediately awoke, and the altered mental status and respiratory depression were reversed.

Luckily, this case has a good outcome from excellent teamwork. The RN mitigated the attending physician's cognitive error. However, the impact of the attending physician's unprofessional behavior on team trust and respect, as well as system contributors to problems in professionalism, will be explored below.

Emphasis on Professionalism in Medical Education

The Accreditation Council on Graduate Medical Education (ACGME) requires that residency programs teach and evaluate six general physician competencies. One of these is professionalism. This competency is defined as carrying out professional responsibilities, adhering to ethical principles, and showing respect, compassion, and integrity in clinical work with patients and members of clinical teams.(12) Physicians' self-monitoring of their physical and emotional state is also essential for professionalism, as is self-care, which includes getting sufficient sleep to make good decisions. The American Medical Association Council on Ethical and Judicial Affairs considers physicians' attention to their own health and wellness, as well as to the health of their colleagues, an ethical imperative.(13)

In addition to personal professionalism, health care organizations should reform work practices and change attitudes toward physician work. Fatigue and physical or emotional exhaustion should be unacceptable risks to safe care, rather than signs of dedication. Recognizing the deleterious effects of fatigue leading to resident burnout and patient safety problems, the ACGME requires all training programs to "educate faculty and residents...to recognize the signs of fatigue...and adopt and apply policies to prevent and counteract the potential negative effects." These policies include specialty-specific duty hour limitations for residents and fellows of 80 hours per week, 30 hours of continuous duty without a break, and at least 1 day in 7 free of clinical duties.(14)

Some physician educators express concern that emphasizing physician self-care and adopting a "shift-work mentality" may interfere with the physician–patient relationship and destroy medical professionalism. These concerns ignore the larger problem of fatigue-related burnout, depression, and emotional defensiveness expressed as cynicism or resentment resulting in detachment and a lack of compassion for patients. These are more serious risks to quality patient care than failing to provide continuous care to patients by a single physician, as demonstrated by self-reported studies of burned-out residents and absence of serious quality problems following the introduction of housestaff hours limitations.(15)

Assessing Professionalism Among Trainees

Identifying and tracking critical incidents of unprofessional behavior, as occurred in this case, is an essential method for tracking professionalism.(16) Another evaluation method used for medical students and residents is obtaining ratings of professional behavior from peers, nurses, telephone operators, and other team members; for example, the National Board of Medical Examiners is testing a survey for use in medical schools.(17) A Professionalism Mini-CEX is a checklist of important behaviors that faculty use to rate performance and provide feedback to students and residents about professional relationships observed during patient encounters.(18) Objective Standardized Clinical Evaluations are examinations in which standardized patients rate a student's or resident's communication and interpersonal skills related to humanism and ethical discussions with patients.(19) Teaching and formative evaluation of professionalism can be conducted at the student or practicing team level through critical incident root cause analysis and reflection on action, which involves guided analysis of the events, their causes and outcomes, the emotional effect on the participants, and how the experience might shape decisions for future action.(20)

What Steps Should Any Health Care Professional Take in This Situation?

In this case, the RN should report the error in judgment and professionalism through the quality improvement process, recommending an assessment of the attending physician for burnout. The report can document unprofessional behavior on several levels: (i) failure to respect the judgment and concern of a team member, (ii) failure at self-assessment of cognitive impairment induced by sleep or other problems, and (iii) failure to responsibly backup a fellow team member. In a high-functioning team, a team meeting on quality of care following this incident could provide an opportunity to design a system that ensures professional competence in all of the members of the team.

The personal care of the unprofessional physician should be managed through a medical professional wellness program.(21) In a high-functioning team, unprofessional behavior can be addressed as a routine aspect of improving teamwork and instilling trust among the members. Unfortunately, there is some evidence that the physicians with the greatest risk for incompetent professionalism seek solo and nonteamwork practice situations (FR Lewis, Jr., MD, oral communication, 2007).

In medical situations, the power differential between physicians and other members of the team may impede handling unprofessional behavior in a collegial way. This leads to ignoring important instances of unprofessional behavior and reporting physicians to medical staffs, licensing boards, or others more interested in action than in remediation. Although there always is a need to protect patients, and some cases of unprofessional behavior are so egregious that this type of disciplinary approach is appropriate, the downside

to this pathway is that it often leads to secrecy, confrontation, and even litigation. Approaching issues of professionalism first as potential systems problems that can be remediated with changes in the system and education in professionalism often lead to the desired outcomes of safe, high-quality care and collegial work relationships. The culture of "no blame," and system responsibility for potential or actual safety issues, can permit a conversation about the root causes of unprofessional behavior.

Although we cannot be sure about the root cause of the unprofessional behavior in this case, we can be fairly certain that burnout was an important contributing factor. Preventing burnout is the responsibility of all physicians and of the health care organization in which they work. (For resources, see Table.) Promoting physician well-being is a new aspect of systems-based practice and professionalism that is beginning to be implemented in the earliest years of training. The new professionalism calls on physicians "to cultivate methods of personal renewal, emotional self-awareness, connection with social support systems, and a sense of mastery and meaning in their work."(5) An investment in education in professionalism and in physician self-care can help prevent a lifetime of subsequent problems in some cases.

Coming Undone: Failure of Closure Device

The Case

A 65-year-old man underwent coronary angiography because of atypical exertional chest pain and shortness of breath. He was found to have coronary artery disease with significant narrowing of the proximal left anterior descending artery and a number of narrowings more distally. A bare metal stent was placed in the proximal lesion. A number of attempts were made to place more distal stents, but they could not be positioned correctly. After the procedure, the femoral artery sheath was removed and hemostasis was achieved with the use of an angio-seal closure device. A cardiovascular surgeon was consulted that day, and bypass surgery was scheduled for 4 days later.

The day after angiography, the patient, who was now home, was active and playing with his visiting grandchildren. The next day, the patient developed bleeding from the catheter site in his groin. The bleeding was not stopped by local pressure, and he returned to the hospital, where he was found to be tachycardic and hypotensive. His hematocrit dropped from 42% to 36%, and a computed tomography (CT) scan revealed a large (14 cm) retroperitoneal hematoma. He was taken to the operating room, and it was discovered the angio-seal closure device had failed and the femoral artery puncture (arteriotomy) was repaired.

The patient subsequently had complications related to the retroperitoneal hematoma, including persistent fever, leukocytosis, ileus, and back pain. His coronary artery bypass surgery was delayed, and while hospitalized waiting for the procedure, he suffered a cardiac arrest and died.

Discharging Our Responsibility

The Case

A 75-year-old man with a history of hypertension, coronary artery disease, and congestive heart failure (CHF) presented to the emergency department (ED) with shortness of breath and fatigue. He had a long history of CHF exacerbations requiring hospitalization and was known to the ED as a "frequent flyer." In fact, he had been discharged from the hospital just 3 days prior. On physical examination, the patient had a low oxygen saturation level with elevated neck veins and crackles on chest auscultation, all consistent with an exacerbation of his CHF.

When asked by the admitting physician what happened, the patient replied, "You know, I was feeling pretty good when I left here, but my breathing just got worse and worse." Upon further questioning, it became clear that the patient had been eating bags of potato chips, not restricting his fluid intake, and only intermittently taking his diuretics. Since discharge, he had gained 6 pounds.

The admitting physician realized that the patient had a poor understanding of his disease and how to care for himself outside of the hospital. In reviewing prior admissions, the physician discovered that the patient had never been given explicit discharge instructions about CHF and had received only a generic medical-surgical discharge instructions handout.

In the hospital, the patient was treated with diuretics, an angiotensin-converting enzyme (ACE) inhibitor, and a beta-blocker, and he improved clinically. At the time of discharge, he was counseled on appropriate activity, diet, medications, his follow-up appointment, and weight monitoring. Subsequently, he did well and was not readmitted to the hospital for more than 2 months.

Medication Reconciliation: Whose Job Is It?

Case & Commentary: Part 1

A woman with a history of seizures was scheduled for repair of a prolapsed rectum. A consultation prior to surgery listed her home medication as

"Neurontin 250 mg." When admitted for surgery, the patient reported to the anesthesiologist that she took Zarontin (ethosuximide) 250 mg twice daily. This was recorded on her preanesthesia care record where another entry for Neurontin had been entered and crossed out. The admitting history and physical note listed her current medications as "See her list." Postoperatively, the patient was prescribed Neurontin (gabapentin) 250 mg twice daily.

Hospital admissions and discharges are complex events, characterized by multiple handoffs among health care providers and numerous changes to the patient's therapeutic plan. The intended medication regimen before, during, and after the hospital stay often becomes a point of confusion for patients and clinicians during care transition points across the hospital and outpatient settings. Much of this confusion is fueled by multiple changes to medication regimens (1), discontinuity of care (2), short hospitalizations, and inadequate patient education.(3,4) Recent research strongly suggests that such confusion is a major cause of medication errors and adverse drug events (ADEs).(5-9) A recent systematic review on errors in medication history at admission estimated that 54%–67% of all admitted patients have at least one discrepancy between the medication history obtained by the admitting clinicians and the actual preadmission regimen and that, in 27%–59% of those cases, such discrepancies have the potential to cause harm.(10-12) A study of hospitalization-related ADEs also found that medication discrepancy was the most common drug-related problem at the time of discharge and the cause of half of all preventable ADEs 30 days after discharge.(13)

Discrepancies such as the one illustrated by this case can be prevented through a process commonly known as medication reconciliation. As defined by the Institute for Healthcare Improvement (IHI), medication reconciliation is a process of identifying the most accurate list of all medications a patient is taking—including name, dosage, frequency, and route—and using this list to provide correct medications for patients anywhere within the health care system. For patients admitted to a hospital, this process involves comparing the patient's current list of medications against the physician's admission, transfer, and/or discharge orders.(14)

Given the patient safety risk posed by medication discrepancies during transitions of care, leading patient safety organizations, such as IHI and the Massachusetts Coalition for the Prevention of Medical Errors, have developed recommendations and tools to help health care organizations build robust medication reconciliation processes.(14,15) The Joint Commission's recent mandate for all health care organizations to "accurately and completely reconcile medications across the continuum of care" has heightened interest in this important patient safety issue and has spurred many hospitals to design and implement reliable and efficient medication reconciliation systems.(16)

Case & Commentary: Part 2

When the order for gabapentin 250 mg twice daily was received in the pharmacy, it was entered as "gabapentin liquid" (gabapentin is not available in tablet/capsule strengths that would allow a 250-mg dose). The pharmacist dispensed gabapentin liquid 250 mg/5 mL with a note in the pharmacy computer record to indicate "dispense size = 120 mL." This comment was necessary so that the pharmacy would know how much was dispensed. This comment also appeared on the prescription label and in the electronic medication administration record (EMAR). The hospital had recently implemented a new EMAR system, and there was no way to suppress this information from appearing on the EMAR. The nurse caring for the patient misinterpreted the EMAR and gave an excessive amount of the gabapentin liquid on two consecutive evenings (the exact amount was not documented). The patient told the nurse that the amount of medicine given seemed to be more than she was accustomed to taking. Shortly thereafter, the patient became lethargic and could not walk. The pharmacist determined that the gabapentin liquid had been refilled earlier than expected and that an overdose had occurred. Although the overdosage was noted at the time, the administration of the incorrect drug (Neurontin, instead of Zarontin) was not recognized until several weeks later when the event was investigated in more detail.

While the goals of medication reconciliation are simple, efforts by hospitals nationwide to address this issue have uncovered daunting challenges.(17) Health care providers are often asked to piece together an accurate medication history using information from multiple and often imperfect sources, including the patient, his/her caregiver, the primary care physician, medical specialists, outpatient medical records, hospital discharge summaries, and community pharmacies. In addition, each of the major disciplines involved, including physicians, nurses, and pharmacists, often have divergent expectations about who is responsible for reconciling medications at various phases of the patient's care and how that should be done. This uncoordinated set of reconciliation activities often leads to either unnecessary redundancy or failure to share key clinical information.

These challenges are well illustrated in this case. First, the preoperative consultant sowed the seeds of this adverse event by obtaining the wrong preadmission medication list (PAML) from the patient. The consultant also failed to verify the medication history; he did not contact the patient's PCP, neurologist, or pharmacist, nor did he attempt to access the patient's outpatient medical record or pharmacy dispensing record. Second, although the medication history was later corrected by the anesthesiologist, the clinician responsible for writing the patient's inpatient medication orders was not alerted about the correction, thus allowing the preoperative consultant's

error to propagate from the outpatient to the inpatient setting. Third, the admitting physician and nurse failed to review the anesthesiology records or reconfirm the patient's PAML with the patient, allowing them to miss additional opportunities to correct the error. Fourth, it is likely that the amended medication list generated by the anesthesiologist was not available to the pharmacist, making it impossible for the pharmacist to compare the admission orders against the patient's PAML. Fifth, both the ordering physician and the dispensing pharmacist blindly trusted the information passed on to them from another clinical colleague, failed to question the unusual dose of Neurontin, and, as a result, missed at least two other opportunities to avert the adverse event.

How might adverse events like the one seen in this case be prevented? While other strategies, such as the use of unit dosing, barcode scanning during medication administration, and better naming conventions to prevent mix-ups between "sound-alike" pharmaceuticals, hold significant promise, the multitude of errors involved in the medication reconciliation process points to the need to re-engineer the process itself. As the best practices for reconciling medications are being defined on the front lines, several common themes have emerged from learning collaboratives (14,15,17) and published literature (7,18,19):

- Given the number of disciplines involved in the medication-use process, a robust medication reconciliation process should include participation by physicians, nurses, and pharmacists.
- The process for medication reconciliation must be clearly defined by a multidisciplinary team, and responsibilities for each component of the process must be assigned to the parties involved. For example, the Figure illustrates a sample medication reconciliation process for surgical patients who are seen by nurse practitioners in the preoperative evaluation center before the surgery and are subsequently admitted into the hospital.(20) Once defined, the process needs to be validated with other front-line clinicians.
- Implementers of the medication reconciliation process need to recognize that no single universal process will meet the needs of all patients entering a hospital, and that a limited number of different processes will need to be developed, depending on the patient population and patients' point of entry into the hospital.
- Implementers should understand that successful implementation of the process will require significant training, education, and support from clinical leaders. Willingness to engage in continuous improvement and monitoring for compliance are likely success factors for a multidisciplinary team.
- Implementers should expect to encounter resistance to the process by staff, because in many cases, staff will be asked to take on tasks that should have been done but were previously done incompletely (or not at

all) due to the lack of time (e.g., asking the admitting physician to obtain an accurate medication history). Implementers should stand ready to articulate the safety benefits of the new process and to emphasize that understanding the patient's medication history is part of good care.
- Patients should be leveraged as a resource in the medication reconciliation process, especially since they stand to gain the most from a safe medication-use process. Patients and families should be encouraged to keep an up-to-date list of medications. They should also understand why they take each of the medications as well as why medication changes occur. In turn, the medical staff should ensure that during the discharge process patients are appropriately educated about any changes in medication regimen.

Using the aforementioned principles, many organizations have begun to experience success.(7,18,19) In addition, as hospitals nationwide tackle this problem, novel approaches have emerged. One such approach involves the use of information technology to facilitate the process of medication reconciliation. Specifically, for health care systems that have access to reliable sources of patients' medication history in electronic format, an electronic tool could facilitate the verification of the patient's medication history and construction of the PAML. Moreover, once verified, the electronic PAML could be shared across multiple disciplines and inform the decision making of physicians, nurses, and pharmacists during the admission and discharge processes. For hospitals that have computerized physician order entry (CPOE) systems, the electronic PAML can also be used to facilitate the ordering of inpatient medications during admission and construction of the posthospitalization medication list during discharge.(20) Hospitals are exploring this approach to increase the reliability and decrease the time burden of the medication reconciliation process. However, this approach, while promising, has not been fully evaluated to determine its effectiveness and cost-effectiveness. Furthermore, as we have learned about the limitations of information technology in other health care contexts, we need to understand that no amount of technology can obviate the need to design a reliable process or secure buy-in from front-line clinicians.

Copy and Paste

The Case

A 77-year-old woman was admitted to a teaching hospital with diarrhea and dehydration after completing her fifth cycle of chemotherapy for ovarian cancer. Her only relevant past medical history included a postoperative pulmonary embolus after hip surgery. This preceded her ovarian cancer diagnosis by several years, and she was treated with 6 months of warfarin with no subsequent events.

The patient was admitted and received intravenous fluids and an infectious evaluation of her stool. The final line of the intern's admitting note also stated that the patient would receive subcutaneous heparin for venous thromboembolism (VTE) prophylaxis, although this was never actually ordered. The patient's care was transferred to a different team the following day, and the accepting intern copied and pasted the plans of the admitting intern into the new note within the electronic health record (EHR). The same note was then copied and pasted on 4 consecutive hospital days and cosigned by the resident and attending, and the patient was ultimately discharged having never received the intended VTE prophylaxis—despite each day's note stating this as part of the plan.

Two days following discharge, the patient developed acute shortness of breath and hypoxia and returned to the hospital, where she was diagnosed with a pulmonary embolus. Only at this admission, and after careful review of the medication record from the previous hospitalization, was it realized that the patient never received any VTE prophylaxis.

Mark My Tooth

The Case

A 45-year-old healthy man was scheduled to have two teeth extracted for progressive dental caries. The patient underwent the extractions, awoke from the anesthesia, and then realized that his upper left molars had been extracted instead of his right. The error was recognized and acknowledged immediately following the procedure. The patient still required extraction of the diseased teeth, which occurred a few weeks later. He developed no significant complication from either surgical procedure other than enduring two rounds of anesthesia because of the error.

Resuscitation Errors: A Shocking Problem

Case & Commentary: Part 1

A middle-aged man presented to the hospital with chest pain. He was stabilized in the emergency department and admitted to the telemetry ward. He later developed torsades de pointes (an unusual form of ventricular tachycardia that can be fatal if untreated) while on telemetry, associated with loss of his pulse. A code blue was called. The cardiology resident arrived and confirmed torsades on the monitor. Defibrillation pads were placed on the patient, but when the nurse tried to connect the pads to the defibrillation unit, the cables did not connect. In the ensuing confusion, it soon became apparent that the pads and the box were not compatible.

Sudden cardiac arrest (SCA) is a leading cause of death worldwide, claiming more than 300,000 lives each year in the United States alone.(1) SCA presents a difficult clinical problem, as it often occurs with little warning and requires a complex set of resuscitative actions to be instituted within minutes. It is perhaps not surprising, therefore, that survival from cardiac arrest is poor, with out-of-hospital SCA survival to discharge generally reported at less than 10%, and survival from in-hospital SCA estimated at 18% from one large national registry.(2-4)

Provided that an electrical shock is applied to the chest quickly, SCA associated with ventricular fibrillation (VF) or ventricular tachycardia (VT) has the best chance of survival. Studies have consistently shown that survival from VF decreases profoundly over the course of minutes in the absence of defibrillation (Figure).(5) Although the provision of cardiopulmonary resuscitation (CPR) ameliorates this effect, this protection wanes quickly. Defibrillation failure rates increase within seconds when CPR is suspended preceding defibrillation.(6)

CPR and electrical defibrillation serve as the essential treatment options for SCA. These therapies are taught to most health care providers, yet performance of these surprisingly complex skills has only recently been objectively measured during actual SCA events and was found to be poor.(7-9) Specifically, CPR parameters are often non-compliant with American Heart Association resuscitation guidelines. Common errors include slow chest compression rates, shallow chest compression depths, hyperventilation, long pauses in CPR before shock delivery, and delivery of electrical defibrillation for non-shockable rhythms. Likely reasons for the variable quality of resuscitation care are infrequent practice of resuscitation skills training by hospital staff and the need for providers to immediately function as a team with others with whom they have not rehearsed.

Unfortunately, defibrillator user errors, such as the one described in this scenario, are not uncommon. In the late 1980s, the Defibrillator Working Group of the U.S. Food and Drug Administration (FDA) reviewed data from the FDA's Medical Device Reporting System (including 1327 reports of defibrillator failures) and from a large number of defibrillator inspections and site visits. They concluded that user errors accounted for most failures and resulted in important defibrillation time delays.(10) Common user errors included holding the defibrillator in a charged state too long (such that the device discharges automatically and requires recharging for actual use), attempting to shock VF in synchronized mode, and inattention to lead selection. These errors have been described in scholarly reviews as well.(11) Additionally, failure to properly maintain and check devices, such that batteries were not properly charged and devices were kept in circulation far in excess of their natural life expectancy of 5–8 years, led to further errors.(10,12) Finally, mismatch of cables with specific defibrillators was described in another published

report.(13) Unfortunately, it is often the case that these errors are only noted during an emergency situation, once cardiac arrest has occurred, such that an equipment problem that might have been easily remedied before an event can suddenly present a major hazard to patient survival.

Case & Commentary: Part 2

The patient remained in torsades until the resident administered magnesium, which resulted in rapid conversion to sinus rhythm. The patient was ultimately stabilized and transferred to the cardiac intensive care unit. He suffered no long-term ill effects.

To reduce avoidable errors, as occurred in this case, the Defibrillator Working Group recommended use of a checklist (see Table) by the clinical operators as well as adherence to a maintenance schedule for both the device itself and accompanying batteries. Additionally, they recommended that all defibrillator users receive training in the specific device(s) they are going to use and continued hands-on experience with the device (in cardiac arrests or training) at least every 3 months to maintain those skills. The recommendation for checklists has been echoed by other experts and has been incorporated into the Advanced Cardiac Life Support (ACLS) guidelines.(14-16)

The Defibrillator Working Group found fewer errors in high-use locations such as emergency departments and critical care units, consistent with the notion that increased experience and frequency of device use result in better familiarity and reduced user error.(10) The availability of different defibrillator models in a given hospital has been shown in simulated situations to result in device confusion and increased time to defibrillation.(17) Uniformity of the make and model of defibrillators has been recommended to address these potential problems.(18)

A variety of methods have been proposed to improve resuscitation care, including increasing the frequency of resuscitation skills training and introducing mock SCA events into clinical care routines. Leadership and group training exercises may help improve team function. Routine incorporation of SCA event debriefing can identify common errors and exploit "teachable moments" for further skills improvement. With regard to equipment usage and supply errors such as those described in this case, whenever possible, equipment should be standardized across an institution or health service provider. This is particularly difficult in larger institutions with many distinct cost centers purchasing defibrillators at varying times. In this case, institutional recommendations for devices should be made widely accessible by resuscitation leadership, such as the hospital CPR or "code" committee, so that uniformity can be maintained when an individual clinical unit seeks to replace outdated equipment. All potential rescuers should receive hands-on,

device-specific training, with refreshers every 3 months for those in low-use clinical areas.

With regard to equipment problems such as those described by the case in question, a daily (or per shift for high-use areas) equipment checklist should be completed by a member of the resuscitation team or assigned nurse located on a given unit or ward. Specifically, a checklist should be used that ensures that there is no damage to the device, that all components match the device and attach correctly, that the defibrillator battery is charged, and that the device is plugged into wall power for recharging (see Table). Since performing this checklist is a way of familiarizing oneself with the device, as many of the potential rescuers as is reasonable should be taught to perform these inspections and rotate in that responsibility. Biomedical technicians or engineers should perform additional checks every 6 months or as recommended by the manufacturer.

Case & Commentary: Part 3

This incident prompted a major review of code blue procedures, an inventory of the types of defibrillator machines and pads, and an effort to crosscheck machine–pad compatibility. The review resulted in the machines and pads being standardized at this particular hospital, in an effort to eliminate the possibility of this error in the future.

The case detailed here illustrates an all-too-common user error that ultimately reflects a larger systems error. It resulted from having multiple devices in one institution and from failing to use a thorough checklist procedure. Such checklists are a proven tool in such industries as aviation, where a highly complex set of equipment must function correctly with essentially zero tolerance for error. However, it must be emphasized that instituting a checklist is necessary but not sufficient—as in aviation, staff must be educated as to the crucial need to strictly follow checklist procedures and must be motivated to embrace a culture of safety that incorporates such tools. CPR committees at hospitals can serve as crucial champions in this systems approach and should advocate strongly for uniformity of devices and equipment as well as for routine device education and assessment. In this important process, CPR committee members and physician champions for resuscitation care should partner with nurse educators through the hospital system to achieve these objectives. Through such advocacy, resuscitation equipment can become both familiar and safe, and cardiac arrest care can be approached with greater confidence by all members of the hospital team.

Informed or Misled?

The Case

A 50-year-old man arrived at the hospital for an elective total knee replacement. Based on preoperative discussions, the patient expected to receive spinal anesthesia. The patient reportedly signed an anesthesia permit required by this hospital that stated that any change in the anesthesia plan must occur in writing. For unclear reasons, the patient ultimately received general anesthesia and suffered the adverse outcome of permanent unilateral hearing loss with tinnitus, an unusual complication. The anesthesia records failed to note or explain any change in the anesthesia plan. The patient was understandably upset about his hearing deficit and also angry about the unexpected change in his anesthesia plans.

Abnormal Volunteer Results

The Case

A healthy 52-year-old woman volunteered to participate in a radiology study in which she underwent magnetic resonance imaging (MRI) of her abdomen and pelvis. Several weeks later, she received a phone call from the study coordinator reporting that a "major abnormality" was discovered on her MRI. She was told to see her doctor as soon as possible. After seeking further evaluation, she was diagnosed with uterine cancer and started on chemotherapy. While her diagnosis was likely hastened through her participation in the research study (as she expressed no symptoms), the patient wondered whether the delay in reporting the MRI findings to her led to growth in the cancer prior to starting treatment.

Beeline to Spine

Case & Commentary: Part 1

An 83-year-old man with coronary artery disease, mild heart failure, a history of repaired abdominal aortic aneurism (AAA), and prior lumbar disk disease (status post L5-S1 fusion) was scheduled for a fusion-augmentation surgery by orthopedics. The patient noted a bulging mass in the middle of his abdomen a few months prior to surgery but did not report this to his providers. Laboratory tests sent for a voluntary medical research study showed an elevated alkaline phosphatase to nearly 800 U/L. These results were reviewed by his primary physician, but no action was taken.

Preoperatively, the patient was evaluated by both the anesthesiology and surgery teams. Given the prior AAA repair, the patient underwent surgery in the

supine position. The fusion augmentation was uneventful, and he was discharged home.

The decision to undergo major surgery requires a careful assessment of the risks and benefits of the proposed procedure. This assessment must appreciate the reality that surgery is a morbid event. For example, the mean 30-day mortality rate in a recent study of 5878 patients undergoing major surgery was 1.5%.(1) Perioperative mortality rates, stratified by American Society of Anesthesiologists' (ASA) Physical Status Class for class I through V, were 0%, 0.2%, 2.2%, 15.2%, and 70%.(1) Postoperative medical complications represent an important source of this morbidity and mortality. The most important medical complications are cardiac, pulmonary, and venous thromboembolic. Preoperative medical evaluation should include a consideration of each of these three sources of risk.

More broadly, clinicians performing a routine preoperative medical evaluation should address several issues. The first is to identify factors that would increase the risk of perioperative complications above baseline and to stratify risk for the principal complications. The second issue to consider is whether preoperative laboratory testing would add to this risk assessment or potentially uncover important risks that would have escaped clinical detection. The next step is to recommend strategies to reduce these risks to the extent that they are modifiable. Finally, the preoperative medical evaluation provides an opportunity for collaboration between medicine, surgery, and anesthesia colleagues. Instances in which such collaboration is particularly important include identification of a previously unrecognized important risk factor, a determination that the risks of the surgery may potentially exceed the benefits, or a recommendation for risk reduction strategies that include the intraoperative and immediate postoperative period.

A careful history is the most important element of the preoperative evaluation. This history seeks evidence for major risk factors for medical complications as well as factors that would influence anesthetic technique and management. Many institutions have developed standardized checklist forms to facilitate the anesthesiologist's preoperative evaluation. Table 1 provides one published questionnaire and the degree of concordance between patient responses and an evaluation by an anesthesiologist.(2) The medical consultant typically does not use a standardized questionnaire but focuses in detail on the impact of established chronic illnesses and potential risk factors for major postoperative medical complications. Guidelines exist to estimate risk of cardiac, pulmonary, and venous thromboembolic complications.(3-6)

Routine preoperative laboratory testing adds little to the clinical estimate of risk. Abnormal tests are uncommon, and most can be predicted on the basis of known medical problems. For example, a large review of a broad array of

potential tests found that the incidence of abnormalities that influenced preoperative management ranged from 0%–3% (Table 2).(7) In all cases, the negative likelihood ratio approached one (meaning that a normal test result does not materially reduce the risk of medical complications). The impact of positive test results is modest; positive likelihood ratios range from 0–4.3. Based on these types of analyses, most institutions in recent years have reduced the number of required preoperative tests. For example, the National Institute for Clinical Excellence (NICE) in Great Britain published recommended standards in 2003.(8) If we apply these standards to our patient, he would receive a complete blood count, renal function tests, and an electrocardiogram. If we apply the recommendations of the above mentioned systematic review (7), he would also receive a chest x-ray.

In this 83-year-old patient, his age and comorbidities would put him at higher risk for cardiac complications, and to a lesser extent, pulmonary problems (back surgery is an intrinsically low-risk procedure for pulmonary complications). According to the Revised Cardiac Risk Index, his estimated risk for postoperative cardiac complications would be 6.6% (9), representing the source of his greatest potential morbidity. His preoperative assessment, including recommendations for risk reduction strategies, should focus on this area. He should also receive appropriate prophylaxis to reduce the risk for surgical site infection (SSI) (10) and venous thromboembolism (VTE).(6) In most institutions, these two areas of prophylaxis are standardized according to a particular surgical specialty and the nature of the specific procedure. In such a scenario, every patient would receive the same SSI and VTE prophylaxis unless a specific contraindication existed. For example, according to standardized, preprinted, routine preoperative orders for back surgery, he may receive a single intravenous dose of 1 gram of cefazolin within 1 hour before the incision. Thus, the responsibility in this case for ensuring that the patient receives SSI and VTE prophylaxis would normally fall to the surgeon.

Case & Commentary: Part 2

One week later, the patient was readmitted with frank jaundice, abdominal pain, and diarrhea. Physical examination revealed a 4x4 cm, easily palpable mass protruding from his mid-abdomen. Computed tomography (CT) scan revealed a widely metastatic pancreatic cancer. There was massive tumor burden along the peritoneum and adjacent to stomach, liver, and bowels. A cancer antigen (CA) 19-9 level was extremely high. When told of his diagnosis of metastatic cancer, the patient immediately said that he wished he had never undergone the spinal surgery.

This response from the patient is completely expected and reasonable. Had he known that he had unresectable pancreatic cancer, with a likely life expectancy of less than 6 months, the most reasonable approach would have

been to cancel elective back surgery. Instead, he underwent unnecessary surgery that conferred risk, took time from his remaining months of life, and resulted in a potential for postoperative pain and complications.

There were several opportunities to prevent this error. The patient had abnormalities in all three elements of the preoperative evaluation: the history, physical examination, and laboratory tests. A careful history that included an open-ended question such as "Do you have any other symptoms or concerns about your health that we didn't already discuss today?" may have captured his concern about the abdominal mass.

According to this case scenario, the abdominal mass was easily palpated; it almost certainly would have been of similar size during his preoperative evaluation. However, I can't fault his physicians on this point. A "complete" physical examination, such as that which would be performed as part of a periodic health exam in a primary care setting, is not required before elective surgery. Examination of the abdomen would not normally be part of the minimum required physical examination before back surgery. A suggested minimum examination includes vital signs and an assessment of the airway, chest, and heart.(11) Additional examination elements would be based on his medical history. So we fall back to the history: did the patient mention the mass or abdominal pain? If he had, each involved physician would have had an opportunity to identify the mass on examination.

Should the elevated alkaline phosphatase have been a clue to his underlying cancer? Unfortunately, in the fragmented system of American health care, the operative team's ability to access laboratory results (or other key patient data) often depends on whether this test was part of the patient's hospital medical record and whether his primary care doctor used the hospital laboratory for blood tests. If a test was performed by an outside laboratory as part of the medical research study, as in this case, only a paper copy may have been in the doctor's office records. If the primary care doctor was community based, and not part of hospital-based practice at the site where his surgery was planned, this test result may not have been available to other physicians involved in his care. Obviously, this situation begs for a unified medical record [such as if the community-based primary care physician used an electronic medical record (EMR) that was part of the hospital's network] or other methods for patient data to cross silos of care.

Communication in the preoperative setting is particularly challenging when physicians practice in different sites and have no access to each other's medical records. In such a setting, each doctor has a responsibility to follow through on any identified factors that may increase risk. This may require a phone call or an email communication to be sure that all doctors are "on the same page." Mandatory formal preoperative assessment clinics are one strategy to identify patients who need additional preoperative evaluation,

optimize medical conditions, and potentially improve outcomes. In one study, for example, anesthesiologists developed a preoperative assessment clinic for patients undergoing vascular surgery, a procedure with a particularly high morbidity and mortality rate.(12) Among 234 patients seen in this clinic, the anesthesiologist identified 26 patients who required further evaluation or were unsuitable for surgery due to significant comorbidities. Despite a modest sample size, the authors found a significant reduction in mortality rates among patients undergoing infrarenal aneurysm repair who visited the preoperative clinic when compared to those who received usual care (4.8% vs. 14.5%). In another study at Brigham and Women's Hospital in Boston, 565 of 5083 patients seen in a preoperative clinic required further information regarding known medical problems, and the authors identified an additional 115 patients with new medical problems.(13) Among the patients with new problems, 20% required review of previous medical records or test results (as could have potentially been the case in this patient) and 80% required additional testing or consultation.

Patients at highest risk for poorly coordinated care are those with multiple physicians, those without a primary care physician who is actively involved in their care, those who receive care from doctors who belong to different health delivery systems with separate information technology systems, those from disadvantaged settings who receive much of their primary care in emergency departments, and those who are less medically literate and are thus less able to describe their detailed medical histories.

Case & Commentary: Part 3

Review of the preoperative assessment by anesthesia and orthopedics revealed no mention of an epigastric mass nor of the markedly abnormal alkaline phosphatase.

Unfortunately, no clear guidelines or written policy statements articulate the ultimate responsibility of each physician before surgery. As a generally accepted standard of care, the consulting primary care physician would be responsible for evaluating all factors that play into the risk-benefit considerations before surgery. In most instances, the primary care physician would have access to the most complete set of medical records and, by virtue of a long-term relationship with the patient, would be most likely to know all details of the relevant past medical history.

With regard to laboratory data (such as the alkaline phosphatase), evidence suggests that a normal test result obtained within the past 4 months can be used as a preoperative test as long as there has been no change in the clinical status of the patient.(14) The primary care physician is responsible for reviewing recent laboratory tests to determine if any results impact

preoperative assessment, and to determine which, if any, should be repeated before surgery.

Alkaline phosphatase would never be a routine preoperative test.(7) However, the abnormal finding of a markedly elevated result in this patient would require further evaluation, independent of the planned upcoming surgery. In an elderly man, cancer (pancreatic, biliary, liver, or metastatic disease to liver) would be the most likely cause of an asymptomatic elevation of alkaline phosphatase. Gallstone disease or intrahepatic cholestasis would each be less likely. It would be necessary to further evaluate the patient and exclude cancer before any consideration of elective surgery. The primary care physician not only failed to consider the impact of a very high alkaline phosphatase on the risk for surgery, he or she failed to undertake an appropriate evaluation independent of the patient's planned back surgery.

The anesthesiologist conducting a preoperative evaluation would normally not be expected to undertake a similarly extensive evaluation nor to obtain office notes from the primary care physician. The anesthesiologist's preoperative evaluation would focus on factors that increase anesthetic risk or modify anesthetic technique. The surgeon would usually defer to the primary care physician regarding medical appropriateness for surgery and the need for any further preoperative medical evaluation. Having said this, it would still have been possible for either of these physicians to have identified this cancer before surgery by asking an open-ended question, such as "Do you have any other health issues or concerns that you would like to discuss before surgery?" or by performing a physical examination.

This case illustrates the importance of a complete preoperative evaluation, the need for meticulous communication among providers, and the potential pitfalls of non-centralized medical information. Dedicated preoperative clinics may reduce the risk of poor outcomes by uncovering risk factors and by recommending additional evaluation or evidence-based risk reduction strategies. The history and physical examination remain the cornerstones of preoperative evaluation.

On the Other Hand

The Case

A young woman with Takayasu's arteritis presented to the hospital with severe abdominal pain. The patient had been diagnosed with Takayasu's a decade earlier. The disease results in arterial stenoses, which can cause ischemia in a variety of organs. One of the diagnostic clues is differential blood pressure (BP) in both arms (if there is more arteritis in one of the arm arteries than the other), and in fact the patient had been noted in the past to

have very different BPs in her right and left arm. This had been recorded in her chart but was not noted in her hospital room or on her person.

The patient was admitted at 6:00 p.m. to the intensive care unit (ICU) for monitoring, pain medication, and intravenous (IV) hydration, in preparation for vascular surgery the next morning. The IV, with normal saline, was started in her left arm.

During the night shift, the midnight BP measurement using the right arm revealed a very low pressure (approximately 70 systolic). The nurse notified the covering resident, giving him a concise description of the patient, her primary admitting diagnosis, the surgery plans, and a report of the vital signs. The resident, who had been given only a brief signout on the patient (that did not include the history of different BPs in the two arms), was quite worried about the hypotension and ordered Levophed (norepinephrine), a powerful IV pressor. He did not examine the patient—if he had, he would have found that her mental status was normal, which might have been a clue that the true BP was not as low as the reading. The nurse took the resident's verbal order for the medication and administered the drug.

When the surgical team arrived in the morning, they were puzzled by the low BP (since the patient appeared to be otherwise stable) and asked that the BP be reassessed, once in each arm. When the pressure was measured in the left arm, it was noted to be within normal range, even as the pressure in the right arm was still very low. The team immediately discontinued the pressor order, believing that the patient's true BP was the one from the left arm, and that the right arm reading was due to local vascular narrowing. Although giving a vasoconstricting medication to a patient with narrow blood vessels could have had catastrophic effects, no adverse outcomes were noted in this case.

Production Pressures

The Case

A 65-year-old man with bipolar disorder was scheduled for maintenance electroconvulsive therapy (ECT), a procedure he had received dozens of times before. These procedures are usually administered in the morning by an anesthesiologist. Later in the morning, that anesthesiologist staffs the preoperative anesthesia clinic. A second anesthesiologist in the group spends the day in the operating room (OR) supervising three nurse anesthetists.

On the day of the scheduled ECT, the clinic anesthesiologist called in sick. The service, which had no policy to cover unexpected absences and rarely cancelled a case, scrambled to try to cover the ECT procedure, finally asking the OR anesthesiologist to attend on the case. He protested, noting that he

was already responsible for overseeing the anesthesia for three surgeries in the OR. But finally, to avoid delays in the ECT administration, he reluctantly agreed to come to the day surgery unit to perform the quick (usually less than 10 minutes) procedure.

After the ECT was performed, the patient did not wake up promptly as expected. The anesthesiologist checked his medication cart and realized that he had inadvertently administered the intermediate-acting muscle relaxant rocuronium, instead of the short-acting agent succinylcholine. He later attributed this error to being rushed and stressed, leading him to pull the wrong vial from the refrigerator. He had never made this mistake before.

The patient was given more sedation to prevent awareness and bag-and-mask ventilation to support his respirations. After about 30 minutes, his neuromuscular blockade was pharmacologically reversed with neostigmine. The patient was informed of the error, and there were no long-term adverse consequences

Antiseizure Medication Disorder

Case & Commentary: Part 1

A 76-year-old man was admitted for evaluation of increasing lethargy, confusion, and decreased appetite. The patient had a past medical history of seizure disorder with a recent admission for uncontrolled seizures, anemia, and hip arthroplasty. His medications included phenytoin 300 mg once a day, phenobarbital 30 mg three times a day, risedronate 35 mg once a week, and iron supplements. On physical examination, his vital signs were unremarkable and he had no fever. By report, neurological exam revealed only confusion and diminished deep tendon reflexes. Laboratory data were significant for a slightly elevated white blood cell count (WBC) and abnormal urinalysis, with 6–10 WBCs. A phenobarbital level was 30 (therapeutic, 10–40 mcg/mL), and phenytoin level was 19 (therapeutic, 10–20 mcg/mL). The rest of his electrolytes, renal function, and liver function tests [aspartate aminotransferase (AST), alanine aminotransferase (ALT), bilirubin, and alkaline phosphatase] were normal. Computed tomography (CT) scan of the head was unremarkable. The providers thought that the patient's mental status change was likely due to urinary tract infection and effects of phenobarbital. The patient was treated with antibiotics, and his phenobarbital was held.

This patient—an elderly man taking phenytoin and phenobarbital chronically for a "seizure disorder"—probably has epilepsy, a disorder characterized by epileptic seizures that recur spontaneously. Epilepsy affects approximately 2 million people in the United States.(1) Antiseizure medications, which control seizures successfully in approximately two-thirds of patients, are the primary

mode of treatment.(2) More than 15 antiseizure medications are commonly used in the United States. The ultimate drug choice is usually made based on patient-specific considerations, including predominant seizure type, drug–drug or drug–disease state interactions, and unique medication-related adverse effects.

Over the past 13 years, many new antiseizure medications have been introduced. Although most of them were initially approved for patients who fail to respond to "standard" agents, some of these newer drugs (e.g., oxcarbazepine, lamotrigine, topiramate) are being used as initial therapy in newly diagnosed epilepsy. In general, the newer medications appear to be equally effective in suppressing seizures as standard drugs and to have many fewer drug interactions than the older "enzyme-inducing" (e.g., phenytoin, carbamazepine, phenobarbital) or "enzyme-inhibiting" (e.g., valproate) drugs.(3) The clinical activity of the standard and new antiseizure drugs against various common seizure types is shown in the Figure. Ease of use is clearly a prominent factor for clinicians in the choice of antiseizure medication. For example, levetiracetam (Keppra), although not FDA-approved for use in newly diagnosed epilepsy patients, is emerging as a common first-choice agent in both hospital and ambulatory settings. Levetiracetam has the advantage of no significant drug-drug interactions, and, unlike most antiseizure drugs, which must be gradually titrated to an effective dose over several weeks, the starting dose of levetiracetam has been shown to effectively suppress seizures.

Antiseizure medications are not easy to use. In a recent study of hospitalized Medicare patients, antiseizure drugs were the seventh most common drug class associated with adverse drug reactions (ADRs)—an important finding given that only 3% of the 8 million inpatients studied were prescribed these medications for seizure disorders.(4) Antiseizure drugs are also used for select psychiatric disorders and for neuropathic pain management.

The safe prescribing and monitoring of antiseizure drugs are challenging for several reasons:

- There is significant interpatient variability in the dosages needed to achieve the twin goals of freedom from seizures and tolerable adverse effects.
- The therapeutic index (ratio between toxic dose and therapeutic dose, a measure of the relative safety of medications) of many antiseizure agents is low.
- Many antiseizure medications have complex pharmacokinetics and drug interactions (particularly older drugs such as phenytoin, phenobarbital, and carbamazepine).

It is likely that all of these features contribute to the relatively high rate of ADRs with these drugs.

Most antiseizure medications are begun at low doses and gradually titrated upward based on clinical response. In patients with infrequent seizures, doses are increased to a serum concentration or daily dose that is generally effective. With older antiseizure drugs, the approach of targeting a serum concentration is usually favored, while a daily dose target is more useful with newer drugs because of the surprisingly poor correlation between serum concentrations of these agents and clinical response. For patients who need rapid protection from seizures, loading doses of select medications can be used, such as oral or intravenous phenytoin, intravenous valproate, or intravenous phenobarbital. Benzodiazepines can be given for near-immediate protection (e.g., intravenous lorazepam for status epilepticus) or as "bridge therapy" (e.g., scheduled oral doses of clonazepam for patients with seizures that have increased in frequency) until an effective oral maintenance dose can be attained. Examples of some of the more common dosing errors made with antiseizure medications are given in Table 1. Additional information on appropriate dosing of antiseizure drugs in adults is given in Table 2.

Case & Commentary: Part 2

Despite these interventions, the patient continued to be confused. A neurology consult was obtained. Review of the laboratory data revealed a serum albumin of 2.4 g/dL. This led to the calculation of a corrected phenytoin level: it was 33 (therapeutic, 10–20 mcg/mL). Phenytoin was held, and the patient's mental status returned to baseline in 72 hours.

Early clinical symptoms of dose-related phenytoin toxicity include dizziness, drowsiness, lethargy, and visual disturbances. As phenytoin levels continue to rise, ataxia and confusion may occur. Less commonly, patients experience an increase in the frequency or severity of seizures during phenytoin intoxication. In hindsight, this patient demonstrated some, but not all, of the classic symptoms of phenytoin toxicity. No mention is made of a medication-related change that might explain the elevated phenytoin level. When phenytoin toxicity is suspected, patients should be queried regarding recent dosage adjustments, changes in product appearance, and alterations in concomitant drug therapies that might influence phenytoin serum concentration (e.g., the addition of a phenytoin metabolism inhibitor such as cimetidine or the removal of a phenytoin metabolism inducer such as rifampin). As is clear from this case, a phenytoin blood level can be quite helpful even when there is no reason to suspect a change in phenytoin response.

Phenytoin is one of the drugs most commonly associated with preventable clinically significant adverse events.(5) Although the drug is highly effective, it

has complex pharmacokinetics and requires careful monitoring and dosage adjustment, particularly in the elderly. The enzymes responsible for phenytoin metabolism (primarily CYP2C9 and CYP2C19) are saturable at drug concentrations near those used in clinical care. The consequence is that even small dosage changes can result in disproportionate changes in phenytoin blood levels and pharmacologic response. While equations can be used to calculate the dosing increment that would achieve a desired increase in phenytoin blood level, a simplified schema for adult patients is to limit dosage increases to 30–50 mg per day, and to increase dosages no more frequently than once every 1 or 2 weeks.

Some knowledge of phenytoin protein binding and the influence that protein binding variability has on phenytoin serum level interpretation is necessary to understand the error that occurred in this case. Phenytoin is approximately 90% bound to plasma proteins, primarily albumin. When considering a phenytoin drug level (such as "the therapeutic range of 10–20 mcg/mL"), it is important to realize that the level represents the total of both protein-bound drug and unbound phenytoin concentrations in serum. However, only unbound phenytoin has access to tissue sites that are responsible for phenytoin efficacy and toxicity.(6) Thus, a total (bound + unbound) phenytoin concentration value—the result reported by most clinical laboratories as the "phenytoin level"—is an indirect measure of the pharmacologically active (unbound) concentration.

Several factors can alter phenytoin protein binding and disrupt this normal 9:1 ratio of bound:unbound phenytoin (see Table 3). In the presence of these factors, phenytoin dosing need not be automatically altered; rather, the interpretation of the "serum phenytoin level" requires special consideration and care. Two common approaches are either to (i) order an unbound phenytoin level to see whether it falls within the unbound therapeutic range of 1–2 mcg/mL or (ii) use calculation methods to adjust the reported total phenytoin serum level to the value that would be expected if protein binding were not perturbed. I generally prefer to check the unbound phenytoin concentration, since calculation methods are not always accurate. For those who wish to use the second method, Table 4 shows how to correct a total phenytoin level for hypoalbuminemia. A different equation is used to correct phenytoin levels for end-stage renal disease, another common source of altered free phenytoin concentrations (Table 4).(7) Since an unbound phenytoin concentration was not reported in this case, the equation in Table 4 was likely used to estimate that this patient's phenytoin level (corrected for hypoalbuminemia) was approximately 33 mcg/mL. This finding led to the appropriate next step—holding phenytoin—which resulted in recovery of the patient's mental status.

Why did it take the patient 3 days to recover? This is not an unusual time course, since the rate of decline in phenytoin concentrations is often

surprisingly slow when toxicity is due to high concentrations of unbound phenytoin. This phenomenon can be explained by saturable metabolism; at high serum levels, phenytoin half-life is much longer than it is at lower drug levels. Thus, the half-life of phenytoin not only varies between individuals, but it also varies *within* an individual depending on the serum concentration at any point in time. In this particular circumstance, the clinical dictum that "phenytoin half-life is about 24 hours" is inaccurate, which is why it took so long for the patient's mental status to recover. This is an important concept to recall—failure to do so might leave caregivers doubting their diagnosis of phenytoin toxicity on day 2 and embarking on inappropriate tests or treatments.

Given the complexity of this situation, one wonders whether a system-level solution might be helpful. Some institutions have in fact replaced total serum concentration monitoring with assays to measure only the unbound ("free") concentration of phenytoin, an intervention that would likely have prevented this case's error or more rapidly led to its recognition. Since such monitoring is more expensive and more time-consuming for lab personnel (an additional manual step is required to dialyze the sample across a filter membrane), one approach to targeting the use of unbound phenytoin monitoring would be to require that it be reported in patients with hypoalbuminemia or end-stage renal failure, which could be automatically triggered by a laboratory decision support engine. Since albumin concentrations are often low in hospitalized patients, another system-level intervention of potential value would be to require an albumin level determination within 30 days of any phenytoin level request. However, even in patients with no apparent alteration in protein binding (i.e., patients who lack any of the features listed in Table 3), unbound phenytoin concentrations more closely correlate with clinical status.(8) Thus, reporting unbound concentration may be preferred for all patients who require phenytoin monitoring.(9)

Another system intervention that can improve standardization of drug therapy—and has been shown to improve both economic and clinical outcomes with antiseizure drug therapy—is implementation of pharmacist monitoring and adjustment of these agents.(10) In 2003, 75% of U.S. states had enacted laws or practice act amendments to permit the enhanced involvement of pharmacists in direct drug therapy management, and, at present, the fastest growing clinical pharmacy service in U.S. hospitals is pharmacist-managed drug therapy.(10,11) Given a national shortage of pharmacists in the United States and their costs, even health care systems and hospitals that cannot afford widespread clinical pharmacist coverage might do well by considering targeted coverage in high-risk prescribing areas, such as antiseizure medications, pain medications, and anticoagulants.

Staggered Sensitivity Results

The Case

A 60-year-old woman with squamous cell carcinoma of the glottis underwent laryngectomy, anterior neck dissection, and pectoralis flap reconstruction of the anterior esophagus. Postoperatively, she was started on clindamycin for surgical site infection prophylaxis. On postoperative day three, increased drainage from the surgical site was noted, which progressed and required a return to the operating room for exploration on postoperative day six. The site revealed purulent material with involvement of the jugular sheath. Cultures of the wound were taken, and the site was irrigated and re-closed.

Two days later, the wound cultures grew *Staphylococcus aureus*. Per hospital protocol, the microbiology laboratory called the nursing unit to report the positive culture, and the patient's nurse informed the physician team. Clindamycin was continued. Three days later, a final sensitivity profile for the *S. aureus* isolate returned, showing resistance to clindamycin. Hospital policy does not call for notification to clinicians by the microbiology lab when a "preliminary" culture result becomes "final" (when final sensitivities become available). At this facility, physicians view laboratory results in a scrolling text–based computer system, which presents results in chronological order according to the time of specimen collection. The final microbiology result and the critical sensitivity results in this case remained in chronological order (now 5 days prior). The physicians did not view the updated culture results, and the patient remained on clindamycin.

The next day, the right internal jugular vein ruptured, and the patient was taken emergently to the operating room. A widespread infection of the surgical site with destruction of the jugular sheath and erosion into the internal jugular vein was noted. The internal jugular vein was ligated and sacrificed. The patient died of sepsis and multiorgan system failure 3 days later.

Back to Basics

The Case

A 48-year-old woman with insulin-dependent diabetes mellitus presents to the emergency department with right upper quadrant pain, fever, and leukocytosis, prompting admission for presumed cholangitis. Overnight, the patient was made NPO (nothing by mouth) in anticipation of an endoscopic retrograde cholangiopancreatography (ERCP) the following morning. The admitting medical team ordered an insulin sliding scale for the patient, and her blood glucose levels became very difficult to control in the ensuing hours. In the morning, the patient developed an anion gap and evidence of mild diabetic ketoacidosis. The physician evaluating the patient in the morning

realized that no basal insulin was ordered and instituted a more appropriate regimen of insulin, and the patient underwent an uneventful ERCP and hospitalization.

Failure to Report

Case & Commentary: Part 1

A well-appearing 9-month-old infant weighing 8 kg presented with urinary frequency and white cells in her urine. The emergency department (ED) physician ordered Rocephin (the brand name for the antibiotic ceftriaxone), 450 mg intramuscularly (IM), for empiric treatment of a urinary tract infection (UTI) to be given immediately.

Several hours later, when removing another vial of ceftriaxone from the automated dispensing cabinet (Pyxis), the nurse noted that there were two vials in the drawer instead of the expected one. In the medicine administration area, the nurse found a partially empty vial of parenteral cefazolin, a different antibiotic that had not been ordered for any patient that night. On the top of the vial was a chalky dried substance, and the admixture remaining in the bottle was cloudy. In this institution, ceftriaxone is routinely mixed with 1% lidocaine to decrease postinjection pain. The resulting mixture is clear and colorless. It was concluded that the infant most likely received 450 mg of IM cefazolin instead of the intended 450 mg of ceftriaxone.

The medications are routinely ordered by the ED physicians as "Rocephin" and "Kefzol" but stocked as "ceftriaxone" and "cefazolin" (Figure). The vials, in the three sizes used to make the admixtures, are all contained in the same Pyxis drawer.

The error-producing conditions that most likely contributed to this mistake—similarly named medications stored in close proximity and an environment predisposed to distractions—should be recognizable to caregivers, as these factors are common causes of medication administration mistakes.(1) These conditions increased the likelihood that the nurse would get the wrong medication from the automated dispenser. Retrieving medications is something nurses do many times during a shift, and, most of the time, it goes as planned. In the few instances when the wrong medication is obtained, it is most often recognized and corrected before administration occurs. In this case, the usual safeguards such as double-checks and read-backs failed, allowing the error to reach the patient. What was different this time? An interview with the nurse involved might provide a clear answer, although the mistake would most likely be attributed to an unexplainable lapse in following procedures.

The nurse's failure to confirm the medication's identity prior to administration falls into the category of an "unsafe act." Merely telling the nurse to be more careful next time does little to improve the safety of the system, especially when the nurse involved in this event is probably the least likely person to repeat the error. To prevent unintentional unsafe acts—slips, lapses, mistakes, or procedure violations—the contributory factors and latent conditions must be resolved.

The contributory factors in this event fall into the environmental category. Some hazards in this category are easier to overcome than others. Periodic pharmacy inspections of all drug storage areas, including automated dispensing cabinets, can be used to identify and resolve unsafe conditions.(2) Separation of inventory will reduce mix-ups caused by look-alike/sound-alike drugs.(3)

The safety hazards caused by a distracting environment are not as easily fixed. Interruptions during drug retrieval may be minimized by creating a zone of safety around the medication storage area. This can be done by either moving medication storage to a quieter location or creating some type of "Do Not Disturb" signage that is posted by the storage area during times when medications are being retrieved. Facilities using this strategy have found that people are less likely to disturb a nurse preparing a medication for a patient when there is a visual reminder.(4,5)

The latent conditions underlying this event must be understood by asking why these situations were allowed to exist. In other words, why are sound-alike drugs stored in close proximity and why haven't steps been taken to reduce cognitive overload on caregivers even though it is well known that both of these factors contribute to medication errors? Often, complacency is the culprit. When the work environment is normally reliable, safe, and accurate, it is easy for people to become complacent—a belief that past experiences will repeat themselves in current situations. Trusting that "the process will not fail" or "a problem will not happen to me" is a latent condition that causes individuals to let down their guard. This trust in the system can also contribute to organizational complacency, creating an environment that lacks a sense of urgency about patient safety.

If nothing is done to reduce complacency, it will undermine the effectiveness of tactics aimed at resolving the contributory factors. Overcoming individual and organizational complacency requires an ongoing dialogue about patient safety with the goal of creating greater awareness of what can go wrong and greater willingness to reduce potential risks and safety hazards.(6)

Case & Commentary: Part 2

The nurse who had given this medication was very upset and spoke with the ED physician on duty about the event, as 450 mg of IM cefazolin is an overdose for an 8-kg baby. The nurse was informed that the medications were essentially equivalent and did not pursue the matter further or report the error to her supervisor or through the institution's incident reporting system.

When the physician failed to acknowledge the potentially harmful medication error, caregivers missed a chance to protect future patients from harm. Undoubtedly, this was not the physician's intention, yet this is a common "knee jerk" reaction following an error. While some observers have attributed this reaction to the medical profession's "conspiracy of silence" (7,8), it is actually a very natural human impulse to hide mistakes so that potential problems or conflicts can be avoided. Couple this natural impulse with professional attitudinal barriers and individual feelings of helplessness, fear, and anxiety, and we have a situation in which it is difficult to admit that a mistake occurred. Without interviewing the physician in this case, the reason for not acknowledging the error is unknown. Because health care professionals often treat their mistakes as personal failures, I'd speculate that the physician may have wanted to protect the nurse and him- or herself from feelings of guilt.(9)

This is an unfortunate case from two perspectives. First, the child received an overdose of antibiotics. By not acknowledging the mistake, the health care team made no attempt to inform the parent of what happened so that potential effects could be mitigated. Second, and just as important, a learning opportunity was lost. How many other patients must be harmed by similar mistakes before the factors that led to the mistakes are fixed?

Learning could have occurred at two levels. Even if a formal incident report was not completed, the physicians and nurses in the unit could have participated in a frank discussion about what had happened and how future mistakes of this type could be averted. One tool drawn from crew teamwork training in aviation is self-critiquing, a team activity that involves debriefing of recently completed activities.(10,11) Such discussions also foster a team awareness of failures, which can help reduce complacency—a probable latent condition in this case. Instead, the message that may have been imparted is, "When things don't go right, hide the mistake" rather than "When things don't go right, openly discuss how to keep it from happening again."(12) By completing an incident report for this event, the learning opportunity would have been expanded to the entire organization.

It is impossible to determine the rate of unacknowledged medical mistakes, especially in the absence of an untoward outcome. Even when caregivers concede that a mistake has been made, it often goes unreported—impeding organizational learning and often individual learning. Underreporting of adverse events is estimated to range from 50% to 96% annually (13,14), and

underreporting of no-harm or "near miss" errors is even greater.(15) How to improve reporting has become a much-researched question in recent years, with the reasons for nonreporting found to be many and varied.(16)

How can health care organizations make reporting a regular part of individual practice? It is tempting to persuade compliance with arguments such as:

- "It's your professional duty."
- "The incident database will help identify improvement opportunities."
- "We can see if our safety improvement efforts are making a difference."

While these are convincing reasons to report incidents, they may not be persuasive enough. For an individual to report an incident, the most important factor is safety—not the patient's, but his or her own. The people must feel safe from undeserved disciplinary action or retaliation. A study of hospital nursing units found that higher reporting rates were correlated with unit members' perception of the risk of discussing mistakes openly.(17) Where there was a climate of fear, willingness to report mistakes was reduced. Other factors that are known to influence reporting (18) are:

- uselessness (perceived attitudes that management would take no notice and was not likely to do anything about the problem);
- acceptance of risk (incidents are part of the job and cannot be prevented); and
- practical reasons (too time consuming or difficult to submit a report).

To encourage reporting, organizations need to minimize these factors and create a forgiving environment in which people feel "psychologically safe" to acknowledge errors. Strategies that have proven to be effective are summarized in the Table. These strategies are central to the success of many incident reporting initiatives. For example, in the 2 years following addition of a 24-hour call center, incident reports submitted to the South Australia Department of Health increased by 275%.(19) The rise in reports was attributed to enhanced reporting accessibility as well as the new culture of openness. A nonpunitive culture and assurance of reporter confidentiality are two factors that have influenced the success of the incident reporting system at the Veterans Health Administration. In the first 5 years since its inception, more than 140,000 incident reports were submitted.(20) Availability of a secure Internet site for anonymous event reporting contributed to a high rate of submissions to the neonatal intensive care incident reporting project sponsored by the Vermont Oxford Network.(21) During patient safety executive walkarounds, leaders at Kaiser Permanente San Diego (CA) Medical Center personally speak with physicians and staff about the importance of learning from mistakes. Leaders' ongoing reinforcement of the organization's "just culture" has contributed to an increase in reporting and discussion of errors and near misses.(22) Visible improvements are another factor influencing

reporting in the Kaiser Permanente initiative. Physicians and staff see that when incidents are reported, problems do get fixed.(23)

Rapid Mis-St(r)ep

The Case

A 5-year-old girl was brought to an urgent care center by her father with a 2-day history of fever to 103°F, sore throat, and diffuse abdominal pain. There was no history of cough or runny nose. On examination, she appeared ill and had a temperature of 101°F. Her posterior oropharynx was erythematous without exudates, and the tonsils were not enlarged. She had tender anterior cervical lymphadenopathy. The remainder of the examination, including the abdominal examination, was unremarkable.

With concern for strep throat, the urgent care physician swabbed the child's throat and performed a rapid antigen detection test (RADT) in the clinic. The "rapid strep test" was interpreted as negative. A culture of the posterior oropharynx was not performed. Urinalysis revealed 3+ ketones and a specific gravity (SG) >1.030. The child was given a diagnosis of viral syndrome and dehydration, and the father was reassured. He was advised to give her antipyretics and extra water and juice and to observe her closely for adequate urine output or worsening of symptoms.

Four hours later, the child appeared more ill to the father and developed a fever of 104°F. Concerned, the father took the child to the nearest emergency department (ED). In the ED, she had a fever of 103.5°F and an erythematous posterior oropharynx and tender lymphadenopathy on examination. The ED physician repeated the RADT. The result was strongly positive for group A streptococcal infection. The child was treated with oral amoxicillin and was afebrile with minimal sore throat 2 days later.

Crossed Coverage

The Case

A 27-year-old woman with a history of congenital heart disease was admitted for cardiac transplantation evaluation. She had already undergone multiple surgeries, including aortic valve replacement for which she was on warfarin with a goal international normalized ratio (INR) level of 2.0–3.0.

On admission, her hemoglobin level was normal and her INR was 2.6. At the admitting hospital, a formal policy required that all inpatient orders for warfarin be rewritten each day to prevent overdosing. The intern caring for the patient ordered her usual outpatient dose of 15 mg x 1. On hospital day two,

the patient's INR had risen to 3.6. The intern did not write the order for warfarin for hospital day two and clearly outlined in the daily progress note that the warfarin was to be held.

After the shift change, the evening nurse noted that the daily warfarin order had not been written. She was puzzled, as she distinctly remembered from signout that the patient was on warfarin for the prosthetic aortic valve. Without checking the progress notes or the laboratory values for that day, she paged the night float intern (not the primary intern caring for the patient) who was cross-covering. Having not received a verbal signout from the primary intern, the cross-covering intern reviewed the written signout on the patient and noted that warfarin was listed as one of the patient's medications. As it turns out, the primary intern had not updated the written signout that day, and warfarin was still listed as an active medication. Without checking the progress notes or the patient's INR level for the day, the cross-covering intern gave the nurse a verbal order to give the patient one dose of warfarin, 15 mg.

The pharmacy dispensed the medication, and the patient received 15 mg of warfarin. The next day, the patient's INR was 5.6; 3 days later, it peaked at 7.7. Oral vitamin K was given to counteract the effects of the warfarin. The patient had a minor nosebleed but no other adverse consequences.

The "Customer" Is Always Right

The Case

An 18-month-old female was brought to the family medicine clinic with a chief complaint of "rash and diarrhea." Five days earlier, the patient's mother noted a rash on her daughter for which she was advised to administer diphenhydramine (Benadryl) as needed. While the rash improved, the patient developed diarrhea and low-grade fever, prompting a visit to the clinic. During the visit, the mother also revealed that her daughter had fallen from a 1.5-foot-high bed a few hours earlier and appeared unsteady. The mother expressed concern that the child might have a fracture and requested an x-ray.

Physical exam revealed a fussy child with normal vital signs and no evidence of ecchymosis, edema, or localized tenderness in the extremities. The child was somewhat unsteady when placed on the floor to stand and remained uncooperative with an attempt to demonstrate her gait. The resident physician's diagnosis was a "viral syndrome" causing the diarrhea and low-grade fever. He attributed the child's unsteadiness to the Benadryl, perhaps exacerbated by the viral infection. He advised the mother that a fracture was unlikely based on the exam findings. The resident discussed his findings with the attending physician, although he did not specifically mention the mother's request for an x-ray.

Later that evening, the mother returned to the emergency department to request an x-ray because of her daughter's inability to bear weight. An x-ray was performed, which showed a nondisplaced fracture of the tibia, requiring placement of a cast. Frustrated with the sequence of events, the mother felt that her concerns at the first visit were not heard.

Right Patient, Wrong Sample

The Case

A 54-year-old man was admitted to the hospital for preoperative evaluation and elective knee surgery. On the morning of surgery, the patient was awakened by the phlebotomist who drew his blood for basic laboratories and type and cross-matching.

To ensure proper patient identification, the hospital had implemented a policy requiring a registered nurse or physician to verify the identity of all patients screened for blood transfusion. In practice, after verification of identity, the nurse or physician was required to initial the patient label on the vial of blood.

As it was the change of nursing shift, the bedside nurse for the patient was not available and there were no physicians on the floor at the time. With another floor of patients still to see, the phlebotomist carried the labeled vial of blood out to the nurses' station, and the label was signed by a random nurse. The sample was sent to the laboratory for analysis.

Later that morning, a laboratory technician noticed a large and surprising change (compared to the previous day's sample) in the hemoglobin value for a different patient on the same floor. She chose to investigate the discrepancy. Upon review, she realized that the vials of blood for the 54-year-old man had been mislabeled with another patient's label by the phlebotomist. The reason the hemoglobins were so discrepant for this other patient was that today's value was that of the 54-year-old man, the wrong patient. On closer examination, it was determined that all the blood samples had been mislabeled, including the vial for type and cross-matching.

Despite the "near miss," the patient suffered no harm, and another blood specimen was drawn prior to surgery.

Crossing the Borderline

The Case

A 24-year-old woman with borderline personality disorder was admitted to an inpatient psychiatry unit following a failed suicide attempt with excess doses

of acetaminophen. The patient had a history of suicide attempts, including episodes of self-inflicted trauma and abusive behavior. Upon admission, the patient was isolative, displaying a flat affect and expressing a desire to harm herself. When her mood significantly improved after several days of restricted activities, the care team provided her with more freedom, hoping it would improve her condition. Despite occasional gestures suggesting ongoing risk for self-harm as well as continued conflicts with the care team, the patient's behavior became focused on a home visit for her upcoming birthday.

As the care team had observed nearly 72 hours of appropriate behavior, the day before her birthday, they granted permission for the patient's request. Later that evening at home, the patient set herself on fire, prompting immediate return to the hospital for necessary treatment. The events prompted a review and a strengthening of the policies regarding formal risk assessment in this patient population.

Hidden Heparins: HIT Happens

Case & Commentary: Part 1

A patient with a history of end-stage renal disease requiring hemodialysis was admitted for evaluation of non-healing ulcers and leukocytosis. She had been admitted 1 month prior for evaluation of peripheral artery disease. During that hospitalization, the patient underwent angioplasty of the right femoral artery, complicated by postoperative gangrene of the right foot requiring above-the-knee amputation. She also developed axillary vein thrombosis, and ultimately a diagnosis of heparin-induced thrombocytopenia (HIT) was made. She was treated with argatroban, and it was noted on the chart that the patient should receive no further heparin.

Heparin-induced thrombocytopenia (HIT) occurs when heparin molecules stimulate formation of a pathogenic IgG antibody (HIT antibody) that leads to platelet activation (promoting thrombosis) and clearance (leading to thrombocytopenia). The typical presentation of HIT involves a hospitalized patient who develops thrombocytopenia within 5–10 days of receiving heparin; decreases in the platelet count to 9/L or by greater than or equal to 50% below the baseline value are generally considered to be significant.(1) Up to half of patients with HIT will experience thrombosis, in either the arterial or venous circulation.(3) This patient appears to have experienced thrombosis (axillary vein thrombosis, and possibly a lower extremity arterial event leading to limb ischemia and amputation) as her primary manifestation of HIT.

In a hospitalized patient, the diagnosis of HIT may be confounded by the presence of other potential causes of thrombocytopenia. Still, a pretest scoring system, such as the 4 Ts—which takes into account the degree

of Thrombocytopenia, Timing of the platelet count decline in relation to heparin use, presence of any Thrombosis, and any oTher potential causes for thrombocytopenia (Figure 1)—may facilitate assignment of a diagnosis.(4) Laboratory studies such as the HIT antibody enzyme-linked immunoassay (ELISA) and the serotonin-release assay can later confirm the diagnosis, but initiation of treatment for HIT should not be delayed pending results of these specialized studies.

Unfractionated heparin (UFH) is associated with HIT more frequently than low-molecular-weight heparin (LMWH). A recent meta-analysis including 7000 medical and surgical patients who received UFH or LMWH as thromboprophylaxis showed a rate of HIT of 2.6% and 0.6%, respectively.(2) As the patient in this case had undergone angioplasty of the right femoral artery for treatment of peripheral arterial disease, it is likely that she received heparin at some point during that hospital stay.

Due to the high risk of thrombosis associated with HIT, the appropriate initial management of the condition includes discontinuation of all forms of heparin (including flushes) and initiation of an alternative anticoagulant, such as a direct thrombin inhibitor (DTI). Argatroban, lepirudin (Refludan®), and bivalirudin (Angiomax®) are DTIs that are commercially available in the United States (Table). The DTI should be continued until the platelet count has recovered *and* the patient is adequately anticoagulated with a coumarin derivative (warfarin). Because of the risk of venous limb gangrene that can result from transient hypercoagulability associated with early warfarin therapy in HIT patients, warfarin therapy should not be started until the platelet count recovers and then only with overlapping DTI therapy. In patients with HIT and thrombosis, as in this case, anticoagulation, usually with a coumarin derivative, should be continued for a minimum of 3–6 months following detection of the thrombosis.(5,6) Even in patients with HIT who present without thrombosis, the risk of thrombosis persists for at least 30 days, with up to 50% of patients developing venous or arterial events.(3) Therefore, patients with confirmed HIT without thrombosis should be anticoagulated (typically with a coumarin derivative) for at least 4 weeks after HIT is detected.(6)

Case & Commentary: Part 2

On this admission, the patient was found to be tachycardic and hypotensive, with excoriations of the skin over the breast, abdomen, right thigh, and gluteal region. Her labs were significant for leukocytosis of 17.1 x 10^9/L and hypoalbuminemia of 2.4 gm/dl. The patient was started on antibiotics (amikacin and vancomycin). Blood cultures eventually grew candida, and amphotericin was added to her regimen. She appeared to be improving with a decrease in white blood cell count (WBC) to 10 x 10^9/L. Over the next few days,

however, she developed ischemia in her right hand, which eventually became cold and pulseless. It was also noted at this time that her platelet count had dropped since admission. On hospital day 8, the leukocyte count increased again, her respiratory status worsened, and she died, presumably from overwhelming sepsis.

In light of the high risk of thrombosis that accompanies the diagnosis of HIT, it is possible that the patient's presenting signs of tachycardia and hypotension stemmed from an HIT-related central venous or arterial thrombotic event, such as myocardial infarction or pulmonary embolism. Leukocytosis does not complicate HIT *per se*, but inflammation or infection from ischemia could lead to an elevated white cell count.

Shortly after admission, this patient did develop signs of arterial insufficiency with right hand ischemia that progressed to pulselessness. Although HIT is complicated by symptomatic venous thrombosis more often than arterial thrombosis (7), arterial thrombosis may occur more frequently in certain patients with HIT, such as individuals with cardiovascular disease.(8)

Interestingly, this patient presented with "excoriations" of the skin. Up to 10%–20% of patients receiving subcutaneous UFH or LMWH who develop HIT will first have erythematous, nodular, plaque-like, or necrotic lesions (Figure 2) at the injection site.(7) Although HIT antibodies are detectable in most of these patients, thrombocytopenia is present in only a minority.(9) We are not told that heparin was ever injected subcutaneously in this case, and the location of some of the lesions (e.g., breast) makes an injection-related phenomenon less likely, although skin lesions that occur at sites that are distant from the location of subcutaneous injection have been reported.(10) Dermal necrosis also has been reported following use of intravenous heparin.(11)

In contrast, coumarin-induced skin necrosis (CISN) rarely occurs when warfarin is introduced in a patient with HIT and typically begins within days of starting the oral anticoagulant. A proposed mechanism for the condition involves worsening of HIT-induced hypercoagulability due to an acute reduction in levels of protein C or S. Localized, progressive, microvascular thrombosis ensues that typically leads to necrosis of the dermis overlying the breast, abdomen, thigh, or leg.(7) We are not told that this patient ever received warfarin, but the dermatologic "excoriation" may well have been a skin manifestation of HIT.

Case & Commentary: Part 3

Autopsy revealed thrombi in the vessels of the skin of breast and abdomen. A thorough review of the chart and hemodialysis records revealed that, during

this second hospitalization, the patient had been repeatedly exposed to heparin during dialysis sessions, despite her recent history of HIT and the chart notes to avoid heparins.

The histologic finding at autopsy of microthrombi in dermal vessels strongly suggests that the skin lesions that were initially observed over the breast, abdomen, and thigh represented sequelae of ongoing HIT, which probably had developed following exposure to heparin during the first admission to the hospital. Although HIT had been documented and treated during that hospitalization, the patient continued to receive heparin in the hemodialysis suite.

A diagnosis of HIT does not necessarily obviate any future use of heparin, but several factors must be carefully considered before heparin is given. Although certain patients may experience no recurrence of thrombocytopenia upon re-challenge with heparin as soon as 1.5 months after an episode of HIT (1), most patients with HIT continue to test positive for HIT antibodies well after the thrombocytopenia has resolved. When measured by ELISA, the median duration of HIT antibody positivity is 85 days.(1) This observation has led to the usual practice of waiting at least 100 days before considering use of heparin in patients with a prior history of HIT and documenting negativity for the HIT antibody before re-exposing to heparin. If re-exposure is absolutely necessary (i.e., for vascular surgery), short-term use of the heparin may be considered with frequent monitoring of the platelet count. Patients with persistent HIT antibodies, as our patient most likely had, who are re-challenged with heparin can develop *rapid-onset HIT*, in which thrombocytopenia and thrombosis develop with alarming speed, sometimes as soon as a day after re-exposure to heparin.(7)

This case underscores the need for safeguards for patients who are diagnosed with HIT to prevent “accidental” exposure to heparin. In our hospital (UCSF Medical Center), the electronic pharmacy profile (WORx, Mediware Information Systems, Lexena, Kansas) of any patient in whom HIT is diagnosed is updated to indicate the diagnosis. If a heparin (UFH or LMWH) subsequently is ordered by a care provider, an alert is generated (Figure 3) that is visible to the hospital pharmacist, who contacts the ordering provider to advise of the prior history. In this regard, patients with a prior history of HIT are “protected” from orders for UFH or LMWH that are written without a knowledge of the patient’s history of HIT, and the protection extends to future admissions. As an additional precaution, a placard indicating “Heparin-Induced Thrombocytopenia: No Heparin” is placed above the bedside in rooms of inpatients who receive the diagnosis, and an allergy is recorded in the medical record.

Unfortunately, in most hospitals, heparins (typically UFH) are stocked in more locations than simply the clinical pharmacy, and patients can be exposed to

the drug, usually as part of a “routine” maneuver such as flushing a venous access device. Administration of heparin in quantities as small as those routinely used to flush central venous catheters and other vascular access devices can lead to HIT antibody formation or HIT itself (12–14), and minor exposure via this route in a patient with persistently circulating HIT antibodies can promote re-emergence or worsening of thrombocytopenia or thrombosis.(15) To reduce the risk of promoting or exacerbating HIT through use of heparin flushes of invasive catheters, some institutions have adopted a policy of routinely using normal saline for their flushes. Such an approach is supported by several studies, including a randomized controlled trial of UFH versus saline flushes for invasive catheters used in the operating suite and a meta-analysis of patency rates of peripheral venous catheters flushed with UFH or normal saline, which found no benefit to UFH for this purpose.(12,16) Heparin is still used routinely to prevent thrombosis of the hemodialysis circuit, however. Because heparin usually is stocked in the dialysis unit, the pharmacy and aforementioned system of alerts can be bypassed.

The significant risk of HIT and its devastating sequelae has prompted consideration of policies that aim to remove heparin from all patient care areas. When such policies are implemented, ordering heparin requires an MD order to the pharmacy, even when the heparin is for flushing of catheters. Implementation of computerized electronic alerts, especially if linked to physician ordering screens, may provide the best method of risk notification, as has been demonstrated in other applications.(18)

Secured But Not Always Safe

The Case

An 84-year-old healthy woman underwent an elective left total knee replacement for degenerative osteoarthritis. She received spinal anesthesia, and the airway was maintained with the use of a laryngeal mask airway (LMA). The 2-hour surgery went well with no reported intraoperative complications. However, while in recovery, the patient's family noted an increase in the size of the patient's neck, prompting an evaluation from the anesthesiologist. Because the patient's airway had been secured with an LMA (as opposed to an endotracheal method), the anesthesiologist recommended simple observation of the neck, apparently believing that an airway complication was relatively unlikely.

The following day, the patient developed a fever with continued fullness in her neck. Antibiotics were started. The patient remained hemodynamically stable with no breathing discomfort, dysphagia, or neck pain. However, on postoperative day 3, she became lethargic and had a marked elevation in her white blood cell count.

The patient was sent for emergency computed tomography (CT) scanning, which revealed retropharyngeal and mediastinal abscesses. Following surgical drainage and continued antibiotic therapy, the patient improved clinically and was ultimately discharged to a skilled nursing facility for knee rehabilitation. In retrospect, the clinicians felt that the infection resulted from a perforation caused by the LMA. After the patient's recovery, the family recalled being reassured before surgery that "this technique is far safer [than endotracheal intubation] with fewer complications."

Urinary Retention Dilemma

The Case

Following an elective thyroidectomy, a 56-year-old man with a history of benign prostatic hypertrophy (BPH) and urinary hesitancy returned to the med-surg unit for monitoring calcium balance (the thyroid is adjacent to the parathyroid glands, which control the body's calcium balance). After returning, the patient began complaining of problems with urination, lower abdominal discomfort, and frequently voiding very small amounts of urine. The nurse administered terazosin (an alpha blocking agent for urinary obstruction), first the 2 mg initially ordered by the physician; the dose was later increased to 10 mg by the surgeon (the patient's pre-surgical dose). The total urine output during the 24 hours following surgery was only 1200 cc (which seemed low in light of the amount of intravenous hydration), and it came in frequent, small amounts.

During this time, the patient became increasingly uncomfortable and restless. During morning rounds, the surgeon learned of the patient's continued difficulty voiding and ordered urinary catheterization. The nurse catheterized the patient and obtained 900 cc of urine (normal post-void residual volume is a few hundred cc). The patient experienced immediate relief. The catheter was then removed, and the patient was discharged a few hours later.

After arriving home, the patient again became increasingly uncomfortable and unable to void more than a small amount. He called his urologist and was seen that afternoon. The urologist placed a Foley catheter that yielded 800 cc urine. The patient again experienced immediate relief. This time, the catheter was left in for a week to allow the bladder to regain tone. During this extended time with an indwelling catheter, the patient took antibiotics to prevent a urinary tract infection.

Getting a Good Report Card: Unintended Consequences of the Public Reporting of Hospital Quality

The Case

A 55-year-old woman with end stage renal disease requiring hemodialysis and coronary artery disease (status post-coronary artery bypass grafting and placement of a St. Jude prosthetic valve) was admitted to the medical service with palpitations and chest pain. She reported missing her scheduled hemodialysis session, and her symptoms resolved with prompt inpatient hemodialysis. In the course of her work-up, it was noted that she was subtherapeutic on her anticoagulation with warfarin, and a heparin drip was initiated with the plan to bridge her until her INR was in the therapeutic range.

Mostly in response to increasing pressure from the hospital's administration to improve compliance with publicly reported quality measures, the attending physician recommended pneumococcal vaccination, and it was administered. Later that day, the patient complained of pain over her right upper arm. The attending told the patient that this was a common complaint after immunization and that it would resolve. The next day, the patient reported that her pain was worse, and the team noted an 8-centimeter hematoma within the muscles of her upper arm. The hematoma resolved spontaneously. There was no permanent harm.

A Troubling Amine

The Case

A 43-year-old woman was admitted to the intensive care unit for symptoms of heart and respiratory failure. She was found to have severe mitral and tricuspid valve regurgitation. She responded well to medical therapy, and surgical valve repair was scheduled. During her initial evaluation, a jaw fracture was incidentally noted. Given the jaw fracture and her valvular disease, an oromaxillofacial surgeon recommended prophylactic antibiotic coverage prior to surgery. Penicillin, 500 mg orally four times daily, was ordered. On the second day of antibiotics, when the nurse compared the drug with the medication administration record (MAR), she noticed that the patient was receiving penicillamine (a non-antibiotic medication used in the treatment of Wilson’s disease and severe rheumatoid arthritis) instead of penicillin and alerted the pharmacy.

A pharmacist reviewed the original handwritten order and saw that penicillin was clearly prescribed. The pharmacist who entered the order into the pharmacy computer system had typed in the code “PENIC” and had received a drop-down box that displayed all formulations and dosages of both penicillin and penicillamine. That pharmacist had incorrectly selected penicillamine as the drug to be given. The final check of the medication (at the time the drug left the pharmacy) compared the drug product against the information in the pharmacy computer system but not against the original handwritten order. The patient suffered no ill effects from the error and received the course of penicillin as originally prescribed.

DNR in the OR and Afterwards

The Case

An 85-year-old woman with dementia took a mechanical fall at her skilled nursing facility (SNF) and suffered a fractured femur. After initial evaluation in the emergency department, the patient was admitted to a surgical unit where the providers contacted the niece, the patient’s health care proxy, to discuss decision making. The providers confirmed the patient’s wishes, including her desire not to be resuscitated (a preference that was articulated in her advance directive, which accompanied the patient to the hospital). The niece agreed that the patient would be a full code during surgery (in other words, the DNR order would be suspended), but then the DNR order would apply for the remainder of the hospitalization.

The patient’s operative course was uneventful and she returned to the surgical unit for routine postoperative care. Several days after the surgery, the nurse who cared for the patient at the time of admission noted her code status to be documented as ‘full code’–quickly realizing that the patient’s DNR wishes had not been reinstated in the chart. Fortunately, the error led to no inappropriate resuscitative measures, but the event did generate a hospital review of DNR orders around surgery.

Triple Handoff

Case & Commentary: Part 1

An 83-year-old man with a history of chronic obstructive pulmonary disease (COPD), gastroesophageal reflux disease (GERD), and paroxysmal atrial fibrillation with sick sinus syndrome was admitted to the cardiology service of a teaching hospital for initiation of dofetilide (an antiarrhythmic medication) and placement of a permanent pacemaker.

The patient underwent the pacemaker placement via the left subclavian vein at 2:30 PM. A routine postoperative single view radiograph was taken and showed no pneumothorax. The patient was sent to the recovery unit for overnight monitoring. At 5:00 PM, the patient stated he was short of breath and requested his COPD inhaler. He also complained of new left-sided back pain. The nurse found that his pulse oxygenation had dropped from 95% percent to 88%. Supplemental oxygen was started and the nurse asked the covering physician to see the patient. The patient was on the nurse practitioner (NP) non-housestaff service; however, the on-call intern provides coverage for patients after the NPs leave for the day. The intern, who had never met the patient before, examined him and found him already feeling better and with improved oxygenation with the supplemental oxygen. The nurse suggested a stat x-ray be done in light of the recent surgery. The intern concurred, and the portable x-ray was done within 30 minutes. About an hour later, the nurse wondered about the x-ray and asked the covering intern if he had seen it. The covering intern stated that he was signing out the x-ray to the night float resident, who was coming on duty at 8:00 PM.

Meanwhile, the patient continued to feel well except for mild back pain. The nurse gave the patient acetaminophen as prescribed and continued to monitor his heart rate and respirations. At 10:00 PM, the nurse still hadn't heard anything about the x-ray so he met with the night float resident. The night float had been busy with an emergency but promised to look at the x-ray and advise the nurse if there was any problem. Finally at midnight, the nurse signed out to night shift, mentioning the patient's symptoms and noting that the night float had not called with any bad news.

This elderly man's experience of discontinuous care is typical in teaching hospitals today. The Accreditation Council of Graduate Medical Education (ACGME) duty hour mandates increased the number of handoffs–the transfer of patient care responsibility from one practitioner to another–throughout the country.(1) The mechanism by which that responsibility and necessary patient information is transferred is referred to as a signout.(2) For example, after duty hours were reduced, UCSF's Internal Medicine residency program experienced a 40% increase in signouts.(1) We estimate that our residents engage in signouts 300 times a month, more often than they attend conferences, meet new patients, or even eat. But discontinuities involve other professions as well, because all care providers working finite hours need to handoff and sign out their patients. For example, this case also illustrates nursing handoffs. In our institution, when one adds up all the provider-to-provider handoffs, 4,000 signouts occur daily, a total of 1.6 million per year. When one considers that 16.9 million patients are admitted to teaching hospitals each year, the number of handoffs and signouts are staggering.(3)

In a previous AHRQ WebM&M commentary (4), a structured handoff was highlighted as a mechanism to improve team communication. This concept is

now the basis for the 2006 Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Patient Safety Goal 2E, which requires all health care providers to "implement a standardized approach to handoff communications including an opportunity to ask and respond to questions." JCAHO's expectations for this goal include interactive communications, up-to-date and accurate information, limited interruptions, a process for verification, and an opportunity to review any relevant historical data.(5)

Case & Commentary: Part 2

The next morning, the radiologist read the x-ray performed at 6:00 PM and notified the NP that it showed a large left pneumothorax. Cardiothoracic surgery service was consulted and a chest tube was placed at 2:30 PM, nearly 23 hours after the x-ray was performed. Figure 1 shows the timeline of coverage and clinical events. Luckily, the patient suffered no long-lasting harm from the delay.

In this case, important information was lost due to handoffs, causing diagnosis and treatment delay and a near miss error. This is not uncommon. Most signout errors are "content omissions" in which critical information is not communicated.(6) Of errors in general, omission errors are common and occur at a rate of 1/100.(7)

Many of these errors are caught before harm reaches the patient, as practitioners have a variety of methods to ensure that gaps in care are managed effectively.(8) Some errors, though, do reach the patient and most of these can be attributed to communication failures, including signout miscommunications.(5) Signouts have also been linked to in-hospital complications and preventable adverse events.(9,10)

One solution to mitigate patient harm due to handoffs is to standardize or structure the signout.(1,2,11,12) Many strategies, proven successful in non-health care industries (13), have been suggested for hospitals and clinics.(2) A recently published review recommends strategies for safe and effective resident signout (including both written and verbal signouts) that can be generalized to all health care providers.(1)

The elements of a safe and effective written signout are included in the mnemonic "ANTICipate": Administrative, New information (clinical update), Tasks, Illness, and Contingency plans.
Accurate *administrative* information, such as patient name and location, is one of the most important components of a written signout according to surveys of internal medicine night-floats at UCSF (Unpublished data from October 2004 evaluation interviews of cross-coverage internal medicine residents at UCSF). *New information* includes a brief history and diagnosis, updated

medications and problem list, current baseline status (eg, cardiac status), and recent procedures and significant events. *Tasks* are the "to-do" list, or the things that need to be completed during cross-coverage. Listing the tasks in "if, then" statements reduces the need for conjecture on the part of the cross-coverage practitioner. For example, in this case, the written signout would include: "Check CXR which was taken at 4:00 PM. If clear, call nurse to communicate results; if PTX, call thoracic surgery." "*Illness*" is the primary provider's subjective assessment of the severity of illness, and contingency planning includes statements that assist the cross-coverage in managing anticipated problems. It is also important to report what therapeutic interventions have been successful in the past–thus giving the cross-coverage provider important historical background to assist in decision making. Given our case, an appropriate contingency plan could be: "If patient is short of breath, try an albuterol inhaler (given history of COPD), but consider pneumothorax since he recently had a subclavian line placed."

Written signouts can take many forms. Computerized templates that specify categories of information necessary for the signout have been recommended. At our institution, many types of templates have been used, including those built on MS Word, Filemaker Pro, and MS Excel. These systems depend on the user for accurate data entry. An evaluation of such a written signout system found wide variability of content accuracy.(14) A technological solution to decrease user-entered false information is to link the signout to the hospital electronic medical record (EMR). An example of this is Synopsis, a platform built within the UCSF Medical Center EMR (Figure 2). Systems like these have the capacity to populate the written signout by importing data from the EMR, such as administrative information, laboratory results, medications, allergies, and code status. Such systems have been shown to improve resident efficiency and the quality of signouts (15), as well as to reduce the risk of signout-related medical injuries.(16)

Although electronic mechanisms for written signout can facilitate the standardization of written content, face-to-face verbal communication adds additional value.(17) Verbal signout should be tailored to the needs and skills of the recipient. For example, a less experienced practitioner who is new to the patient may require more information in the signout than an experienced practitioner who is familiar with the patient. Verbal signouts should take place in a designated place and time, free from distractions and interruptions (such as pagers and telephone calls), with access to up-to-date information. The information transmitted should be structured in a format that is consistent for each signout. An example of such a structure is SBAR (Situation-Background-Assessment-Recommendation), a communication tool originating in the Navy that has been effective in health care communication.(18) At UCSF, our internal medicine residents are expected to verbally signout administrative information, a brief history, tasks, and anticipated problems on all patients who are perceived to be ill or who have plans in flux. It takes

approximately 7 minutes to complete this process for 10 patients. The receiver of signout should "repeat-back" or "read-back" the information in the tasks, thus allowing for interactive questioning to clarify information.(19) For example, in our case, the receiver would repeat-back: "So, I should check the CXR which was taken at 4:00 PM and act upon the results–was there another one taken before or after 4:00?"

Case & Commentary: Part 3

The team subsequently learned that the night float resident had mistakenly examined the radiograph done immediately postoperatively rather than the chest x-ray done at 6:00 PM, and therefore did not see the film with the large pneumothorax.

Although few data have documented an improvement in signout processes or outcomes due to implementation of a structured signout system, JCAHO mandates and expert opinion strongly advocate for such systems.(1,2,11,20,21) Implementing these changes may seem relatively easy, but they are not, even with the most advanced EMR and the availability of experts.(22) Fortunately, many teaching hospitals and residencies, having recognized the consequences of poor signouts on quality and safety, now seem ripe for transformation.

At UCSF, the transformation to a system-wide structure of written and verbal signout was facilitated by a conceptual framework to manage the change, using Kotter's 8-step approach.(23)

- 1. Establish urgency. We first established a sense of urgency. Residents recognized the urgency of improved signouts quickly, but the introduction of the JCAHO patient safety goal added to the medical center's sense of urgency.
- 2. Form a powerful guiding coalition. We then formed a powerful coalition which included the main stakeholders: Information Technology (IT), Medical Center, and Graduate Medical Education (GME) leadership.
- 3. & 4. Create and communicate a vision. We created a vision, a signout system that could grow with our new EMR, making resident work more efficient and the signout process safer for patients. We then actively communicated that vision to leadership at numerous committee meetings.
- 5. Empower others to act on the vision. We empowered others to act by engaging the medical center IT and GME leadership to help the core group of "champions" move forward in development of Synopsis.
- 6. Plan for and create short-term wins. We designed a "rounds report" linked to Synopsis (Figure 2), allowing for information consolidation and tracking increasing resident work flow efficiency. We also piloted the project on our non-teaching service, which had previously lacked a

robust signout system, thus gaining enthusiasm prior to the resident roll-out.
- 7. Consolidate improvements, creating more change. Synopsis spread organically once residents saw its capacity on one of the pilot units.
- 8. Institutionalizing new approaches. We institutionalized this new system by passing policies at the GME and Medical Center level.

By using these 8 steps, coupled with a comprehensive training program, we were able to train the majority of our residents on safe and effective signout strategies. At this point, more than 50% of the patients at our 600-bed acute care hospital are cared for with the assistance of Synopsis, and this percentage continues to grow.

Signouts are a reality of life in academic and community hospital settings. Although each signout introduces risk, the strategies outlined above can improve the processes for signouts, thereby reducing the potential for error.

It's All in the Syringe

The Case

A 33-year-old man with type 2 diabetes presented to his physician's office to discuss his diabetes management. The patient admitted not taking his medications or checking his blood sugars regularly. In the office, his blood sugar was 335 mg/dL, so the nurse practitioner (NP) ordered 6 units of regular insulin to administer.

After the medical assistant brought the insulin and syringe, the NP prepared the medication and injected the insulin. Immediately after the injection, the NP discovered that a tuberculin syringe was used instead of an insulin one. As a result of the error, the patient inadvertently received 60 units of insulin rather than 6 units. The patient was given orange juice, a sandwich, and his blood sugars were closely monitored for 4 hours with no significant events.

Miscalculated Risk

The Case

A healthy 36-year-old man was admitted to a teaching hospital for acute low back strain after lifting his 2-week-old infant. He received Vicodin (hydrocodone and acetaminophen) on an "as needed" basis. After 2 days, the intern was instructed to switch the patient to long-acting oral morphine in anticipation of discharge. After the first dose of MS Contin (controlled-release oral morphine), the patient was noted to be somnolent; 3 hours later, he was in respiratory distress. He was intubated and transferred to the intensive care

unit. The ICU team evaluated his recent analgesic use and determined that he had received a dose of MS Contin that far exceeded his previous Vicodin requirement. The patient subsequently developed acute respiratory distress syndrome (ARDS) and sepsis, presumably related to aspiration. He remained in the ICU for 2 weeks and required pressors for blood pressure management. Eventually, the patient recovered fully and was discharged home.

Physical Diagnosis: A Lost Art?

Case & Commentary: Part 1

A 57-year-old male with T8 paraplegia from a remote gunshot wound, hypertension, and diastolic dysfunction presented from home with 1 week of intermittent fevers, chills, increasing shortness of breath, and low back discomfort. Due to neurogenic bladder, the patient performed self-catheterization daily. Initial physical examination was recorded as follows:

> *General: Mild respiratory distress with audible wheezing Vitals: Blood pressure 110/62, Pulse 106, Respiratory rate 18, Temp 37.8°, Room air saturation 100% HEENT: Crusting periorbitally, no edema, extraocular movements intact, pupils equal round and reactive, dry tongue Neck: No meningismus Resp: Increased work of breathing with diffuse rhonchi, crackles bilaterally Cardiovascular: Tachycardic without murmurs or gallops, normal apical impulse, 2+ pulses throughout, no lower extremity edema Abdomen: Normal active bowel sounds with some tenderness to palpation over the suprapubic area Skin: Stage I gluteal cleft decubiti GU examination: Deferred Neuro: Strength 5/5 upper extremities, 1/5 bilaterally lower extremities with flexion contractures; sensation absent below T8.*

The history and physical examination remain the backbone of medical evaluation and assessment. However, the many advances in both laboratory and imaging technology and the pace of modern medicine have resulted in the physical examination being abbreviated and undervalued, and viewed (subconsciously, perhaps) as redundant.

Although few studies examine physical diagnosis skills over successive generations of physicians, skill and familiarity with certain bedside maneuvers and confidence in eliciting physical signs appear to have declined, with increased dependence on the aid of a radiologist or first-tier laboratory data. The new student on the wards soon finds that skills at the computer in getting data back and arranging for tests to be done are valued as much or more than learning to percuss well or hear a pericardial friction rub. At times, it almost seems as if the patient in the bed is an icon for the real patient who exists in the computer, and 'rounds' (a word that in this context connotes

motion) are conducted with the participants immobile and seated in a room and with the patient represented either on an index card or a PDA (personal digital assistant) screen.

The reasons for this trend are complex. Physician reimbursement has become increasingly volume-driven, with little or no financial reward for one's ability to pick up subtle physical examination findings and with little time for that kind of detailed examination. One can get into the habit of reflexively ordering a series of tests to traverse assorted diagnostic algorithms. The many 'protocols' for various conditions are well intended, provided the physician has picked the right algorithm based on the history, physical, and initial laboratory tests. The higher sensitivity and specificity offered by laboratory and radiologic testing makes it more likely that a physician might be reluctant to make a clinical diagnosis that could be readily made at the bedside (of say splenic enlargement, aortic stenosis, or pleural effusion) until the echocardiogram or CT scan is reported. The result is that we see few people percuss the chest, and fewer still do it with any confidence or knowledge of the normal boundaries of chest resonance.

Case & Commentary: Part 2

Initial laboratories were significant for a white blood cell count of 20.9 with 82% segs, bicarbonate of 19, blood urea nitrogen of 27, and creatinine of 1.7. Urinalysis revealed 2+ protein, +nitrite, 3+ leukocyte esterase, 3+ blood, 10-25 white blood cells, and 10-25 red blood cells. Electrocardiogram revealed sinus tachycardia only. Chest radiograph revealed a bilateral interstitial edema pattern. The initial assessment by the female night float resident was sepsis from a urinary tract source and acutely decompensated diastolic heart failure. The patient was managed with afterload reduction, diuresis, oxygen, and intravenous antibiotics and was evaluated for myocardial infarction with serial enzymes and electrocardiograms.

Studies comparing the sensitivity and specificity of bedside diagnosis with that of laboratory and radiographic testing can be complicated and difficult to interpret, particularly when comparisons are made between, say, trainees and established physicians. One such study cites the inability of intensive care unit personnel to accurately determine the jugular venous pressure (JVP), calling instead for central venous access for determination of this parameter.(1) In that study, medical students performed best, with residents and attending physicians the least accurate at JVP assessment. This somewhat unexpected result was probably because the medical students involved in this study had participated in weekly cardiology rounds with examination of all observed patients' JVP for the duration of their rotation, whereas the residents and attending admitted to infrequent attempts to routinely assess JVP. Furthermore, the medical students in this study were unaware of the patients'

clinical diagnoses, whereas residents and staff physicians had been given this information.(1) Such diagnostic information can bias a "retrospective" physical examination. The residents and staff perhaps subconsciously attempted to correlate their examination findings with what they expected to observe. The study illustrates the need for physicians to continually use and sharpen their examination skills and their use of specific maneuvers, lest these degrade over time.

It has long been said that physicians order an increasing number of tests because we are practicing 'defensive' medicine in an increasingly litigious environment. But, it is also likely that physicians order so many tests because we have lost confidence in our abilities to extract meaningful information from the physical examination. In particular, physicians seem to lack the confidence to say that an examination of a certain body part is normal, and no further testing is needed. In this regard, physicians in the United States differ from our colleagues in Canada and England, who tend to be frugal with their testing. The consequences of excessive reliance on diagnostic tests to convey information that should have been elicited on physical examination are twofold: first, there is time delay (often a day or two) in diagnosis as one awaits the test results; second, the patient is exposed to the risk and side effects of tests that may not be necessary. These risks include both the obvious unwarranted financial expense to the patient and the healthcare institution, but also the possibility for serendipitous discovery of "incidentalomas"—laboratory or radiographic abnormalities that are unrelated to the presenting complaint. The full impact of these incidental findings has yet to be defined, but the costs of follow-up imaging, additional laboratory testing, and increased patient concern of serious yet still undefined illness are obvious.(2)

Despite a growing body of literature questioning the value of the routine examination (3), this aspect of the physician-patient encounter is clearly valued by the patient. In one study, 90% of patients expected their blood pressure to be measured and their heart, lungs, abdomen, and reflexes be examined.(4) Even if routine examination may not be essential to actual patient care, we believe the skilled examination is critical to the development of the physician-patient relationship. Done well, it earns trust, patient confidence, and perhaps increasing patient compliance.

Case & Commentary: Part 3

The following morning, the patient was handed off to the daytime medical team. Genitourinary examination was again "deferred," and the treatment plan continued. Later that day, the attending physician examined the patient and found ecchymotic, edematous scrotal skin, a purulent perirectal fistulous tract, and perirectal crepitus. Urology and general surgery were contacted

immediately. Shortly thereafter, the patient underwent surgical debridement for Fournier's gangrene, a life-threatening form of necrotizing fasciitis of the perineal area.

The practice of "handing off" patients necessitated by the 80-hour work week imposed on physicians in training might compound the risk of patients like this falling through the cracks. There is inevitably a tendency to rely heavily on the admitting physician's initial assessment and diagnosis, and the labels given the patient tend to stick. Bias creeps in. Rarely is the patient thoroughly reexamined by the physician completing the treatment plan. Frequent reassessment of the patient, rather than diligent follow-up of previously ordered laboratory tests, is more beneficial to correct clinical care. The old clinical saw, "There is no substitute for laying hands on your patient," remains true today, perhaps more than ever.

Physicians may defer examining parts of the body that seem unlikely to contribute to the presenting complaint. Patients may have impairments that make them unable to voice what is bothering them. Paraplegia or other conditions with sensory impairment represent a distinct class of comorbidities requiring diligent and thorough examination, similar to the common practice of examining a diabetic patient's feet regardless of the presence or absence of podiatric complaints. The chief complaint of these patients is often secondary to an underlying condition that resulted from sensory impairment. One of us (G.R.T.) has seen a patient with spinal cord injury who was transferred from an outside hospital for urinary tract infection. The patient voiced no complaints and was anxious to be discharged. The resident in charge of his care incidentally noted subcutaneous crepitus in the arm while measuring the blood pressure. The patient was subsequently found to have extensive necrotizing fasciitis of the shoulder and abdominal soft tissues.

Necrotizing fasciitis is a perfect example of a clinical condition in which one might make the diagnosis at the bedside and in which delay can be deadly. This is predominantly a clinical diagnosis with the direct visualization of the involved area being critical, along with recognizing the patient's apprehension and early signs of distress. What is not seen is not diagnosed. The common practice of "deferring" aspects of the physical examination viewed as non-essential was unfortunately responsible for this patient's initial incorrect diagnosis. Several factors can lead to deferment of a close examination of the genitals or areas in proximity to it, and one such factor is when physician and patients are of different genders. Factors that lead to deferral of the genital examination include a lack of confidence in performing an examination of a member of the opposite sex, fear that the patient will see this as an unnecessary examination, and difficulty in finding a chaperone.(5) Often, if one sees a patient had a rectal examination in the emergency department or by some previous examiner, and the stool guaiac has been done, there is a sense that one no longer needs to go near the genital area.

Medical education revolves around future doctors watching and learning from their faculty and seniors. The "apprentice" may only become as good as those under whom they train, and certain time honored and still valuable physical diagnosis skills may no longer get passed on with regularity. Attending physicians and others in educational roles must be sure to model these skills and be vigilant to ensure that what they are passing on is accurate and performed correctly.(6) The reassurance offered to those in training by watching their faculty member correctly make diagnoses at the bedside and forego more sophisticated testing would likely motivate them to put greater value on these skills.

It seems unlikely that physical examination skills in North America will ever come back to their apogee, when this art form was practiced with great skill by the likes of Osler (Figure), Cabot, and so many others. At present, internists can become board certified without having their skills tested at the bedside by certifying examiners. This would be the equivalent of allowing commercial pilots to fly us around without anyone having demonstrated that they were capable of flying. Reliance on program directors to sign-off on the residents' clinical skills is putting too much faith in the system of residency training. There is nothing like a national clinical skills examination at the bedside to elevate the standard of bedside practice. The Fellowship examinations in England and Canada, although they can be quite subjective, nevertheless create a housestaff training culture that values physical diagnosis skills—at least as much as doing 'board review' questions. Skilled clinicians test the candidate at the bedside on real patients to see if they can sort out valvular heart disease or pick up all the physical signs that suggest the presence of an internal capsule thrombosis and stroke. There is at present a 'clinical skills exam' for medical students, which in our opinion, based on conversations with recent test takers, tests everything but the kind of true clinical skills that are tested in other countries; it does little to test the ability of the candidate to palpate an enlarged spleen or detect a pleural effusion by percussion or localize a lesion in the nervous system with a skilled neurological examination. Taylor and colleagues attempted to correlate USMLE exam scores, clinical skills exam scores, and undergraduate grade point averages (GPA) with intern performance measured by residency program director surveys. Rankings by program directors were most highly correlated with undergraduate GPA, followed by the interpersonal skills component of the clinical skills exam, USMLE step 2 scores, USMLE step 1 scores, and then step 2 clinical skills exam scoring.(7) Even if there had been a direct correlation between the exam and intern performance measured by residency program director, the kind of clinical skills we are discussing in this commentary are simply not tested at the student or resident level.

One of us (A.V.) has had the opportunity to see students and residents from the United States working in clinics in Africa or India. What is most gratifying is how quickly these young physicians pick up and see both the utility of the

bedside examination and its limitations in a resource poor setting and how they come to see how valuable are the 'routine' laboratory and radiological tests that are rationed and not routine in these settings. More importantly, they discover that developing such skills is very rewarding and that they can translate these skills well to their residency programs when they return. The only way to bring rounds back to the bedside (where they belong) and to raise the level of physical diagnosis skills is for students and residents to see these attributes being modeled by attending physicians and senior residents. The generation of physicians who practiced in this fashion and were masterful at the bedside is beginning to retire. Without leadership in this area from regulatory organizations and specialty societies, this skill set will continue to disappear.

Over Not So Easy

The Case

A 62-year-old woman with end-stage liver disease was hospitalized for recurrent variceal bleeding. On admission, she reported allergies to a number of medications as well as a food allergy to eggs. The patient was adamant about appropriate documentation of her allergies, especially her food allergy because "scrambled eggs almost killed me." Consequently, her medication and food allergies were clearly displayed on her medical chart as well as her wristband.

On hospital day 1, she underwent successful banding of a bleeding varix. Post-procedure, she developed some mild hepatic encephalopathy and was treated with lactulose. She was slightly disoriented but alert, and her diet was advanced—the diet order at the time was "low-salt diet."

She remained clinically stable until the morning of hospital day 2, when she had acute onset of tachypnea with audible wheezing and hypoxia. She recovered quickly with administration of continuous albuterol, hydrocortisone, and antihistamines. At the time of the event, one of the clinicians noticed that her breakfast tray, sitting by her bedside, included a plate of half-eaten bacon and eggs. She did not recall eating the eggs, probably because of her encephalopathy. She had no long-lasting complications from the allergic reaction.

One ACE Too Many

The Case

A 72-year-old man with coronary artery disease, diabetes, and recently diagnosed congestive heart failure presented to the emergency department

(ED) with chest pain. An acute myocardial infarction was ruled out. Because his admission medication regimen did not include an angiotensin-converting enzyme (ACE) inhibitor, one was started before discharge. He had no known renal dysfunction. Two weeks later, he presented to the ED with fatigue, lethargy, and a critically elevated serum potassium level. Shortly thereafter, he suffered a cardiac arrest and died.

The patient had previously been receiving outpatient care from an ancillary clinic of the hospital. When the ED physician called to inform the clinic of the patient's death, the primary care provider recalled that the patient previously had been treated with an ACE inhibitor and had developed hyperkalemia after 1 week of therapy. The ACE inhibitor had been discontinued at that time.

Moving Pains

Case & Commentary: Part 1

A 90-year-old woman, whose son was a prominent nonclinical member of the medical school faculty, was admitted to the acute care ward of the school's teaching hospital with a urinary tract infection and pneumonia. After developing hypoxemia, on hospital day 2, she was placed on 2 L/min oxygen by nasal cannula. On hospital day 3, her hypoxemia worsened, as did her mental status. A head CT was ordered. She was placed on a non-rebreather mask (NRM) at 15 L/min to maintain her oxygen saturations. This change in respiratory status occurred while the primary nurse was occupied by the critical needs of another patient, so another nurse and the respiratory therapist placed the patient on the NRM. The primary nurse completed the transport stability scale (TSS—a local instrument used to assess a patient's stability for transport and to determine the need for a nurse or physician to travel with the patient) at the nurses' station in preparing her patient for transport to the CT scanner. Because the nurse was unaware of the change in her patient's respiratory status, she recorded that the patient required only 2 L/min oxygen by nasal cannula. Accordingly, the TSS score did not signal a need for a nurse or physician to accompany the patient. Therefore, the patient was taken to the CT scanner by two transport personnel/escorts and her son, the physician-faculty member.

The increased risk of morbidity and mortality during intrahospital transport of critically ill patients is well described in the literature and has led to the publication of formal guidelines for such transports by the Society of Critical Care Medicine and the American College of Critical Care Medicine.(1) Despite the obvious risks (frequently due to sudden changes in clinical condition) of intrahospital transport for patients in acute medical wards, the issues surrounding patient safety for transport for non-ICU patients have not been well described. In fact, although we were able to find a few reports of "best

practices" in abstract form or shared via listserv communication, we could not find any standardized, endorsed guidelines for safe transport of this patient population, nor any peer-reviewed article on the subject.

Even in the absence of formal guidelines, most hospitals have recognized the risk of intrahospital transport and have developed their own policies to help manage the process. Unfortunately, our impression is that many of these policies lack some essential elements. First, many policies lack clear standards for patient assessment, including the elements of an assessment, its timing, and the responsible party. Second, many are silent on the levels of intervention required, nor do they outline contingency plans should a patient's status change during the course of transport. Many policies are vague as to who should transport the patient under a variety of circumstances. Finally, even hospitals with reasonably robust policies rarely have systems in place to ensure that the policies are actually followed "in the trenches."

In this case, the hospital did have a system for assessing and communicating the clinical stability of the patient, but the assessment recorded on the transport stability sticker did not reflect the patient's immediate pre-transport condition. Enforcing an acceptable timeframe for the pre-transport assessment is an essential element of a transport standard and policy. In part because of the timing of the assessment (before her deterioration), the patient was sent off the unit accompanied by two "transport personnel/escorts." In general, such transport personnel are unlicensed and have variable training and responsibilities. Currently, there is no requirement for basic training or certification for unlicensed staff who transport patients without a nurse or physician, despite the fact that such personnel may need to identify a patient's change in status or even serve as "first responders" from time to time.

Case & Commentary: Part 2

As the transporters prepared to leave the floor with the patient, one of them noticed that the patient had labored breathing. He suspected that a nurse should travel with them but did not question the nurse's assessment on the transport stability form. During transport, the patient continued breathing through her NRM, which was connected to an oxygen tank.

Once the patient arrived in radiology, the CT technician noticed that NRM bag was deflated and the oxygen tank had a regulator that limited oxygen delivery to 4 L/min. The technician connected the NRM to the wall oxygen source at 15 L/min for the study and located an appropriate tank (that would allow higher-flow oxygen) for the trip back to the unit. After the study, the patient was switched to this new tank at 15 L/min and awaited transport. The tank was

noted to have 1000 lbs of pressure by the CT technician. The two transporters arrived, and the patient left radiology to return to her room.

In the elevator, one of the transporters realized that she no longer heard the flow of oxygen and that the NRM bag was deflated. When they returned to the floor, she immediately called for help. The patient was reconnected to the wall oxygen source in her room at 15 L/min. However, by that time, the patient was noted to be severely hypoxemic and markedly short of breath. Over the next hour, her condition continued to worsen. Because she did not wish to be intubated, she expired approximately 30 minutes after arrival to the floor. A root cause analysis later attributed the death, at least in part, to inadequate delivery of supplemental oxygen and insufficient observation during the transport process.

Although it is tempting to ascribe this tragic outcome to technical problems with oxygen delivery systems and process problems with transport, it would be a mistake to ignore some of the sociocultural and communication issues that were undoubtedly at play. Try to picture the scene at the patient's bedside before the patient was rolled out of her room to the scanner. The two transporters see the dyspneic patient and wonder whether a nurse should be present, but the transport scale says that it isn't necessary. It would take a very strong culture of safety to empower them to approach the nurse or a physician to question what appeared to be a clear-cut assessment (of course, there was no way they could know that the assessment had been done hours earlier and was now irrelevant to the current situation). Moreover, they were probably reassured by the presence of a physician, the patient's son; there was no way they could know that this physician worked in a nonclinical department.

The son, too, was placed in a terribly difficult position. We don't know if he shared the transporter's concerns about his mother's stability, but, as a nonclinician, he may have been unsure. Moreover, his role was to be a family member, not a health care provider—always a tricky balance, and one that has become trickier since the patient safety movement has begun encouraging patients to "speak up" when they see something wrong.(2,3) Finally, as a faculty member at the institution, he may well have struggled with whether to assert himself as a "VIP," worried that he would be branded as being overly demanding. In analyzing this case, it is easy to shuffle all these issues to the bottom of the deck (after all, creating a new transport protocol is far easier than trying to dampen authority gradients or think through the appropriate role of patients' family members in ensuring safety), but it would be a mistake to omit them from consideration and possible intervention.

Returning to more concrete matters, let's consider the issue of delivering supplemental oxygen. One study of intrahospital transport of non-ICU patients found that oxygen therapy was frequently interrupted.(4) In this study, the

authors reported high levels of variability among hospitals in the responsibilities of respiratory care practitioners and nurses for oxygen therapy on acute care units. As we consider the issues surrounding the delivery of oxygen to the patient in this case, a number of questions arise: Who is adequately trained to assess oxygen delivery devices for transport? What is the required assessment of the oxygen system? When is it done? What are the contingency plans if the patient's condition changes en route? The critical care guidelines recommend that the oxygen source have an adequate supply to provide for the patient's needs (flow rate over time of transport to and from destination) plus a 30-minute reserve.(1) Respiratory therapists are best prepared to provide education and be involved in improving care related to oxygen therapy and should be brought into any discussions regarding how to make intrahospital transport safer.

Recommendations for Improving the Safety of Intrahospital Transport

To address this important—and we believe underreported and understudied—patient safety issue, hospitals should first assess their current practice and policies. This assessment should include a review of the following elements: which patients are being transported and to which locations, pre-transport assessments, transport personnel competency and responsibilities, handoff communication, necessary equipment and supplies, and transport monitoring (Table).

Examples of Best Practices

Hospitals will have variable answers to the questions posed in their review of practice and resources, and the literature does not include scientific assessments of various strategies and practices. Nonetheless, our review of the literature, monitoring of listserv communiqués, and discussion with various providers has pointed us to certain practices worthy of consideration.

First, the use of a TSS or another tool that standardizes the pre-transport assessment is an essential component of safe intrahospital transport.(5) However, this case clearly demonstrates that the tool itself will not ensure safety. Developing a structure for how, when, and by whom it is used and ensuring competency for its use is as important as the instrument itself. One hospital uses a "Ticket to Ride" system, in which the ticket serves as the communication form between sending and receiving personnel. The ticket includes patient identification, stability, and risk information. The transport personnel are responsible for ensuring the nurse completes the ticket and that the ticket is with the patient until return to the home unit. Another best practice is a checklist system used by the sending nurse. The checklist outlines the essential steps of patient identification, pre-transport assessment (including need for analgesia or sedatives), notification to

providers and accompanying personnel when necessary, and checking supplies and equipment necessary for transport.

There are many implications for further study of patient safety during intrahospital transport of acutely ill patients. Identification of risk factors for negative outcomes associated with intrahospital transport of acutely ill patients would help inform the development of a useful pre-transport assessment tool. Hospitals often retrospectively identify these risk factors after sentinel events occur (eg, patients with escalating oxygen therapy requirements, as in this case). Other risk factors, such as altered mental status, morbid obesity, and use of sedative agents and/or sleep apnea, may not be familiar to care providers. Intervention studies are needed to evaluate system improvements, such as transport teams or innovative communication systems.

Partly because the issue of transport tends to "fall between the cracks" of divisions, departments, and providers, it has been the subject of too little research, too few innovative quality improvement practices, and possibly too little regulation. The time has come to rectify this, lest more patients fall victims to the risk of moving around the hospital.

Right? Left? Neither!

Case & Commentary

A 79-year-old woman presented to an after hours clinic with a 1-week history of diarrhea and progressive weakness. Due to signs of dehydration, the patient was directly admitted to the hospital. Past medical history was notable for stroke with residual left-sided hemiparesis, hypertension, coronary artery disease with ischemic cardiomyopathy, peptic ulcer disease, asthma, and obesity. Two weeks prior to this admission, she had spontaneously developed right ankle and foot pain and had been evaluated in the emergency department (ED) of another hospital. The family was told of a possible fracture and a splint was applied. She was instructed to follow up with an orthopedist as soon as possible. Due to transportation difficulties, the patient was not seen in follow up.

On physical examination, she was afebrile and appeared weak. She had a left-sided hemiparesis. The right ankle and foot were in the same splint that had been applied 2 weeks earlier. When examined, the ankle had a normal range of motion with no localized tenderness. A stool specimen collected in the ED was subsequently positive for Clostridium difficile *toxin. At the time of admission, a release of information was signed and faxed to the other hospital to obtain records of the recent ED visit for the ankle and foot injury. The family requested an orthopedic consultation to expedite work-up. Outside records of*

the previous ED visit did not arrive promptly, so another x-ray was taken of the right foot and ankle. This x-ray was read by the radiologist as showing a right ankle trimalleolar fracture and dislocation. The consulting orthopedist reviewed the x-ray report then briefly examined the patient. Surgery was recommended and discussed with the family, and consent was obtained.

The next morning, the patient was taken to the operating room (OR), and spinal anesthesia was administered. The orthopedist was scrubbed and was preparing to operate. The ankle x-ray was on the view box in the OR. Prior to making an incision, the orthopedist reviewed the x-ray and was shocked to notice that it was a left ankle x-ray showing a trimalleolar fracture. A prompt examination of both of the patient's ankles under anesthesia did not demonstrate any clinical evidence of fracture or dislocation. The x-ray was clearly labeled as belonging to the patient. Stat x-rays of both ankles were then done in the OR. The left ankle was intact, and the right showed an intact ankle with a healing fracture of the fifth metatarsal bone.

During the ensuing confusion, one of the OR technicians recalled that another patient had undergone an operative reduction-internal fixation (ORIF) of a left ankle trimalleolar fracture 2 days prior. It was later confirmed that the x-ray showing the left ankle trimalleolar fracture was mislabeled by date and patient and belonged to this other patient who already had surgery.

The spinal anesthesia was reversed, and the patient was returned to her room and fortunately did not have any consequences. Full disclosure and an apology were given to the family.

The patient continued to recover from the dehydration and colitis and was able to be discharged from the hospital. Treatment for the metatarsal fracture consisted of a supportive boot. By the time of discharge, a faxed copy of the ED records from the outside hospital had been received. Included in these records was an x-ray report describing a non-displaced, fifth metatarsal fracture of the right foot.

Performing an invasive procedure on the wrong patient should never happen. Neither should operating on the wrong side of the right patient. Reliable estimates of the frequency of this kind of adverse event are not available. The data that do exist suggest that events like these are underreported to the voluntary sentinel events database of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), as well as to state programs that require adverse event reporting.(1-3) Wrong-patient or wrong-site invasive procedures may be uncommon but “for patient and doctor it is the ultimate nightmare.”(4)

Broadly speaking, adverse events in hospitals occur through two different mechanisms. A single mistake, if it is serious enough, may cause harm by

itself. Alternatively, and more commonly, many smaller errors may occur—not one of which alone is severe enough to cause harm. In combination, however, as seen in this case, they become toxic. James Reason has developed a powerful explanatory model to understand adverse events that occur by the second mechanism, which he has called “organizational accidents.”(5) Synthesizing the work of many psychologists, accident experts, and organizational sociologists, Reason provides a conceptual framework that delineates how errors made by individuals interact with system defects in complex organizations to cause harm.(5) Like other complex organizations, hospitals put defenses into place to prevent errors from doing harm. Examples of such defenses include training programs; safety protocols, policies, and procedures; and computerized decision support tools. Every layer of defense has weaknesses. If an error gets past one defense, another layer of defense usually prevents harm from occurring. Adverse events occur only when all the defenses around a particular patient's situation have been circumvented by many errors. Reason has referred to this framework for understanding adverse events as the “Swiss Cheese Model.”(6)

Let us review this adverse event to determine (i) which of the two causal pathways was involved (single error versus Swiss cheese); (ii) whether the Swiss cheese pathway was causative and which defenses failed to prevent harm; and (iii) what remedial action might be called for. We will start by identifying the primary errors made by individuals during the course of this patient's care that contributed to causing the event.

The first error (or series of errors) occurred 2 weeks prior to admission when the staff in the ED who diagnosed the non-displaced metatarsal fracture failed to communicate this diagnosis clearly and unambiguously to the patient and her family. If the patient and family had known the correct diagnosis of her foot pain and reported that history at the time of admission, this mishap might have been prevented, particularly if that information had been supplemented by confirmatory documentation from the ED. The next group of errors occurred when the patient was admitted. The physician in the ED who examined the patient and found a normal right ankle failed to communicate his or her findings to the physician responsible for admitting the patient or to the consulting orthopedic surgeon. The case summary does not identify the admitting physician, but since the patient was admitted primarily to treat dehydration, it is unlikely that she was admitted directly to the service of the orthopedic surgeon. It is not clear from the case narrative whether the ED physician ordered the repeat foot and ankle radiographs while the patient was in the ED or the consulting orthopedic surgeon ordered them after the patient had been admitted. If the ED physician ordered them, he or she erred further in not personally reviewing the films. If the patient was admitted to an internist or other primary care physician, that physician also erred in not examining the patient and her x-rays.

The case summary does not reveal how the patient's foot and ankle radiographs were mislabeled in radiology, but it is very likely that several errors were involved. Initially, an erroneous report on the patient was generated showing a right trimalleolar fracture with dislocation. It is highly implausible that the patient's actual films were misread by the radiologist. A non-displaced fifth metatarsal fracture can hardly be mistaken for a trimalleolar fracture with dislocation. As we learn later, it is far more likely that a different patient's films were somehow mislabeled with the current patient's identifying information and current date. Why the initial erroneous report identified the side of the trimalleolar fracture as right is also unclear. Did the radiologist misread the side of the trimalleolar fracture because the order for the current patient called for right foot and ankle films?

By any reasonable standard of judgment, the orthopedic surgeon committed by far the most serious errors in this case. The orthopedist failed to elicit or to discover the history of the patient's previous diagnosis or treatment. The history reported by the patient's family was not consistent with the x-ray findings. It is very unlikely that any hospital would let a patient with a displaced trimalleolar fracture (at risk for vascular compromise) leave the ED in a splint without an orthopedic consult. Had the orthopedist obtained this history, he or she might have been led to question the x-ray findings. Compounding this error, the orthopedist “briefly examined the patient.” It is difficult to comprehend how even a brief physical examination of this patient's foot and ankle could not have caused this physician to question the radiographic diagnosis. One is forced to suspect that the surgeon may not have removed the bed covers and visualized the right ankle. This single error is serious enough, but the surgeon made it even worse by recommending surgery on the basis of this incomplete evaluation, obtaining “consent” (which could hardly be called informed) and scheduling the operation.

The final set of errors occurred prior to the patient receiving spinal anesthesia. Surgical site verification was not conducted prior to the patient going to the OR or prior to administering spinal anesthesia. JCAHO has recommended a series of steps to prevent wrong-site, wrong-side, and wrong-person procedures.(7) The Universal Protocol clearly delineates these steps, which include (i) a preoperative verification process to ensure that all studies and records are available, have been reviewed, and are consistent; (ii) marking the operative site; and (iii) a “time out” to conduct a final verification of the correct patient, procedure, and site prior to starting the procedure.(7) There is no indication in this case that any of these procedures were undertaken. While a recent study notes the fact that the effectiveness of preoperative verification protocols has not been evaluated (8), there is every reason to believe that in this case the patient would have been spared an unnecessary spinal anesthesia if the Universal Protocol had been properly applied. The patient was spared unnecessary surgery at the last moment when the orthopedist discovered that the presumptive diagnosis was wrong.

We suspect that the orthopedic surgeon was prompted to review the x-rays in the OR after finally recognizing that the ankle he or she was “preparing to operate” on looked nothing like an ankle with a trimalleolar fracture/dislocation.

Which adverse event pathway did this case follow? This is clearly an example of the Swiss cheese pathway (Figure). There was no single, critical error. Many individuals made many errors. Many defenses failed to protect this patient. Communication failed in several instances (eg, between the first ED and the patient, between the second ED physician and the orthopedist, between the admitting physician and the orthopedist). Policies and procedures were inadequate (eg, mislabeling of the x-ray, failure to implement the universal protocol). Teamwork failed in the OR when no one—nurses, OR technicians, the anesthesiologist—observed that the patient's ankle appeared normal, and no one questioned whether the procedure should continue. The failure of the orthopedist to perform an adequate history and physical examination on the patient prior to surgery stands out as the most serious individual error. But even that error combined with the second-most serious error (the mislabeling of the ankle x-ray) was not sufficient to cause this adverse event. Many other individuals, including the staff in the first ED, the second ED physician, the admitting physician, and the OR staff, had the opportunity to stop this sequence of errors before the patient was harmed. Only when all the defenses surrounding this patient failed did she experience the harm of unnecessary spinal anesthesia.

While some might call this case a “near miss” or close call—a situation that could have led to an adverse event but did not—we would call this case an adverse event. This patient was subjected to spinal anesthesia for no reason. Although the risks are low, spinal anesthesia is occasionally associated with severe risks, such as cardiac arrest and neurological complications.(9)

The institution at which this adverse event occurred should consider several remedial actions to strengthen its defenses. The process of identifying and labeling radiographs should be reviewed to discover exactly how the errors occurred in this case and improved to avoid them in the future. The Universal Protocol should be implemented in all ORs and procedure areas. The multiple communication failures suggest the need for a formal protocol to delineate precisely how responsibility for care is handed off from the ED to admitting physicians and consultants. Finally, the actions of the orthopedist should be examined by the appropriate peer review committee.

Citrate Mix-Up

The Case

A 36-year-old woman with multiple sclerosis, diabetes, and chronic renal failure was transferred from a skilled nursing facility (SNF) to the hospital for treatment of an infection. On admission, an order was written for Bicitra, 30 mL four times daily—a medication that she had been receiving in the SNF. The hospital pharmacist filled the order with Polycitra instead of Bicitra, and dispensed a 473-mL container. (Polycitra is a combination product containing citric acid and potassium citrate; Bicitra contains only citric acid.) Assuming the Polycitra was dispensed in the appropriate quantity for a single dose, the nurse gave the patient the bottle and a straw and instructed her to drink the entire amount.

When the nurse on the next shift noticed the empty container with the straw, she interviewed the patient. The patient confirmed that she consumed the entire amount and said that it tasted good. The physician was notified. A STAT serum potassium level was >8 mEq/L (normal 3.5-5), and her blood glucose was 600 mg/dL (normal

The patient was treated with Kayexalate (sodium polystyrene sulfonate) and an insulin infusion, and she recovered within 24 hours without further complications.

Cups of Error

The Case

An 87-year-old man was 5 days postoperative from a decompressive laminectomy. Although he suffered from dementia, he remained alert and oriented with only mild short-term memory loss. During his stay at a rehabilitation unit, a nursing student administered a “cup” of medications that included clopidogrel (Plavix), carbidopa-levodopa (Sinemet), prednisone, rivastigmine tartrate (Exelon), and risperidone (Risperdal). Unfortunately, this cup of medications belonged to another patient on the unit. As a result, the patient became drowsy with mild nausea and hypotension, but the symptoms resolved within 24 hours without further event. After learning about the error, the family requested no further care from any nursing students.

On this particular unit, nursing students receive supervision from a senior nursing instructor. The unit's policy required that only the instructors access Pyxis (an automated drug dispensing system) when administering medications. In this case, the instructor attempted to save time by having the eight nursing students prepare their medications from Pyxis at the same time; after preparation, the instructor reviewed each student's understanding of the medication(s) and preparation accuracy. After this process was completed, the students left each of their patients' medication(s) in a “cup” on the counter in the medication room. When the time came to administer the

medication(s), the student in this case picked up the wrong cup of medications for her patient.

The error was discovered when a different student expecting to give the above medications reviewed the ones in her cup and discovered the wrong medications—also a near miss for her patient.

Insert Omission

The Case

A multiparous woman presented to the gynecology clinic requesting intrauterine contraceptive (IUC) placement (Figure). She was appropriately counseled on the risks and benefits of the IUC and at that visit had a normal Papanicolaou test and negative cultures for gonorrhea and *Chlamydia trachomatis*.

As instructed, she returned a week later while having menses for placement of a copper IUC. The gynecologist placed the IUC without difficulty and showed the patient how to palpate the IUC strings. One month later, the patient presented to the clinic because she was unable to find the strings. On pelvic examination, the gynecologist was also unable to locate the strings. A pelvic ultrasound revealed a 7-week intrauterine pregnancy and an IUC. By dates, the patient was approximately 3-4 weeks pregnant at the time of IUC insertion, and the “menses” was probably implantation bleeding.

The patient was referred to a perinatologist who recommended that the IUC remain in place. The patient subsequently had an elective termination of pregnancy without complication. As a result of this error, the clinic now requires urine human chorionic gonadotropin (HCG) testing prior to procedures in premenopausal women regardless of menstrual or sexual history.

Language Barrier

The Case

A previously healthy 10-month-old girl was taken to a pediatrician's office by her monolingual Spanish-speaking parents when they noted that their daughter had generalized weakness. The infant was diagnosed with iron-deficiency anemia. At the time of the clinic visit, there were no Spanish-speaking staff or interpreters available. One of the nurses spoke broken Spanish and in general terms was able to explain the girl had "low blood" and needed to take a medication.

The parents were thankful for the attention and nodded in understanding. The pediatrician wrote the following prescription in English:

Fer-Gen-Sol iron, 15 mg per 0.6 ml, 1.2 ml daily (3.5 mg/kg)

The parents took the prescription to the pharmacy. The local pharmacy did not have a Spanish-speaking pharmacist on staff, nor did they obtain an interpreter. The pharmacist attempted to demonstrate proper dosing and administration using the medication dropper and the parents nodded in understanding. The prescription label on the bottle was written in English.

The parents administered the medication at home and, within 15 minutes, the 10-month-old vomited twice and appeared ill. They took her to the nearest emergency department, where the serum iron level 1 hour after ingestion was found to be 365 mcg/dL (therapeutic levels are 60-180 mcg/dL). She was admitted to the hospital for intravenous hydration and observation. Serial serum iron levels and electrolytes were monitored. She was asymptomatic for the remainder of the hospitalization and discharged the following day with no apparent sequelae.

Upon questioning, the parents stated that they had administered a household tablespoon of the medication, approximately 15 ml or 43 mg/kg (a 12.5-fold overdose). At the time of discharge from the hospital, the nurse counseled the parents on proper dosing through a hospital interpreter.

Is the "Surgical Personality" a Threat to Patient Safety?

Case & Commentary: Part 1

A 7-year-old boy with acute lymphocytic leukemia presented for insertion of a portacath. The surgeon utilized a supraclavicular approach for the guidewire placement and was having significant difficulty obtaining venous access. During this period, the surgeon began to yell at the members of the operating room (OR) team for a variety of issues, including the degree of chatter in the OR, the failure of the OR staff to anticipate his next request, and their failure to move the patient into his desired position to place a Bovie pad. This behavior did not surprise the OR team, as this surgeon had a reputation for being “old school” and possessing poor communication skills.

On the next attempt to pass the guidewire, it appeared to pass into the left ventricle. This was noted by both the X-ray technician and the anesthesiologist, neither of whom were willing to speak up given the senior surgeon’s reputation of berating team members who gave unsolicited input on “his case.”

The first joke I ever heard about surgeons had as its punch line: “Oh, that’s God, he just thinks he is a surgeon.” The act of practicing surgery requires a very specific skill set—excellent eye–hand coordination that translates into excellent manual skills, the ability to act decisively on uncertain knowledge under time-limited situations, and a willingness to improvise when the unexpected occurs—all of which creates the aura of the surgeon as a Hemingwayesque hero who displays grace under pressure. But neither the aura nor the skill set preordains a certain personality. In fact, there is great variation in social skills, interpersonal style, and individual demeanor within any group of surgeons—what *is* shared by both self-effacing and soft-spoken surgeons and by arrogant, brashly assertive ones is the ability to rise to the occasion, to do what is necessary, to project a calming confidence when odds suddenly and unexpectedly become long. Nonetheless, the myth of a surgical personality persists in the organizational culture of the modern hospital.

One of the surgeons I shadowed while gathering data for *Forgive and Remember: Managing Medical Failure* (1) appeared to be the perfect embodiment of the surgical personality. It was as if he entered the operating room directly from central casting. He strode into rooms and instantly commanded the spotlight. His grooming was immaculate; his unwrinkled surgical scrub suits possessed a military crease. His posture was ramrod straight. He was tyrannical in the demands that he made upon residents, nurses, and, to be fair, himself. He directed public verbal abuse at residents when their performance failed to meet his unsparing standards.(1)

Had I shadowed only one surgeon, I might have conflated this surgeon’s boorish behavior with those qualities necessary to achieve clinical excellence. However, I saw a number of this surgeon’s colleagues who achieved the same results, displayed the same level of surgical skill, and were able to make the same time-pressured decisions under conditions of uncertainty while treating others with respect.

A surgical personality exists, although it is misnamed and overly specified. As illustrated in this case, its features include wielding authority in an overbearing way and treating subordinates in a psychologically abusive manner. Individuals in positions of authority who misuse authority to humiliate those under their control are not in short supply in the workplace, medical or otherwise. As with most clichés and stereotypes, probably more surgeons behave this way than other physicians; however, there is no shortage of the surgical personality among physicians in all specialties. Exactly how this particular style became associated with, tolerated by, and perhaps even encouraged within surgery is a topic worthy of some reflection.

The practice of surgery has always been closely associated with the battlefield. Some of the hierarchical patterns of authority so observable in surgical practice and training surely owe something to surgery’s close

connection with the military. The attending surgeons whom I observed in the 1970s (for the first edition of *Forgive and Remember*) honed their skills serving in MASH units in Korea; they were trained by physicians who learned their craft in World War II; and many surgeons, now in their early sixties, saw service in Vietnam.

Surgeons have always served in the military, but they have never been *of* the military, in that many surgeons (particularly those exhibiting the surgical personality) maintain a near complete disregard for organizational rules and behavior. This characteristic is surely maddening to administrators who try to create rule-based order within the hospital. “True surgeons” will not allow what they feel is in their patients’ best interest to be compromised by organizational policies and procedures. Yet, the same surgeon that treats organizational rules with such disdain demands total obedience from those that work under them.

At one time, the demands for quick compliance with orders and the intolerance of delay may well have served the patient’s interest. But those days are long gone. Surgical procedures now require complex teamwork among radiologists, anesthesiologists, nurses, and a variety of specialists. For instance, the development of minimally invasive fiber-optic surgery has increased the demands for coordination within the operative suite. Procedures that were once two-handed have become four-handed.(2) This evolution in the nature of surgery now means that the surgical personality is not just a vestigial presence but a counterproductive one as well.

Case & Commentary: Part 2

The dilator and peel-away covering were placed over the wire and the catheter was threaded into place. The surgeon then injected multiple boluses of saline and Hypaque dye, and the child became tachycardic and hypotensive, with narrowing of the pulse pressure. Severe respiratory variation was noted on the pulse oximeter tracing. The anesthesiologist voiced his belief that the surgeon had placed the device in the pericardial space and demanded that he perform an immediate pericardiocentesis. Instead, the surgeon insisted on removing the portacath and closing the skin incision. Over the next 10 minutes, the child’s cardiovascular status deteriorated, requiring boluses of epinephrine. Once pericardiocentesis was finally performed, the child immediately improved and more than 200 cc of bloody fluid were drained. Ultimately, the patient required two pericardiocenteses and was intubated overnight in the PICU. He required readmission and a repeat surgery several weeks later and had a delay in administration of his intrathecal chemotherapy.

Once it becomes clear that a particular practice or leadership style hinders our achieving important goals, the question arises: Why did we tolerate this

state of affairs for so long? So long as social arrangements seem natural, so long as they go unchallenged, and so long as we cannot imagine an alternative, we tolerate them. Wisdom is said to reside in recognizing that which we are powerless to change, so why aggravate ourselves over the unchangeable? The question is not why "the natural" order is tolerated. Rather, we need to ask: Under what conditions are social arrangements once thought unassailable and uncontested challenged?

The most obvious challenge to the unthinking acceptance of the surgical personality came with the publication of the Institute of Medicine (IOM) report on the prevalence of preventable adverse events in medicine.(3) That document identified dysfunctional responses to error characterized by "naming, blaming, and shaming" individuals.(1) The problem with such responses is that they inhibit the sharing of knowledge that would serve to prevent mistakes from being repeated. The IOM report not only decried dysfunctional approaches to managing errors; it also pointed to lessons that medicine had to learn from industries that had made significant progress in emphasizing safety.

In high-technology organizations, in which production processes are characterized by tight coupling—in other words, the timing of sequencing is critical—and complex or unpredictable interactions, accidents have been said to be "normal." The seemingly oxymoronic term, "normal accident," indicates that accidents are a consequence of the way work is organized. Small errors, innocent in themselves, combine stochastically with other minor deviations to create unexpected, unpredictable accidents and errors. Normal accident theory suggests that, in complex human endeavors, accidents are inevitable and that efforts at prevention yield limited results.

A number of theorists who have studied high-technology organizations that manage to operate without baleful consequences challenge this counsel of despair. These theorists have developed the theory of highly reliable organizations.(1,5) For example, on the flight decks of aircraft carriers, safety is achieved in multiple ways. Any member of the crew is empowered to wave off a landing—judgments of safety trump formal rank. Crew members are rotated through the different assignments of the flight deck, so all workers possess not only an understanding of their responsibility but also a global knowledge of flight deck operations. Finally, the lessons of experience are communicated through a dense oral culture—inexperienced workers are schooled through vivid narratives elaborating threats to safety.

Karl Weick has shown that organizational culture is itself a source of high reliability and safety.(6) Two elements are critical to safety cultures. First, there is the inculcation of core values in members of an organization or profession. This has an important consequence: when activities are dispersed and not amenable to supervision from a central source, organizational leaders

can have some confidence in the rationales that support decisions made in the field. Second, those in charge communicate to other team members how important they are for early detection and communication of impending problems. For Weick, “safety cultures” seek wisdom rather than knowledge alone, couple confidence in skill with humility, and promote respectful and “heedful” interactions. Had this been the culture in the OR during the case described above, the X-ray technician and anesthesiologist might have felt free to express their concerns about the guidewire placement, which could have prevented this error.

A number of factors are critical if safety cultures are to become a reality rather than a rhetorical goal. First, there needs to be an increased emphasis on the importance of teamwork early in medical training. Next, physicians need to be taught the dangers that “the captain of the ship” doctrine presents to safety. A dense oral culture that celebrates the benefits to safety and quality care that teamwork provides (similar to that which exists on aircraft carrier flight decks) needs to be developed and circulated. When I did the fieldwork for *Forgive and Remember*, the oral culture of surgeons celebrated individual professional responsibility. Now, that oral culture needs to be reformulated so that heroic action that creates safety is seen to flow from the coordinated action of team members. Finally, there needs to be intolerance from organizational leaders of the behaviors that characterizes the “surgical personality.” The system changes necessary for high quality and safe care are impossible unless we recognize and change those counterproductive behaviors that, in too many cases, have been allowed to persist without challenge.(7)

The Wet Read

Case & Commentary: Part 1

A 66-year-old man with prostate cancer and known bone metastases presented to the emergency department with a gradual increase in back pain and difficulty ambulating. Initial radiographic evaluation demonstrated stable metastatic bone lesions in the lumbar spine without evidence of cord compression. The patient was admitted for pain control with intravenous morphine and started on patient-controlled analgesia (PCA). Admitting laboratory studies were notable for mild anemia. Renal function, LFTs, and coags were within normal limits. CXR and urinalysis were unremarkable.

On the night of hospital day 2, the patient developed acute shortness of breath and was found to be tachycardic and slightly less responsive. His oxygenation was 78% on room air and 92% when placed on a non-rebreather mask. ECG showed evidence of right heart strain, and a room air blood gas revealed a pH of 7.33, a CO_2 of 50, and a paO_2 of 55. Given the high suspicion for pulmonary

embolism, the resident physician ordered a computerized tomography (CT) angiogram of the lungs. The on-call radiology resident read the study, contacted the ordering physician, and reported that his findings were consistent with a large pulmonary embolism in the right main pulmonary artery. As the patient was mildly hypotensive and had hypoxemic respiratory failure requiring intubation and mechanical ventilation, a decision was made to administer thrombolytic therapy.

The following morning, the patient's condition improved with normalization of blood pressure, improved oxygenation, and increased level of consciousness. While the team was rounding and discussing plans for extubation, the radiology attending called the ICU and reported that the final reading of the CT angiogram showed no evidence of a pulmonary embolism. He explained that what was initially read as a large pulmonary embolus was in fact a large artifact (Box) on the image cut reviewed by the overnight resident.

In teaching hospitals, radiology residents have traditionally provided preliminary interpretations during off-hours for patients in the emergency department and on inpatient wards.(1) In most cases, the only off-hours services provided by attending radiologists were in interventional radiology. For other types of radiologic studies, attending radiologists have generally followed up on preliminary reports (known as “wet-readings”) from night residents the next morning or at certain times on weekends.

Recent studies have shown that the frequency of significant errors by radiology residents is very low. Although minor discrepancies, unlikely to have a significant impact on patient care, have been reported in 3% to 7% of readings, the rate of major discrepancies that may alter patient care ranges from less than 1% to around 2.3% of cases.(2-8) These recent findings are in contrast to a single earlier study that found major and minor discrepancies at a rate of 5% and 11%, respectively.(9) Even with the low discrepancy rates shown in recent studies, several have shown higher discrepancy rates when readings have been performed by the most junior residents.(5,7,10) Interestingly, these overall rates of resident errors are similar to the rate of interobserver differences among attending radiologists. Moreover, the error rates are substantially below those found when attending emergency department physicians' readings are compared with those of attending radiologists.(5)

Nonetheless, concern persists about the unusual instance in which a resident's misread film results in a patient being sent home without appropriate treatment or in a patient receiving improper surgery or other therapies. Many faculty in academic radiology departments have debated appropriate off-hours coverage for years. These debates must weigh the fact that residents' off-hours experience is an important part of their professional

development, building their confidence and judgment in a semi-independent environment.(6)

Case & Commentary: Part 2

In light of the new reading, the team decided the clinical decompensation was likely due to aspiration and mucous plugging secondary to oversedation from narcotics. The right heart strain noted on ECG was determined to be an old finding from mild unexplained pulmonary hypertension. The patient did not have bleeding complications from the thrombolytic therapy. He was extubated and ultimately discharged to a skilled nursing facility for rehabilitation.

Fortunately, no harm came to the patient in this case. But it might have. How could this error have been prevented? Attending radiology faculty could certainly provide off-hours coverage, but few would want to work through the night on a regular basis. Large radiology departments tend to have very busy night schedules for CT and plain radiographic images. Typically, academic departments are filled with radiologic subspecialists (eg, chest, abdomen, or MRI) who often have limited their practices to selected areas and do not feel comfortable covering cases outside their area. For such departments to provide off-hours coverage with faculty would be difficult indeed, requiring multiple subspecialists to be on every night.

Another approach has been the use of general radiologists reading the films remotely through teleradiology.(11) These radiologists can cover a number of hospitals at the same time. Private practice radiologists use these services (which may involve domestic or international teleradiology) much more frequently than academic departments, where residents perform overnight coverage. As these general radiologists lack the subspecialty training found in academic centers, the quality of service may be less.(12) And if a general radiologist only provides the preliminary report and the subspecialist academic faculty reads the film again the next morning, the costs for the services may become quite high, since only one interpretation will be reimbursed.

When radiology trainees provide preliminary reports, back-up support by attending faculty for difficult cases must be readily available. Often, faculty provide coverage from home through web-based access to the Picture Archive and Communications System (PACS).(1) An attending with high-speed internet access can review a single case or a few cases from home overnight. It would, however, be very difficult to provide this level of review for all cases because home access may be slower and offer fewer features than the typical PACS workstation in the hospital.

Residents on call are often reluctant to call the attending faculty, fearing that such calls would signal that they are not capable of handling the situation themselves. To help decrease this underutilization, many departments have established rules for when a resident needs to seek assistance. Ideally, no patient would undergo surgery or other invasive procedure based on radiographic findings without an attending radiologist's review. A safeguard such as this (if extended to the use of thrombolytic therapy) may have prevented the error in this case. In addition to these criteria, when a referring physician in the emergency department or elsewhere in the hospital wishes to have an attending radiologist's review for whatever reason, they should be able to trigger that home review.

Timely next-day review of off-hours cases and immediate communication of discrepancies in interpretation are critical. These cases must be reviewed early enough in the day to provide the referring physicians comfort that further actions (such as surgery) will be based on the most up-to-date and accurate information from the imaging studies. Residents' preliminary interpretations should be conveyed in writing to the requesting physician. Whenever there is a discrepancy after attending review, these changes need to be immediately communicated with the referring physician with a clear indication of the change. If the referring physician has taken action on the patient based on an erroneous preliminary report, that physician needs to be able to refer to the original reading if there is any question about the care.

To provide the safety net for these resident preliminary readings while protecting the residents' training experience, the UCSF department of radiology developed a “wet-read” computer system (Figures 1, 2, and 3).(13) This system provides the resident with a convenient report generation system for preliminary findings, which are immediately communicated to referring physicians either on their PACS workstation or via pagers or hand-held devices. The next morning, the attending radiologist indicates agreement with the resident report or indicates a change, the magnitude of the change, and whether it might alter care for the patient.

This automated system also allows for emergency department physicians to record their image findings, especially if they reviewed the images before the radiology resident or attending. If the resident finds an abnormality missed by the emergency department physician, he or she calls right away to alert them. All of these preliminary reports are stored in the computer system permanently, although the dictated report and then the finalized report replace them as the most-up-to-date information displayed when the patient's medical record is accessed. This system also automatically records discrepancies and provides reports indicating the frequency and significance of errors for all physicians involved. Our system has found error rates similar to others that have been published: 0.47% major, 4.00% minor, 1.52% questionable, and 94.01% no errors.

The frequency of significant errors by radiology residents is very low when compared with attending reviews the next day. Nevertheless, errors do occur and their implications can be severe if they result in inappropriate triage or therapy. Because having full-time coverage by academic radiologists does not currently seem feasible and teleradiology provided by general radiologists may be inferior to that provided by subspecialty radiologists, perhaps “higher-risk” cases could be identified and lead to automatic attending back-up reads. For example, higher-risk cases might include those read by more junior reviewers, or those whose interpretations could prompt procedures or life-threatening therapies. In addition, formal policies could be created to trigger involvement of the attending and efforts could be made to change the culture to increase resident willingness to involve the attending. Ideally, all institutions would have computer systems that would ease provision of off-hours coverage from home and facilitate timely communication with referring physicians.

Collegiality vs. Competence

The Case

A 91-year-old man with coronary artery disease was taken to the operating room (OR) for semi-elective repair of a 10-cm abdominal aortic aneurysm (AAA). The procedure was relatively uneventful, and the infrarenal aneurysm was repaired. The patient’s estimated blood loss was more than 1000 cc, and he received 2-3 units of cell saver blood. As the fascia was being closed, the surgeon noted pooling of blood in the surgical field. The patient’s abdomen was re-explored, at which time he began bleeding profusely from multiple sites, including the surgical wound, endotracheal tube, nasogastric tube, and intravenous catheter sites, all consistent with the development of disseminated intravascular coagulation (DIC).

The surgeon mechanically reinforced the anastomosis sites, but they continued to bleed. Surgeons assisting with the case, as well as the anesthesiologist, recommended packing and closing the abdomen to tamponade the bleeding and transferring the patient to the ICU for further medical management. The attending surgeon opted to give blood products and continued to attempt local control of the bleeding with little success. The patient was finally closed and transferred to the ICU 6 hours after the DIC was first noted. He had received more than 20 units of blood products and was acidotic on multiple pressors. At this time, the attending surgeon left the hospital, and the patient was managed primarily by the chief resident.

The next morning, the patient continued to require multiple pressors and a bicarbonate drip and had fixed pupils. The attending surgeon opted to bring the patient back to the OR for a second look. He found clotted blood but no

treatable lesions; no interventions were undertaken. The patient subsequently had progressive hypotension, did not respond to resuscitative measures, and died.

The attending surgeon was known to have had multiple surgical complications in previous cases, and had been formally investigated twice for inability to meet the standard of care. Given his seniority, longevity, and respected position in the medical center, his credentials were never formally restricted; rather, it was informally requested that he not perform certain procedures, including AAA repair.

Liposuction Gone Awry

The Case

A 54-year-old man with HIV was referred to a plastic surgeon for cosmetic surgery. In the plastic surgeon's office, he underwent neck and facial liposuction with eyelid tightening under local anesthesia. There were no complications at the time of the procedure and the patient was sent home.

After arriving home, the patient noticed an expanding neck mass near the incision site and progressive shortness of breath. He contacted the plastic surgeon, who directed him to the nearest emergency department. Upon arrival, the patient was in severe respiratory distress and needed an emergent tracheostomy, secondary to neck swelling and edema. He was taken to the operating room, where he was found to have a laceration of the external jugular vein. The vessel was repaired and the patient required a prolonged stay in the intensive care unit. He eventually was discharged to home.

Workaround Error

The Case

A retired 81-year-old physician with metastatic colon cancer was admitted to an acute care hospital with pneumonia and congestive heart failure (CHF). After his acute hospitalization, he was transferred to a skilled nursing unit to complete antibiotic therapy. Cancer chemotherapy was scheduled to begin after discharge.

Three days after transfer to the skilled nursing unit, the patient complained of nausea. Intravenous ondansetron (Zofran) was ordered. Approximately 1 hour after the first dose of ondansetron, he was found unresponsive and in respiratory distress. Stat labs were ordered, and his blood glucose was 23 mg/dL. The patient had no history of diabetes or hypoglycemia.

He was given glucagon and transferred to the intensive care unit. Laboratory studies showed an insulin level of greater than 1500 micro-units/mL (upper end of the reference range: 17 micro-units/mL). Intravenous glucose and glucagon were continued, and his blood glucose stayed in the low 40 mg/dL range for several days. Ultimately, he was discharged without any permanent disability from the event, but he was in a weakened state and his chemotherapy was delayed.

The incident led to an internal review of the case. In this skilled nursing unit, many of the nurses remove medications from the Pyxis machine (an automated dispensing device) and insulin from the refrigerator and place them in portable medication carts that are then taken to the bedside. The nurse who was caring for the patient the night of the first ondansetron dose worked infrequently and had an especially heavy workload that evening (she was caring for nine patients on her shift). When her portable medication cart was inspected, ondansetron and insulin vials were found to be next to each other. It was presumed that she mistakenly administered insulin instead of ondansetron.

Deciphering the Code

The Case

An 85-year-old man with advanced oxygen-dependent chronic obstructive pulmonary disease (COPD) presented to the emergency department (ED) with increasing shortness of breath and cough. Initial evaluation demonstrated worsening hypoxemia and a chest x-ray showing a new, large left-sided pleural effusion. A therapeutic thoracentesis was performed, which relieved the patient's symptoms, but the etiology of the effusion remained unclear.

At the time of admission, the resident asked the patient about his advance directives, and he stated his wish to be DNR/DNI (do not resuscitate/do not intubate). The patient's wife confirmed that her husband never wanted to be "shocked or placed on a breathing machine." The resident placed a note in the chart to document the discussion.

A few days later, the patient was found unresponsive and pulseless. A code blue was called. The on-call resident (different from the admitting resident) responded and found the patient to be in ventricular fibrillation. Unaware of the patient's advance directive, the resident successfully resuscitated the patient (with medications and shocks) and transferred him to the ICU. The resident then contacted the patient's wife, who reiterated the patient's wishes to not undergo such measures. Immediately following this discussion, the patient again became pulseless, and resuscitative efforts were appropriately withheld. The patient died within minutes.

At this particular hospital, the policy was that residents should both document any code status discussion and enter a DNR/DNI “order” (to be cosigned by the attending later) in the electronic medical record. In this case, the discussion with the patient regarding code status was appropriately documented, but a specific DNR/DNI “order” was not entered into the medical record. Had the order been entered, it would have triggered the placement of an easily visible wristband onto the patient by the nursing staff, who would have also documented the order in their nursing records (neither of which happened). Even though there was no formal DNR order in the electronic record, the nurses might have chosen not to “call the code” had they seen the record of the code status discussion in the resident’s progress note. Unfortunately, there was no computer terminal at the patient’s bedside (and there were no longer any paper medical records), and so the bedside nurses had no access to the record of the DNR discussion, which contributed to the error. The end result was that the patient was resuscitated when he explicitly told his providers that he wished not to be.

Lost in Transition

Case & Commentary: Part 1

A 41-year-old woman came to the emergency department (ED) with mental status changes. She had been diagnosed with a urinary tract infection and started on oral ciprofloxacin 4 days earlier. She had fever, nausea, and vomiting in the days preceding presentation. She did not have headache, focal weakness, or numbness. Past medical history was otherwise unremarkable.

On physical examination, the patient was afebrile, with sinus tachycardia (heart rate 123 beats per minute) and otherwise normal vital signs. Able to follow most commands, she was alert but oriented to person and place only. Neurologic examination was otherwise non-focal. There were no signs of meningeal irritation.

Approximately 40 minutes after the patient arrived, initial laboratory results returned and included white blood cell count 12.7 K/μL with 89% granulocytes, hematocrit 20.2%, glucose 204 mg/dL, blood urea nitrogen 36 mg/dL, serum creatinine 1.4 mg/dL. Urinalysis showed moderate blood. Platelet count was pending at that time.

Sixty minutes after arrival, the patient was admitted to the internal medicine service with a diagnosis of anemia and hematuria in the setting of a urinary infection. The medicine team completed the admission paperwork, with plans to administer empiric broad-spectrum antimicrobial agents and packed red blood cells for the severe anemia. The outgoing ED physician had just

completed the shift and signed the patient out to the oncoming colleague as "admitted," with care already transferred to the internal medicine service.

Transitions are necessary in any industry with continuous operations, and health care is no exception. Shift changeover occurs when two or more workers exchange mission-specific information, responsibility, and authority for an operation.(1,2) This moment of care has been characterized as both an opportunity for rescue and a threat to safety.(2,3) Most health care teams now consist of far more than one nurse and one physician—with each additional worker responsible for care, the potential for error or rescue increases. The ability to effectively conclude one level of care and transfer to the next is critical to quality and safety in the ED.

Any discussion of shift changeover involves the complex interplay of two or more individuals working in a broader system. Certain features are common to most ED handoffs. Geography often dictates a starting and ending point (ie, bed 1-10). Interruptions occur frequently. Physicians often perform sign-over separately from nurses and other specialists. The chart or other formal written documentation is rarely used for transitions.

On the other hand, many of the aspects of ED transitions are highly variable.(4) Transition can occur in front of the patient, at a remote setting, or anywhere in between. The hand-off can be predominantly interactional or transactional. That is, the transition may be a two-way dialogue that leads to "shared sense-making," or it can be a one-way purge of information. In all cases, the ongoing demands of the ED necessitate that handoffs be characterized by both brevity and completeness.

Although few EDs have formal systems for transition, one can identify four phases in most ED handoffs.(5) These phases include (i) pre-turnover, (ii) arrival, (iii) meeting period, and (iv) post-turnover. These phases tend to be common in all health care settings with high consequences for failure, like the ED.(6,7)

Examples of effective transition can be found in other highly reliable organizations such as nuclear powered submarines, trauma centers, and NASA. Los Angeles–class nuclear submarines use "precise, unambiguous, impersonal, and efficient" language between the officer on duty and the sonar technician to navigate safely. Commands, readbacks, and monitoring help bridge authority gradients and ensure the crisis-resistant performance vital to safety.(8) Dedicated local and regional trauma centers also depend on operational and clinical excellence to achieve "failure-resistant performance." For example, a trauma nurse asks if anyone has informed the operating room (OR) of a patient's pending transfer to the OR. Acknowledgment and action from the team leader follow this inquiry, ensuring that all the providers have situational awareness and that there is timely transit to the OR.(9) These are

only a few of the useful strategies. In fact, in an article on handoff strategies, Patterson describes 21 techniques used by NASA, nuclear power plants, railroad dispatch centers, and ambulance dispatch centers.(10) The techniques include verbal, face-to-face, and interactive questioning that is coordinated with written summaries prior to shift change. Additionally, readback, limits on interruptions, unambiguous transfer of responsibility, and pre-turnover data scans are all used to ensure joint sense-making at the completion of transition.(10)

Case & Commentary: Part 2

Four hours after arrival, the laboratory called the ED to report a critical lab result, a platelet count of 4,000/mm^3 (normal range 150,000-400,000). The critical result was received by the ED unit secretary. It is unclear who this information was passed on to, but neither the ED attending nor the internal medicine service was made aware of this lab result.

Sixteen hours after the patient presented to the ED, the internist noted the abnormal finding when checking the morning lab data. She made a tentative diagnosis of thrombotic thrombocytopenic purpura (TTP). The patient required transfer to the ICU because of progressive deterioration in mental status and was eventually intubated. Hematology consultation was obtained to initiate emergent plasma exchange for treatment of TTP.

The evaluation of mental status change demands the best of the entire health care team. Work-up and decision making vary from patient to patient and fit poorly into clinical care algorithms. Care must be customized. Arriving at the correct diagnosis often involves multiple practitioners; lengthy, detailed, and occasionally invasive work-up; and explicit attention to detail. TTP is a rare (15 patients per million per year) clinical syndrome characterized by low platelets, anemia, fever, mental status change, and acute renal failure. Accurate evaluation, diagnosis, and treatment of TTP are barometers of both the competency of individual providers and their teams, as well as the quality and safety of the system. Transitions in care magnify weaknesses present in individuals, teams, or the broader system.

Communication and Cognition: Evaluating System and Human Actions

Given the rarity of TTP and the often ambiguous and non-specific clinical presentation (eg, fever, anemia), cognitive errors are common and often lead to delays in diagnosis. The disease is fatal in up to 90% of cases without effective treatment, but prompt treatment with plasma exchange can be lifesaving.(11,12) In this case, two major mishaps resulted in late administration of plasma exchange, the communication of serious lab abnormalities, and the recognition of the clinical entity, TTP.

Communication and the System: Failure to Identify Serious Laboratory Abnormality

A combined human and system error resulted in delay in acknowledgment of low platelets. At sign-out, the "platelet count was pending." Two human-transition issues arise. First, most clinicians recognize that a delay in reporting a test often means the result is abnormal (the extra time reflects the lab's protocol to perform further authentication prior to reporting the test result to the caregivers). Thus, knowing that all other CBC results were obtained should raise the suspicion that the unreported platelet count was abnormal. Making this assumption, the outgoing team must make it explicitly clear this test result should be evaluated prior to disposition or further management. Additionally, the outgoing team must ensure that the incoming team has clearly understood this request and the reason for it. The most notable system error is that there simply was no consistent process established to deliver the information to the care team.

A variety of methods are used in the ED and across health care to communicate important information such as critical test results. Direct, face-to-face communication is frequently the most desirable and effective way of assuring flawless transfer of information. However, indirect methods such as text-paging, email alerts, indirect communication (via overhead calls or two-way messaging), color-specific paper charting, or written documents are also used to deliver ancillary test results. Whatever method is chosen (direct communication is the best), it also needs to be coupled with a shared interpretation of what constitutes critical results. Such interpretations cannot be made in a vacuum but require an appreciation of each patient's unique characteristics. For example, a hematocrit of 24% in a patient with coronary disease and no history of anemia constitutes a medical emergency, while the same hematocrit in a young patient with chronic renal insufficiency would barely elicit a yawn.

Cognition and the Human: Failure to Reach the Correct Diagnosis

In this case, errors occurred at several of the transitional phases: pre-turnover, meeting, and post-turnover. In the pre-transition phase, the ED doctors were content with the diagnosis of urinary infection as the cause for altered mental status and demonstrated anchoring bias as contradicting evidence was set aside. During the transition itself, it was unclear who was responsible for follow-up and interpretation of these results—a systems problem. Finally, after the turnover, the clinicians became subject to a framing effect, as all the findings were considered in light of the diagnosis of "urinary tract infection and anemia," rather than reconsidering the new information as it came in.(13) In this way, the case illustrated Canadian ED physician and safety expert Pat Croskerry's observation, "When the diagnosis is made, the thinking stops."(13)

Case & Commentary: Part 3

Despite these interventions, the patient's status continued to deteriorate. The patient died the following day, within 48 hours of presentation to the ED.

TTP requires timely treatment in order to reduce mortality. It shares this time dependency with many other ED diagnoses and situations, many of which have been converted into quality metrics (eg, 10 minutes to EKG for patients with chest pain, or 240 minutes to antibiotics for patients with pneumonia). These time-dependent outcomes invariably rely on many individual processes and interactions; the transition phase is just one of these. As Richard Cook notes, "Catastrophe requires multiple failures—a single point failure is not enough."(14)

Communication failures fall into three categories.(15) First, *system failures* occur when communication channels are used infrequently, are non-functional, or are non-existent. Second, *message failure* occurs when there is poor or non-existent transfer of information. Third, *reception failure* occurs with misinterpretation or late arrival of proper information. In one recent study, a written (computerized) sign-out sheet for surgical residents augmented verbal sign-out and was widely adopted.(16) It was able to centralize and organize information and daily work. Another recent analysis describes "collaborative cross-checking" as a way to improve resilience of the health care transition.(17) In one illustrative case, a nurse overheard a confusing order at sign-over and questioned the order with the physician. The order was re-evaluated, which prevented a potential catastrophe. That case illustrates that proximity may well be serendipity, and that cross-checking can serve as a valuable rescue mechanism.

Confusion With Acetaminophen

The Case

Parents brought their 5-year-old son to the emergency department (ED) with a 24-hour history of fever, cough, and frontal headache. Physical examination, vital signs, and laboratory evaluation were unremarkable. The patient was discharged with a diagnosis of viral syndrome after receiving one dose of acetaminophen in liquid form. Two days later, the patient returned to the ED with continuing fever and new rigors, vomiting, lethargy, and right upper quadrant abdominal pain. Laboratory evaluation indicated that acetaminophen levels and PT/INR were elevated.

Further discussion with the parents revealed that they misread the instructions about administering liquid acetaminophen. They gave multiple doses of 20 mL (48 mg/mL solution equaling 960 mg per dose) instead of the

correct dose for their 20-kg child (6 mL = 288 mg). The patient was admitted to the hospital, given intravenous N-acetylcysteine, and his symptoms improved over the succeeding days. His acetaminophen levels declined, and he was safely discharged home without further events.

An Outpatient 'Zebra'

The Case

A 64-year-old man presented to the outpatient clinic with a chief complaint of left foot pain and numbness. His past medical history included lumbar disc disease, hypertension, and active tobacco use. A medicine resident evaluated the patient, diagnosed sciatica due to existing disc disease, and prescribed appropriate analgesics after discussion with a supervising attending. Three weeks later, the patient continued to experience left foot pain but also developed localized swelling. A different resident (and supervising attending) evaluated the patient, ordered plain films that showed no evidence of fracture or osteomyelitis, and prescribed antibiotics for cellulitis. During the following week, the patient's symptoms continued, and he received evaluations from two additional residents, one of whom ordered a bone scan that confirmed no evidence of osteomyelitis.

The next week, the patient returned with persistent foot symptoms, and yet another provider noted a decreased pulse in the left foot and referred urgently for vascular evaluation. The patient ultimately received a diagnosis of left superficial femoral artery occlusion and underwent successful vascular bypass within a week. Though the delay in diagnosis might not have prevented a surgical procedure, the diagnostic errors produced repeated visits, continued symptoms, and an ineffective treatment plan for nearly 5 weeks despite many opportunities for earlier intervention.

An Ounce of Prevention

Case & Commentary: Part 1

A 47-year-old woman was admitted to the plastic surgery service after a motor vehicle collision with major trauma to her right hand, which required repair with use of an abdominal flap. On the second postoperative day, the patient suffered a sudden cardiopulmonary arrest. After successful resuscitation, a chest CT revealed a massive pulmonary embolism.

Venous thromboembolism (VTE) is a common condition, with an incidence of 1.5/1000 per year in all U.S. adults and at least 1% of hospitalized patients.(1) Deep vein thrombosis (DVT) is associated with a 30-day mortality rate of less than 2% (in fact, many cases go undiagnosed and undetected), but pulmonary

embolism (PE) is far more serious, with an overall 30-day mortality of approximately 10%.(2) Most early PE deaths are due to acute right ventricular failure, whereas late PE mortality often is caused by the underlying conditions that predisposed to the clot. In the United States, more than 100,000 patients per year die from PE.(3)

The most common VTE risk factors include surgery, trauma, cancer, congestive heart failure, chronic lung disease, age older than 70 years, obesity, bed rest, prior VTE, thrombophilic disorders, and acute respiratory failure. Recurrences are common: more than 50% of surgical patients with a previous history of VTE who do not receive prophylaxis will develop postoperative DVT.(4) Nearly one in five surgeries (even in the absence of additional risk factors) results in VTE if neither pharmacologic nor mechanical prophylaxis is applied.(5) That number skyrockets to more than 50% in patients undergoing total hip and total knee replacement who fail to receive prophylaxis.(6) Spinal surgery, pelvic surgery, and neurosurgery also place patients at particularly high risk of VTE.

Trauma, particularly of the lower extremities and pelvis, increases the risk of VTE. PE has been identified at autopsy in as many as 60% of patients with lower-extremity fractures (7), and mortality has been attributed to PE in as many as 50% of patients dying after hip fracture.(8) The incidence of VTE increases with time after the traumatic event. Autopsy-confirmed PE in patients surviving less than 24 hours after trauma has been demonstrated in 3.3%, increasing to 5.5% in those surviving up to 7 days. PE was found in 18.6% of those surviving a longer period.(9) The risk of VTE after major trauma to the upper extremity is less clear. In this setting, lower-extremity DVT often is caused by prolonged bed rest; the risk increases when surgery and general anesthesia are required. Upper-extremity trauma enhances the risk of upper-extremity DVT.(10) The risk of symptomatic PE in patients with lower-extremity DVT ranges between 15% and 30% (11), and it occurs less often (3%) in patients with upper-extremity DVT.(10)

Case & Commentary: Part 2

Review of the patient's chart revealed no pre- or postoperative DVT prophylaxis.

Without knowing the full extent of this patient’s trauma and the presence of additional risk factors, it is impossible to say if prophylaxis should have been administered. The critical point for clinicians is to consider this risk and make appropriate, evidence-based decisions about prophylaxis in all hospitalized patients.

Despite detailed North American guidelines, VTE prophylaxis continues to be underutilized. In a registry of 5,451 consecutive patients with ultrasound-confirmed DVT from 183 United States institutions, only 42% of inpatients had received prophylaxis within 30 days prior to developing acute DVT.(12) In this registry, compliance with guidelines was better in surgical than in medical patients.

VTE prophylaxis recommendations differ for the various surgical settings (Table). According to current consensus guidelines from the American College of Chest Physicians (ACCP) (13), prophylaxis should be administered in all trauma patients with at least one additional risk factor. Low-molecular-weight heparin (LMWH) is recommended as pharmacologic prophylaxis. In some patients, however, the use of LMWH may be precluded, usually because of the risk of bleeding. In such patients, mechanical prophylaxis, including graduated compression stockings or intermittent pneumatic compression devices, should be considered. Ultrasound surveillance, seeking evidence of DVT that would tip the scales toward anticoagulation (or, if that is too risky, placement of an inferior vena cava [IVC] filter), is recommended in high-risk trauma patients not receiving pharmacologic prophylaxis. The ACCP recommends against the routine (ie, prophylactic) use of IVC filters in trauma patients. Newer retrievable IVC filters may be useful for patients with transiently increased risk of both clotting and bleeding complications, and many institutions now use them in this setting. Although permanent IVC filters reduce the risk of PE, there is a tradeoff: the risk of DVT at 1 year, particularly due to filter thrombosis (Figure 1), is double that of patients without filters.(14)

Case & Commentary: Part 3

The patient was aggressively resuscitated and started on systemic anticoagulation with heparin, and then warfarin. After a 3-day stay in the intensive care unit, the patient was transferred to the floor. Ultimately, she was discharged to home without any evidence of anoxic brain injury or permanent pulmonary sequelae from her PE.

In 2003, the American Public Health Association (APHA) created a national coalition to advocate for greater awareness of DVT and PE among health care providers and the general public.(15) The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has been encouraged by the APHA to make adherence to DVT prevention guidelines part of its accreditation process. As of now, specific actions from JCAHO have not been undertaken, and DVT prophylaxis still is not part of ratings for hospital performance.

Continuing medical education (16) and computerized electronic alerts (17,18) can increase physician utilization of VTE prophylaxis. In a randomized controlled trial of 2506 high-risk patients who did not receive prophylaxis, a

single computer alert to the responsible physician doubled the prophylaxis rate and reduced the VTE rate at 90 days by 41%.(19) The computer program used eight common risk factors to determine each hospitalized patient's risk profile for VTE on a daily basis. Each risk factor was weighted according to a point scale: the major risk factors of cancer, prior VTE, and hypercoagulability were assigned a score of 3; the intermediate risk factor of major surgery was assigned a score of 2; and the minor risk factors of advanced age, obesity, bed rest, and the use of hormone-replacement therapy or oral contraceptives were assigned a score of 1. An increased risk of VTE was defined as a cumulative risk score of at least 4. In patients with a VTE risk score greater than or equal to 4, the computer program used medical record numbers to randomly assign 1255 eligible patients to an intervention group, in which the responsible physician was alerted to a patient's risk of DVT, and 1251 patients to a control group, in which no alert was issued. The alert was sent once for each patient (Figure 2). The physician was required to acknowledge the alert and could then withhold or order prophylaxis, including graduated compression stockings, pneumatic compression boots, unfractionated heparin, LMWH, or warfarin. The results of this trial suggest that hospitals with adequate information system resources should consider implementation of electronic alerts to increase the awareness of VTE risk, to improve the utilization of prophylaxis, and to reduce the rates of DVT and PE.

Slippery Slide Into Life

The Case

A 25-year-old woman presented to the hospital in labor and at full gestation after receiving uncomplicated prenatal care. A third-year obstetrics and gynecology resident delivered the infant under attending supervision via vacuum-assisted vaginal delivery. Following delivery of the shoulders, the resident turned to place the vacuum device on a nearby equipment stand. During that time window, the patient adjusted her positioning while on the birthing bed (creating an inadvertent push), and the infant slid out of the vaginal canal, slipped out of the resident’s hands, and dropped headfirst onto the floor.

The infant suffered a left parietal fracture and hematoma at the site of impact. Although he required close observation and neurosurgical consultation, no intervention was indicated. In reviewing the incident, staff interviews suggested that both noise and confusion of roles among the labor and delivery team contributed to the error, which, through luck alone, led to no long-term sequelae for the infant.

Discharged Blindly

The Case

An elderly blind man developed a deep vein thrombosis during his hospital stay. At discharge, he was to receive enoxaparin (Lovenox) for self-administration at home in addition to other medications. Before leaving the hospital, he was given written information sheets regarding his medications and received counseling from a nurse and a pharmacist. They did not notice that the patient was blind.

Several days after discharge, the patient called the primary care triage nurse and stated that he had been discharged with a bag of medications and some injections, but that he could not administer them because he could not read the instructions.

After retrieving his chart, the triage nurse noted that the patient was blind and, upon questioning, also learned that he lived alone. The patient was subsequently readmitted to the hospital for continuation of anticoagulation therapy.

Low on the Totem Pole

Case & Commentary: Part 1

A fourth-year medical student on rotation in the pediatric intensive care unit (PICU) was invited to observe the operative repair of a congenital heart lesion in the pediatric cardiac surgery operating room (OR). When the student arrived in the OR, the patient was already intubated and anesthetized, and procedures were under way to prep the patient for surgery. The student observed one of the team members insert a Foley catheter into the female patient. He was surprised to see that no efforts were made to perform "sterile prep" prior to insertion. However, being new to this setting and assuming different practices were used in pediatric patients, the student dismissed the incident and did not mention it to anyone in the OR.

In a previous issue of AHRQ WebM&M, a senior medical student thoughtfully discussed the pressures students feel when they witness an error and struggle with the questions of whether and how to bring up the issue [See related commentary]. Since I completed medical school soon after Watergate, I won't attempt to remember how students feel when put in such a position. I will, however, use this case to discuss the concept of authority gradients and how they relate to creating a culture of safety.

Health care is remarkable for its interdependencies across personnel. Think of this PICU. There, highly trained neonatologists and surgeons work side-by-side with, and are often dependent on, fellows, residents, and students. These

medical personnel are exceptionally important to the care of patients. But equally important, and often more important, is a virtual army of nurses, respiratory therapists, clinical pharmacists, and clerks. These individuals play a vital role in ensuring the quality and safety of care; each may be the one to witness an error in the making, and each must share in the ever-changing flow of information—everything from the patient's creatinine level to the concerns of the patient's family. It is difficult to think of another workplace where such a diverse group of people work so closely together and are so dependent on each other to create positive outcomes.

In all of this, the medical student occupies a particularly challenging position. Status in such workplaces comes because one is either *an authority, in authority*, or both. He is neither. In fact, the usual hierarchy in the medical workplace, with physicians at the top of the heap, is set on its head: within moments, the savvy student recognizes that the ICU nurse has far more setting-specific knowledge than he, often more than senior physicians. During my first day of internship, one of my colleagues taught me this lesson quite vividly. Admitting a complex patient with an acute myocardial infarction and heart failure, he failed to prescribe a certain indicated medication to the patient. On rounds the next morning, the attending, a senior and highly revered teacher, gently asked him why he failed to begin the medicine. Bleary eyed, he murmured, "Well, the nurse didn't suggest it." I admired his honesty.

In witnessing a practice that he thought might be unsafe and not knowing what to do with his concerns, the student thus faces a predicament. Coupled with his feeling that his worries might be unfounded (maybe this procedure doesn't require aseptic technique) is the massive authority gradient: he is about as low on the totem pole as one can get in that ICU, and, unless this issue has been addressed proactively, he is unlikely to raise his concerns.

How could this be done? It might be as simple as giving all students a primer on using the hospital's incident reporting system or having the clerkship director or attending state at orientation, "You're likely to see some things during this rotation that you're not sure about. Sometimes, you'll wonder whether a given practice is in error or is putting the patient at risk. I want you to page me if you see such a thing, and we'll talk it through. I know that's hard—I remember what it felt like to be in your position, wondering whether you knew enough to be sure that what you were seeing was wrong, and what would happen if you raised an alarm. But you're in a unique position to catch things—you have the time to observe things that I don't, and you bring a fresh set of eyes and ears. So please, let me know if you have any questions or concerns."

Note that, even if he is given a protocol for reporting errors and safety concerns but perceives that the culture is not supportive of such action, he is

unlikely to come forward. As business consultants like to say, “Culture eats strategy for lunch.”

Case & Commentary: Part 2

The student followed the patient during her PICU course. On postoperative day 3, the student found that the patient had been febrile overnight and a urine culture had grown Pseudomonas aeruginosa. *On rounds, the student presented this new data, including the account of the Foley placement in the OR. The patient’s Foley catheter was discontinued and appropriate antibiotic coverage provided. Subsequent urine cultures were negative. After rounds, the student was approached by two attendings, separately. One remarked that the information about the catheter should not have been presented on rounds due to concerns that patients and family members might overhear. The second attending told the student this information should have been conveyed at the time of the incident. Neither attending commended the student for reporting the incident to the team. Shortly thereafter, the student submitted a report outlining the events in the OR to the institutional patient safety office.*

Sexton and colleagues surveyed operating room personnel, asking whether they perceived teamwork as being strong.(1) The results are shown in the Figure. Note that nearly 80% of attending surgeons, clearly atop the authority chain, perceived teamwork to be strong, while only 10% of anesthesia residents, at the bottom, felt the same way (proving, as always, that one should virtually never ask the leader to assess the quality of teamwork). One can only assume that students’ perceptions would have been even worse.

Perhaps more germane to the patient safety question, Sexton asked both surgeons and commercial airline pilots whether they would want someone to question them if they thought they were doing something wrong. Virtually every pilot answered in the affirmative. A generation ago, aviation learned the lesson from several horrible accidents that tragedy can often be averted when everyone feels comfortable raising their concerns to the pilot, and the pilots welcome these questions.(2) Crew Resource Management (CRM) programs, implemented since the early 1980s, encourage this kind of cross talk, focusing in part on encouraging everyone to speak up if they have concerns. In the exercises, pilots learn that the messages that they send—spoken or unspoken—when someone does question their action indelibly cements the culture. If a pilot snaps, or even subconsciously assumes a disdainful facial expression, when a junior colleague raises a concern, the likelihood that similar concerns will be raised in the future plummets.

Unfortunately, when Sexton asked surgeons the same question, nearly half said that they would not want their coworkers to raise safety concerns during

surgery.(1) The message to those lower on the authority gradient (namely, everyone) is unmistakable: speak only at your own risk. This is certainly the message this student received from the first attending when he finally spoke up on rounds. Perhaps the second attending meant to be supportive, but by failing to acknowledge the student's position and predicament, she may have implied that the student had handled this poorly. The student's actions could have been simultaneously applauded and gently critiqued had the attending simply said, "I really appreciate you bringing this concern up. I know it's really hard to do. In the future, if you see something like that happening, please come right to me. It's the only way we can keep our patients safe."

How can we establish a culture in which individuals feel comfortable breaching authority gradients to raise safety concerns? First, there has to be a clear protocol for reporting: it does little good to establish culture if the workers don't understand the practical aspects of reporting. Second, evidence is accumulating that specific teamwork training, modeled on CRM, can help establish the desirable climate among the rank-and-file workers.(3) My colleagues and I (physicians, nurses, and pharmacists) recently received a grant from the Gordon and Betty Moore Foundation to begin such a program at UCSF (along with Kaiser Permanente Hospital in San Francisco and El Camino Hospital), using actual commercial airline pilots to help conduct the training.

Finally, an unmistakable message needs to be set by senior leadership about the necessity and moral imperative to "stop the presses" when someone witnesses a possible error or breach in a safety protocol. Because of the massive production pressure, health care workers feel uncomfortable raising an alarm when they merely suspect, but are not sure, that something is wrong. Rather than risking a false alarm and its accompanying stigma, they have learned to say, "Oh, it's probably okay, " and let it slide. We have documented one case in which this dynamic helped lead to a patient's cardiac resuscitation being aborted in error (4), and another in which a patient received an invasive cardiac procedure intended for another patient.(5)

In fact, I have come to believe that this issue is at the core of an institution's safety culture. There are a number of superb, validated tools to measure the institutional culture of safety.(6-8) They provide a very important snapshot across a number of dimensions, and I strongly encourage their use. My test, however, is much simpler.

Consider the lowest person in the hierarchy of a hospital, perhaps a young ward clerk (it could just as easily be a medical or nursing student). He or she witnesses something that seems wrong—perhaps the OR is calling for a patient but there is no consent in the chart. The patient's surgeon is the chief of cardiac or neurosurgery, a highly respected and prominent surgeon. He is

known to have a bit of a temper. In fact, he has been known to throw things in the OR, and let's say he has good aim.

The clerk knows that making herself 100% sure that the OR is calling for the right patient will take a couple of telephone calls, and so might delay the start of the case by 10 minutes. She sees that the day's OR schedule is jam-packed. But, even after weighing all that, her primary concern is for the patient's safety, and she decides to confirm that everything is right. And it is. It was just a paperwork snafu, and the patient really was supposed to go to surgery. Ten minutes later, she releases the patient to the transporter.

So here is the question: what happens to the clerk? Do her colleagues snicker at her, whispering just out of earshot during coffee breaks, while the surgical residents cut her an "Oh, she's the one" look on rounds later that day? Or does the hospital CEO (and the surgeon) take a moment to pat her on the back, making it clear that gutsy acts like hers—stopping the presses when you're not sure everything is right, rather than doing so only when you're absolutely sure they are wrong—are precisely what must be done to ensure patient safety?

I recently posed this test to an audience of 1000 at the National Patient Safety Foundation's annual conference in Orlando, asking how many worked in institutions that would pass my test. About five hands went up. We have a long way to go.

The medical student in this case is to be commended for raising his concerns. Creating a culture in which he was comfortable doing so *in real time*—as the procedure was being carried out and his concerns materialized—is the hard work we face. This will take leadership, new training programs, and specific reporting protocols. Until we take up this work and find the resources to support it, we will lack a culture of safety, and patients will be harmed unnecessarily.

One Dose, Fifty Pills

The Case

A middle-aged man was admitted to the medical service of a teaching hospital with suspected vasculitis. When the initial diagnostic studies failed to provide a definitive diagnosis, the team decided to treat the patient empirically with high-dose steroids.

When discussing the patient on morning rounds, the senior resident instructed the intern quite clearly to "give the patient one gram of steroids." After rounds (and some quick math), the intern ordered:

“Prednisone 20 mg tabs 50 pills PO x 1 now”

After receiving the written order, the pharmacist contacted the intern to clarify the order. She suggested to the intern that the one gram of steroids probably was supposed to be given in an intravenous form. The busy and harried intern stated firmly that he wished to give the patient fifty 20-mg pills. When the pharmacist persisted in questioning the order and gently suggested the intern may want to contact his senior resident for clarification, the intern refused and replied, “You can give it with a tablespoon of Maalox.”

The patient was brought fifty 20-mg pills of prednisone and became angry and frustrated as he swallowed pill after pill. He developed mild nausea and heartburn while taking the prednisone.

The following day, upon review of the medication record, the senior resident found the error. The oral prednisone was stopped, and the patient was correctly given a gram of intravenous methylprednisolone (Solu-Medrol). He eventually recovered from his vasculitis and was discharged in a stable condition.

Infused, Not Ingested

The Case

A patient in the ICU was scheduled for a CT scan. The nurse prepared the patient by administering contrast, an unfamiliar task for this particular nurse. Rather than giving the Gastrografin solution orally via a nasogastric tube (the appropriate route), the nurse took the bottle of contrast, mixed it in a 250-cc bag of normal saline, and infused it intravenously.

When the patient arrived for the study, the radiology technician asked the nurse whether the patient received the “oral” contrast solution. The nurse responded, “Yes,” and quickly removed and discarded the IV bag. Suspecting an error, the technician contacted the radiologist, and they discovered an IV bag marked “contrast” in the trash after the nurse departed from the radiology suite.

The nurse was subsequently approached about the error and failed to disclose the actual events. The physician caring for the patient did not inform the family of the error until the following morning, stating he wasn’t certain of the consequence of receiving oral contrast intravenously. As it turned out, the patient developed acute renal failure, but it resolved without any significant sequelae.

Following the event, the nurse was fired. The nurse reported that his primary role involved non-ICU care, and this was the first time he administered contrast or transported a patient for a radiology study. He “floated” to work in the ICU that particular day due to staffing issues. The hospital responded by marking all oral contrast bottles “PO ONLY—NOT IV.”

Reconciling Doses

Case & Commentary: Part 1

A 68-year-old man with a history of diabetes and atrial fibrillation maintained on warfarin presented to the emergency department (ED) with fever and mental status change. Lumbar puncture was attempted three times without success; empiric treatment for meningitis was started. Further examination revealed an area of cellulitis, and intravenous antibiotic therapy was changed accordingly. At the time of admission, the patient was unable to recite his medication history, and his wife was unclear about the doses. However, the EMS run-sheet had a list of the patient’s medications and doses. The patient was started on the medication regimen per the EMS report.

Medication reconciliation is defined as the process of collecting the best medication history possible, verifying the list, and comparing it to orders written at admission, transfer, and discharge. Although reconciliation is always useful, it is particularly crucial when patients are unable to provide a complete and accurate medication history or when the history is not available to those who must make treatment decisions.

Evidence supporting the need for and the value of medication reconciliation is strong. More than half of all medication errors occur at the interfaces of care.(1) A review of 22 studies by Canadian researchers found (in the absence of reconciliation) errors in up to 67% of patients’ prescription medication histories.(2) Researchers at Johns Hopkins reported that an average of ten prescriptions needed to be changed weekly in the ICU after errors were identified through a reconciliation process.(3)

Implementation of a successful medication reconciliation process ensures that each of the members of the health care team has access to the list of medications that the patient was taking prior to admission, what was ordered at transitions of care, and a method to communicate an intentional medication change or discontinuation. Rather than hoping that a medication was appropriately discontinued and not overlooked, this intervention provides a process to facilitate and standardize communication.

The value of medication reconciliation has been demonstrated “on the ground” by a number of institutions, most prominently Luther Midelfort

Hospital, a Mayo affiliate.(1) Based on this work and the data cited earlier, medication reconciliation has been one of the recommended changes for teams participating in Institute for Healthcare Improvement (IHI) collaboratives to reduce adverse drug events. Accordingly, when the IHI launched its 100,000 Lives Campaign (4) to promote six changes proven to improve patient care and prevent avoidable deaths, medication reconciliation was chosen as the focus of efforts to reduce adverse drug events. Moreover, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) also selected medication reconciliation as one of its 2005 National Patient Safety Goals.(5)

An important step in the process is to collect the best medication list possible. Many patients can and do provide accurate medication histories. When, as in this case, cognitive, cultural, or other barriers prevent them from being able to provide an accurate medication history, it is important to identify effective ways to collect this history, accepting that the list may initially be incomplete. Interviewing family members and contacting primary care physician offices and local pharmacies may improve the accuracy of the list. Some hospitals have worked with ambulance staff to remind them to pick up prescription bottles or medication lists that may be attached to refrigerators or medicine cabinets. Each organization should have a process to continually improve the system for collecting this medication history.

Case & Commentary: Part 2

After 2 days, the patient was transitioned to Augmentin. While in hospital, the patient had been receiving 5 mg of warfarin at bedtime, which, according to the EMS intake sheet, was his usual outpatient dose. The team did not confirm this dose with the patient's family, primary physician, or pharmacy. At the time of discharge, his INR was noted to be 4. Realizing the warfarin dose was too high, the team instructed the patient to decrease his dose to 3 mg at bedtime and to have his INR rechecked in 3 days. After 3 days, his INR was 10. He was treated with vitamin K. Two days later, the patient returned to the ED with back pain, lower extremity weakness, and incontinence. He was found to have an epidural hematoma, which was emergently evacuated. One week post-operatively, the patient still had neurologic deficit.

Implementing a medication reconciliation process may represent a change in work flow, requiring more time from staff members. But organizations should be encouraged by those who have successfully implemented a medication reconciliation process as part of a larger medication safety program.(6)

To implement a successful medication reconciliation process, organizations should first examine the system presently in place.(7) Using a high-level flow diagram may be helpful in determining the different entry points into the

hospital. An example can be found here. A similar diagram for transfers and discharges will help the team understand what is in place and how to develop a system to support medication reconciliation at each stage.

It is necessary to have a champion and a multidisciplinary team to work on testing different changes that will lead to the desired system. A useful instrument to record the team members and their roles is available here. Senior leadership support is necessary to align the process with other hospital initiatives, provide resources for the project during its development, and remove barriers.

Due to the many entry points for admission into a hospital, each hospital's different levels of care, and each hospital's varied populations, there is no one way to implement this process throughout the hospital. Accordingly, organizations cannot expect to roll out a reconciliation process overnight. Using a proven improvement methodology (eg, such as the "Model for Improvement") (8), hospitals can test and implement changes in different settings, using the results of these experiences to inform dissemination.

Medication reconciliation is a multidisciplinary process. Selecting who should be involved in each step along the way should be based on available resources and who can best complete the task. For example, a physician, nurse, pharmacist, or pharmacy technician can collect the medication history.(9) Although pharmacists have been identified as being more effective in taking such a history, there is no reason that they cannot train others to do this well.(10) An effective model may be one in which nurses collect a medication history, pharmacists verify the information, and physicians use the resulting list to aid in making decisions about drug therapy. Physicians also complete the last step described: document reasons or intentions to discontinue, change, or hold medications in a manner that is clear to all.

Forms to collect medication histories have been employed by many organizations. Some have adapted the forms to serve as both a medication list and an order form. Adding columns indicating whether a medication should be continued, discontinued, or placed on hold minimizes re-writing and facilitates communication among disciplines. This model may not be effective in all organizations. As with any new process, hospitals must determine if the changes introduce new opportunities for errors. Forms have also been used in the transfer and discharge process. Placing the list in a prominent place in the chart or using colored paper facilitates access to this information. Several examples of useful forms can be found on the Web sites of the Institute for Healthcare Improvement and the Massachusetts Coalition for the Prevention of Medical Errors.

To complete the process of medication reconciliation, at the time of discharge, the discharge prescriptions must be reconciled with the most

recent inpatient orders and the patient medication list prepared at admission. This comparison is useful to screen for therapeutic duplication, possible drug interactions, omissions, or medications not ordered during the inpatient stay.

Technology, if well designed and implemented, can be a useful adjunct to medication reconciliation. Systems whose electronic medical records allow medication histories to be downloaded from an electronic nursing documentation system onto a form reduce the time-consuming and error-prone process of manually completing forms. At discharge, reformatting the patient medication profile from the pharmacy system into a prescription form can streamline the discharge prescription process.

Patients can play a significant role in helping to design a process as well as being active participants in medication reconciliation. Organizations such as McLeod Health in South Carolina (11) have engaged patients in developing a state-wide universal medication form. Individually, patients should be encouraged to carry their medication lists and present them at each health care visit. An example of a patient medication card, which can facilitate this process, can be found here.

Time of Death?

The Case

An 80-year-old woman with multiple illnesses, including chronic obstructive pulmonary disease (COPD), was found pulseless and cyanotic in her hospital bed. A code was called, which involved intubation, the administration of several parenteral medications, and prolonged chest compressions. The “final rhythm” was deemed agonal and the code was “called” after approximately 15 minutes. Virtually all the members of the code team left the room, leaving behind only a single nurse to clean up. Not 3 minutes later, the nurse emerged from the room, breathlessly declaring that the patient had a strong pulse and was now breathing spontaneously. After initially dismissing her observations as representing agonal respirations, clinicians reevaluated the patient and found her to be in a perfusing rhythm with spontaneous breathing. She was transported to the ICU, where she languished for several days before supportive efforts were discontinued because of her poor neurologic prognosis.

The nurse had seen numerous codes, but never participated in one until that night. She was trained and certified in cardiopulmonary resuscitation (CPR) but had never trained with the other team members and didn’t recall being trained in how to “call” the end of codes. She commented on how difficult it had been to squeeze the Ambu bag toward the end of the code, a fact she did not raise with the code team leader during the code itself.

The code team never came together to discuss this error (the premature pronouncement of death); rather, at the end of the code they all wandered off and resumed their usual jobs.

The Wrong Channel

The Case

A 28-year-old woman in labor began receiving treatment with magnesium sulfate for preeclampsia. Initial dosing started at 50 mL/hour using a multi-channel medication pump (Figure). Additional infusions from the pump included lactated ringers (125 mL/hour) and Pitocin (12 mL/hour). The three pump chambers were located side by side on the device. Following placement of epidural anesthesia, a fetal heart rate deceleration occurred due to maternal hypotension. A fluid bolus with lactated ringers was ordered. The nurse increased the pump rate to 500 mL/hour, but within 20 minutes, the patient reported feeling warm, weak, short of breath, and flushed.

While checking the pump, the nurse realized that she had inadvertently increased the magnesium sulfate rate instead of the lactated ringers. The infusion was stopped immediately. The patient remained weak and areflexic for about 20 minutes, prompting administration of calcium gluconate. She was monitored closely until her symptoms fully resolved. Afterward, she successfully delivered a healthy infant.

Double Trouble

Case & Commentary: Part 1

A 79-year-old man with diabetes mellitus was admitted to the hospital with hypoglycemia. His medication regimen included Glucovance, a combination of metformin and glyburide. Upon discharge, the patient was instructed to stop the Glucovance and to begin monotherapy with Glucophage (metformin).

The case begins with the patient having been admitted to the hospital with hypoglycemia. Since the patient's prior diabetic history is not described, we do not know whether he was started on these two oral hypoglycemic agents as his initial treatment. If so, this may have placed him at increased risk for this adverse drug event (ADE). Starting therapy in an elderly patient with a single agent is generally a safer strategy, and many patients will achieve adequate control of blood glucose with monotherapy alone.

Although most medication errors do not result in injury, the extensive use of medications by the geriatric population places many older patients at risk. A recent study assessed the incidence and preventability of ADEs among older

persons in the ambulatory clinical setting.(1) Interestingly, hypoglycemic agents were among the most common causes of preventable ADEs in this study. The overall rate of ADEs was found to be 50 per 1000 person-years of observation, with a rate of 14 preventable ADEs per 1000 person-years. If these findings hold true for all Medicare enrollees, then more than 1,900,000 ADEs—more than a quarter of which are preventable—occur each year among the 38 million Medicare enrollees. Approximately 180,000 of these ADES would be life-threatening or fatal, and more than 50% of these may be preventable. Most errors associated with preventable ADEs occur at the prescribing and monitoring stages of pharmaceutical care; however, problems with patient adherence are cited as a contributing factor in more than 20% of ADEs that occur in the ambulatory setting.

Case & Commentary: Part 2

A few weeks after his hospitalization, the patient presented to the emergency department (ED) with mental status changes. A fingerstick glucose test was 40 mg/dL. According to the patient, his only medication was Glucophage. The patient recalled an occasional skipped meal. He did not recall taking extra doses. Upon review of his medication bottles, the ED staff found that he was actually still taking Glucovance, not Glucophage.

This case highlights many important opportunities to improve medication safety in older patients, including (i) the "start low and go slow" philosophy when initiating and intensifying a therapeutic regimen in the geriatric patient, (ii) the importance of anticipating confusion from sound-alike medications, (iii) the responsibility of the health care team to provide careful instructions to patients about their medications, and (iv) the need to improve communication and information transfer at times of transitions in care between different health care settings—in this instance, discharge from hospital to home.

Of particular relevance to this case, the combination drug product containing both metformin and glyburide is marketed under the name Glucovance, and metformin alone is marketed under the name Glucophage. Although Glucovance may offer advantages in simplifying use of a multi-drug regimen with a single pill, here, that added convenience may have resulted in confusion for this patient about the nature of his treatment regimen. The patient may have mistakenly believed that he was already being treated with a single drug (single pill = single drug), and this misunderstanding may have been compounded by the similarity in drug names. The Institute of Medicine report "To Err is Human" included a recommendation that the Food and Drug Administration require pharmaceutical companies to test proposed drug names to identify and remedy potential sound-alike and look-alike confusion with existing drug names.(2) [Go to related commentary]

Despite its clear importance, the issue of patient adherence to a prescribed regimen has received very little attention in the literature concerning preventing ADEs. Most studies of preventable ADEs have been conducted in hospital and long-term care settings, where all aspects of pharmaceutical care are presumed to be supervised; generally the patient is given little, if any, responsibility for medication administration or monitoring. In contrast, in the ambulatory setting, such responsibilities do extend to the patient and/or family members and therefore require new levels of patient and family education by physicians, nurses, or pharmacists. This process is often compromised by hurried interactions or haphazard processes, leading to the provision of incomplete or confusing information. This can be particularly risky for elderly patients on complex medication regimens.

Safety issues may arise soon after hospital discharge due to discontinuities in care or communication.(3) In one U.S. teaching hospital, 19% of discharged medical patients experienced an adverse event within a month, one-third of which were considered preventable.(4) Another third were judged "ameliorable" because their severity could have been reduced with better monitoring or earlier response to the problem. Another study conducted in a Canadian teaching hospital yielded similar findings. In this study, 17% of the post-discharge adverse events required rehospitalization and 3% resulted in death.(3) Of particular note, this study identified type 2 diabetes mellitus as an independent predictor of a post-discharge adverse event. Some specific examples of drug-related adverse events occurring after hospital discharge are listed in the Table.(3)

Although research data are limited, a number of recommendations for preventing medication errors in older patients can be inferred from observational studies. Medication reconciliation is a "process of identifying the most accurate list of all medications a patient is taking—including name, dosage, frequency, and route—and using this list to provide correct medications for patients anywhere within the health care system."(5) Medication reconciliation is particularly important at the time of hospital discharge. Each time a patient moves from the hospital setting to the ambulatory, rehabilitation, or long-term care setting, providers should review with the patient and/or responsible family member previous medication lists alongside the list of medications prescribed at discharge and reconcile any differences. This process should take place both prior to leaving the hospital and again promptly after transition to the new setting of care. When an error related to problems in medication reconciliation is identified, it is useful to systematically analyze its root causes, using an instrument such as the Medication Discrepancy Tool (Figure) produced by the Care Transitions Program at University of Colorado at Denver and Health Sciences Center.

Interventions involving multidisciplinary teams that are initiated in the hospital or ED setting and that follow the patient into the community can prevent

medication errors and other drug-related problems.(6) Instruments designed to enhance the identification of discrepancies between the medications prescribed in acute care settings and what elderly patients actually take after discharge may be particularly useful.(7) The community pharmacist's role in preventing medication errors in elderly patients may be helpful but has not been adequately examined.(8) Given the potential importance of this intervention, it should be formally assessed.(9)

The Institute for Safe Medication Practices (ISMP) is a nonprofit organization with a mission to provide error-reduction strategies to the health care community, policy makers, and the public. ISMP advises patients to insist that their physicians inform them of the generic and brand names of each of their medications, as well as each medication's spelling and specific indication.(10) Explaining that some pills contain multiple pharmacotherapeutic agents must be considered a critical part of this activity, as emphasized by this case. ISMP has also recommended that patients schedule a "brown-bag check-up" (11) with their primary care physician, a dedicated time to review all current prescribed and over-the-counter medications, which they should bring to the doctor's office.

Adverse medication events are common, and the elderly are at particular risk due to need for multiple medications and complexity of dosing regimens. Providers should review all new medications with patients and family members, with specific emphasis on possible points of confusion, and perform medication reconciliation at all transitions of care. Patients should have a comprehensive understanding of their own medication regimen. Such efforts may have prevented the hypoglycemic event described in this case.

PCA Overdose

The Case

A 49-year-old woman underwent an uneventful total abdominal hysterectomy bilateral salpingo-oophorectomy. Postoperatively, the patient complained of severe pain and received intravenous morphine sulfate in small increments. She remained alert and oriented and, while in the post-anesthesia care unit (PACU), she began receiving a continuous infusion of morphine via a patient-controlled analgesia (PCA) pump.

A few hours after leaving the PACU and arriving on the floor, she was found pale with shallow breathing, a faint pulse, and pinpoint pupils. The nursing staff called a "code" and the patient was resuscitated and transferred to the intensive care unit on a respirator. A search for reversible causes was unrevealing and, despite aggressive supportive care, the patient had no improvement in her mental status. Several days later, an

electroencephalogram result revealed no brain activity. Based on family wishes, life support was withdrawn and the patient died. Review of the case by providers implicated a PCA overdose, though no autopsy was performed to exclude other etiologies. The precise mechanism of the overdose was never elucidated.

Surprise Wire

The Case

A 39-year-old man with a history of liver disease presented to the emergency department (ED) with gastrointestinal bleeding and altered mental status. Due to his clinical condition in the ED, he required intubation as well as placement of a right femoral central venous catheter (CVC). In the ICU, his nurse experienced some difficulty using his central line, but she was able to draw blood back from all three ports. Over the course of the next week, the patient's condition improved, allowing for successful extubation and transfer out of the ICU. On the day of transfer, the ICU nurse removed the patient's femoral catheter but discovered the guidewire (used at the time of placement in the ED) still in the patient's femoral vein. The nurse removed the wire easily and without incident.

Later investigation revealed that the ED physician, who placed the central line, inadvertently left the guidewire in place and failed to account for the missing guidewire at the end of the procedure. Although the error increased risk for an infectious or thrombotic complication, removal of the catheter occurred prior to any adverse event, and the patient was unharmed.

Impatient Inpatient Dosing

Case & Commentary: Part 1

An elderly man with a diagnosis of acute deep vein thrombosis (DVT) during a hospital stay was started on warfarin 5 mg at bedtime and enoxaparin (a low-molecular-weight heparin).

Warfarin is among the most commonly prescribed drugs. Because excessive dosing can lead to major bleeding, it is also near the top of the list of drugs that lead to serious adverse events in elderly patients.(1) Physicians who use warfarin must know its fundamental pharmacology in order to properly initiate therapy and thereby ensure patient safety.(2)

Pharmacology of Warfarin

First, warfarin acts by inhibiting the action of vitamin K, which is required to carboxylate and thereby activate four clotting factors (II, VII, IX, and X).(3) This inhibition translates to prolongation of blood clotting times, measured using the prothrombin time or the international normalized ratio (INR). Because warfarin inhibits the action of vitamin K, exogenously administered vitamin K can overcome the effect of warfarin, leading to synthesis of normal clotting factors with normalization of clotting.

Second, warfarin is metabolized in the liver by the P450 cytochrome CYP2C9. It has a half-life of degradation of approximately 35 hours, which means that when a fixed dose is administered orally, it takes approximately 7 to 9 days before the warfarin level or INR reaches a steady state.(4) Patients with liver disease or patients who take medications that inhibit CYP2C9 require less warfarin.

Third, warfarin is highly protein bound to albumin, and it is the free or unbound warfarin level that interferes with activation of the clotting factors.(5) This means that hospitalized patients who have a low level of albumin are much more sensitive to warfarin because there is less protein binding and thus a higher level of free warfarin.(6) Patients in the hospital are often very sick, and those with an albumin level less than 1.8 can be expected to be very sensitive to warfarin. As patients recover out of the hospital, they generally require a higher dose of warfarin.

Fourth, there is wide inter-subject variation in the dose of warfarin required to raise the INR to a therapeutic level, eg, an INR of 2.5. The average dose is approximately 4.3 mg, but the range is from 0.5 to 15 mg/day.(7) Older patients require less warfarin (1% reduction in clearance per year after age 55), men generally require more than women, and heavier patients require a higher dose.(8,9)

Fifth, the anticoagulant response to warfarin, measured using the prothrombin time or INR, is used to determine the correct dose. It is important to remember that the initial INR response to warfarin depends not only on the serum level of free warfarin but also on the rate of degradation of normal clotting factors, particularly factor VII (half-life of 6 hours).

To summarize, in the elderly patient in this case, when we initiate warfarin therapy we should expect: (i) a low maintenance dose of warfarin, perhaps 3 mg/day, and (ii) a 7- to 9-day time lag before the INR reaches steady state. After the first dose of warfarin, it will take approximately 20 hours before there is any significant change in the INR (because factor VII levels first have to fall), so that the *INR value measured just 10-12 hours after the first dose is of little clinical use*. In the average person, the INR value measured the morning after a 5 mg dose (given at 17:00 pm) is usually normal or less than 1.1. A very sensitive individual will have an INR of greater than 1.3, indicating

that a maintenance dose of approximately 1 mg will be needed to achieve the usual therapeutic INR of 2-3.

Clinical Rules for Initial Dosing of Warfarin

Among hospitalized patients, particularly elderly patients, start with 5 mg of warfarin. Other factors associated with lower warfarin requirements include a body mass index (BMI) less than 20, liver disease (including passive congestion from congestive heart failure), and being treated with a drug that inhibits warfarin metabolism (eg, metronidazole, trimethoprim-sulfamethoxazole, erythromycin, fluconazole, amiodarone, and others [Table 1]).(10)

Give the first dose of warfarin as early in the day as possible, not at 5:00 in the evening. The longer the time interval between the first dose and the initial INR measurement, the more the INR will truly reflect the sensitivity to warfarin. If the time interval is too short, the physician should order another INR later in the day (at about 3:00 pm) and use this result to judge the best next dose of warfarin. Optimally, the amount of time between the first warfarin dose and the INR measurement should be as close to 20 hours as possible; 12 hours is too short.

In elderly patients, even if the INR on day 2 is less than 1.1, it is prudent to administer a second dose of 5 mg. If the patient is young and if the INR on day 2 is less than 1.1 twenty or more hours after the first dose, 10 mg can be given.

Case & Commentary: Part 2

The intern checked the INR the next day and noted it was 1.0. He increased the warfarin order to 10 mg at bedtime. The following day, the INR was 1.2. In response, he increased the warfarin dose again to 15 mg at bedtime. On the fourth day of warfarin therapy, the INR was 1.8. The intern then wrote an order for 20 mg at bedtime.

The day 3 morning INR was 1.2 following a 5-mg dose on day 1 and a 10-mg dose on day 2. This INR value should be interpreted as reflecting the effect of the initial 5-mg dose. Using a personal digital assistant (PDA)-based computer-dosing tool called WARFDOCs, which is based on a previous DOS-based Bayesian Forecasting program called DrugCalc®(11), the estimated steady-state dose of warfarin is 3.54 mg, assuming the patient is 80 years old and weighs 170 pounds. The computer modeling predicts that if 10 mg is given on each of the next 2 days, the INR value will be 4.0 on day 5, a potentially dangerous level. Giving even higher doses will lead to an even faster rise in the INR. WARFDOCs was developed as part of an AHRQ-funded patient-safety project. The PDA version will be publicly available soon.

The morning after a 15-mg dose of warfarin was given on day 3, the day 4 INR was 1.8. The WARFDOCs program projects that the steady-state dose is still 3.55 mg, and it predicts that giving just 10 mg on day 4 will result in a supratherapeutic INR of 3.3 on day 5, rising to an INR of over 7 on day 6. Because the intern did not have any first-hand experience dosing warfarin, an even higher dose of 20 mg was administered on day 4 and, not surprisingly, the day 6 INR was greater than 9.0, a level at which spontaneous bleeding can occur.

Using the WARFDOCs dosing program (Table 2) to model this patient's expected response to a daily dose of 5 mg, we see that the INR is expected to rise slowly but steadily. The model predicts that it takes 5 days to achieve an INR of just over 2.0; it would take approximately 12 days to attain the predicted steady-state INR of 4.7.

If one wanted to shorten the time required to achieve a therapeutic INR of 2.5, one could give a modestly higher dose of 7.5 mg on days 4 and 5 and then drop the dose to 3.5 mg thereafter. This requires considerable experience or use of the computer software. A better plan would be to exercise patience and just use low-molecular-weight heparin (LMWH) (as a "bridge") for 7 days while the INR rises slowly to 2.32, then stop the LMWH and reduce the warfarin dose to 3 or 4 mg, testing the INR every few days.

Case & Commentary: Part 3

On day number 6, the INR was over 9.0. The patient developed an acute episode of bleeding that required transfusion. Anticoagulation was stopped and vitamin K was given.

This serious dosing error could have been prevented in three ways. First, someone experienced in dosing warfarin should have been supervising this intern. This could have been a nurse, a hospital pharmacist, the attending physician, or an anticoagulation nurse/pharmacist specialist.(12,13) Second, the intern could have used computer modeling.(11,14-16) Third, the intern could have used a validated nomogram.(17,18) Several publications have shown that computer modeling of warfarin leads to more accurate dosing than routine dosing by physicians.(11,19,20) Finally, data also suggest that a pharmacist's overview of anticoagulant care reduces the incidence of adverse outcomes.(21) Supervision or primary management of warfarin by a dedicated anticoagulation pharmacist probably would have prevented this error entirely.

In summary, warfarin dosing is a potentially dangerous process, particularly in the hospitalized patient. In the absence of clinical experience, a provider should take advantage of the expertise of pharmacists or specialized anticoagulation personnel to aid in dosing decisions. In the near future, this

process will be simplified and made safer with computer-based management tools. For now, many clinicians will use such tools as stand-along adjuncts, accessed either through their computers or hand-held PDAs. Ideally, the WARFDOCs calculator will be integrated into the hospital or outpatient clinic's electronic medical record (EMR) system. When a first-time warfarin dose is ordered, the computer would capture the demographic data (age, height, weight, etc.) along with all INR levels and warfarin doses. Subsequently, each time an INR is measured after warfarin is administered, the engine would show a steady-state dose prediction and the expected value of the INR over the next 2 days if the steady-state dose is given. This would require no work by the physician, and the program would seamlessly provide data upon which the doctor could base the next dosing decision. Such a vision may be realized in many health care organizations in the next few years.

Blind Spot

The Case

A 36-year-old woman with no significant past medical history underwent right nephrectomy in the left lateral position. The surgery was uncomplicated—her blood pressures intraoperatively were within 20% of her baseline, and she did not have significant blood loss. Immediately after surgery, the patient complained of "blurriness" in one eye. This was attributed to eye ointment applied during the surgery and no further work-up was pursued.

Two weeks later during a clinic visit, the patient complained of blindness in the left eye. She was emergently referred to an ophthalmologist and diagnosed with retinal ischemia as a complication of surgery. Three months after surgery, the patient still had partial visual loss.

Two Pills, Same Drug

The Case

A 34-year-old woman with AIDS developed a fever and hypotension due to suspected pneumonia. Her past medical history included several AIDS-related complications, but a recent test showed that her viral load was undetectable on a drug regimen of stavudine, lamivudine, and Kaletra (a combination pill containing lopinavir and ritonavir). Given her critical condition, an infectious disease consultant recommended changing her stavudine, which is associated with lactic acidosis, to abacavir. The intern caring for the patient used a preprinted antiretroviral order template (paper form) to execute the

medication orders, requesting a new agent, Trizivir, a combination pill containing abacavir, lamivudine, and zidovudine.

The following morning, a pharmacist noted that the patient's revised orders called for continuation of stavudine, lamivudine, and Kaletra in addition to the new order for Trizivir. The patient was thus set to receive double doses of lamivudine and thymidine analogs, any of which could be terribly toxic in overdose. Apparently, the execution of orders via the template did not automatically cancel the other, free-form orders, a processing issue the intern failed to recognize. Fortunately, the pharmacist caught the error minutes before scheduled administration, and the patient suffered no adverse event, because only Trizivir was administered.

Getting to the Root of the Matter

The Case

A 65-year-old man with atrial fibrillation, lung cancer, and chronic renal insufficiency presented to the emergency department (ED) with shortness of breath. His vital signs were significant for a respiratory rate of 32, a temperature of 102.4°F, and an oxygen saturation of 87% on a 100% non-rebreather. A chest X-ray showed a right middle infiltrate. Due to respiratory distress, the patient was intubated.

Shortly thereafter, the patient became hypotensive with a systolic blood pressure (BP) of 65 mm Hg. Fluid resuscitation was continued while BP was supported with phenylephrine and vasopressin. Phenylephrine was changed to norepinephrine. After 8 hours, arterial blood gas test revealed a pH 7.23, Pco_2 23 mm Hg, Po_2 161 mm Hg and base excess –16, lactate 6.2 mmol/L (normal 0.5 – 2.2 mmol/L). A pulmonary artery catheter was placed, and initial numbers were—surprisingly—more consistent with cardiogenic shock than septic shock, with a central venous pressure of 13-17 mm Hg, pulmonary capillary wedge pressure of 19 mm Hg, cardiac index (CI) 1.8 L/min/m^2, and systemic vascular resistance (SVR) of 1500 dynes/sec x cm^{-5}. Norepinephrine was weaned rapidly. The patient remained on vasopressin. An echocardiogram showed global decrease in contractility, with an ejection fraction 45% and mild right ventricular dilatation. Shortly thereafter, it was discovered that the patient had been receiving 0.4 units/min of vasopressin, rather than the intended dose of 0.04 units/min. Vasopressin was discontinued.

Within the next few hours, the patient's condition improved. The CI and mixed venous oxygen saturation increased to 3.8 L/min/m^2 and 75%, respectively, and the SVR decreased to 586 dynes/sec x cm^{-5}. A creatine kinase (CK) peaked to 7236 U/L, CKMB to 37 U/L. The patient was treated with fluids and antibiotics and had an uneventful recovery.

Pregnant With Danger

The Case

A 35-year-old woman, 38 weeks pregnant, presented to the emergency department (ED) in the middle of the night complaining of left leg pain. She also had some mild lower back pain, but no other symptoms. Hospital policy stated that all patients greater than 20 weeks' gestation should go directly to labor and delivery unless their problem was clearly unrelated to the pregnancy. At ED triage, the pain was deemed to be non-obstetrical in nature, and so she was evaluated in the ED rather than being sent to labor and delivery.

Physical examination revealed her left leg was slightly cooler than the right leg but was otherwise unremarkable. A Doppler venous ultrasound revealed no evidence of deep venous thrombosis, but there appeared to be decreased blood flow to the leg in the left-lying position with normal blood flow in other positions. After many hours of evaluation and observation in the ED, the pain was diagnosed as musculoskeletal. To facilitate evaluation by her obstetrician, she was transferred briefly to labor and delivery. Fetal monitoring was normal and the patient was discharged home.

The following morning, the patient's husband found her dead at home. An emergency cesarean section was performed in the ED, but both the mother and the infant expired. Autopsy revealed a ruptured aortic dissection.

Discharge Against Medical Advice

The Case

A 50-year-old man with a history of alcohol abuse and alcohol-induced dementia was admitted to the medical service with mild alcohol withdrawal. He was also found to have a proximal humeral fracture, and the orthopedic consult recommended surgical repair. The patient was treated with benzodiazepines for his alcohol withdrawal and remained medically stable. After hearing the risks and benefits of surgery from the physicians, the patient refused.

In light of the patient's chronic dementia and acute delirium due to alcohol withdrawal, formal mental status testing was performed, which indicated that the patient lacked the capacity to make medical decisions. A psychiatry consultation supported this determination.

On hospital day 4, at approximately midnight, the patient stated to his nurse that he wished to leave the hospital. Neither the floor nurse nor the charge

nurse was aware the patient had been found to lack decision-making capacity. They contacted the nightfloat covering resident and informed her that the patient wished to leave. The resident glanced at the chart, asked the patient a few questions, and allowed him to leave against medical advice (AMA).

The primary medical team was informed the following morning about the discharge. They had no contact information for the patient, and he could not be located. What happened to him is unknown.

Diagnosing Diagnostic Mistakes

Issue #1

Overcalling error due to evaluation of a case with knowledge of the patient's outcome (hindsight bias); especially in the face of no gold standard for diagnosis.

Illustrative Case—Doctor, Don't Treat Thyself

A 50-year-old radiologist presented with shortness of breath and interpreted his own chest x-ray as being "consistent" with pneumonia. Later the patient died of a myocardial infarction and pulmonary edema. Several radiologists reviewed the chest x-ray (after the outcome) and reported it "consistent" with pulmonary edema. The case was deemed by the discussant to "dramatically and tragically" illustrate a diagnostic mistake.

We don't believe that this case represents a preventable mistake or even a missed diagnosis, since, in our view, useful classification systems for preventable mistakes cannot include cases with no gold standard for the diagnosis. We recognize that this stringent standard, if widely applied, may suggest that diagnostic error cannot be defined by outcomes of care.

By "gold standard" we mean a high level of agreement about the criteria for diagnosis, such that different observers would agree when applying the criteria. The lack of agreement among observers trying to discriminate pneumonia from heart failure on a chest x-ray of a dyspneic patient is partially due to ambiguity in the criteria for making these diagnoses. For example, the overall accuracy of the evaluation of dyspnea is imprecise.(3) Studies suggest that variation between observers when assessing patients accounts for at least some of the inaccuracy in assessing the value of classic signs and symptoms of heart failure.(4) In one study, two university radiologists could identify chest x-ray signs of pneumonia with only "fair to good" reliability and were especially poor in defining the pattern of infiltrates.(5)

Given the ambiguity in the diagnostic criteria for heart failure and pneumonia and the imperfect agreement for interpreting the chest x-ray, radiologists who know a patient's outcome interpret chest x-ray findings differently than radiologists who are unaware of the ultimate outcome (hindsight bias).(6,7) In the case at hand, it is irrelevant that the first radiologist was the patient; this discrepancy could occur between any two radiologists. Subjective criteria will be influenced by who, when, where, and how judgments are made.

The best way to minimize the impact of hindsight bias is to ignore the outcome. The outcome (good or bad) for a patient should not be revealed when trying to classify diagnostic mistakes. Evaluation of an adverse event should be done by an independent review panel following a structured, evidence-based assessment of the processes—not the outcomes—of care.(8)

Issue #2

Overcalling error due to failure to consider the spectrum of clinical presentations and the consequences of competing diagnoses.

Illustrative Case—Crushing Chest Pain: A Missed Opportunity

A 62-year-old woman is admitted with crushing chest pain and treated for possible myocardial infarction (MI). She later dies of an aortic dissection (AD). The case, when discussed on AHRQ WebM&M, was felt by the discussant to be a diagnostic error.

This case does not represent a missed diagnosis or a preventable error for several reasons. First, clinical presentations of a particular disease vary. Some dissecting aneurysms can be noted by the most casual of observations (i.e., wide and expanding mediastinum in a patient known to have an aneurysm), while some can be missed even after utmost scrutiny. In our judgment, this case is an example of the latter. The discussant claimed that the diagnosis was missed due in part to failure to note a small calcium deposit on the chest x-ray (again noted in hindsight), but the AHRQ WebM&M presentation had to magnify the finding on the radiograph in order to render it visible to readers (Figure). It is not clear how many observers, blinded to the outcome, would miss this finding, but surely some would. Before this case could be classified as an error, we would need to show that trained observers, blinded to the outcome, would see the radiologic finding and would, correctly and earlier in the patient's course, have made the diagnosis of dissecting aneurysm.(9) Second, the quality of the literature addressing various diagnostic tests for AD is poor. Reports of the accuracy of diagnostic tests are biased by retrospective reviews of charts of patients known to have suffered from AD.(10-12) Certainly those reports do not include patients requiring a magnified view of a small abnormality.

In addition to the failure to consider the spectrum of disease presentations, another reason for mislabeling is the failure to consider the consequences of competing diseases as the cause of a patient's complaints. The diagnostic process is not static; instead, it is a fluid refinement of possible diagnoses.(13) Yet potential cases of missed or delayed diagnoses often come to light when a "surprise" diagnosis is found—one different from the diagnosis being pursued and/or treated. This surprise diagnosis is too often assumed to be "missed." This case illustrates that missing one diagnosis may be preferred to missing another.

The dissecting aneurysm case is one in which (i) several serious diseases may explain the patient's complaint; *and* (ii) empiric treatment of one may increase the chance of death in another; *and* (iii) the value of diagnostic tests to differentiate one disease from another is unknown or poorly studied. For example, MI, acute coronary syndrome (ACS), pulmonary embolus (PE), and AD are all in the differential diagnosis of the patient's complaints. These diseases take varying times to diagnose and have markedly different probabilities of occurrence, and each has different risks and benefits for diagnostic testing or delaying effective therapies.

The result of these uncertainties may require a physician to act on one disease to the detriment of another. For example, a workup for AD may delay life-saving anticoagulant therapy for someone who is having ACS. Since ACS is more common than AD in most clinical situations, more harm than good may come from an overzealous attempt to not miss AD.

While this tradeoff has not been formally analyzed, we believe that such an analysis would conclude that AD represents a virtually insoluble diagnostic problem for many of its clinical presentations. To illustrate why, we performed a "back of the envelope" decision analysis. In it, we assumed that the ratio of AD:ACS for patients presenting with chest pain is at most 1:250.(14-16) We further assumed that if we found AD without delay (through the use of a perfectly accurate test), the patient's life would be saved. We then assumed that a delay in anticoagulant therapy for ACS that occurs while assessing all patients for AD would lead to a 1% increase in death or myocardial infarction.(17,18) In summary, we assumed a 100% marginal improvement for making the diagnosis of AD and a 1% marginal improvement for early therapy for patients with ACS. These assumptions bias the analysis for making the diagnosis of AD (since, in real life, some people do die even when the diagnosis is made promptly). Given these assumptions, a vigorous search for AD in all patients that delayed anticoagulation for possible ACS would kill or cause MI in 2-3 patients with ACS for every patient with AD whose life would be saved. We use this threshold model of decision making as our criterion standard in diagnosis care evaluations.(19) This standard requires that explicit, evidence-based tradeoffs for competing diagnoses be considered before asserting that a preventable diagnostic mistake may have occurred.

The Forgotten Med

The Case

A 78-year-old woman with a history of chronic obstructive pulmonary disease (COPD) came to the hospital with increasing shortness of breath and chest pain. Although she had no history of diabetes, her glucose level on admission was nearly 300 mg/dL. Along with initial treatment, the admitting physician prescribed once-daily insulin (glargine) and ordered finger-stick glucose checks four times daily (QID), with sliding-scale coverage for persistently elevated glucose values.

The patient ruled out for a myocardial infarction, and her COPD exacerbation improved after initial treatment. After 3 days, she was transferred to a skilled nursing facility (SNF) for continued observation and intensive respiratory treatments. Medication orders from the acute care ward were continued at the SNF.

Three days later, a physician evaluated the patient and reviewed her progress. He noted that, while glucose values in the hospital ranged from 150-250 mg/dL, glucose levels currently ranged from 90-140 mg/dL (essentially normal). Therefore, thinking that the patient's glycemic control had improved, he discontinued the QID glucose checks and insulin sliding-scale orders. However, he failed to notice the existing order for glargine, a long-acting insulin.

Four days later, the patient became unresponsive. The physician ordered stat blood cultures, electrolytes, and a head CT scan. As staff prepared to transport the patient to radiology, the lab called to report a critical value—a glucose level of 22 mg/dL. The physician immediately ordered intravenous dextrose followed by an infusion, which led to a rapid improvement in the patient's mental status. Luckily, the patient suffered no subsequent events, her glargine was discontinued, and she continued her rehabilitation at the SNF.

The incident led to an internal review of the case. The physician acknowledged that he had seen the glargine order earlier in her SNF stay but had forgotten about it when he discontinued the glucose checks and sliding-scale insulin orders. Also, as in most hospitals, the nursing medication administration record (MAR) listed the once-daily dose of insulin in a different location than the sliding-scale insulin, because one is a regular medication and the other given as needed. This seemingly added to the confusion among the day and night nursing staff—since it was the latter who administered the evening glargine and the former who performed the glucose checks and would have administered the sliding-scale insulin therapy.

Compare and Contrast

Case & Commentary: Part 1

A 76-year-old woman came to the emergency department (ED) complaining of vomiting, dehydration, and abdominal pain. An abdominal x-ray revealed a pattern consistent with a partial small bowel obstruction. She was admitted to the hospital. Her blood urea nitrogen (BUN) was 32 mg/dL and her creatinine was 1.4 mg/dL. The patient underwent a contrast-enhanced abdominal CT to look for a lead point in the bowel obstruction. She received no therapies designed to decrease the risk of contrast nephropathy.

In this case, we do not know the patient's baseline serum creatinine concentration and whether her kidney function was stable or acutely deteriorating. Given the small bowel obstruction, she may have been volume depleted due to vomiting and poor oral intake. If we assume that she has chronic kidney disease (CKD), and the creatinine of 1.4 mg/dL reflected her baseline, we can use the MDRD (Modification of Diet in Renal Disease Study Group) formula (1) (go to related site) to estimate the glomerular filtration rate (GFR). This formula adjusts for body surface area, which is necessary when comparing a patient's estimated GFR to normal values, or to the levels defining the stages of CKD. Body surface area of 1.73 m^2 is the normal mean value for young adults. Thus, using the MDRD formula, her GFR would be 37 mL/min/1.73 m^2, a rate that would be classified as stage III (moderate) chronic kidney disease by the National Kidney Foundation guidelines.(2) However, since her weight was not provided, we cannot calculate an estimated creatinine clearance using the Cockcroft-Gault formula.

Administration of contrast in patients with baseline renal dysfunction can result in contrast nephropathy (CN), most commonly defined as an increase of ≥ 0.5 mg/dL or ≥ 25% in the serum creatinine concentration within 48 hours following contrast exposure. Patients with normal kidney function and no risk factors (Table 1 [3]) have a very low incidence of CN. In one study of older patients receiving coronary angiography, the incidence of CN was only 1.2% in patients without risk factors but increased to 11.2% with one risk factor and more than 20% with two risk factors.(5) The incidence of dialysis-requiring CN is much lower, less than 1% in a large study of 1,826 patients undergoing coronary intervention.(6)

In addition to the risk factors listed in Table 1, other possible risk factors for CN include older age (with normal kidney function), concomitant use of selected drugs (amphotericin B, cyclosporin A, tacrolimus, diuretics, and non-steroidal anti-inflammatory drugs), proteinuria of any cause, and peri-procedural complications and hypotension. Thus, some risk factors for CN are modifiable (volume of contrast, type of contrast, reduced renal perfusion),

whereas others are non-modifiable (ie, patient-related factors such as age, chronic kidney disease, diabetes, and heart failure).(4) But whether they are or are not modifiable, it is important to consider the patient's level of risk before choosing whether to perform a contrast study and, if so, whether to employ strategies that may modify the risk of CN.

Case & Commentary: Part 2

By hospital day number 3, the patient's urine output was minimal and the BUN and creatinine had risen to 70 mg/dL and 3.5 mg/dL, respectively. Her small bowel obstruction continued to improve and no surgical intervention was necessary.

The timing of this patient's renal decompensation is consistent with CN. Unfortunately, there are no effective therapies for established CN. Thus, physicians should focus efforts on prevention. Avoiding contrast entirely is the safest and simplest option. Consultation with a radiologist may direct the clinician to non-nephrotoxic imaging modalities, such as ultrasound, magnetic resonance, and nuclear medicine studies. Computed tomography without contrast may also yield satisfactory results, depending on the type of clinical situation. Angiography can be performed with non-nephrotoxic CO_2 contrast. Consultation with a radiologist is often quite helpful in determining whether alternative studies can provide the needed imaging without the risk of CN. If contrast cannot be avoided, the total volume should be minimized. Physicians should avoid other nephrotoxic drugs if at all possible.

The type of contrast may be important in reducing the risk of CN. Studies have shown that iso-osmolar and low-osmolar contrast are less nephrotoxic than traditional, high-osmolar contrast. A meta-analysis comparing low-osmolar contrast material with traditional agents found a reduced risk of CN in patients with chronic kidney disease.(7) A recent randomized clinical trial found that iodixanol, an iso-osmolar agent, was less nephrotoxic than low-osmolar iohexol in patients with diabetes and an elevated serum creatinine concentration undergoing coronary or aortofemoral angiography.(8)

Pharmacological interventions for CN prophylaxis include N-acetylcysteine, hydration with saline or isotonic sodium bicarbonate, and methylxanthines (theophylline and aminophylline). Ineffective strategies include calcium channel blockers, mannitol, furosemide, atrial natriuretic peptide, endothelin antagonists, dopamine, fenoldopam, and hemodialysis. A recent review cogently summarized the approach to pharmacological prophylaxis for CN.(9) Given the low incidence of CN in the general population, prophylactic strategies should be limited to patients at high risk.

The original report of N-acetylcysteine prophylaxis appeared in 2000 and garnered considerable attention.(10) The regimen includes four oral doses of acetylcysteine, 600 mg twice daily, starting the day before the contrast study. N-Acetylcysteine produced a relative risk of 0.1 in the incidence of CN (defined as increase of 0.5 mg/dL in the serum creatinine concentration) compared with placebo. Subsequent clinical trials produced conflicting results, leading to dampening of enthusiasm for this approach. However, several meta-analyses of acetylcysteine have also been published, with the majority reporting an overall benefit.(11)

In part because of the lingering questions regarding N-acetylcysteine's true benefits in preventing CN, a recent trial of isotonic sodium bicarbonate generated significant interest.(12) One hundred and nineteen subjects with baseline serum creatinine greater than 1.1 mg/dL were randomized to volume expansion with either isotonic sodium bicarbonate or normal (0.9%) saline. The infusion rates were 3 mL/kg/hour for 1 hour before, and 1 mL/kg/hour for 6 hours after, radiocontrast exposure. These patients did not receive N-acetylcysteine. The incidence of CN (defined as a 25% increase in serum creatinine within 2 days of exposure) was 1.7% in the bicarbonate group vs. 13.6% in the saline group. Low rates of CN were subsequently confirmed in an open-label study of 191 patients given a simplified isotonic sodium bicarbonate infusion with radiocontrast exposure.

Hemodialysis and hemofiltration may remove a fraction of administered radiocontrast, but the relatively low incidence of CN, even among high-risk patients, does not warrant their application. The largest hemodialysis trial randomized subjects to a single hemodialysis session following contrast exposure but failed to reduce the incidence of CN and other complications.(13) Marenzi and colleagues published a controversial study of prophylactic continuous hemofiltration.(14) Subjects received hemofiltration immediately before, and for 18 to 24 hours after, coronary angiography. The hemofiltration group had a lower incidence of CN (5% vs. 50%). However, because CN was defined as a change in serum creatinine—and hemofiltration directly decreases serum creatinine concentration—it is difficult to interpret the results of this study.

A recent meta-analysis of theophylline and aminophylline concluded that these agents reduce the rise in serum creatinine following radiocontrast exposure.(15) Unfortunately, most of the theophylline and aminophylline studies did not report the fraction of subjects experiencing a discrete risk (e.g., ≥ 0.5 mg/dL increase in serum creatinine). So here, too, it is not entirely clear how best to interpret the value of these prophylactic therapies.

Case & Commentary: Part 3

Due to continued oliguria and persistent uremia, hemodialysis was started on hospital day number 5.

The role of CN in the development of end-stage renal disease is undefined, and the vast majority of cases of CN are reversible. However, severe or repeated episodes of acute kidney injury may increase the risk of progressive chronic kidney disease.

CN has been linked to mortality, morbidity, and prolonged length of stay. A cohort study of 16,248 inpatients receiving a variety of diagnostic imaging studies found a mortality rate of 34% in those with CN compared to only 7% in those without CN; adjustment for differences in co-morbidities yielded a 5.5-fold increase in the odds of death associated with CN.(16) Other investigators reported that in-hospital mortality for patients with acute renal failure requiring dialysis following coronary intervention was 35.7%, with a 2-year survival of only 18.8%.(6) In another study of 359 patients undergoing coronary stenting, CN was associated with a median length of stay of 6 days, compared with only 1 day without CN.(17)

How could this complication have been avoided in this patient? An algorithm for radiocontrast use in high-risk patients should include risk assessment, avoidance of contrast exposure, determination of medical necessity, and prophylaxis (Table 2).(18,19) Low-risk patients have a low incidence of nephropathy (1% or less) and need not receive any prophylaxis. Among high-risk patients, chronic kidney disease and other risk factors should be considered relative (not absolute) contraindications to radiocontrast exposure. Diagnostic information gained from computed tomography may yield critical diagnostic information or allow an important therapeutic intervention with potentially life-saving results. Therefore, if a contrast study is what is required to appropriately manage a patient at patient at high risk for CN, he or she should receive it with appropriate prophylaxis and monitoring. In one study, elderly patients with chronic kidney disease were half as likely to undergo coronary angiography despite equivalently appropriate clinical indications.(20)

In summary, CN is a possible complication of radiographic studies, particularly in patients with baseline renal dysfunction. The clinician considering the use of a contrast study in an at-risk patient must consider first the possibility of using alternative non-contrast–requiring imaging and next the urgency of the clinical situation and the possibility of delaying imaging to administer prophylactic modalities. However, urgent diagnostic studies should not be delayed for fear of inducing nephrotoxicity, as the delay-associated hazard frequently outweighs the risk of CN. If contrast is to be administered, all efforts should be made to avoid nephrotoxic medications before and after radiocontrast exposure. In addition, the dose of the contrast should be minimized, and iso-osmolar contrast material is preferable. Finally, N-acetylcysteine and isotonic sodium bicarbonate have been shown to decrease

the risk of CN in at-risk patients. However, the current literature does not allow for an evidence-based choice between these two options, nor does it support combining both prophylactic agents.

Hold the tPA

The Case

A 74-year-old woman with a history of atrial fibrillation on warfarin therapy came to the emergency department (ED) 1 hour after the sudden onset of aphasia and right-sided weakness. A non-contrast CT scan of the brain revealed blurring of the left gray-white junction with no hemorrhage, consistent with an acute left middle cerebral artery ischemic stroke. Less than 3 hours had elapsed since the onset of her symptoms, making her a potential candidate for thrombolysis. There were no contraindications to tissue plasminogen activator (tPA) administration at the time, but laboratory results, including a complete blood count (CBC) and coagulation studies, were pending.

In order to expedite treatment (crucial because research finds benefit for thrombolysis in acute stroke only if administered in the first 3 hours; see below), the ED physician wrote an order for an appropriate dose of intravenous (IV) tPA and asked a nurse to obtain the dose from the pharmacy. The nurse returned from the pharmacy and placed the medication at the patient's bedside. A second ED nurse caring for the patient read the order in the patient's chart and administered the tPA bolus. Five minutes later, the lab results returned—the INR was elevated at 4.5, an absolute contraindication to thrombolytic therapy.

The patient was transferred to the neurological ICU. She underwent serial CT scanning, which did not show hemorrhagic conversion of her ischemic stroke. She didn't suffer any other bleeding complications, but she was unable to receive many elements of standard ischemic stroke care, such as permissive hypertension. Eventually, she died of stroke-related complications.

Around the Block

The Case

A 77-year-old woman with multiple medical problems was admitted to the hospital for an elective knee replacement. The orthopedic surgeon, recognizing the risk of deep vein thrombosis (DVT), prescribed enoxaparin (Lovenox) for DVT prophylaxis at the time of admission. The anesthesiologist felt that an epidural anesthetic would be safer than general anesthesia in this patient, and placed an epidural catheter to administer the anesthetic (Figure 1). The

surgery went well, but soon after surgery the patient developed new onset lower extremity weakness. A "stat" MRI scan revealed a spinal hematoma (Figure 2). Despite prompt recognition, the patient was permanently paralyzed from the waist down.

A retrospective analysis of the case revealed that the admission order form included the statement "Lovenox is not recommended in patients with an epidural," located right next to the check box used to order enoxaparin. A nurse and pharmacist had countersigned the signature block next to this warning.

Techno Trip

The Case

A 70-year-old woman was admitted to a community hospital after developing confusion and right-sided weakness. A CT scan of her brain showed an acute subdural hematoma. The hospital arranged a transfer to large referral center for urgent neurosurgical evaluation. The radiology department at the community hospital had recently implemented an electronic picture archiving and communication system (PACS). Instead of printed films, the patient was sent with a compact disk (CD) containing copies of relevant studies. On arrival at the referral center, a right-sided hemiparesis was confirmed on physical exam. The accepting surgeon inserted the CD into a local computer. The CT image that appeared on the screen showed some brain atrophy, small, old strokes, and a large left-sided subdural hygroma, but no acute hemorrhage. The surgeon felt that the patient had a stroke, admitted her to the stroke unit, and consulted neurology.

The next day, a consulting neurologist found a set of more recent images while scrolling through the PACS disk. These demonstrated the acute subdural hemorrhage for which the patient had been transferred. The subdural was urgently evacuated, and the patient improved after a prolonged period of rehabilitation.

Hidden Mystery

Case & Commentary: Part 1

A 45-year-old woman with a history of morbid obesity and diabetes mellitus was transferred to a tertiary care center for management of diffuse abdominal pain, vomiting, and subjective fevers. Upon transfer, the patient was febrile with stable vital signs. Examination revealed a diffusely tender abdomen with chronic erythematous changes extending over her abdomen including her panniculus. Empiric broad-spectrum antibiotics were started for presumed

cellulitis. The consulting surgeon recommended repeat abdominal imaging, but the patient was unable to fit in the CT scanner or MRI due to her obesity. She was observed and her abdominal pain was treated with opiates.

Obesity is a major health care problem in the United States (1,2), accountable for tens of thousands of preventable deaths each year.(3) Obesity is generally defined by using the Body Mass Index (BMI), with a BMI > 25 kg/m2 defining overweight, BMI > 30 kg/m2 defining obese, and BMI > 40 kg/m2 defining morbidly obese patients. Obesity increases the likelihood of a multitude of diseases.

This case demonstrates that obesity poses challenges for both diagnosis and treatment. Due to the high prevalence of obesity in the United States and its negative health consequences, understanding the difficulties and complexities in caring for such patients is paramount. Interventions considered routine in other patients, such as transportation, physical examination, diagnostic imaging, and nursing care, pose unique challenges in this population.

Transportation.—The simple act of moving the obese patient from one part of a hospital to another is often fraught with difficulty. Luckily, some innovative solutions have been recently developed. For example, some institutions assign extra personnel to help transport obese patients, or use multiple slider boards turned perpendicular to the patient. Some equipment has been designed specifically and is commercially available for morbidly obese patients, including soft stretchers, patient carts, operating room tables, and hospital beds. Medical equipment supply stores are likely to have additional items such as mechanical lifts, large wheelchairs, and commodes designed for such patients.

Physical Examination.—As seen in this case, morbid obesity makes physical examination more difficult. Increased width of subcutaneous fat, particularly the abdominal panniculus, interferes with auscultation, palpation, and inspection of many organ systems. Getting the morbidly obese patient into the correct examination position may be extremely difficult. In many patients, an adequate physical examination is achievable, but often requires extra effort (sometimes supplemented by special equipment) on the part of the patient and physician to ensure this occurs. For example, an obese patient's "hypertension" is frequently "cured" by the use of a sufficiently wide and long sphygmomanometry cuff.

In my experience, pain perception may also be altered in the morbidly obese patient. When such patients have significant intra-abdominal pathology, the combination of diminished physical examination findings and an increased pain threshold may lead the physician to false diagnostic conclusions. This phenomenon may have contributed to the error in this case.

Diagnostic Imaging.—As seen in this case, medical imaging of the morbidly obese patient is challenging. Standard radiographs may not be able to visualize the entire body part, requiring multiple panoramic-type views to be taken. Computerized tomography and magnetic resonance machines often have weight and circumference restrictions, usually with upper limits in the range 300-350 pounds.(4) Ultrasound images are frequently obscured by morbid obesity.(5-7)

Nursing Care.—Delivering routine and intensive nursing care is also more difficult in the morbidly obese patient. Cardiac and pulse oximetry monitoring, wound care, blood draws, intravenous catheter placement, skin care and prevention of pressure ulcers, respiratory and ventilator support, and correct administration of medications can all be challenging in the morbidly obese patient.(8,9)

Airway Management.—Management of the airway in an obese patient can be extremely difficult. Morbidly obese patients develop oxygen desaturation more quickly than non-obese adults. Bag-Valve-Mask ventilation is more difficult because of reduced pulmonary compliance, increased chest wall resistance, increased airway resistance, abnormal diaphragmatic position, and increased upper airway resistance. The risk of aspiration is greater in obese patients because of a larger volume of gastric fluid, and an increased intra-abdominal pressure with higher incidence of gastroesophageal reflux.

As in the non-obese patient, endotracheal intubation remains the method of choice for controlling the airway. Obesity increases the risk of intubation by inhibiting the physician's view of the laryngeal structures during orotracheal intubation. In an Australian study of 85 cases of difficult intubations, obesity, limited neck mobility, and poor mouth opening accounted for two thirds of all the contributing factors.(10) Morbidly obese patients often have short necks; this combination has been strongly correlated with difficult intubation.(11) Intubating the morbidly obese patient in the semierect position may facilitate a better view of the glottic opening. The Intubating Laryngeal Mask Airway (ILMA) and the Combitube have both been successfully utilized in the setting of failed endotracheal intubation in morbidly obese patients.

Venous Access.—Venous access in morbidly obese patients can be extremely difficult and time consuming. One study found that the extra skin punctures during catheter placement and the delayed catheter changes in obese patients led to more catheter-related infections and thrombosis.(12) Careful attention and monitoring of intravenous access sites is extremely important. Central line catheters are more difficult to obtain, and a second health care worker is often needed to retract panniculus for the physician attempting central line access.

Medications.—Morbidly obese patients are likely to have markedly altered medication pharmacokinetics, resulting from variations in volume of distribution, renal clearance, hepatic metabolism, protein binding, and concomitant disease states. The volume of distribution of a drug is correlated with drug lipophilicity. Drugs with a higher affinity for adipose tissue tend to have an increased volume of distribution. However, there are some striking exceptions that complicate the medication dosing process. The complexity of drug pharmacokinetics in obese patients and limited data creates a dilemma for clinicians.

In general, drug dosing in obese patients can be based on ideal body weight (IBW), total body weight (TBW), or somewhere in the middle (IBW plus some percentage of the excess weight). An empiric formula for the "somewhere in the middle" approach is Dosing Weight = IBW + 0.3(TBW-IBW). A recent article provides a detailed review of medication dosing in the critically ill morbidly obese.(13) Ideally, individual drug dosing is based on clinical research data in obese patients. When such data are lacking, the loading dose of a drug should be based on its hydrophilic or lipophilic properties. IBW, or IBW plus some percentage of the excess weight over IBW, should be used for hydrophilic medications, whereas TBW should be used for loading doses of lipophilic drugs. Maintenance dosing should be based on possible or observed changes in total metabolic clearance. If metabolic clearances are unknown, maintenance dosing based on IBW is advised. Careful monitoring of clinical end points, signs of toxicity, clinical response, and serum drug levels are strongly advised when giving medications to morbidly obese patients.

In summary, obesity presents significant challenges to virtually every step of the diagnostic and therapeutic process. A thoughtful, tailored approach—taking advantage of insights from research, experienced personnel, and technological and mechanical aides—must be applied to ensure safety.

Case & Commentary: Part 2

Six days later, the patient developed fevers, hypotension, and leukocytosis. Examination revealed newly identified gangrenous panniculus in the deep skin folds. The patient was taken to the operating room for presumed necrotizing fasciitis. On surgical exploration, she was found to have a colocutaneous fistula arising from perforated sigmoid diverticula. She died of multiorgan failure after a complex several-month hospital course.

Quality of Care of Obese Patients.—Morbidly obese patients have been found to experience delayed acute medical care; they are also less likely to receive preventive care services, either as a result of patient or physician factors.(14-16) Although some of these problems relate to the physical fact of obesity itself, there is also an attitudinal component. Studies have demonstrated

negative physician attitudes and discrimination towards morbidly obese patients.(17,18) Obese patients report feeling misunderstood and mistreated by medical personnel, resulting in prejudicial and discriminatory attitudes and behavior.(19) Taken together, these studies indicate that obese patients' medical care might well fall below the standard of care.

Surgery in the obese patient presents special challenges. In part owing to longer operative times, morbidly obese patients experience more surgical wound infections and have a higher rate of sepsis.(20,21,22) One study of 23,056 patients found that 23%, 31%, and 38% of normal weight, obese, and extremely obese patients, respectively, had perioperative events and complications.(23) Given the surgical technical difficulty and postoperative complication rates in morbidly obese patients, it is possible that surgeons are more reluctant to operate on these patients as promptly and for the same indications as in non-obese patients.

What Can Be Done to Improve Quality and Safety in the Care of the Obese Patient?

It appears that physicians are not being adequately trained and prepared to identify and treat morbidly obese patients.(24,25) Given the prevalence of obesity in our society today, it is very important for medical schools and residency training programs to provide education specific to the care of the morbidly obese patient. Medical students' knowledge has been significantly improved by rotating on a bariatric surgical service.(26) Specific medical school intervention using video, audio, and written components has lead to improved attitudes by medical students of obese patients one year after the intervention.(27)

By increasing individual physician awareness of the specific challenges related to the examination, diagnosis, and treatment of morbidly obese patients and by educating providers about the tools and interventions available, we may improve the care delivered to this population.

On O.R. Off?

The Case

An elderly man was admitted to the vascular surgery service with rest pain in his leg. Angiography demonstrated peripheral artery disease with anatomy suitable for revascularization. A consulting cardiologist recommended a stress echocardiogram to evaluate the patient's risk for surgery. While awaiting those results, the vascular surgery service tentatively scheduled the patient for surgery the next morning after obtaining informed consent. Shortly after making their decision, the surgeons learned that the stress echocardiogram

showed marked abnormalities warranting a cardiac catheterization and delay of surgery. The surgeons contacted the operating room and informed them that the case was canceled. When the team rounded on the patient later that evening, he was asleep, so the surgeons chose to defer their discussion of the new course of action with him until the morning. The surgeons documented the change of plans in the patient's chart, but failed to inform the nursing staff. The patient remained "NPO" overnight in anticipation of the cardiac catheterization. Due to unexplained events, the operation was not canceled on the schedule.

The next morning the patient was taken to the OR holding area as the first case of the day. Meanwhile, the vascular surgery team rounded on the patient only to discover him missing from his bed. They assumed he was undergoing cardiac catheterization. Due to time restrictions and the desire to start promptly, staff did not ask surgeons to mark the operative site in the holding area outside the OR. The patient was taken to the operating room, intubated, and given a general anesthetic. When the OR staff contacted the vascular surgeon to start the case, he stated that it had been canceled. The patient awakened without event and suffered no adverse consequences from the error. Cardiac catheterization and peripheral arterial bypass surgery were later completed successfully.

Preventable Rash

The Case

A 35-year-old man with HIV was being followed in an outpatient internal medicine clinic. At a routine visit, screening laboratories were checked. The clinic never contacted the patient about his laboratory test results, and he assumed they were normal. He returned to his normal lifestyle, including occasional unprotected sexual activity.

One month later, he developed a rash. The outpatient clinic was unable to see him immediately, and recommended he go to the urgent care clinic. The urgent care provider reviewed his lab results and discovered that his tests for rapid plasma reagin (RPR) and Treponema antibody were both positive. Examination was notable for a classic syphilitic rash (Figure), confirming the diagnosis of secondary syphilis. The patient was treated with penicillin in the urgent care clinic. However, he subsequently developed a Jarisch-Herxheimer reaction and was admitted to the hospital.

Carpe Diem (Seize the Day)

The Case

A 53-year-old man presented for a new patient visit at a local medical clinic. He had several chronic medical conditions including hypertension, hyperlipidemia, depression, osteoarthritis, and a seizure disorder. His medications included phenytoin for his seizure disorder. Two months prior to this presentation, the patient called the on-call physician worried that he had suffered a seizure. The patient requested a "handicapped" license plate because of increasing difficulty walking long distances due to his osteoarthritis. To his surprise, the physician informed him of the need to alert the Department of Motor Vehicles (DMV) about his seizure disorder. The patient reported that his neurologist allowed him to drive "only to and from work" because his seizures were "nocturnal." Despite the patient receiving treatment from several physicians over the years, this was the first time a physician explained the need to report his condition to the DMV. The patient was very upset with the treating physician, but the physician felt he was complying with the law.

Discharge Fumbles

Case & Commentary

Case #1 A 59 year-old man with severe but well-controlled congestive heart failure, on spironolactone and other appropriate medications, was discharged following a brief hospitalization for leg cellulitis. His pre-admission medication regimen was included on his discharge orders. Within days of discharge, the patient began to feel lethargic and nauseated. He presented to the emergency department (ED) with these complaints and was found to be in acute renal failure, with a serum potassium level of 7.1 and a sodium level of 122. Upon review of his discharge orders, it was discovered that the spironolactone was mistakenly prescribed at a dose 8 times higher than his admission dose.

Case #2 A patient was admitted for atypical chest pain. During the course of her stay, she was evaluated by neurology for memory deficit. She was placed on Reminyl (galantamine hydrobromide, a medication for Alzheimer's disease), 4 mg twice daily to be increased to 8 mg twice daily in one month. Upon discharge, an order was written to "discharge on current medications." The patient presented to the ED the following day with mental status changes. She was found to be profoundly hypoglycemic. Review of her discharge medications revealed an inadvertent addition of Amaryl (glimepiride, a medication for diabetes). It was determined that the pharmacy mistook the original order for Reminyl as Amaryl.

Patient safety problems, similar to the two illustrative cases, are exceedingly common in the early discharge period. Recent studies performed in three hospitals and two countries demonstrate that approximately 1 in 5 medical

patients experience an adverse event during the first several weeks after hospital discharge.(1,2) Many of these events result in symptoms only; however, approximately one third of them are associated with disability and half of them are associated with use of additional health services. The following discussion describes types of post-discharge adverse events, their epidemiology, important health system factors contributing to them, and potential solutions.

Types of adverse events affecting patients after discharge Several types of adverse events may occur following discharge. The most prevalent are medication related, also known as adverse drug events (ADEs). As illustrated in these cases, ADEs, which include outcomes where an error in drug ordering or prescription filling harms the patient, account for about two thirds of all adverse events. However, ADEs more commonly include reactions typically associated with a medication's known pharmacologic activity; for example, constipation secondary to narcotic analgesics.

Although ADEs make up the majority of adverse events, there are other important types as well. With shortened length of stays, nosocomial infections often become clinically apparent only after patients go home. Procedural complications, such as a post-lumbar puncture headache, may also have a delayed onset. Lastly, diagnostic and therapeutic errors account for approximately 10% of post-discharge adverse events.

The frequency of diagnostic and therapeutic errors may be underestimated. Patients in the post-discharge research studies were followed for, at most, one month. This may be too short a follow-up duration to identify poor outcomes related to such errors. For example, if a hospitalist fails to arrange appropriate follow-up for a patient with a solitary pulmonary nodule on chest radiograph, it may be several months before the problem becomes clinically apparent.

Patient and health system factors contributing to post-discharge adverse events Very little is known about factors associated with post-discharge adverse events. With respect to patient factors, longer lengths of stay, a diagnosis of diabetes mellitus, and more medications prescribed at discharge all appear to confer increased risk.(2,3) With respect to number of medications, the risk does not appear to be linear. The risk appears to be stable, or gradually increase, until the number of prescribed medications exceeds 12, at which point it dramatically increases. On first glance, being prescribed 12 medications appears extraordinary; however, this is not terribly unusual nowadays. In addition to the number of medications, the type of drug is also important. The following medication classes are associated with higher risk and therefore demand close attention: corticosteroids, anticoagulants, diabetic medications, antibiotics, and narcotic analgesics.(3)

Regarding the discharge process itself, a lack of preparation appears to be associated with adverse events. Patients who are unable to remember a discussion with their care provider about the side effects of their medication are at a three-fold greater risk of experiencing an adverse event than patients who can recall such information.(3) Other preparatory work that might be important are reconciling pre- and post-hospital medication profiles, going over follow-up plans, and providing patients options for what to do if things go wrong.

Health system factors are also important. Patients see multiple providers before, during, and after a hospital encounter. These providers are often practicing in different locations. Communication amongst these providers is, in most circumstances, very poor. For example, in a recent audit of discharge summaries at our hospital, the median delay between patient discharge and discharge summary generation was 14 days. As well, it may take as much as 7 additional days for a treating physician to receive the document by mail.(4)

Besides the timeliness of the discharge summary, its content and availability are two other common deficiencies. Often, summaries lack important information describing the most responsible diagnosis, the results of important tests, the medications prescribed at discharge, or the follow-up plans.(4) In addition, although discharge summaries are created for most patients, only a minority of physicians following the patient actually receive the document.(5) This often happens because the hospital sends the letter to the family doctor but does not send it to the patient's multiple other physicians. This final point is important, as recent research demonstrates an association between hospital readmissions and availability of the discharge summary by the follow-up physician.(5)

Poor 'hospital-to-community' communication is only one 'system' problem negatively impacting patient safety at the time of discharge. Patients often have trouble getting in contact with a physician from the hospital. This is sometimes required to discuss new symptoms, the side effects of medications, or that follow-up is not proceeding as planned. Another problem is the lack of infrastructure to adequately monitor patients' conditions or test results after they get home. Infrastructure, such as clinic space on the medical ward, is required so that when patients need to be closely followed after discharge, either because their condition is vulnerable or because a problem has developed, they can be seen by the doctors who cared for them while hospitalized.(1)

Improving the safety of hospital discharge Can the frequency of post-discharge adverse events be reduced? One-third of post-discharge adverse events are preventable; in addition, another one third of events are considered 'ameliorable' (ie, one that is not preventable but whose severity could be reduced if corrective measures were instituted earlier and more

effectively).(6) An example of the latter is a patient who develops *C. difficile* diarrhea following discharge. Such an event is ameliorable if the diarrhea goes undetected by the health care team and is then complicated by severe dehydration or sepsis. On the other hand, if the diarrhea is picked up early and the patient responds to treatment, it will not be ameliorable. Overall, close to two-thirds of post-discharge adverse events are preventable or ameliorable. Therefore, there is good reason to hope that the safety of the discharge process can be substantially improved, although empirical data to support this hope are lacking.

Patient safety at hospital discharge is truly a system issue. Therefore, interventions to improve care at this interface will necessarily involve hospital decision makers and a multi-disciplinary health team, including community-based providers. However, patients and their family members, as well as hospital providers, can make important contributions to improving safety on their own. As there are few randomized trials testing interventions, most of the suggestions below are based on extrapolation from the preceding discussions.

Patients have an important role to play during the post-discharge period (Table 1). They must be empowered to recognize and speak up about the development of important new health problems and complications. They must understand their follow-up plans. Lastly, they need to have a back-up plan for when things go wrong. Family members should be encouraged to participate in any education, as patients may have trouble understanding the information, especially as they are often quite ill even at the time of discharge.

Hospital providers can also improve care at the time of discharge (Table 2). For all patients, they need to anticipate the opportunities for post-discharge adverse events and put in place appropriate plans to deal with these. All patients should be prepared for discharge in a manner as outlined above. Providers need to recognize particularly vulnerable patients—such as those on high-risk or large numbers of medications, and patients with multiple diagnoses who have received intensive treatments in the hospital over prolonged periods of time—and make special arrangements for them. Specific interventions could involve arranging an early follow-up visit, enlisting the help of a pharmacist to provide extra education before discharge, telephoning the family doctor to let her know the likely problems that will develop, and arranging home visits by a nurse. Much of this happens already, but a more systematic approach to the problem will help.

Various system interventions can be implemented, but they will require support from a hospital or health care organization. In-hospital case management with intensive nurse follow-up has been demonstrated to reduce hospital readmissions, especially in heart failure patients.(7-10) Systematic telephone call contact with patients by a pharmacist within days of discharge

has been shown to reduce emergency department visits in one small study.(11,12) Automating discharge summary generation will help distribute hospital information in a timely fashion.(13) Hospital-based follow up clinics on the medical ward where the patient was admitted could provide a venue for monitoring patients.

Conclusion Safety problems frequently do occur at discharge. Despite a preliminary understanding of what causes those problems, more research is needed to better elucidate both the problems and potential solutions. In the meantime, practitioners, health planners, and researchers must take sensible steps to prevent the large burden of adverse events that occurs at or soon after hospital discharge.

Overriding Considerations

The Case

Mrs. G visited her obstetrician for first trimester routine prenatal care. The obstetrician offered genetic testing for a variety of conditions, including Tay-Sachs and Canavan's diseases, since both Mrs. G and her husband, a healthy 35-year-old physician, were of Ashkenazi Jewish descent. Mrs. G consented to be tested and told the obstetrician that she would discuss with her husband that evening whether he wanted to have the genetic tests. The obstetrician gave Mrs. G consent forms and information to take home to her husband. The obstetrician also entered laboratory test orders in the computerized order entry system for the genetic screening panel for both Mrs. G, since she had consented to be tested, and for Dr. G, assuming he would consent to be tested. However, the obstetrician did not mention this to Mrs. G.

At home that evening, Dr. G reviewed the materials and told his wife that he definitely did not want to be tested. Several weeks later, Dr. G visited his primary care doctor for a check-up. The physician ordered routine screening laboratory tests (fasting lipid profile, complete blood count, and urinalysis) through the computerized order entry system, and the next morning Dr. G presented to the laboratory for testing. The laboratory and its computer system were the same as used by Mrs. G's obstetrician.

Unbeknownst to Dr. G, the phlebotomist drew samples not only for the routine testing ordered by his primary care doctor but also for the genetic screening, because it was listed in the computer even though Dr. G had not consented. In doing so, the phlebotomist overrode the computerized alert that prompted him to be sure the patient had consented; he assumed that the physician must have obtained consent before ordering the tests. Ten days later, the obstetrician called Mrs. G to give her "the good news" that all her

screening tests were normal. The obstetrician mentioned incidentally that her husband tested positive as a carrier of Canavan's disease. This disclosure caused some distress, but no physical harm. No increased level of care was needed.

Mark My Limb

The Case

A patient went to the operating room (OR) for surgery on the lower leg. Per the Universal Protocol, the surgeon marked the proper leg prior to bringing the patient to the OR. The patient was placed in the prone position and anesthesia was administered. A "Time Out" was performed, during which all the team members met and confirmed the procedure. The nurse began to prep the patient's lower leg, but the anesthesiologist felt that something wasn't right. After stabilizing the patient, he checked the chart and discovered that the nurse had scrubbed the wrong extremity. He notified the team members and stopped the procedure. The patient had come just minutes away from having surgery on the wrong leg, but no harm occurred. The correct leg was then prepared, and the patient underwent successful surgery.

A "Weak" Response

The Case

A primary care physician on call for his group received a call at 9:00PM from a 68-year-old man. He said, "They started me on a new pill for my blood pressure and now I feel really weak." The physician asked how long ago the new medication was started. "Three days," the patient replied.

The patient could not recall the name of the drug, but he found the bottle of tablets, whose label read hydrochlorothiazide 25 mg. He stated that he had been taking one pill per day as instructed. The patient reported also taking lisinopril 20 mg daily for more than a year.

The physician, attributing the symptoms to the new medication, instructed the patient to stop the hydrochlorothiazide. He told the patient to use his home blood pressure cuff after the call and to come into the clinic right away if systolic pressure went above 180 mmHg. Otherwise, the patient was told to make an appointment to see his regular doctor to get a different medication for his blood pressure.

Three days later, the patient was hospitalized with sudden onset of right arm and leg weakness, as well as difficulty speaking. He was found to be in atrial fibrillation with a ventricular response of 120 beats per minute.

On reviewing the patient's symptoms and confirming with the patient's regular physician that the atrial fibrillation was new, the admitting physician judged that the patient became weak due to the new atrial fibrillation and rapid ventricular response rather than to potassium depletion, hyponatremia, or other effects of the hydrochlorothiazide. The findings on neuroimaging were strongly suggestive of an embolic stroke. The patient was begun on warfarin for atrial fibrillation and received rehabilitation while in hospital, but still had weakness and some word-finding difficulties 6 weeks later.

Hard to Swallow

The Case

An elderly man underwent hernia surgery. Postoperatively, the patient developed a transient ischemic attack (TIA) and respiratory difficulties. The nurses noted that the patient, whose speech was normal before surgery, now had slurred speech and choked on thin liquids. The neurologist recommended a swallowing study.

A speech pathologist evaluated the patient and found him to be at high risk for aspiration. On the consultation form, she recommended that the patient be made NPO. She didn't think the recommendation was important enough to "bother" the physician, and recorded it only on the consultation form. In keeping with standard practice at the hospital, speech pathologists, respiratory therapists, and physical therapists write their notes in a special section of the chart, not in the core daily progress notes area, which is the part of the chart that all physicians read. The physician did not see the form, and the patient continued to receive thickened liquids. Two days later, the patient suddenly aspirated, arrested, and died.

The hospital investigates all critical incidents through the Quality Management Department and the Vice President of Medical Affairs. This particular case was reviewed within an hour of the patient's death. Subsequently, the VP of Medical Affairs submitted a protocol to the medical staff executive committee concerning swallowing evaluations. This protocol, now in effect, permits the speech pathologist to write the order to make the patient NPO if the bedside swallowing evaluation is suspicious for the risk of aspiration. Hospital personnel felt that physicians would accede to speech pathologists' recommendations to keep a patient NPO (for aspiration risk), and that it was safer to have the physicians "pre-authorize" an NPO order than risk a repeat of this scenario by waiting for a physician's order.

Electronic Err

The Case

A 75-year-old woman with coronary artery disease presented to the emergency department (ED) with chest pain that that had not responded to three sublingual nitroglycerin tablets at home. Supplemental oxygen and nitroglycerin paste resulted in resolution of the patient's symptoms, but she was admitted for cardiac monitoring and serial cardiac enzymes to rule out myocardial infarction.

The patient gave a clear history to the admitting internist, but could not recall the names of some of her medications, nor could she remember any of the doses. The hospital was able to access the electronic health record (EHR) of the large multi-specialty clinic where the patient received her medical care. The admitting physician printed the medication list from that EHR. The most recent note in her ambulatory chart listed warfarin, aspirin, clopidogrel, diltiazem CR, metoprolol XL, and atorvastatin—so he wrote orders for those medications with doses as stated in the medication list.

One hour later, the admitting physician received a page from the telemetry floor. The nurse informed him that the patient had developed a junctional rhythm with a heart rate less than 40 and stated, "She looks really bad." She was given atropine stat, which resulted in improvement in the heart rate and the patient's general appearance.

On reviewing the patient's outpatient record in greater detail, the physician found a recent cardiology note. The note listed the same medications documented elsewhere in the EHR, but also documented his plan to discontinue diltiazem and decrease metoprolol due to recent episodes of symptomatic bradycardia.

Neither the EHR medication list nor the most recent note from the primary care physician reflected these changes, but a call to the patient's pharmacy confirmed that she had not refilled her diltiazem and that metoprolol had been prescribed at a lower dose than before. Thus, the patient had been given 100 mg of metoprolol XL and 180 mg of diltiazem CR by the hospital admitting physician, rather than the 50 mg of metoprolol XL and no diltiazem intended by her outpatient cardiologist. The patient remained clinically stable, but did rule in for a myocardial infarction with a troponin that peaked at 8. Whether the infarct resulted from the medication error or had already occurred at the time of admission was unclear, but the physician did inform the patient of the error.

The Institution's Response

After a discussion of this case at the clinic's monthly safety and quality improvement meeting, a physician and nurse audited a small random sample of patient records. Medication lists commonly lagged far behind clinic notes, frequently containing medications no longer received by the patient, omitting new medications, and failing to document changes in dose. Analogous discrepancies were found for problem lists: patients' main EHR problem lists often continued to list problems long since resolved and failed to include new problems.

The clinic approached the EHR vendor to ask about modifications to the current system that would allow automatic updating of medication and problem lists or, in the absence of such a system, add a flag to medication and problem lists indicating that the patient has been seen in clinic more recently than the date of the last change to the medication list. The vendor thought that the latter solution could be implemented over a 6- to 12-month time frame. In the meantime, clinic nurses added a medication review to vital signs and weight prior to each patient's appointment with a physician.

Lap Burn

The Case

A woman was scheduled for an elective diagnostic laparoscopy for dysfunctional uterine bleeding. After accessing the abdomen with the trocar without complication, the surgeon inserted the laparoscope but found that she needed to reposition the trocar. She removed the laparoscope and placed it on the tray in front of her. After adjusting the trocar, she picked up the laparoscope and noticed the drapes were melted where the distal tip of the scope had been placed. The drapes had been covering the patient, and examination revealed a second-degree burn of the thigh. The burn healed without any scarring.

Moved Too Soon

The Case

A 67-year-old man was admitted to a general hospital ward after undergoing a laminectomy. Two hours after arriving, while the patient was still groggy from anesthesia, a nurse entered the room and stated that it was time to administer his clonazepam. As the patient began to take the medicine, his daughter (who happened to be a nurse) stated that she didn't think he should be receiving clonazepam and asked the nurse to double check prior to administration. The nurse returned after checking and asked, "Aren't you Mr. X?" The patient said, "No, I am Mr. J."

It turned out that, due to a bed shortage, Mr. J was to be moved down the hall, and Mr. X, a seizure patient scheduled to be transferred out of the neuro-ICU that afternoon, was to be moved into that room. The room change was made on the hospital's computer before the patients were physically moved. Thus, when the nurse checked the computer, it showed that Mr. X was in that room and due for his clonazepam.

Thin Air

Case & Commentary: Part 1

A 73-year-old woman was admitted to the hospital with fever and back pain, and was diagnosed with pyelonephritis. The morning after admission, she became hypotensive and short of breath. Her oxygen saturations were 70%. She was placed on high-flow oxygen with little benefit. A chest x-ray showed diffuse pulmonary infiltrates consistent with acute respiratory distress syndrome (ARDS). The patient was intubated for type I (hypoxemic) respiratory failure, and placed on high flow oxygen. Shortly thereafter, the respiratory therapist arrived and noticed that the patient was being treated with compressed air—not oxygen.

In this case, it seems that both the high-flow oxygen mask and the self-inflating bag were hooked up to an air flowmeter, not an oxygen flowmeter. The hospital gas supply delivers gas under pressure to outlets in clinical settings.(1,2) In a ward room, or bay in the Emergency Department or ICU, these are typically on wall panels at the head of the bed. The working pressure for such outlets for both air and oxygen are about 45-55 PSI, a pressure too high to deliver directly to masks and bags. A flowmeter is connected to the outlet to meter gas at an appropriate flow rate, typically 1-15 liters per minute, at only slightly higher than ambient pressure. Such flowmeters are used to provide gas to bags, masks, nebulizers, and other simple ventilatory devices. More complex devices—like ventilators or anesthesia machines—have hoses carrying compressed gas attached directly to the compressed gas outlets.

The flowmeters used for air and oxygen are nearly identical, differing to the casual observer, if at all, only in the color-coding of the knobs or "Christmas Tree adapter," which provides a place to securely attach delivery tubing and other portions (Figure 1). Green adapters are meant for oxygen and yellow adapters are meant for air. Although the flowmeter itself may be physically designed to insert into only its specific gas port (see below), the threading for connection between the flowmeter and the Christmas tree adapter is universal in size. Thus, it is possible for an air flowmeter to have the green Christmas tree adapter attached instead of a yellow one (Figure 2). Someone attaching the delivery tubing might easily attach it to the green Christmas tree

adapter, expecting it to be connected to the oxygen flowmeter and not noticing that it is actually an air flowmeter plugged into an air outlet. Even with the appropriate color Christmas tree adapter, it is quite possible to attach the tubing to the wrong flowmeter, especially in a crowded space under high stress and time pressure. Further, tubing from multiple airway devices may be attached to the various flowmeters simultaneously (eg, a self-inflating bag, a nebulizer, and a face mask), making recognition difficult.

How frequently such swaps occur is not known, but they do so often enough that on March 5, 2002 a Patient Safety Advisory on this topic was issued by the Veterans Health Administration Warning System. It is probably even more common for oxygen tubing to become disconnected from a correct flowmeter during a resuscitation. This issue is not easily recognized when a facemask or self-inflating bag is used, because these devices provide little feedback as to the gas flow rate.

Case & Commentary: Part 2

The patient was transferred to intensive care and died the next day of overwhelming sepsis and systemic inflammatory response syndrome (SIRS).

In this case, although errors occurred in providing supplemental oxygen, the patient's underlying disease was likely severe enough to cause death even in the absence of errors. Nonetheless, a typical response to such an event would be to blame clinicians for being ignorant, or lacking vigilance. However, employing human factors engineering concepts to this case would be more productive. In addition to avoiding a culture of blame and striving to identify root causes, the solutions offered by this approach rely on improving the design of artifacts in the world rather than relying on labels, instructions, training, or the usual admonition to "be more careful."(3)

Much of the gas delivery system is designed to avoid hooking up the wrong gas hose to a compressed gas port through the use of physically non-interchangeable gas-specific connectors. While there are several such systems, perhaps the strongest is called the Diameter Index Safety System (DISS) (Figure 3). It is physically impossible to insert the oxygen hose or flowmeter into any other port, or to attach something inappropriate into the oxygen port. However, this safety net is incomplete. The threaded output of the flowmeter is "one size fits all" and fits yellow, green, and clear Christmas tree adapters. If some sort of diameter-indexed system were extended also to the flowmeter output port, or if the Christmas tree adapter was molded into the device, no crossover of the adapters could occur. That would solve the problem of the mismatched adapters, but it still would not prevent attachment of oxygen tubing to a non-oxygen flowmeter. A gas-specific non-interchangeable fitting for low-pressure oxygen tubing would be possible to

produce, but is not currently a standard. Thus, the protection is not carried all the way to the end-user.

A physical arrangement that precludes doing the wrong thing, like the gas-specific non-interchangeable connector, is an example of an engineered safety device (ESD), and a forcing function.(3) Other forcing functions include "lockins," "lockouts," and "interlocks."(4) Lockins maintain a condition, and prevent easy exit from a sequence of actions until the right conditions are met. Lockouts prevent easy entrance to a dangerous set of actions or a segment of software, without the proper conditions and access authority. Interlocks enforce correct sequencing or isolate events in time; often they are used to prevent one action from being taken while another is already active. There are a variety of examples of these forcing functions in health care.(5)

In addition to the indexing system for connectors for bulk-supplied compressed gases, there is an indexing system for medical gas cylinders, called the "Pin Index System."(1,2) Each cylinder has a specific pattern of holes into which the matching pattern of pins from the appropriate regulator must fit (Figure 4). This helps to prevent the wrong regulator (in calibration and in color-code) from being attached to a cylinder. For example, I recently asked for an E-cylinder of oxygen to transport a critically ill patient, and the nurse complained that the regulator wouldn't fit on the tank properly. The nurse had inadvertently brought a CO2 cylinder (gray in color) instead of an oxygen cylinder. The Pin Index System prevented the oxygen regulator from being attached to the CO2 cylinder, perhaps saving the patient's life (since, once mounted under the bed, it would have been difficult to detect this error). Ventilation with 100% CO2 would rapidly cause a cardiac arrest in the patient, and the usual resuscitative measures of promoting a clear airway, adequate breathing, etc., would have only worsened matters (by promoting more exchange of the wrong gas) if the gas swap were not discovered.

Engineered safety devices and forcing functions are very common in anesthesiology, where experience has shown that good intentions, warnings, or vigilance are not sufficient to ensure patient safety. For example, the anesthesia machine itself has flowmeters to control the flow of oxygen, nitrous oxide, and air. In the heat of a crisis, or at the end of an anesthetic, the anesthesiologist might reach back to turn off the nitrous oxide and turn up the flow of oxygen, but inadvertently do exactly the opposite. Modern anesthesia machines contain a mechanical, pneumatic, or electronic oxygen proportion limiting control system that physically prevents selecting an oxygen concentration of less than 25%.(6-8) Another forcing function is the mechanical "vaporizer interlock" that prevents activating more than one vaporizer delivering a volatile anesthetic gas (eg, Isoflurane) at a time.(6-8)

Engineered safety devices and mechanical forcing functions are less common in the rest of medical practice. In radiation therapy or X-ray units, interlocks

may prevent activating the radiation while the door to the unit is open. Most computer-based systems have forcing functions in software that double checks for irreversible actions (eg, "Do you really want to empty the trash?"). However, frequent users sometimes click this by habit even when they do not mean to approve the action.(4) This kind of behavior was a factor in a set of catastrophic errors with radiation therapy equipment.(9)

Despite effective forcing functions, near misses and errors may still occur. For example, in another case I asked for an oxygen cylinder, and was brought a CO2 cylinder with a CO2 regulator attached (these are used for certain purposes in cardiac surgery). The Pin Index System played no role here, since it forces the correct regulator on the matching tank and there was no mismatch in this case. There is no engineered safety device to ensure that the gas flowing is in fact oxygen. The anesthesia machine has alarms for oxygen concentration, but these are not yet used for in-hospital transport situations. Fortunately, I noticed the gray color (color-coding is another safety feature) of the tank.

There are also "procedural forcing functions" in which the standard procedures call for personnel to verify certain conditions before allowing actions to proceed. The requirement for a two-person check of blood products before administration to the patient is an example. The recently standardized "timeout" required by JCAHO and the VA before surgical incision is a procedural forcing function by which surgery cannot proceed unless all team members have re-verified the patient's identity, the proposed surgical procedure, and the exact site of surgery. Procedural forcing functions like this can be valuable if implemented systematically, and if the team is in fact empowered to act as an interlock. However, procedural forcing functions are relatively weak due to psychological factors such as haste, complacency, and a behavior termed "social shirking." Social shirking occurs when "members of an organization find it to their advantage to evade their work responsibilities and trust that the efforts of others are sufficient...to meet their goal."(10) When shirking is present, checks that are independently redundant in theory are neither independent nor redundant in practice.

What are potential specific solutions to the problem of mismatched adapters on flowmeters? One solution is to eliminate air flowmeters in most patient care settings. They appear to be used for two main purposes: to administer nebulized medications (eg, bronchodilators), and to provide humidified air to patients with a tracheostomy. Yet, nebulized medications can be delivered as safely using oxygen in all but a handful of cases. For those rare cases, either an air flowmeter or an air cylinder and flowmeter could be available. For patients with a tracheostomy, the humidified gas is usually administered via large bore tubing from a device that attaches directly to the flowmeter, without a Christmas tree adapter (Figure 5). Hence, many hospitals have banished air flowmeters with these adapters. Other sites have found this hard

to do, because they argue that it requires more storage space and more effort to obtain the air devices in the cases where they are truly needed. The VA Advisory suggests converting color-coded Christmas tree adapters to clear ones (Figure 6) so that the adapter itself conveys no information as to the gas' identity, forcing the user to look at the flowmeter itself. This may not be a very effective way to alter the frequency of connecting the tubing to the wrong flowmeter.

Ultimately, indexing the tubing and fittings might be the better solution. In addition, following the lead of the anesthesia machine, developing oxygen analyzer systems for low-pressure oxygen delivery systems, allowing verification of oxygen concentration, would reduce errors related to gas administration.

Reaction to Dye

The Case

A patient was referred to urology after having several episodes of gross hematuria. The urologist thought that the patient might have a renal mass and sent him to radiology for a CT scan. The patient stated that he was not allergic to x-ray dye. Therefore, the resident radiologist told the technologist to proceed with contrast material administration for contrast enhancement. Soon after the injection, the patient went into anaphylactic shock on the CT table. Luckily, the patient was rapidly resuscitated and suffered no permanent harm. On later questioning, the patient stated that he was "very allergic" to shellfish. On further inquiry, including an exhaustive review of all of the patient's allergies, he stated that he was extremely allergic to iodine in all forms.

Security Lapse

The Case

A medical student learned that the hospital's radiology image library was accessible throughout the university's computer system, meaning that patient x-rays could be viewed in dormitories, libraries, and at public terminals. Moreover, the images were accessible through the Internet, on a Web site that didn't require any user identification or password.

Concerned that the public accessibility of this information constituted a violation of patient privacy, he alerted another medical student who worked in the ethics department and asked her to speak with her faculty mentor. She did, but relayed that her mentor was unconcerned with this problem. During the student's Health Insurance Portability and Accountability Act (HIPAA)

training, he again became concerned that, by not securing patient privacy, the hospital was in violation of HIPAA regulations and vulnerable to lawsuits. The student spoke with several faculty members in the medicine department regarding his concerns. The faculty members seemed surprised by the student's findings, but did not advise him to contact the hospital's HIPAA compliance officers nor undertake that action themselves.

Several months later, during the course of one of the student's clinical clerkships, he again mentioned the lack of security to an attending physician, who became very concerned and contacted the head of the hospital's HIPAA compliance office. Within hours, the office contacted the student for further description of the violation, and within a week the security problem was repaired. The total time elapsed between the student's initial identification of the problem and the hospital's solution was 18 months, several of which were after the April 2003 deadline for HIPAA compliance.

Caution, Interrupted

The Case

A 55-year-old man with acute myelogenous leukemia and several recent hospitalizations for fever and neutropenia presented to the emergency department (ED) with fever and hypotension. After assessment by the emergency physician, administration of intravenous crystalloid and empiric broad-spectrum antibiotics, the patient was assessed by his oncologist. Based on the patient's several recent admissions and the results of a blood culture drawn during the last admission, the oncologist added an order for Diflucan (fluconazole) 100 mg IV to cover a possible fungal infection.

Because intravenous fluconazole was not kept in the ED, the nurse phoned the pharmacy to send the medication as soon as possible. A 50 ml bottle of Diprivan (propofol, an intravenous sedative-hypnotic commonly used in anesthesia) that had been mistakenly labeled in the pharmacy as "Diflucan 100 mg/50 mL" was sent to the emergency department. Because the nurse also worked in the medical intensive care unit, she was quite familiar with both intravenous Diflucan and Diprivan. When a glass bottle containing an opaque liquid arrived instead of the plastic bag containing a clear solution that she expected, she thought that something might be amiss.

As she was about to telephone the pharmacy for clarification, a physician demanding her immediate assistance with another patient distracted her. Several minutes later, when she re-entered the room of the leukemia patient, she forgot what she had been planning to do before the interruption and simply hung the medication, connecting the bottle of Diprivan to the patient's subclavian line.

The patient's IV pump alarmed less than one minute later due to air in the line. Fortunately, in removing the air from the line, the nurse again noted the unusual appearance of the "Diflucan" and realized that she had been distracted before she could pursue the matter with the pharmacy. She stopped the infusion immediately and sent the bottle back to the pharmacy, which confirmed that Diprivan had mistakenly been dispensed in place of Diflucan.

The patient experienced no adverse effects—presumably he received none of the Diprivan, given the air in the line, the infusion time of less than a minute, and the absence of clinical effect (Diprivan is a rapidly-acting agent). Nonetheless, the ED and pharmacy flagged this as a potentially fatal medication error and pursued a joint, interdisciplinary root cause analysis, which identified the following contributing factors: (i) Nearly 600 orders of medication labels are manually prepared and sorted daily; (ii) Labels are printed in "batch" by floor instead of by drug; (iii) The medications have "look-alike" brand names; (iv) A pharmacy technician trainee was working in IV medication preparation room at the time; and (v) The nurse had been "yelled at" the day before by another physician—she attributed her immediate and total diversion of attention in large part to her fear of a similar episode.

Poor Prognosis

Case & Commentary: Part 1

A 91-year-old woman presented with 2 days of nausea and vomiting. Physical examination revealed a palpable mass in the right groin without bowel sounds. A CT scan of the abdomen showed an incarcerated hernia complicated by small bowel obstruction. The patient was taken to the operating room for resection under general anesthesia. After extubation, she developed stridor, requiring re-intubation. Otorhinolaryngology (ENT) evaluation revealed no evidence of laryngeal edema; however, there was evidence of significant extrinsic compression of the trachea. A CT scan revealed a thyroid mass. A fine needle aspiration (FNA) biopsy was performed but was inconclusive. A repeat FNA was performed.

The attending physician held a family meeting to discuss the patient's prognosis and direction of care. He told the family the prognosis was likely very poor, as he suspected malignancy. Given this news, the family decided not to pursue surgical intervention (tracheostomy).

Physicians are frequently called upon to make predictions about expected patient survival and to disclose those predictions to patients. Research has also shown that both types of prognostic tasks are extremely difficult for physicians.

Results of a survey of a random sample of 1,311 US internists suggest that the average internist addresses the question "How long do I have to live?" ten times per year, withdraws life support five times per year, and refers patients to hospice-based palliative care five times per year.(1) Among these physicians, 60% reported that they found prognostication emotionally "stressful," and their stress with prognostication was highly associated with self-perceived prognostic inaccuracy.

Data on physicians' prognostic accuracy primarily comes from studies of physicians caring for patients already enrolled in palliative care. These studies reveal that, on average, physicians make inaccurate prognostic estimates; the direction of their error, overwhelmingly, is optimistic, with physicians overestimating survival by a factor of three.(2-8) In one study, 343 physicians provided survival estimates for 468 terminally ill cancer and non-cancer patients at the time of patient referral to hospice-based palliative care. These estimates were then compared with patients' actual survival. Physicians were accurate in their prognoses approximately 20% of the time, overestimated survival more than three times as often (63%), and underestimated survival in only a minority of instances (17%).(8)

Research has queried whether such systematic prognostic overestimation by physicians may in part explain the unexpectedly "short" survivals observed in patients referred for hospice-based palliative care. Results of the above-noted survey suggest that physicians believe an optimal length of stay in hospice is 3 months (9), yet the observed median length of stay is only 3 weeks.(8) Perhaps some of this observed inconsistency results from physicians' optimistic bias in prognostication.

This particular patient differed from those enrolled in the studies mentioned above in that she did not yet have an established "terminal illness." Since the science of prognosis is anchored in disease diagnosis and extent, this patient's diagnostic ambiguity contributed to making prognostication quite challenging. On one extreme, if the patient's neck mass was a result of anaplastic thyroid cancer (ie, a rare and rapidly fatal form of thyroid cancer), her estimated median survival would be approximately 4 months (10), and the immediate institution of supportive (and non-curative) care would be an appropriate clinical approach to managing the airway compromise. On the other hand, if her neck mass was the result of a benign goiter, her estimated median survival would probably be quite similar to her baseline age-related expected survival of approximately 4 years (11), and the institution of supportive care would not be a conventional approach to management of the airway compromise. Depending on the characteristics of the goiter (eg, diffuse, multinodular) and the approach of the endocrinologist (eg, trial of T4-suppression therapy, reductive surgery, and/or radioactive iodine), other approaches would be more conventional.

Given the very wide prognostic range associated with this patient's neck mass—4 months vs. 4 years—and the associated wide range of clinical approaches, for this patient, a tissue diagnosis would help to narrow this prognostic range and thus better define the immediate clinical approach. Although a clinician might be tempted to assume that a large mass is cancerous, studies of consecutive thyroid aspirations in community hospitals suggest that cancer explains only 5% to 6.5% (12,13) of nodules.

Case & Commentary: Part 2

After further discussion, the family decided to withdraw care, because the patient had stated previously that she did not want to be intubated for a long period. Shortly after extubation, the patient died. A few days after the patient's death, the results of the second FNA were obtained. The biopsy revealed a benign nodular goiter.

The patient, family, and physician in this vignette experienced the uncommon situation of a pessimistic prognostic error. The events described are surprising and raise an important question: why was the FNA done if its results were not going to influence care?

A natural concern in this case is whether the patient's advanced age somehow influenced the decision to pursue a less complete diagnostic approach. It is certainly hard to imagine that a 37-year-old woman would have been managed this way. However, it is possible that there were other life-limiting comorbidities (eg, a previously diagnosed advanced cancer, severe dementia, class IV congestive heart failure) and/or poor functional status that influenced her underlying or baseline prognosis and thus might explain the clinical approach.

A general clinical approach to this patient can be borrowed from the field of oncology, which is currently struggling to develop systematic approaches or algorithms that acknowledge and integrate important prognostic variables (both cancer-related and non-cancer-related) to guide cancer treatment decisions in elderly patients.(14) For example, a comprehensive geriatric assessment (CGA) can yield information about functional status and comorbidities, which, along with sex and chronological age, have prognostic relevance and can be integrated to generate an estimate of baseline life expectancy.(14) The physician compares the expected survival from the untreated illness or illnesses being considered (eg, anaplastic thyroid cancer vs. benign goiter) to this estimate of baseline life expectancy. If the baseline life expectancy is greater than that of the untreated condition, the physician then needs to decide if the diagnostic procedure and/or the disease-specific treatment would result in excess morbidity and mortaility (ie, decide if the interventions are "tolerable"). If diagnostic procedure tolerance and/or

treatment tolerance is deemed adequate, then the patient may benefit from further work up and, ultimately, therapy directed at the illness or the illness under consideration.

In this case, no comorbidity or functional status information is provided, but we do know that the patient was a 91-year-old woman. Life-tables indicate that 50% of 90-year-old American women will live at least an additional 3.8 years, with 25% living less than 1.8 years and 25% living at least 6.8 years. Since the expected survival from the most aggressive thyroid cancer (ie, anaplastic histology) is only 4 months and the expected survival from the most benign explanation for the neck mass (ie, benign goiter) will be unlikely to impact life-expectancy meaningfully, most algorithms would recommend biopsy. If on the other hand, the patient had a severely life-limiting illness already (eg, stage IV lung cancer), the results of the biopsy would not impact decision-making and thus would not be needed. In this latter case, supportive care for the lung cancer would be an appropriate approach.
The Figure outlines an approach to such clinical decision-making for elderly patients with cancer.

Doctor, Don't Treat Thyself

The Case

A 50-year-old radiologist presented to the emergency department of the community hospital where he worked and reported increasing shortness of breath over the past several days. His medical history was notable for hyperlipidemia, which had been discovered 10 years earlier after he presented with unstable angina and required coronary bypass surgery. He stated that he had no chest pain whatsoever and repeatedly emphasized that he had been completely free of cardiac symptoms since his surgery 10 years ago.

Physical examination revealed tachypnea (25 respirations per minute), tachycardia (110 beats per minute), and bilateral lower lung field crackles. A chest x-ray was obtained and read by the patient himself, who declared it to show bilateral infiltrates clearly indicative of pneumonia. Because it was after midnight and no other radiologist was in-house, the admitting internist did not question the reading of the radiologist–patient. The admitting physician ordered blood cultures and prescribed intravenous ceftriaxone as well as oral levofloxacin as empiric coverage for community-acquired pneumonia.

Several hours later, the nurse paged the admitting physician to say that the patient's blood pressure was plummeting. The physician ordered a 500-cc intravenous bolus of normal saline for presumed hypovolemia or early sepsis. He came to see the patient after the bolus had been administered (30

minutes later) and found the patient profoundly dyspneic. A blood gas revealed a pH of 7.2, pCO2 of 50, and pO2 of 50 on high-flow oxygen.

The physician told the nurse to call a code, in order to alert the emergency physician on duty, and to bring the "crash cart." The emergency physician arrived promptly and began preparations to intubate, but the patient went into cardiac arrest. The initial rhythm was ventricular fibrillation, but degenerated into asystole, from which the patient never recovered. He was pronounced dead after 30 minutes of resuscitative efforts.

The emergency physician had asked that a troponin be added to the blood work drawn at the time of the code. The next morning, on reviewing these results, the internist saw that the troponin had been markedly elevated. The incident prompted an internal review by the hospital, during which several radiologists reviewed the initial chest x-ray and reported it as clearly consistent with pulmonary edema. Autopsy confirmed a large anterior myocardial infarction and prominent pulmonary edema.

Glucose Roller Coaster

The Case

A 71-year-old woman with congestive heart failure was admitted to the hospital. Her medical history was significant for dialysis-dependent, end-stage kidney disease and coronary artery disease. She did not have a preadmission diagnosis of diabetes.

While in the step-down unit on the evening of admission, the patient had a routine phlebotomy sample drawn, and the blood sugar level was 674 mg/dL. At 11:30 pm, the nurse notified the covering intern, who telephone-ordered 10 Units of regular insulin to be given subcutaneously. At 1:10 am, a finger-stick glucose level was 50 mg/dL, and the intern verbally ordered 1 amp of D50 to be given intravenously (IV). At 3:00 am, a phlebotomized specimen revealed a glucose level of 19 mg/dL, and the intern verbally ordered another amp of D50 IV, as well as a D10 drip. At 5:27 am, a finger-stick glucose was 99 mg/dL. At 11:00 am, a phlebotomy sample revealed a blood glucose level of 351 mg/dL. Another covering intern was notified, and 8 units of regular insulin were ordered to be given subcutaneously. At 3:40 pm, the patient was unresponsive, and a finger-stick glucose level was 13 mg/dL. Two amps of D50 were verbally ordered, and follow up finger sticks were in the normal range.

Later, it was discovered that many of the phlebotomy specimens had been drawn above an IV line infusing dextrose solution. The step-down nurse was re-educated regarding blood draws in relation to lines. Despite multiple

episodes of hypoglycemia, all subsequent glucose levels were normal and this patient suffered no lasting harm.

The Worst Headache

The Case

A 48-year-old woman with a history of migraine headaches and hypertension presented to her outpatient clinic with a 4-day history of headache. While shopping 4 days earlier, she experienced sudden onset of a severe diffuse headache—"maybe the worst headache I've ever had." She sat down because of the pain and associated nausea.

She had presented to clinic later that day, where a nurse practitioner assessed her symptoms as consistent with her prior migraines, and recommended that she simply start the regimen that she had used in the past (ibuprofen and ergotamine tartrate/caffeine [Cafergot®]).

When her symptoms remained severe, she returned the following day to the urgent care center. A staff physician agreed with the nurse's diagnosis and reassured the patient that there simply had not been enough time for the medications to take effect. He administered intramuscular ketorolac and oral prochlorperazine, with substantial improvement in her symptoms. An appointment was made for her to follow-up with her primary care physician 3 days later in case symptoms persisted, and also to discuss initiation of a medication for migraine prophylaxis.

When the patient returned for her clinic visit in the late afternoon 3 days later, she initially stated that her symptoms had resolved. On closer questioning, however, she stated that she continued to experience headaches when straining (eg, during bowel movements) or bending over. Her physical exam, including visualization of both retinas, was normal.

The physician regarded the initial acute presentation as very worrisome for subarachnoid hemorrhage (SAH). However, her subsequent clinical course seemed too benign, even with the lingering headaches. Given that he had not completely ruled out the possibility of hemorrhage, he arranged for her to have a CT scan and asked the radiologist to page him immediately with the results. He also gave the patient clear instructions to call him if her symptoms worsened.

The radiologist paged the primary physician later that evening to inform him that the head CT was normal. Knowing that the CT is not 100% sensitive for subarachnoid hemorrhage, the physician telephoned the patient the next morning to see how she was doing. She had just woken up, but thanked him

for calling and stated that she felt much better—then the phone went dead. At first, the physician thought she had simply hung up, but since it was rather abrupt he called back and received a busy signal. He called 911.

EMTs found the patient on the floor, arousable only to painful stimuli. MR angiography in the emergency department demonstrated a posterior circulation aneurysm (Figure 1), which was clipped later that day. The patient required a ventriculoperitoneal shunt, but her postoperative course went well, with complete neurologic recovery.

Novel Drug Misuse

Case & Commentary: Part 1

A 48-year-old man was admitted to the intensive care unit after a motor vehicle collision. The patient experienced severe crush injuries after spending 7 hours pinned under a large vehicle at the bottom of a ravine while awaiting rescue. He underwent bilateral fasciotomies of the lower extremities for compartment syndrome. Post-operatively the patient developed renal failure; an Acute Physiology and Chronic Health Evaluation II (APACHE II) score was 26. Recalling an article in the New England Journal of Medicine reporting a decrease in mortality associated with early administration of drotrecogin alfa (activated) to patients with elevated APACHE scores and sepsis, the team decided to start the patient on the drug.

Severe sepsis is defined as sepsis associated with acute organ dysfunction.(1) Each year in the United States, approximately 750,000 cases of severe sepsis occur, more than one quarter of which are fatal despite advances in medical care.(2) Drotrecogin alfa (activated) is a recombinant form of human activated protein C, an endogenous protein that promotes fibrinolysis and inhibits thrombosis and inflammation. It appears to be an important modulator of the coagulation and inflammation associated with severe sepsis.(3) Drotrecogin alfa (activated) is approved by the Food and Drug Administration (FDA) for mortality reduction in adult patients with severe sepsis who have a high risk of death as determined, for example, by an APACHE II score greater than 25.(4) This approval is based on a large multicenter, randomized, placebo-controlled trial (PROWESS) that showed that treatment with drotrecogin alfa (activated) was associated with a 6.1% absolute reduction in 28-day mortality in patients with severe sepsis compared to placebo (24.7% vs. 30.8%, p=0.005).(3)

Patients included in PROWESS had a known or suspected infection, 3 or more signs of systemic inflammation (temperature ≥38° C [100.4° F] or ≤36° C

[96.8° F]; heart rate ≥90 beats/min; respiratory rate ≥20 breaths/min, PaCO2 10% immature neutrophils), and sepsis-induced dysfunction of at least one organ system for less than 24 hours. Patients had to receive the drug within 48 hours of the onset of sepsis. Patients were primarily excluded if they had any condition that increased the risk for bleeding, including active internal bleeding, recent hemorrhagic stroke, intracranial or intraspinal surgery, severe head trauma, intracranial mass lesion, platelet count

The mortality benefit of drotrecogin alfa (activated) was largest in the sickest patients, such as those with an APACHE II score >25. Since the original PROWESS study, a follow-up study has confirmed a large, sustained benefit in sicker patients with an improvement in survival that remains highly significant over a follow-up period of more than 2.5 years.(5) At the same time, the follow-up study found little benefit in less sick patients, and another randomized trial of patients with sepsis but low risk of death (ADDRESS) was recently stopped by the Data Safety and Monitoring Board on the basis of clear lack of effect. Drotrecogin alfa (activated) does have anti-coagulant properties, and there was a trend to an increased incidence of serious bleeding in the therapy arm in PROWESS (3.5% vs. 2.0%, p=0.06). However, serious bleeding occurred primarily in patients with an identifiable predisposition to bleeding, and blood-transfusion requirements were similar between groups after adjustment for duration of survival. Several large uncontrolled series since PROWESS have reported similar bleeding rates.

The reasons for the observed benefit in sicker patients coupled with an apparent lack of benefit in less sick patients have been the subject of great controversy and debate.(6-10) Answers at the current time are largely speculative, but two partially interrelated possibilities seem most likely. First, the *relative* risk reduction in mortality is constant across the spectrum of severe sepsis, yielding an *absolute* risk reduction in less sick patients that is too small to be detected statistically given sample size constraints of the current studies. Second, as in the first case, the relative risk reduction in *sepsis*-related mortality is constant, and therefore associated with smaller absolute reductions in less sick patients. However, the *absolute* risk of death due to bleeding is constant, and nullifies any potential benefits from reduced sepsis-associated mortality in patients at lower risk of death from sepsis.

Even though the reason for the absence of clear benefit in less sick patients is unknown, strong evidence supports the FDA recommendation that drotrecogin alfa (activated) be considered in the treatment of patients who present with severe sepsis, with the key caveats that the therapy be reserved for patients who are at high risk of death and who are not at undue risk for bleeding.

Case & Commentary: Part 2

Eighteen hours after infusion, the patient developed severe bleeding and hemodynamic instability requiring multiple transfusions and aggressive fluid resuscitation to maintain hemodynamic stability. Review of the case by the clinical pharmacist noted that the patient did not have signs or symptoms consistent with sepsis. The patient's organ dysfunction was due to severe rhabdomyolysis.

Ensuring appropriate use of novel and potentially toxic therapeutics is a challenging endeavor. FDA-approved labeling indications help to guide clinicians in the use of a new therapeutic agent. Off-label use, however, is permitted, as occurred here. Hospital pharmacy and therapeutics (P&T) committees use methods such as mandatory consults, checklists, and pharmacy review to control the use of potentially toxic medications. This approach can be very effective, but it may miss opportunities to improve care through provider education. Evidence-based guidelines developed by professional medical societies help to bridge the gap in terms of provider education. Unfortunately, guidelines are expensive to develop and disseminate, and they are often ignored. The pharmaceutical industry, with its massive detailing and advertising efforts, is particularly effective at reaching providers but has an obvious conflict of interest when it comes to guiding physicians in the choice and use of its own medications. The coordinated efforts of each of these groups may be required to ensure appropriate use of new medications. Such a multi-pronged approach could match FDA indications with P&T oversight and disseminate professional medical society guidelines using unrestricted pharmaceutical industry sponsorship.

Some efforts to improve the care of critically ill patients have used portions of this approach. For instance, the Surviving Sepsis Campaign (11) is an international effort to increase awareness and improve outcome in severe sepsis. Using unrestricted industry educational grants, a group of international critical care and infectious disease experts came together to develop guidelines that the bedside clinician could use to improve outcome in severe sepsis and septic shock. No industry members were on the committee, and no industry input influenced guidelines development. The next phase of this program will be dedicated to the use of the management guidelines to evaluate the impact on clinical outcomes.

While these concepts apply to any novel therapeutic, specific issues surround the use of high-cost biopharmaceutical agents. Cost alone may limit the use of these new agents, even in the face of strong evidence in favor of their use. On the other hand, the profit potential of these high priced products may lead to marketing efforts that result in increased and sometimes inappropriate use. This is a dynamic tension that our health care system will have to increasingly grapple with in the coming years.

Case & Commentary: Part 3

The patient later died due to complications from his multiple injuries.

The decision to administer drotrecogin alfa (activated) to this patient whose organ system failure was not due to sepsis was an error, one that could have been avoided in a number of ways. Perhaps the most relevant are provider education and P&T-based controls. If the team caring for this patient were aware of the indications and contraindications for drotrecogin alfa (activated), its use and the attendant bleeding complications could have been avoided. A checklist-based pharmacy review prior to dispensing this medication would have revealed the contraindication as well. Wong-Beringer and colleagues used such an approach in an order form, which included explicit inclusion and exclusion criteria and which required infectious disease and critical care specialist approval prior to dispensing the drug (Figure).(12) Their approach was applauded as a way not only to prevent inappropriate use, but also to increase awareness of patients who might benefit from treatment.(13)

While this case is tragic in that it represents a potentially avoidable error of commission, perhaps the greatest threat to patient safety associated with drotrecogin alfa (activated) is the error of omission.(14) As with other proven life-saving interventions, such as aspirin and beta-blockers in coronary artery disease and angiotensin-converting enzyme inhibitors in congestive heart failure (15), failure to treat must be viewed as a medication error that leads to unnecessary morbidity and mortality.(14) Anecdotal reports suggest that drotrecogin alfa (activated) is frequently underutilized, even in patients with clear indications for its use. The drug's high cost, concerns about safety, and failure to recognize eligible patients are thought to underlie some of this underutilization.(13) However, as reviewed above, when given to appropriate patients, the risks of bleeding are clearly outweighed by the overall gains in survival. This gain in survival has now been demonstrated to be sustained over a prolonged follow-up, information that was considered by the Centers for Medicare and Medicaid Services when they ruled that the Medicare program would reimburse hospitals for use of drotrecogin alfa (activated). Furthermore, several studies have demonstrated that, despite the initial drug acquisition cost, drotrecogin alfa (activated) has a very acceptable cost-effectiveness profile, similar to, or better than, many well-adopted health care interventions.(16-18)

Unfortunately, P&T restrictions and FDA labeling are unlikely to prevent errors of omission. Educating providers about the indications, contraindications, and cost-effectiveness (16) of this intervention will be essential to increasing use of this life-saving medication. Other approaches that may prove useful and which are reviewed elsewhere include academic detailing using local opinion leaders, paper or computer-based reminders, and case audit and feedback.(19)

Even with all of these approaches, influencing providers to take a particular course of action is challenging. Recognizing this, some hospitals are establishing teams of emergency department and intensive care unit specialists to facilitate rapid sepsis identification, assessment, and treatment.(20) This sort of systems-based approach has been effective in other disease states, such as acute ischemic stroke or myocardial infarction, where rapid diagnosis and treatment is central to improving outcomes.

Bowel Prep

The Case

The patient is a 73-year-old woman who 20 years ago underwent treatment for breast cancer. At her daughter's suggestion, the patient requested referral for colonoscopy, as she understood there was an increased risk of her having a second malignancy.

At four feet ten inches tall, the patient was petite, weighing only 88 pounds. Her primary care physician referred her to a gastroenterologist whose practice consists of ambulatory endoscopy. In his practice, patients are not routinely seen in advance of their procedures, so the patient called the gastroenterologist's office and was given instructions for her bowel prep. When she inquired about whether the "dose" of the prep needed adjustment given her small size, the nurse told her that this was the "standard" dose. The nurse asked no further questions.

The patient used the bowel prep as instructed, and her husband found her unresponsive on the morning of her scheduled colonoscopy. She was taken to the hospital and found to have significant electrolyte abnormalities including hyponatremia, hypokalemia, hypophosphatemia, hypocalcemia, and hypomagnesemia, all believed to be complications of the bowel prep. She was re-hydrated, her electrolytes were corrected, and she was discharged home after 48 hours.

Allergy to Holter

The Case

A 52-year-old man was admitted for palpitations and chest pain. As part of the evaluation, on hospital day 4 the patient was sent to the cardiac clinic to start a continuous recording of his electrocardiogram via Holter monitor.

Since the patient was ambulatory and had gone for other tests on his own, he was told to go to the cardiology clinic for a check-up of his heart rhythm. He

was handed a "Request for Consultation" form, on which there was only one word: "Holter." The form did not state the patient's name or the department.

The patient had been told the clinic was on the fifth floor of the ambulatory building, so he took the elevator to that floor. He presented himself to the reception desk of the first clinic he saw—the allergy clinic (which is on the same floor as the cardiology clinic)—where the nurse took his consultation form, and told him, "Mr. Holter, you are in the right place." She then proceeded to conduct a complete pin-prick skin sensitivity test on his back, which showed no evidence of allergies. Armed with a form that showed his "Holter" test was negative, the patient walked back to his ward.

Upon his return, the patient told his ward nurse, "I've just finished the Holter test." —"And where is the Holter device?" asked the nurse. —"It is on my back and does not hurt at all!"

The nurse looked at the patient's back and realized that he had had an allergy test. She then escorted him to the cardiac clinic to have an actual Holter monitor placed. There was no harm (fortunately) to the patient, other than an unnecessary test and a brief delay in the ECG recording.

Additional investigation revealed that the patient was able to read and there was no language barrier. The workload for the allergy clinic nurse was light. She had merely glanced at, but did not read, the consultation form. Since it was not the first time a patient had received an unnecessary allergy test, the hospital published the event in their incident report newsletter and changed the signs to clinics on that floor. The nurse retired from practice (as previously scheduled) the following month.

The Result Stopped Here

The Case

A 91-year-old female was transferred to a hospital-based skilled nursing unit from the acute care hospital for continued wound care and intravenous (IV) antibiotics for methicillin-resistant *Staphylococcus aureus* (MRSA) osteomyelitis of the heel. She was on IV vancomycin and began to have frequent, large stools.

The attending physician ordered a test for *Clostridium difficile* on Friday, and was then off for the weekend. That night, the test result came back positive. The lab called infection control, who in turn notified the float nurse caring for the patient. The nurse did not notify the physician on call or the regular nursing staff. Isolation signs were posted on the patient's door and chart, and the result was noted in the patient's nursing record. Each nurse who

subsequently cared for this patient assumed that the physician had been notified, in large part because the patient was receiving vancomycin. However, it was IV vancomycin (for the MRSA osteomyelitis), not oral vancomycin, which is required to treat *C. difficile*.

On Monday, the physician who originally ordered the *C. difficile* test returned to assess the patient and found the isolation signs on her door. He asked why he was never notified and why the patient was not being treated. The nurse on duty at that time told him that the patient was on IV vancomycin. The float nurse, who had received the original notification from infection control, stated that she had assumed the physician would check the results of the test he had ordered. Due to the lack of follow-up, the patient went three days without treatment for *C. difficile*, and continued to have more than 10 loose stools daily. Given her advanced age, this degree of gastrointestinal loss undoubtedly played a role in her decline in functional status and extended hospital stay.

The Wrong Shot: Error Disclosure

Case & Commentary: Part 1

A 10-year-old child from India presented to his pediatrician's office for a school physical. The child had no past medical history, was in excellent health, and all immunizations were up to date with the exception of Hepatitis B. The physician discussed the issues around vaccination with the patient's father and obtained consent. The nurse drew up the vaccine and the physician administered it. After administration, the physician went to record the lot number and discovered that a dose of vaccine for Hepatitis A had been given instead of Hepatitis B.

Adverse drug-related events are common in both the inpatient and the outpatient setting. Studies of hospitalized patients find that up to 6.5% had an adverse drug event and about 25% of those were preventable.(1) While less is known about adverse drug events in outpatients, a recent study demonstrated that over 25% of outpatients had experienced a recent adverse drug event, with 40% of those being either ameliorable or preventable.(2)

Ethicists have long recommended that patients be told about all harmful errors, to demonstrate respect for patients and foster honesty in the patient-provider relationship.(3,4) Increasingly, hospital policies and regulatory agencies also require disclosure of "unanticipated outcomes."(5) Yet disclosure of errors, particularly discussion of the details of the event, continues to be uncommon. In one recent national survey of both the public and physicians, only one-third of respondents who had personally experienced a medical error said that the involved health care professionals had disclosed the error or apologized to them.(6)

When a harmful error takes place, patients first want an explicit, jargon-free statement that an error occurred and a basic description of what the error was and why it happened.(7) Patients dislike explanations that seem evasive. Second, patients want to understand the implications of the error for their health and how their health care workers will deal with the consequences. Third, patients want to know how the physician, other health care workers, and the health care system will learn from this error; understanding how future errors will be prevented is more important to patients than many physicians appreciate. Fourth, patients want their physician to apologize, which demonstrates that the physician genuinely cares about what happened.

However, health care workers may hesitate to provide this information to patients. Studies of physicians' attitudes have identified several important barriers to disclosure, such as physicians' fear of litigation, concern about whether the information might harm patients, and discomfort with how to share the information.(7-9) These barriers can lead physicians to "choose their words carefully" when talking to patients about errors, mentioning the adverse event but avoiding explicitly stating that an error occurred. In addition, physicians want to apologize to patients but worry that doing so will increase their legal liability. Physicians further wonder whether to take personal responsibility for an error, especially given the patient safety movement's emphasis that most errors are not failures of individual providers but rather breakdowns in the system of care.

This "disclosure gap"—namely the mismatch between recommendations that all harmful errors be disclosed to patients and the evidence that, in practice, such disclosure is uncommon—has two potential interpretations. Clinicians may appreciate that error disclosure is "the right thing to do" but experience insurmountable obstacles in their attempts to tell patients about errors. Alternatively, this disclosure gap may reflect under-appreciated but morally relevant complexities in the decision about whether and how to disclose errors to patients. For example, the patient in this case suffered minimal if any harm; it is even possible that the inadvertent administration of a dose of Hepatitis A vaccine may have helped the patient. Little is known about whether disclosure of errors that cause minor harm or disclosure of near misses is desirable from either patients' or physicians' perspectives.

Case & Commentary: Part 2

Without hesitation, the physician informed the father that the wrong vaccine had mistakenly been given to the boy. He explained the usual indications for Hepatitis A vaccination and emphasized that this vaccine would not bring any harm to the boy and may even protect him from illness in the future. He suggested that the boy still receive the Hepatitis B vaccine. The father became

extremely angry. He refused to allow further vaccination and proceeded to report the incident to the clinic administrator.

Patients' reactions to hearing about such an event depend in part on the content of the disclosure as well as the communication skills used to deliver this information. Patients especially value understanding how an error happened and how recurrences will be prevented, information physicians (as in this case) often fail to share with patients. We believe that an essential component of narrowing the disclosure gap is for physicians to begin conceiving of error disclosure not as "service recovery" but rather as an integral component of quality improvement.(10) The father might have been less angry had he learned that, as a result of this error, such vaccines were now being stored in separate and clearly labeled spots in the physician's office. Furthermore, the need to tell the family about an error's cause and prevention may stimulate the physician to think more critically about why the error happened and develop a robust prevention plan, thereby enhancing the quality of future care. Determining exactly how an error happened and formulating a plan for preventing recurrences can be especially challenging in the outpatient setting, where the resources to conduct formal error analyses may be absent.

Empathic communication techniques can also help physicians respond to patients' anger.(11) Empathy refers to the process of understanding and explicitly acknowledging patients' feelings, and listening carefully as patients share their distress. As in other difficult communication situations, such as delivering bad news, the health care professional must listen attentively and offer support when a patient is expressing a powerful emotion, whether the emotion is sadness, anxiety, or even anger.(12) Usually, the intensity of the patient's feeling will diminish as the physician listens, acknowledges, and, when appropriate, validates the feeling in a caring fashion. Communicating empathically can be especially challenging in the setting of an error, when the patient's upset emotions may be explicitly directed at the physician.

For some patients, anger following a medical error leads them to file a malpractice claim. Considerable debate currently exists about whether full disclosure of medical errors makes malpractice claims more or less likely. Many have argued that skillful disclosure may assuage such anger and lessen the chances of a malpractice claim.(13-15) However, skeptics argue that the reason few injured patients actually sue is because they were unaware that the error occurred, and that more open disclosure could actually precipitate lawsuits.(16) Even a remote chance that error disclosure could prompt a malpractice suit is worrisome to physicians, given the impact such a claim could have on physicians' already skyrocketing malpractice premiums, as well as the need to report successful claims to the National Practitioner Databank and hospital credentials committees. Wholesale tort reform and adoption of a no-fault malpractice system would clearly facilitate full disclosure of errors to

patients. Yet, the current political climate is unlikely to support such dramatic tort reform.(17) In the meantime, individual clinicians must still decide what to tell patients about medical errors. Overall, we recommend that clinicians respond to medical errors with an underlying assumption of full disclosure, but work closely with experienced risk managers throughout the disclosure process to minimize unanticipated legal risks.

Case & Commentary: Part 3

After the vaccine incident, the physician in this case felt responsible for the loss of trust and the missed opportunity to administer an important vaccine to a child.

Physicians frequently experience powerful emotions following a medical error.(7,18-20) As highly responsible individuals, it is not surprising that most physicians will feel a sense of shame and culpability for errors, disappointment about failing to practice medicine to their own standards, and fear about possible law suits. For some physicians, the emotional aftermath of an error can include physical symptoms such as sleeplessness, difficulty concentrating, and anxiety.

We believe that addressing health care workers' emotional needs following errors is critically important. The presence of such emotional distress can diminish physicians' well-being and impair the disclosure process. Some distraught physicians may mistakenly assume that an adverse event was due to an error and disclose this information to the patient, when on closer analysis the adverse event was actually not preventable. For other physicians, feelings of guilt and embarrassment can prevent them from disclosing a serious error to the patient. While physicians may desire to discuss the circumstances of the error and their feelings with a trusted colleague, many risk managers warn that such conversations between physicians can be subpoenaed in a court of law.

Institutions can take several steps to improve error disclosure. First, they can provide emotional support for health care workers as an explicit component of their patient safety program. In addition, they should offer communication skills training and the opportunity for physicians to practice disclosing errors, analogous to workshops that teach physicians to discuss other difficult topics such as end-of-life care. We have used standardized patients to allow surgeons to practice disclosing a major error and to receive feedback; to date, these surgeons report this to be a valuable and novel learning experience. Finally, education of physicians and other health care workers about the causes and prevention of errors can dispel the misperception that errors are usually the fault of individual providers.

Lethal Vertigo

The Case

A 64-year-old woman, with no prior medical history, complained of sudden onset of severe vertigo and vomiting, without headache. Her initial blood pressure in the emergency department (ED) was 170/90 (at about 4:00 PM). Physical examination was limited because the patient's vertigo dramatically worsened when she opened her eyes. Neurological exam was grossly normal—the patient could follow commands and there was no focal weakness. A provisional diagnosis of labyrinthitis was made, and prochlorperazine (Compazine) 10 mg IV was administered. An hour later, however, the patient noted little improvement, and so lorazepam 2 mg IV was given. An hour after that, the patient was signed out to a second attending, who administered atropine 0.5 mg IV. Four hours later, she was signed out to a third attending. At that point (10:00 PM), the physician decided to hold her overnight in the ED and admit her if she was not better in the morning. At 11:00 PM, the patient complained of a headache and was given acetaminophen 650 mg by mouth. An hour later, the patient sustained a cardiopulmonary arrest and could not be resuscitated.

Autopsy revealed that the patient had died of a cerebellar hemorrhage. A subsequent review of the case indicated that the death was potentially avoidable, had life-saving neurosurgery been performed within the first few hours of her ED presentation.