Problem: As we began our Thanksgiving holiday last week, we were saddened to hear the news of yet another tragic medication error that claimed the life of a 69-year-old Seattle woman, caused in large part by unlabeled basins of solution in the interventional radiology procedure room. During coil placement under cerebral angiography to repair a brain aneurysm, a patient was accidentally injected with an antiseptic skin prep solution, chlorhexidine, instead of contrast media. Both solutions were clear and available on the sterile field in unlabeled basins. The hospital's recent decision to switch antiseptics from a brown povidone-iodine solution to a clear chlorhexidine solution resulted in a latent failure - two look-alike, clear solutions on the sterile field that were previously distinguished by color. This latent failure was revealed when the unlabeled solution basins were mixed up.

During the procedure, the clear chlorhexidine solution was placed in an unlabeled basin identical to that used to hold the contrast media. Neither basin was labeled, so both solutions looked exactly the same. At the end of the procedure, contrast media was supposed to be injected into the patient's artery for radiographic visualization. Unfortunately, the chlorhexidine was drawn into the syringe, and the patient received the antiseptic, which is highly toxic when injected intravascularly. Within 2 hours, the patient suspected that something was very wrong. Acute, severe chemical injury to the blood vessels of the leg restricted circulation to the muscles, causing profound injury and swelling of her leg. During the following 2 weeks, the patient's condition deteriorated. She underwent a leg amputation, and then suffered a stroke and multiple organ failure, which led to her death.

What went wrong during the procedure was detailed in a staff memo from the hospital's quality committee and chief of medicine, and was subsequently released to the public (and posted on its website) in what the Seattle news media described as an "unusual step of publicly explaining, and apologizing for, the error." According to hospital leaders, the decision to publicly disclose the error was part of a broader initiative started 5 years ago to create a culture of safety and to make harmful medical errors more transparent. The apology states that, while no single individual is responsible for the tragedy, the mistake is due to a larger systems problem that allowed two clear solutions to be confused, for which all hospital staff assume responsibility. The apology further states, "Talking about these issues openly is painful and difficult, but only in doing so can we acknowledge the reality of the flawed systems that exist in healthcare today - and arm ourselves with information to do something about it." Apparently, these are not hollow words intended to placate the patient's family and the public; according to the Washington Department of Health, the hospital has been commendable with reporting adverse events during the past 3 years. The patient's family also reports that they've been treated well, and that they appreciate the hospital's full disclosure of the error.

Unlabeled medications and solutions on the sterile field have caused many other errors, some with tragic outcomes. One of our earliest reports appeared in the July 1989 Medication Error Reports column in the journal Hospital Pharmacy. A news reporter for the Miami Herald died during a surgical procedure to remove a cancerous eye.
An unlabeled specimen cup filled with glutaraldehyde, to preserve the patient's enucleated eye, was misidentified as spinal fluid that had been removed to reduce cerebral pressure because the malignancy had spread to the brain. The spinal fluid was in an identical unlabeled cup. Near the end of the procedure, an anesthesiologist accidentally injected the glutaraldehyde intrathecally, believing it was the patient's spinal fluid. In our June 18, 1997 newsletter, we reported several errors in which unlabeled cups or basins on the sterile field led to errors. In one case, the patient was injected with hydrogen peroxide instead of lidocaine for local anesthesia, but suffered no adverse reaction. Three other cases involved errors with unlabeled medication or solution containers in settings outside the operating room (OR). One patient received lidocaine instead of contrast media during angiography, leading to a grand mal seizure. In a similar setting, contrast media was infiltrated around an injection site instead of lidocaine for local anesthesia just prior to angiography. Local tissue damage resulted. Another patient being treated in a hospital-based physician's office sustained severe burns to his genitals when the physician mistakenly applied TBQ (a cationic germicidal detergent with a pH of 13) from an unlabeled bottle, believing it contained vinegar, which was needed to bleach the wart to improve visibility.

Let these and the most recent tragic error serve as a loud wake-up call to remedy risks with unlabeled medications and solutions on the sterile field. While you may not have experienced a serious sentinel event despite poor labeling practices, you shouldn't wait until a patient is harmed in your facility to take action. Lest you think the problem is limited to just a few hospitals, recent findings from the 2004 ISMP Medication Safety Self Assessment, gathered from more than 1,600 hospitals, show that less than half (41%) always label containers (including syringes, basins, or other vessels used to store drugs) on the sterile field, even when just one product or solution is present. Eighteen percent do not label medications and solutions on the sterile field at all, and another 42% apply labels inconsistently. Although this represents an improvement from the 2000 findings (25% reported full labeling; 24% reported no labeling), surprisingly, this rather basic safety measure is not widely implemented in hospitals. This is particularly disturbing because patients undergoing a surgical procedure cannot intervene on their own behalf. They are typically sedated or anesthetized, and thus, feel more vulnerable to errors at this time.

**Safe Practice Recommendation:** Develop and implement policies and procedures for safe labeling of medications and solutions used in perioperative settings, including traditional ORs, ambulatory surgery units, labor and delivery rooms, physicians' offices, cardiac catheterization suites, endoscopy suites, radiology departments, and other areas where operative and invasive procedures may be performed. For reference, consider the following recommendations, most of which are mentioned in the Association of PeriOperative Registered Nurses (AORN) recently published Guidance Statement: Safe Medication Practices in the Perioperative Practice Settings.

**Provide labels.** Make labeling easy by purchasing sterile markers, blank labels, and preprinted labels prepared by the facility or commercially available that can be opened onto the sterile field during all procedures. To minimize staff time, prepare surgical packs ahead of time with sterile markers, blank labels, and preprinted labels for all anticipated medications and solutions that will be needed for the case. (Since providing labels that can be used effectively on basins and syringes in the sterile field can be challenging, please contact us if you would like to share your successful ideas with others.)

**Require labels.** Require labels on all medications, medication containers (e.g., syringes, medicine cups, basins), or other solutions on and off the sterile field, even if there is only one medication or solution involved. Also require labels on all solutions, chemicals, and reagents (e.g., formalin, saline, Lugol's solution, radiographic contrast media, etc.) that are used in the perioperative units.

**Differentiate look-alike products.** If drug or solution names are similar, use tall man lettering on the labels to differentiate them, or highlight/circle the distinguishing information on the label. When
possible, purchase skin antiseptic products in prepackaged swabs or sponges to clearly differentiate them from medications or other solutions and eliminate the risk of accidental injection.

Label one at a time. Individually verify each medication and complete its preparation for administration, delivery to the sterile field, and labeling on the field before another medication is prepared. Verify any medication listed on the physician's preference list with the physician before delivery to the sterile field, labeling, and/or administration.

Confirm medications and labels. Require the scrub person and the circulating nurse to concurrently verify all medications/solutions visually and verbally by reading the product name, strength, and dosage from the labels. (If there is no scrub person, the circulating nurse should verify the medication/solution with the licensed professional performing the procedure.) When passing a medication to the licensed professional performing the procedure, visually and verbally verify the medication, strength, and dose by reading the medication label aloud. Keep all original medication/solution containers in the room for reference until the procedure is concluded.

Re-verify with relief staff. At shift change or relief for breaks, require the entering and exiting personnel to concurrently note and verify all medications and their labels on the sterile field.

Discard unlabeled medications. Don't assume that you know what is contained in an unlabeled syringe, cup, or basin. Discard any unlabeled solution or medication found in the perioperative area (including the sterile field) and report the event as a hazardous condition. Nothing should leave the hand unless it is labeled.

Conduct walk-arounds. Perform regular safety rounds in perioperative areas to observe labeling procedures, promote consistency, and inquire about barriers to implementing this important safety practice.

Pharmacy presence in the OR. While an OR is sometimes considered "foreign ground" for a pharmacist, establishing close ties between pharmacists and the OR staff (via satellites or regular on-site presence) could help spur practice changes that are needed to improve labeling on the sterile field.

Enhance awareness. Tell memorable stories to perioperative staff about tragic mix-ups that have occurred in other facilities when medications and solutions were unlabeled on the sterile field to help motivate practice changes. A multidisciplinary perioperative safety team comprising nurses, technicians, pharmacists, and physicians from various sites where invasive procedures are performed might also help to improve consistent labeling as well as enhance interdisciplinary relationships.

Oversight from external agencies. Accrediting, regulatory, and standard setting agencies should consider safe labeling practices in perioperative settings when developing national patient safety goals and initiatives.