A Loud Wake-up Call
Unlabeled Containers Can Lead to Fatalities
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Problem: During a procedure for a coil placement in a female patient undergoing cerebral angiography to repair a brain aneurysm, clear chlorhexidine solution was placed in an unlabeled basin identical to a container used to hold contrast medium. Neither basin was labeled, so both solutions looked exactly the same. At the end of the procedure, contrast medium was to have been injected into the patient’s artery for radiographic visualization. Unfortunately, chlorhexidine was drawn into the syringe; the patient received the antiseptic, which is highly toxic when it is injected intravenously.

Within two hours, the patient suspected that something was very wrong. Acute, severe chemical injury to the blood vessels of the leg restricted circulation to her muscles, causing profound injury and swelling of her leg. During the next two 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.

The hospital’s recent decision to switch antiseptics from a brown povidone–iodine solution to a clear chlorhexidine solution resulted in an error that was not immediately apparent—two look-alike, clear solutions on the sterile field (the area immediately around a patient that has been prepared for a surgical procedure) that had previously been distinguished by color. This latent failure was revealed when the unlabeled solution basins were mixed up.

Unlabeled medications and solutions on the sterile field have caused many other errors, some with tragic outcomes. One of our earliest reports at the Institute for Safe Medication Practices (ISMP) appeared in 1989 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, which had been intended 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.

The ISMP reported several errors in which unlabeled cups or basins on the sterile field led to errors. In one case, the patient received an injection of hydrogen peroxide instead of lidocaine for local anesthesia. Fortunately, the patient experienced no adverse drug reactions.

Three other cases involved errors with unlabeled medication or solution containers in settings outside the operating room. One patient received lidocaine instead of contrast medium during angiography, leading to a grand mal seizure. In a similar setting, contrast medium instead of lidocaine was infiltrated around an injection site for local anesthesia just prior to angiography, and 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 T.B.Q. Environmental Disinfectant Cleaner (Steris Corp.)—a cationic germicidal detergent with a pH of 13—from an unlabeled bottle. The physician thought that the bottle contained vinegar, which was needed to bleach the wart to make it more visible.

These mishaps and the most recent tragic error should serve as a warning to minimize risks with unlabeled medications and solutions on the sterile field. Although many health care professionals might have not experienced a serious sentinel event despite poor labeling practices, no one should wait until a patient is harmed before taking action.

Safe Practice Recommendation: Policies and procedures for safe labeling of medications and solutions used in perioperative settings must be developed and implemented in traditional operating rooms, ambulatory surgery units, labor and delivery rooms, physicians’ offices, cardiology centers, and endoscopy suites, radiology departments, and other areas where invasive surgery may be performed. The Association of PeriOperative Registered Nurses (AORN) has issued some recommendations:

1. Labels should be provided for all medications and solutions.
   a. Staff personnel can easily accomplish this step by purchase and labeling, which can then be purchased and labeled by the facility or can be purchased. They should be able to be opened onto the sterile field during all procedures.
   b. To minimize staff time, surgical packs can be prepared ahead of time with these markers and labels for all anticipated medications and solutions that will be needed for each case.

2. Labels should be required.
   a. All drugs, medication containers (such as syringes, medicine cups, and basins) and solutions should be labeled on and off the sterile field, even if only one product is involved.
   b. Labels should also be required on all solutions, chemicals, and reagents (e.g., formalin, saline, Lugol’s solution, and radiocontrast media) that are used in perioperative units.

3. Look-alike products must be differentiated from each other.
   a. If the names of a drug and another solution are similar, “tall man” lettering should be applied to these labels so that all staff members can easily distinguish one product from the other; alternatively, the distinguishing information on the label can be highlighted or circled.
   b. When possible, antiseptic products for the skin should be purchased in prepackaged swabs or sponges to clearly continue on page 732
differentiate them from medications or other solutions and to eliminate the risk of accidental injection.

4. **All medications and labels should be confirmed.**
   a. The scrub person and the circulating nurse should be required to verify all medications or solutions visually and verbally by reading the product name, strength, and dosage from the labels.
   b. If there is no scrub person, the circulating nurse should verify the medication or solution with the licensed professional who will be performing the procedure.
   c. When the person passes the medication to the licensed professional who will be performing the procedure, he or she should visually and verbally verify the medication, its strength, and the dose by reading the medication label aloud.
   d. All original containers of medications and solutions should be kept in the room for reference until surgery is completed.

5. **Unlabeled medications should be discarded.**
   a. Staff members should not assume that they know what is contained in an unlabeled syringe, cup, or basin.
   b. All unlabeled solutions or medications found in the perioperative area (including the sterile field) should be discarded.
   c. If an unlabeled product is found, this event should be reported as a hazardous condition.
   d. No unlabeled drugs or solutions should leave anyone’s hands.

6. **Walk-arounds should be conducted.** Staff members should conduct regular safety rounds in perioperative areas so that they can observe labeling procedures, promote consistency, and ask about any barriers to implementing this important safety practice.

7. **More pharmacy personnel should be present in the operating room.** Although operating rooms are sometimes considered off limits for pharmacists, establishing close ties between pharmacists and the operating team (via satellite or by in-person visits) may help spur necessary practice changes to improve labeling on the sterile field.

8. **Perioperative staff members should be apprised of errors involving unlabeled products.**
   a. To encourage practice changes and to enhance awareness, staff members should inform perioperative personnel about tragic mix-ups that have occurred in other facilities when medications and solutions were unlabeled on the sterile field.
   b. A multidisciplinary perioperative safety team that includes 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.

**REFERENCE**


The reports described in this column were received through the USP–ISMP Medication Errors Reporting Program (MERP). Errors, close calls, or hazardous conditions may be reported on the ISMP Web site (www.ismp.org) or the USP (www.usp.org) Web site or communicated directly to ISMP by calling 1-800-FAILSAFE or via e-mail at ismpinfo@ismp.org.