Root Cause Analysis

Shaping Systems for Better Behavioral Choices: Lessons Learned from a Fatal Medication Error

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On the morning of July 5, 2006, a 16-year-old patient came to St. Mary's Hospital in Madison, Wisconsin, to deliver her baby. During the process of her care, an infusion intended exclusively for the epidural route was connected to the patient's peripheral IV line and infused by pump. Within minutes, the patient experienced cardiovascular collapse. A cesarean section resulted in the delivery of a healthy infant, but the medical team was unable to resuscitate the mother. The medication error and its consequences were devastating for the patient's family, the nurse who made the error, and the medical team that labored to save the patient's life.

The media attention surrounding the error became a firestorm that accelerated through the national provider and safety community when the nurse was charged with a criminal offense (Sidebar 1, page 153).

These events set in motion intense internal and external scrutiny of the hospital's medication and safety procedures. The hospital's internal analysis revealed that the involved nurse bypassed multiple sequential safety procedures involving patient identification, verification of the "five rights" of medication administration, and use of the bar-code medication administration system. In addition, it also identified multiple latent systems issues. To further understanding about latent systems gaps and process failure modes, the hospital invited the Institute for Safe Medication Practices (ISMP; Horsham, PA) to conduct an independent root cause analysis (RCA) of the event. This article presents a summary of the RCA, and the president of the hospital comments on the lessons learned from this event.

The Event

The patient presented at St. Mary's Hospital, a 440-bed community teaching hospital, at approximately 9:30 A.M. Although she was three hours late for her scheduled induction, the nurse

For editorials, see pages 147–151.

Article-at-a-Glance

Background: In July 2006, a 16-year-old patient came to the hospital to deliver her baby. During the process of her care, an infusion intended exclusively for the epidural route was connected to the patient's peripheral intravenous line and infused by pump. The patient experienced cardiovascular collapse. A cesarean section resulted in the delivery of a healthy infant, but the medical team was unable to resuscitate the mother. The media attention surrounding the error accelerated through the national provider and safety community when the nurse was charged with a criminal offense. These events set in motion intense internal and external scrutiny of the hospital's medication and safety procedures.

Root Cause Analysis (RCA): To further understanding about latent systems gaps and process failure modes, an independent RCA of the event was conducted in June 2007. An external consultant team conducted a one-week evaluation of the medication use system and the organization's current environment, systems and processes, staffing patterns, leadership, and culture to help shape the recommended improvements. For each of the four proximate causes of the event, performance-shaping factors were identified. Although the hospital's organizational learning was painful, this event offered an opportunity for increasing organizational competency and capacity for designing and implementing patient safety. Structures and processes, including safety nets and fail-safe mechanisms, were implemented to promote safer behavioral choices for providers.

Actions Taken: The hospital took a number of clinical steps to improve the safety of medication administration, including removing the barriers to scanning medication bar codes, implementing consistent scanning-compliance tracking, and providing teamwork training for all nursing and physician staff practicing in the birth suites.

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Sidebar 1. What Happened to the Nurse Involved in the Error?

The nurse was charged with a felony criminal offense, which was eventually reduced to a "no contest" plea to two misdemeanor counts of illegally administering prescription medications. On the basis of the conviction, the State of Wisconsin Department of Health and Human Services imposed restrictions on the nurse's ability to participate in any capacity in the Medicare, Medicaid, and all Federal health care programs for five years. The Wisconsin Department of Regulation and Licensing also suspended her license for nine months, and the hospital terminated her employment.

who had been assigned to her care had one other patient who was not in active labor and therefore was able to begin admissions procedures. The nurse spent most of the next two hours discussing and exploring family dynamics with the patient and her mother. Although the admission profile was completed, a bar-coded identification band was not applied to the patient's arm.

It was during this time frame that the patient reportedly expressed a desire for epidural pain management during labor. At approximately 11:30 A.M., the patient's membranes were ruptured by the physician to begin the induction process. The nurse discussed epidural pain management with the physician, who stated his plan to assess the patient in 30 minutes and then make a decision about the epidural.

The nurse then accessed the automated dispensing cabinet (ADC) to withdraw Lactated Ringer's solution, pitocin, delivery kit medications, and a bag of epidural solution. As she was returning to the patient's room, a colleague handed her the intravenous (IV) penicillin that had been ordered per protocol to treat the patient's strep infection. The nurse then prepared and started an infusion using an infusion pump. The nurse acknowledged that during preparation of the infusion, she did not look at the medication bag carefully, verify the five rights of medication administration, or attempt to scan the bar code on the infusion bag. The nurse stated she planned to get the IV initiated, start an education video on the birthing process, and then scan the infusion bag to document the administration. Within a few minutes, the patient had seizure activity, respiratory distress, and then cardiovascular collapse, which the team initially attributed to an allergic reaction to penicillin. Despite vigorous resuscitation, the patient remained asystolic, and the team suspected that something other than a penicillin reaction was the cause of the patient's collapse.

The patient was moved emergently to one of the birth suite operating rooms, and a healthy infant was delivered by emergency cesarean section. Resuscitation efforts continued for 80 minutes, with multiple causes of the collapse considered and ruled out. The patient remained asystolic and apneic, and resuscitation was discontinued at 1:43 P.M. (13:43). A few minutes later, a partially infused epidural solution bag and an unspiked penicillin bag were discovered, and it was determined that the patient had received an IV infusion of fentanyl and bupivacaine instead of penicillin.

The RCA

Conducting the RCA

St. Mary's invited ISMP to conduct an on-site RCA of the adverse event. In June 2007, the ISMP team, consisting of a physician, two pharmacists, and two nurses, conducted a one-week on-site evaluation of the medication use system at St. Mary's Hospital. For two days, a pharmacist and nurse from this core consultant team focused entirely on investigating the event. To conduct the investigation, the consultants obtained information primarily from the sources listed in Table 1 (page 154).

The team's task was to understand the chronologic sequence of events that led to the tragic outcome, become acquainted with the commercially available point-of-care (POC) bar-coding system used at the hospital, and then to thoroughly explore the event until both the immediate (proximate) and underlying (root) causes were identified. This was accomplished primarily by reviewing pertinent hospital documents, conducting confidential interviews with key staff, gathering information about the systems and technology available at the time of the event, and visiting all areas of the hospital associated with the event and/or associated with the processes that led up to the event.

The team's goal was to answer the questions posed in Table 2 (page 154). The team also evaluated the organization's current environment, systems and processes, staffing patterns, leadership, and culture to help shape the recommended improvements and offer guidance on how to achieve them within the context of the hospital milieu.

Findings from the RCA

Significant findings from the RCA, which were formally presented to the hospital in August 2007, are now discussed.* Definitions of key terms can be found in Table 3 (page 155). A short summarization of the performance-shaping factors that contributed to the error can be found in Table 4 (page 156).

Proximate Cause 1. **The epidural medication (fentanyl and bupivacaine) was brought into the patient's room before it**

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Table 1. Event Investigation Information Sources*

Before On-Site Consultation

- Telephone calls with key hospital leadership, including the president
- Extensive telephone interviews with the nurse most directly involved in the error
- Pertinent written hospital policies and procedures in place at the time of the event
- Written hospital policies and procedures introduced as a result of the event
- Public documents related to professional licensure action and criminal charges against the nurse most directly involved in the error
- Published studies and literature about technology work-arounds
- Published literature about similar adverse events
- Reliable sources of information about the pathophysiology of adverse outcomes associated with administering epidural bupivicaine and fentanyl by the intravenous route of administration
- Applicable regulations, standards, and guidelines from the Centers for Medicare & Medicaid Services (CMS), the Wisconsin State Department of Health, The Joint Commission, the American College of Obstetricians and Gynecologists (ACOG), the Association of Women's Health, and Obstetric and Neonatal Nurses (AWHONN)

On-Site Consultation

- Hospital's internal RCA report and supporting documents
- Patient's medical record
- Scheduled and random interviews with:
  - —Members of the hospital administrative council
  - —Hospital president
  - —Director of quality and safety
  - —Risk manager
  - —Human resources staff
  - —Nurse manager of the obstetrical unit
  - —Pharmacy director
  - —Pharmacy staff
  - —An obstetrician
  - —The hospital's RCA team
  - —Anesthesia staff who provide services in the obstetrical unit
  - —POC bar-coding system coordinator and technology staff
  - —Nurses on the obstetrical unit
  - —Representatives from the obstetrical unit practice council
  - —Staff nurses from other clinical units who use POC bar-coding system
  - —Nurse managers from other clinical units where system used
- Demonstration of the POC bar-coding system with hands-on experience
- Tour of the obstetrical unit
- Tour of other clinical units using the POC bar-coding system
- Phone interview with the patient's obstetrician on the day of the event

After On-Site Consultation

- Discussions with other members of the ISMP consulting team
- Discussions with obstetrical nurses from other hospitals where POC bar-coding systems are used

* RCA, root cause analysis; ISMP, Institute for Safe Medication Practices; POC, point-of-care.

Table 2. Questions Posed During ISMP's Investigation of the Event*

1. What Happened?
Beginning with knowledge of the adverse outcome, the ISMP team interviewed staff involved in providing care to the patient before, during, and after the initial error to determine what happened.

2. What Normally Happens?
The ISMP team asked staff who perform the types of tasks associated with the event how they usually carry them out. Knowing the norm helps determine the reliability of processes involved in the sentinel event.

3. What Does the Hospital Policy/Procedure Require?
After learning what happened and what normally happens, the ISMP team asked staff what hospital procedures require them to do to learn what was supposed to happen.

4. Why Did It Happen?
The ISMP team interviewed staff involved in the event to learn the proximate and root causes behind each human error, procedural deviation, and any other at-risk behaviors that led to the event.

5. How Was the Hospital Managing the Risk Before the Event?
The ISMP team interviewed staff involved in the event, managers, supervisors, and other key leadership in the hospital to learn how the organization was previously managing the types of risks that led to the event. The team sought to learn what types of safety measures were already in place at the time of the event.

* ISMP, Institute for Safe Medication Practices.

was needed or prescribed. The initiating action that set the stage for this event was the nurse's bringing the bag of epidural fentanyl and bupivacaine into the patient's room along with the bag of IV penicillin, allowing for the possibility of a mix-up between the two bags. During analysis of the event, there was discussion—sometimes hindered by hindsight bias—regarding the appropriate time for bringing epidural medication into an obstetrical patient's room, particularly because most epidural medications are controlled substances. It is uncertain whether, before this event, staff at the hospital believed that the availability of an epidural medication in the patient's room before it was prescribed or needed constituted a serious risk. Nevertheless, several performance-shaping factors led to the decision to bring the epidural medication into the room before it was

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Table 3. Definitions

Term	Definition
Adverse event	An injury resulting from a medical intervention
Hindsight bias	The tendency to believe, after learning of an outcome and why it happened, that one could have foreseen it and prevented it; the tendency to oversimplify and misrepresent the conditions that led to an error once the outcome is clear and the correct pathways/decisions that would have improved the outcome are known
Human error	Inadvertently doing other than what should have been done; the failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan to achieve an aim (error of planning)
Inattentional blindness*	Also known as *perceptual blindness*, this is the phenomenon of not being able to see things that are actually there. This can be a result of having no internal frame of reference to perceive the unseen objects, or it can be the result of the mental focus or attention that causes mental distractions. The phenomenon is due to how our minds see and process information.
Latent system failures	Errors in the design, organization, training, or maintenance of systems that lead to operator errors and whose effects typically lie dormant in the system for lengthy periods of time
Proximate cause	A cause that directly or with no intervening action produces or leads to the adverse event
Performance-shaping factors†	Attributes in the system, technology, and environment and a person's internal characteristics that affect the likelihood of human errors or at-risk behaviors (unsafe practice habits)
Root cause analysis	A process for identifying the most basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a harmful adverse event

* Green M.: "*Inattention blindness" & Conspicuity.* 2009. www.visualexpert.com/Resources/inattentionalblindness.html (last accessed Feb. 10, 2010); Angier N.: Blind to change, even as it stares us in the face. *The New York Times*, Apr. 1, 2008. http://www.nytimes.com/2008/04/01/science/01angi.htm?_r=2&ex=1207713600&en=204&oref=slogin (last accessed Feb. 10, 2010); Wikipedia: *Inattentional Blindness.* http://en.wikipedia.org/wiki/Inattentional_blindness (last accessed Feb. 10, 2010).

† Stamatelatos M., et al.: *Probabilistic Risk Assessment Procedures Guide for NASA Managers and Practitioners.* Version 1.1. Prepared for the Office of Safety and Mission Assurance, Aug. 2002. http://www.hq.nasa.gov/office/codeq/doctree/praguide.pdf (last accessed Feb. 12, 2010).

needed or prescribed.

During the admission process, the nurse felt that the patient was very anxious about labor. She seemed especially frightened during the rupture of membranes, which prompted the nurse to suggest to the obstetrician that the patient receive an early epidural. The nurse believed the obstetrician was amenable to the suggestion, would return to further assess the patient as labor progressed, and would then consult anesthesia when the patient was ready for the epidural.

Before this event, obstetricians did not routinely document their plan of care for patients in labor, particularly in regards to anesthesia services. As in many instances before the event, the nurse anticipated the obstetrician's plan of care and, on the basis of their previous conversation, brought the fentanyl and bupivacaine bag into the room so that it would be available for the early epidural.

Anesthesia staff in the past had expressed dissatisfaction with patients' state of readiness for an epidural on their arrival on the unit. This dissatisfaction had placed considerable pressure on nurses to ensure that the patient was ready for an epidural before anesthesia staff arrived. Elements of patient readiness for an epidural were poorly defined and prone to variability, reflecting individual anesthesia staff preferences. Thus, a unit-based practice council had developed guidelines before the event to improve the process of readying patients for epidurals. On the basis of these guidelines, several nurses had developed a laminated to-do checklist, which included retrieving the epidural medication for anesthesia personnel before their arrival on the unit. Yet, nurses still found it difficult to anticipate the arrival time of anesthesia staff because they did not directly communicate with them. Obstetricians always notified anesthesia staff to request epidural analgesia and to let them know when they thought that the patients would be ready.

At the time of the event, nurses were responsible for retrieving epidural medications from the ADC. The nature of care provided to patients in labor often makes it difficult for nurses to leave the room for medications and supplies; thus, anticipated supplies, including medications, were often brought into patients' rooms ahead of time.

Before receiving a signed order, nurses routinely brought epidural medications into patients' rooms after the obstetricians called anesthesia staff to request a consult. Anesthesia staff would typically sign a preprinted order set for the epidural analgesia after it had been started.

The nurse involved in the error also decided to bring the medications into the room because she believed that seeing the actual medication bag and demonstrating how the drug would be administered would help reduce the patient's anxiety. Other

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Table 4. Proximate Causes and Performance-Shaping Factors*

Four Proximate Causes of the Event	Performance-Shaping Factors That Contributed to the Event
1. The epidural medication (fentanyl and bupivacaine) was brought into the patient's room before it was needed or prescribed.	■ A gap in communicating and documenting the obstetrician's plan of care for the patient
	■ Work flow that favored collection of all needed supplies up front
	■ Previous anesthesiology-staff dissatisfaction with the readiness of patients on arrival in the room to administer epidural medication
	■ Difficulty anticipating the time of arrival of anesthesia staff because nurses did not directly communicate with them
	■ Previous practice of bringing epidural medication into the patient's room before it was formally prescribed on the patient's medical record
	■ Selection of training tools influenced by the patient's level of anxiety
2. The nurse picked up the wrong medication (epidural fentanyl and bupivacaine), failed to read the label fully, and prepared the medication for IV infusion instead of the intended drug (IV penicillin).	■ Similarities in general physical appearance of both medications
	■ Familiarity with more routine medications such as penicillin, which lessened vigilance
	■ Faded perceptions of risk and inattention blindness when reading the label on the bag
	■ Epidural delivery system that allowed the use of IV tubing
	■ Distractions and fatigue, which increased the risk of an error
3. The nurse did not place an identification band on the patient, which was required to utilize the bar-coding system to match the prescribed drug therapy with the selected/administered drug therapy.	■ Difficulty leaving the patient's room to obtain the identification bracelet
	■ Familiarity with the patient due to the one-on-one nature of assignments in the obstetrical unit
	■ Prior tolerance of administering medications to obstetrical patients who did not have an identification band
4. The nurse failed to use the available POC bar-coding system, which could have detected the drug-selection error before administration.	■ Inability to scan the patient's identification bracelet to initiate the POC bar-coding system
	■ Recent implementation of the POC bar-coding system, contributing to a 50% unitwide average compliance rate with scanning medications and solutions
	■ Suboptimal training of obstetrical unit staff and minimal experience with this nurse using the system because of vacation during the initial implementation week
	■ Unanticipated work-flow and scanning problems that led to bypassing the POC bar-coding system and a work environment that was sometimes negative regarding use of the technology

* IV, intravenous; POC, point-of-care.

alternatives were available to teach the patient about epidural analgesia. However, at the time of the event, the nurse did not appear to foresee any risk with using the actual medication as a teaching prop.

Proximate Cause 2. **The nurse picked up the wrong medication (epidural fentanyl and bupivacaine), failed to read the label fully, and prepared the medication for IV infusion instead of the intended drug (IV penicillin).** Several performance-shaping factors contributed to the mix-up between the epidural fentanyl and bupivacaine bag and the IV penicillin bag, which had both been brought into the room and placed near each other on a counter. First, the physical appearances of the bags were similar (Figure 1, page 157; available [in color] in online article). Both medications had been prepared in 150-mL piggyback-type bags, although the fentanyl and bupivacaine bag looked somewhat larger because it actually contained 240 mL, whereas the penicillin bag contained 180 mL. Both bags were labeled with the same-size pharmacy-applied orange labels, and both were available on the counter. A 3-inch x 1¼-inch pink warning label, "For epidural use only," appeared on the front of the epidural bag, and a smaller pink warning label appeared on the back of the bag. However, the nurse did not see or misinterpreted the warning signs, despite their apparent visibility. Inattentional blindness and a faded perception of risk contributed to this error, as described in detail:

■ **Faded perception of risk.** The nurse had given many patients IV penicillin before the day of the event, and the familiarity of the drug allowed the perception of risk to fade while she prepared the medication for administration. In fact, the risk of making a mistake with the more "routine" medications such as penicillin was higher, given that much more conscious double-checking tended to occur when administering less typical medications. Familiarity with the intended product reduced the attention given to reading the label.

■ **Inattentional blindness.** When someone performing a task fails to see what should have been plainly visible—in this case, a pink warning sticker—and he or she cannot explain why it happened, the cause is usually rooted in inattention blind-

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ness, a condition that all people exhibit periodically.[1] When reading a label, most of the visual processing occurs outside of conscious awareness. Far more information than can be processed is visualized.[2] To combat information overload, the brain scans and sweeps until something sticks out to capture its attention. Unfortunately, the brain is a master at filling in gaps and making do, compiling a cohesive portrait of reality based on just a flickering view.[1] In this case, we presume that the orange color of the pharmacy label captured the nurse's attention and that anything lying outside the initial capture of attention—such as the actual drug name on the label and the pink warning label—got short shrift. How the brain sees the world and how often it fumbles the job is further influenced by distractions and fatigue.

Photos of the Intravenous (IV) Bags

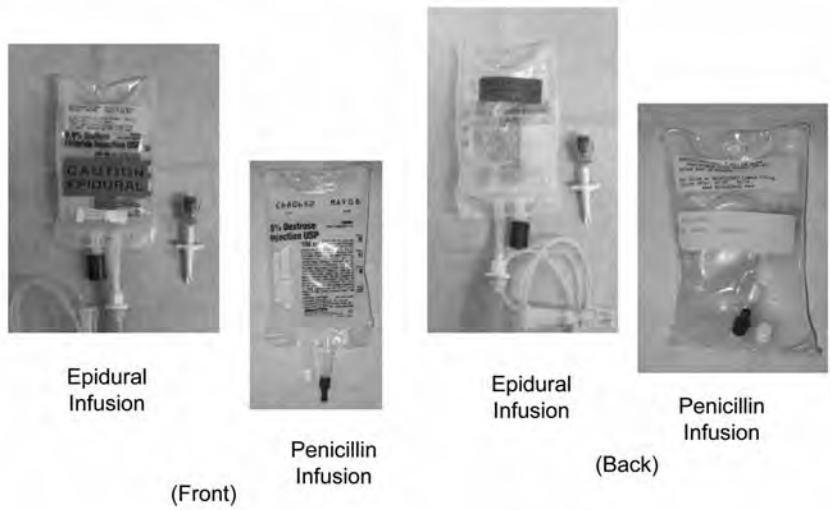

Figure 1. *The epidural and IV (penicillin) medications were in the same-size containers, and both had orange pharmacy-applied labels; the pink warning labels on the epidural bag helped to differentiated the products but were overlooked, reflecting inattentional blindness. (Available in color in online article.)*

On the day of the event, the nurse was easily distracted during medication administration because of continuous interaction with the patient and other visitors in the room. She had spent most of the morning attempting to assuage what she perceived to be the patient's fear of childbirth. While she was in an anteroom beginning to organize all the medications and supplies that she had brought into the room, the patient kept asking questions. Consequently, the nurse brought all the medications and supplies to the patient's bedside so that she could talk to the patient directly while preparing her medications. The patient's boyfriend (and baby's father) had just arrived, and tension was noticeable between him and the patient's mother, who was also in the room. To help diffuse tension, the nurse decided to show an educational video to the patient and baby's father as soon as she started the patient's IV and penicillin dose. The nurse also had another patient on her mind whom she had prepared that morning for the probable delivery of a nonviable fetus. The nurse was also fatigued on the day of the event. The day before, she had worked for two consecutive eight-hour shifts and then slept in the hospital before coming on duty again the following morning. She had signed up to cover extra shifts left open by several nurses who were on temporary leave. After completing her first shift, the nurse was initially told that she would not be needed for the evening shift. However, given personal circumstances, the nurse was allowed to stay for the evening shift while another nurse scheduled for that evening received paid time off. Feeling fatigued halfway through the evening shift, the nurse expressed a desire to go home. However, her departure would have left the unit inadequately staffed, so she completed the shift and slept in the hospital after she finished around 12:30 A.M. (00:30) to avoid an hour's commute home. The nurse's fatigue the following morning increased her likelihood of making an error.

An additional issue is a long-standing design flaw: interconnectivity of tubing used for both epidural and IV solutions.[3,4] The epidural fentanyl and bupivacaine infusion bag allowed spiking with tubing intended for an IV infusion. Had the IV tubing been incompatible with the epidural bag access port, the nurse's selection of the wrong bag would have been noticeable.

Proximate Cause 3. **The nurse did not place an identification band on the patient, which was required to utilize the bar-coding system to match the prescribed drug therapy with the selected/administered drug therapy.** Several performance-shaping factors played a role in the nurse's violation of patient identification processes and policies associated with medication administration. Until several months before the event, nurses on the obstetrical unit had been lax about placing identification bands on patients. Because of patients' more immediate needs on arrival on the unit, the admission process—which includes applying an identification band—was often delayed, as in this case. Identification bands also arrived on the unit several hours after admission, and it was difficult to leave the room to pick up the bracelet. Nurses felt that they knew their patients after

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spending several hours of continuous time with them, lessening the urgency of placing identification bands on patients before administering medications. Thus, lack of uniform application of identification bands had become the norm on the unit, demonstrating the phenomenon of "normalization of deviance."[5]

Changes had been made before the event to print identification bands on the unit and require their immediate application, particularly before nonemergent medication administration. With this event, however, longstanding tacit tolerance of this risk by staff and managers increased the nurse's comfort level with delaying application of the identification band on the patient. Because the patient did not have an identification band on at the time of medication administration, the required procedure for patient identification before drug administration was not followed, and the available POC bar-coding system could not be used.

Proximate Cause 4. **The nurse failed to use the available POC bar-coding system that could have detected the drug-selection error before administration.** Several performance-shaping factors contributed to the nurse's failure to use the available POC bar-coding system. The obstetrical unit was one of the last units in the hospital to implement this system, in large part because of the anticipated difficulties in meshing its use with the typical work flow in an obstetrical unit. Plans to implement the technology previous to the actual start date had been postponed for about a year because the unit was not "ready" for the technology. In particular, a system to ensure that identification bands could be printed and available on the unit without delay needed to be developed before the technology could be implemented on the unit. After this system was in place—a few months before the event—implementation began.

Unanticipated work-flow issues and scanning problems arose during the initial weeks of implementation, contributing to episodes of bypassing the system until the issues could be resolved. Scanning of clear IV bags was especially problematic. The same problem was likely encountered on other units that had already implemented the technology. However, little or no training was provided to the obstetrical unit staff regarding this potential problem before the go-live date. Some nurses on the unit had discovered helpful strategies, such as holding a white piece of paper behind the bag so that the bar code could be picked up; other nurses developed work-arounds to bypass the technology, such as hanging an IV bag and then manually entering the information to document administration. As typical with any new technology, unitwide compliance with scanning applicable drugs was about 50% early in the fourth week of implementation when the error occurred.

The nurse involved in the error had only used the system once during the first week of implementation and then had not returned to work until 5 days later, when her scanning compliance rate decreased from 50% to 38%. Thereafter, her compliance rate fluctuated; on most days, she did not use the system to scan IV solutions in plastic bags. The "super-user" who had been available to assist staff during the first week was less available in subsequent weeks. The bar-coding system was also nonfunctional on at least 1 of 10 days that the nurse had been on duty since implementation.

Until problems with scanning the bags could be resolved, the nurse appeared to be functioning under the belief that her supervisor had told staff on the unit not to let the bar-coding system interfere with their ability to administer medications, and that problematic containers, such as clear IV bags, could be temporarily hung first and then entered manually while the solutions were infusing so they could be documented. As did other nurses before the event, the nurse did not try to scan the IV bag that contained what she thought was penicillin. Anticipating scanning problems, she hung the bag first and planned to retrieve the identification band from the nurses' station and try to scan the bag after she started the educational video for the patient and her visitors.

Staff training before implementation of the bar-coding system was suboptimal for the reasons that follow, which also contributed to instances when the nurse involved in the event, and other nurses on the unit, bypassed the technology's safety features:

- The training materials and test cases were not specifically tailored to the unique conditions under which medications are prescribed, dispensed, and administered on the obstetrical unit.
- Some nurses described the training sessions as long and tedious, believing that too much information was provided at one time to absorb it properly.
- Implementation of the technology occurred about three weeks after the training, so application of the training sessions was not immediate or optimal.

Additional Lessons Learned from the Rescue Efforts

When the patient experienced seizure-like activity, the nurse quickly assessed the patient, discontinued the IV medication she had just started, and called rapid response and code teams. Those attempting to rescue the patient initially suspected a penicillin allergy or an amniotic fluid embolus—both lucid dif-

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ferential diagnoses, given the information provided to the rescue team. Nevertheless, the differential diagnoses did not include the potential for a medication error (other than an allergic response to penicillin). This lesson learned is not meant to be critical of the resuscitation efforts the patient received. Given the unlikely chance of a better outcome when dealing with bupivacaine toxicity, the resuscitation efforts were still heroic and yielded the safe delivery of a healthy infant who has achieved expected milestones. But the index of suspicion regarding a medication error should be heightened if a patient experiences a rapid, unexpected deterioration in his or her condition.

Recommendations Stemming from the RCA

Recommendations stemming from ISMP's analysis of the event, which health care organizations can use to prevent similar occurrences, can be found in Table 5 (page 160), Table 6 (page 161), and Table 7 (page 161). Although the hospital's organizational learning was painful, this event offered an opportunity for increasing organizational competency and capacity for designing and implementing patient safety structures and processes. These structures and processes must be designed to promote safer behavioral choices and to include safety nets and fail-safe mechanisms for patients and providers. In the following section, the president of St. Mary's Hospital [F.D.B.] discusses organizational learning and actions taken in response to the event and the RCA.

Commentary (Frank D. Byrne, M.D.)

Organizational Learning

From the moment I was informed of the tragic event at St. Mary's, I knew that we would never be the same. For nearly a century, patients have entrusted us with their care. How could such an event happen at our hospital? After all, we have been a leader in initiating new safety technologies, we've been recognized nationally for our patient safety efforts, and we're a founding member of the Madison Patient Safety Collaborative. Our patients didn't need to worry about safety, just healing.

Yet in one moment in July 2006, that all changed. In the span of an instant, a young patient died, a caregiver's long career abruptly ended, many health care professionals began to question their career choice, multiple agencies converged on our hospital with intense scrutiny, and our short- and long-term organizational goals shifted dramatically. In summary, we were forever changed.

The only way that we could make sense of this senseless tragedy was to learn everything we could about how and why this happened and turn it into learning for the organization as a whole, for each of us individually, and for anyone else who would listen. This approach is helping us heal and enabling us to honor our commitment to the patient's family that we would do everything possible ensure that a similar event doesn't happen to anyone else.

We started the process with heartfelt apologies to the patient's family and acknowledgement that there had been a medication error. We then initiated immediate measures to deal with the situation, learned what went wrong, and set in place a process for long-term improvement. We have discussed the event and the aftermath with internal stakeholders within our 20-hospital health care system (SSM Health Care) and with colleagues at state and national professional organizations—through Webcasts, a panel discussion at a national nursing conference,[6] and presentations for professional societies and for a total audience of nearly 2,000 individuals. Appropriately, our focus has now moved to sharing with other health care and patient safety organizations nationwide. That is why we committed to collaborating with ISMP to write this article. Although different stakeholders in health care all view the events that contributed to this tragedy through a different lens, we all agree that improvements are best made through a broad discourse involving caregivers, suppliers, insurers, patient safety advocates, and regulatory and accreditation agencies.

How did St. Mary's change as an organization? The organizational culture of St. Mary's is built around collaboration and shared decision-making between staff and management. Our environment is one of trust, in which professionals are expected to think critically, make wise choices, and partner with management to design safer systems of care. This event reminded us that trust must be tempered with vigilance and that senior leadership has final accountability for ensuring that our systems are robust and well designed.

We learned that open doors and listening posts are not enough to guarantee that concerns reach the administrative table. At least twice a month, each member of the senior leadership team conducts walk-rounds at a minimum of two units at each department—clinical and nonclinical—to learn more about the safety concerns of staff members. On these walk-rounds, the team frequently poses the question, "In terms of your work at St. Mary's, what do you worry about when you go home?"

As a result of this event, we also learned about resiliency and the importance of supporting one another—and that we don't need a tragedy to call on that support.

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Table 5. General Recommendations Stemming from Analysis of the Event*

Recommendation	Details
Document a plan of care.	Communicate and document the obstetrician's plan of care for the patient in labor, including initial impressions regarding anticipated analgesia as labor progresses.
Provide team training.	Optimize communication and teamwork among the obstetrical team. (A free team-training toolkit, *Team Strategies and Tools to Enhance Performance and Patient Safety,*† is available.
Define patient "readiness" for an epidural.	Define how nurses should prepare patients for epidural analgesia. Include a time line, steps to accomplish before calling anesthesia staff and performing the procedure, details about documents (e.g., order form) that should be available for anesthesia staff and their location (room or chart), and a checklist to guide the process (similar to an OR readiness checklist).
Contact anesthesia when the patient is ready for epidural.	The obstetrician should consult with anesthesia staff to discuss the plan of care for analgesia during labor. However, the primary nurse should call anesthesia when the patient is actually ready for the epidural.
Establish dedicated anesthesia staff for obstetrics.	When possible, assign dedicated anesthesia staff to provide obstetrical services to enhance teamwork and communication among the obstetrical team, and to standardize the processes used in the preparation and delivery of epidural analgesia.
Require anesthesia to retrieve epidural medication.	Require anesthesia staff to obtain any medications they plan to administer to the patient once they arrive on the unit or to bring the medications with them to the unit. If the medications are in an ADC, furnish anesthesia staff with individual access codes, and if possible, segregate the medications used for this purpose from other drugs in the ADC.
Differentiate epidural bags.	If possible, use a different size or shape container for epidural analgesia to differentiate it from IV medications used in obstetrics during labor. For example, provide epidural medications in syringes for administration via a syringe pump if no other medications are administered via a syringe pump on the obstetrical unit.
Apply warning stickers.	Apply a large warning sticker in a unique color (e.g., yellow) on both sides of the epidural bag. Apply a small warning sticker over the access port used to spike the bag.
Reduce interruptions when carrying out medication administration.	***Quiet zone.*** Establish a quiet zone for preparing medications. Advise the patient and family when the nurse needs to move to the quiet zone so that patients and families understand that minimizing unnecessary interruptions is important for safety. Except in urgent/emergent situations, prepare medications in the quiet zone, not at the bedside. ***Supplies in procedural kits.*** Ensure that procedural kits related to the birthing process contain all the necessary equipment and supplies, eliminating the need for staff to leave the bedside to search for items.
Reduce the risk of staff fatigue.	Establish maximum work hours per day/week that are allowed (e.g., 12 hour/24-hour period, 60 hours/week, minimum of 8 hours between all shifts) for direct caregivers.‡
Establish independent double-checks.	Establish a system of independent double-checks between anesthesia staff and the primary nurse to verify the epidural medication before administration. *(A double-check process as stated would not have prevented the sentinel event. The nurse thought she was hanging penicillin, not an epidural medication, so she would not have sought out an independent double-check. However, enhancing safeguards with epidural medications should heighten staff attention when preparing and administering this high-alert medication.)*
Apply an identification band before drug administration.	Assign responsibility to the charge nurse to bring admission paperwork and the patient's identification bracelet to newly admitted patients' rooms as soon as they are available. Require application of the identification band *before* nonemergent medications are administered so the patient's identity can be verified properly using two unique identifiers (and an available POC bar-coding system can be employed).
Consider a medication error in the differential diagnoses.	Assign a professional (generic position such as a pharmacist or nursing supervisor, not an actual individual) who responds to codes/rapid response calls to evaluate the medications and solutions the patient has received in the prior 24 hours and investigate the possibility of a medication error if the patient has an unanticipated deterioration in condition.
Establish bupivacaine toxicity treatment protocols.	Establish protocols to identify and treat bupivacaine toxicity, and make them available on code carts and other key treatment areas as a reference where the medication might be utilized.§
Use less-toxic drugs.	Consider potential use of alternative, less toxic, anesthetics to replace bupivacaine.

* OR, operating room; ADC, automated dispensing cabinet; POC, point-of-care.

† King H.B., et al.: Team STEPPS: *Team Strategies and Tools to Enhance Performance and Patient Safety.* Jun. 2008. Agency for Healthcare Research and Quality, http://www.ahrq.gov/downloads/pub/advances2/vol3/Advances-King_1.pdf (last accessed Feb. 10, 2010).

‡ See Appendix 1. Hours of Work Scheduling and Staffing Framework (available in online article).

§ Rosenblatt M.A., et al.: Successful use of a 20% lipid emulsion to resuscitate a patient after a presumed bupivacaine-related cardiac arrest. *Anesthesiology* 105:217–218, Jul. 2006; Weinberg G.: Lipid infusion resuscitation for local anesthetic toxicity: Proof of clinical efficacy. *Anesthesiology* 105:7–8, Jul. 2008; Warren J.A., et al.: Intravenous lipid infusion in the successful resuscitation of local anesthetic-induced cardiovascular collapse after supraclavicular brachial plexus block. *Anesth Analg* 106:1578–1580, May 2008; Institute for Safe Medication Practices (ISMP): IV lipid emulsion for bupivacaine toxicity. *ISMP Medication Safety Alert!* 11(25):3, 2006.

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Table 6. Recommendations for Organizations with Point-of-Care (POC) Bar-Coding Systems*

Recommendation	Details
Educate patients about bar-coding technology.	As part of the admission process, educate patients and families about the bar-coding system. Tell them to expect nurses to use the scanner before all medications are administered, including IV or epidural medications. Encourage patients to speak up if identification bands have not been applied or scanned before medication administration.
Use compliance reports to drive improvements.	Review periodic scanning-compliance reports. If the data show a problem with noncompliance, have the unit manager speak with the involved nurses to uncover the underlying reasons. Plan and implement changes that will reduce the frequency of software or hardware problems that have led to bypassing the technology. Measure compliance rates over time to determine if actions are successful.
Conduct an FMEA.	Conduct an FMEA related to use of the bar-coding technology to uncover and address additional problems that have not yet been addressed.
Remedy scanning problems.	Remedy issues with scanning problematic medication containers (e.g., clear plastic IV bags) so that they can be read consistently and accurately.

* FMEA, Failure Mode and Effects Analysis; IV, intravenous.

Table 7. Recommendations for Organizations Planning Point-of-Care (POC) Bar-Coding Systems*

Recommendation	Details
Conduct an FMEA and a readiness assessment.	Commission interdisciplinary teams of staff to conduct FMEAs related to implementation of bar-coding technology, taking into consideration any unique needs of each unit. Also have the teams complete the ISMP's *Readiness Assessment for a Bedside Bar-Coding Drug Administration System.*† Use the findings from the FMEAs and readiness assessment to identify targeted areas for improvement, and begin to build the infrastructure needed to support future technology.
Provide education and implement the technology as soon as possible after training.	Plan educational programs and tutorials for staff using the findings from the FMEAs and readiness assessment and other potential barriers to bar-coding technology listed below. Ensure that the training materials provide specific, applicable examples for staff who work in diverse units. Also include potentially problematic situations and how they should be handled, such as the following: ■ Problematic bar codes (e.g., bar codes on clear plastic IV bags, wrinkled or crushed bar codes caused by the delivery system, packages with more than one bar code) ■ Use of the technology for nonstandard orders *—Administration of home medications* *—Sample medications* *—Nonformulary drugs* *—Split tablets* *—Parenteral medications with multiple ingredients* *—Doses from multiple-dose containers* *—Medications that can be given by multiple routes* *—Medications given or started only if specific conditions exist* *—Scheduled and prn orders for the same drug* *—Stat or urgent medications* ■ Equipment problems (e.g., scanner with dead batteries, scheduled and unscheduled downtime, hardware troubleshooting) ■ Work-flow issues ■ User mistakes (e.g., accidentally scanning the product twice, accidentally pressing the wrong control button) ■ Process to report problems
Provide training on return to work.	Develop a plan for providing staff who are absent during part or all of the initial phase of implementation with one-on-one training support when they return.
Plan to provide super-users.	Identify super-users who will receive more extensive training to provide "go-live" support, 24 hours/7 days week, for a minimum of 2 months.

* FMEA, Failure Mode and Effects Analysis; IV, intravenous; prn, as needed.
† American Hospital Association, Health Research and Educational Trust, Institute for Safe Medication Practices*: Pathways for Medication Safety: Readiness Assessment for a Bedside Bar-Coding Drug Administration System.* http://www.ismp.org/Tools/PathwaySection3.pdf (last accessed Feb. 10, 2010).

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Table 8. Clinical Steps Taken to Improve Safety of Medication Administration

1. Re-educating 100% of staff and new nurses on medication administration. To assess the effectiveness of this re-education, we use a medication administration competency assessment process, which includes a written test and a return demonstration on the clinical unit, developed by the clinical nurse specialist team.
2. Systematically identifying and correcting causes of inability to scan, such as half tablets, liquids, or damaged medication bar codes*
3. Implementing consistent scanning-compliance tracking and consequences if the standard is not met in a functioning system. In addition to manager review of monthly scanning compliance reports from the bar-code medication administration system, we implemented an exception-reporting process for nurses to use to indicate reasons why they were unable to scan a medication dose before administration. This information was used to systematically place a scannable bar code on all medications dispensed from the pharmacy. In addition, progressive discipline procedures were implemented for failure to scan a medication before administration, unless an appropriate exception to scanning was noted.
4. Adding a pink epidural warning label over the infusion port on epidural bags as a mechanical hard stop so that caregivers realize that this is an epidural infusion. Because this was a new practice for pharmacy, we audited a random sample of epidural bags on a weekly basis for the first 90 days after initiation and found 100% compliance with the revised procedure.
5. Changing the physician and nurse protocol for labor epidurals to specifically require an order before the nurse can retrieve the medication
6. Training of 100% of the nursing and physician staff practicing in the birth suites in TeamSTEPPS™ teamwork training†
7. Training of 100% of employees in a commercially available program on a just culture and "safe choices" when carrying out work, which is taught by members of the senior leadership team

* See Table 9.

† Agency for Healthcare Research and Quality: TeamSTEPPS™: *National Implementation*. http://teamstepps.ahrq.gov (last accessed Feb. 10, 2010).

Table 9. Most Frequent Reason Why Medications Not Scanned Prior to Administration

1. No bar code on dose
   a. Split tablet
   b. Liquid medication in syringe
   c. Barcode on outer box/wrapper discarded with first use (ointment, eye drops, inhalers)
   d. Patient's own medication; no bar code
2. Bar code damaged
   a. Bar code torn when unit dose peeled open
   b. Bar code on ointment "crimped" with successive administrations
3. Bar code hard to read with the scanner
4. To avoid system default to the next scheduled dose when the current dose is being administered beyond the acceptable time frame set in the bar-coding system
5. Patient off nursing unit; bar-code administration system not available
6. Patient registration not complete; emergency drug needed

Actions Taken

To better understand and anticipate patient safety risks, we have instituted safety systems such as the "Good Catch" program (in which staff report near misses), and a NoHARM Team (an interdisciplinary team that meets weekly to identify trends in occurrences and good-catch data), and we conduct proactive risk assessments.

Despite our best intentions, the confidence we have in a highly competent staff, and our safety systems, we also have taken additional clinical steps, as listed in Table 8 (above), to improve the safety of medication administration.

We also developed and implemented an hours-of-work policy, which defines the number of hours a nurse can work consecutively without time off (Appendix 1, available in online article).

Additional system changes (Tables 5–7) were made subsequent to the RCA, and methods for assessing compliance with revised procedures have been devised. Data reflecting compliance with these changes are periodically reported to the hospital's administrative, quality and safety, and clinical committees.

As we made these changes, one of the biggest challenges we faced was the need for rapid decision making and system redesign in the face of intense regulatory scrutiny from the Centers for Medicare & Medicaid Services (CMS) and the Wisconsin Department of Health Services. St. Mary's had spent 15 years building a shared governance model, in which staff embrace ownership for making decisions about clinical practice and systems. Therefore, staff expressed concern when they learned that leadership, in the urgency of the moment, were making decisions about clinical practice and system redesigns without their input. For example, counter to our culture of staff ownership and shared governance, we developed the exception-report process for failure to scan a medication dose before administration (Item 3, Table 8) without consulting the nursing practice council or the housewide medication process improvement team. In the intervening three years, we have attempted to restore the staff's sense of trust in shared governance through our housewide shared-decision-making model. This model—Whole Systems Shared Decision Making (WSSDM)—includes five systems-level councils: operations, education, patient care, quality improvement and safety, and coordinating. Membership for each council is drawn from staff, managers, and senior leaders working together in partnership to fulfill the mission of the organization and the trust our patients and community place in us.

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Conclusion

St. Mary's Hospital's day-to-day reality includes constant recognition of patient safety as a guiding principle and reflection point. Patient safety isn't a program; it is the foundation on which we need to base all that we do. We take nothing for granted, and although we practice in a culture of trust, we must consistently verify that our systems are being safely designed and used in the way intended. Our patients, families, and colleagues deserve our watchfulness and our commitment to getting every detail of care right. J

Panel Members: Chris Baker, R.N., Ph.D., F.A.C.H.E, Administrative Director/Quality & Safety Systems; Joan Ellis Beglinger, R.N., M.S.N., M.B.A., F.A.C.H.E., F.A.A.N., Vice President for Patient Services; Frank Byrne, M.D., F.A.C.H.E., President; Carla Griffin, R.N., M.S.N., Director/Birth Suites; Peggy Weber, R.N., M.S.N., Parish Nurse (on the panel because she provided Critical Incident Stress Debriefing for hospital and physician staff after the event); all from St. Mary's Hospital.

Judy Smetzer, R.N., B.S.N., is Vice President, Institute for Safe Medication Practices (ISMP), Horsham, Pennsylvania. **Christine Baker, R.N., Ph.D.,** is Administrative Director, Quality and Safety Systems; and **Frank D. Byrne, M.D.,** is President, St. Mary's Hospital, Madison, Wisconsin. **Michael R. Cohen, R.Ph., M.S., Sc.D.,** is President, ISMP. Please address correspondence to Judy Smetzer, jsmetzer@ismp.org.

Online-Only Content

See the online version of this article for

Figure 1. Photos of the Intravenous (IV) Bags

Appendix 1. Hours of Work Scheduling and Staffing Framework

References

1. Green M.: *"Inattention blindness" & Conspicuity.* 2009. http://www.visual-expert.com/Resources/inattentionalblindness.html (last accessed Feb. 10, 2010).

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Figure 1. Photos of Intravenous (IV) Bags

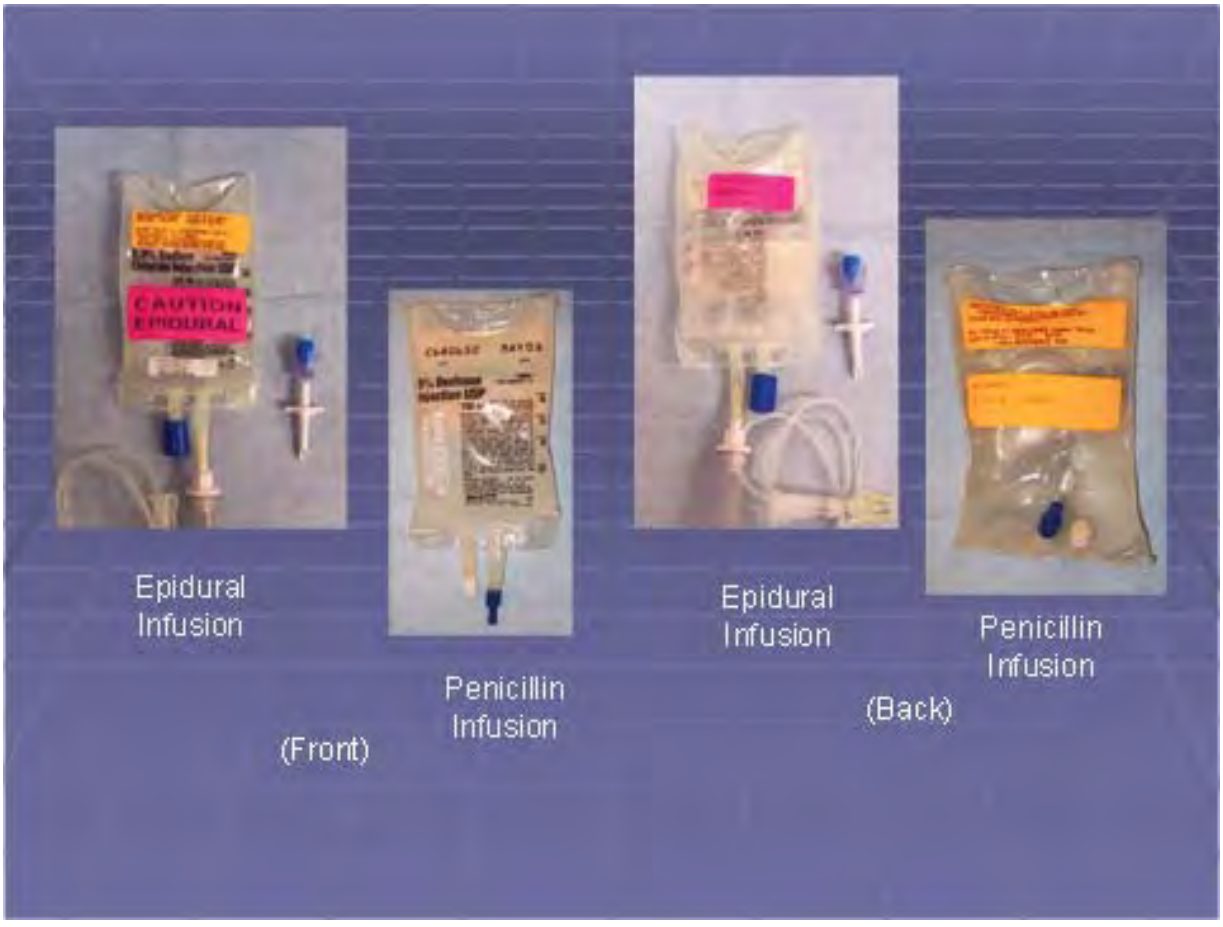

Figure 1. *The epidural and IV (penicillin) medications were in the same-size containers, and both had orange pharmacy-applied labels; the pink warning labels on the epidural bag helped to differentiated the products but were overlooked, reflecting inattentional blindness.*

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Appendix 1. Hours of Work Scheduling and Staffing Framework

Purpose: This framework has been developed to guide scheduling and staffing practices for clinical staff who are involved in direct patient care. It is understood that this is a complex issue and absolute rules may inadvertently detract from the safety of the environment. We will continually strive to balance the community's need for acute care services, availability of adequate numbers of clinical professionals, and scheduling practices that reflect reasonable limits on clinical staff work hours. We will monitor our adherence to this framework, evaluate situations in which we are unable to practice as defined, and work to develop system changes that help us to continue to balance the needs of the patients and clinical staff. This framework defines our approach in meeting the daily fluctuation in demand during normal operations.

Scope: This framework applies to clinical staff who are involved in direct patient care decisions and actions. Departments included are Nursing, Medical Imaging, Laboratory, Cardiology, Respiratory Therapy, Rehabilitation Services, Pharmacy, and Patient and Family Services/Care Management.

Scheduling:

- Clinical staff will be scheduled, for direct patient care, a maximum of 12 hours in any 24-hour consecutive period.
- Staff will be scheduled in a manner intended to meet anticipated patient care needs.

When demand for patient care exceeds available clinical staff:

- Staff who are on duty and scheduled to work an 8-hour shift may be asked to stay for an additional 4 hours. Staff who are scheduled for 8 hours on the shift following the shift with a staffing need may be asked to report to work 4 hours early.
- Staff who are not scheduled to work may be called to determine their availability to fill a staffing need.
- If a staffing need cannot be met utilizing the above methods, staff who are currently working may volunteer to stay for a maximum of 16 consecutive hours of direct patient care.
- No staff member will work more than 16 hours of direct patient care in any 24-hour consecutive period.
- Staff who work 16 hours in any 24-hour consecutive period will have a minimum of 12 consecutive hours of off-duty time before returning to work.
- Clinical staff who are asked to report early, to stay after their regular shift, or to work an extra shift may decline the additional work at their discretion. Extended shifts or extra shifts will not be mandated.
- No clinical staff member should accept additional work if they are concerned that by continuing to work they could adversely affect safe patient care practices.

Call:

When departments utilize an on-call system to cover hours in the department, the on-call assignments will be distributed as equitably as practical among employees. The call structure will meet the patient care needs of the department. The following guidelines will be followed:

- Individual departments can distribute the call hours based on patient care needs, staff preference, or department needs.
- In the event an employee is scheduled for extended call shifts (e.g., 12, 16, 24, 48 hours), the employee will not be engaged in more than 16 hours of direct patient care in a 24-hour consecutive period.
- If the staff member does work 16 consecutive hours of direct patient care, the staff member will have a minimum of 12 consecutive hours off before returning to work.
- Departments will have a structure in place to assure that the above guidelines are met.

Unforeseen Emergent Circumstances:

When a disaster or other emergent circumstance arises this framework does not apply. These circumstances include and are not limited to:

- Any declared national, state or municipal disaster or other catastrophic event.
- The implementation of the hospital's disaster plan.
- Any circumstance in which patient care needs require specialized skills throughout the completion of a procedure.

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