ISMP Medication Error Report Analysis

No Unlabeled Containers Anywhere, Ever!

Where Did This Come From?

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These medication errors have occurred in health care facilities at least once. They will happen again—perhaps where you work. Through education and alertness of personnel and procedural safeguards, they can be avoided. You should consider publishing accounts of errors in your newsletters and/or presenting them at your inservice training programs.

Your assistance is required to continue this feature. The reports described here were received through the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program. Any reports published by ISMP will be anonymous. Comments are also invited; the writers' names will be published if desired. ISMP may be contacted at the address shown below.

Errors, close calls, or hazardous conditions may be reported directly to ISMP through the ISMP Web site (www.ismp.org), by calling 800-FAIL-SAFE, or via e-mail at ismpinfo@ismp.org. ISMP guarantees the confidentiality and security of the information received and respects reporters' wishes as to the level of detail included in publications.

NO UNLABELED CONTAINERS ANYWHERE, EVER!

Just when you think you've made significant headway with a persistent unsafe practice, an error creeps up and disappointment sets in. The error serves to remind you just how vulnerable patients are to human error and to expose the fact that strategies you may have thought were in place to prevent the error are either ineffective or not implemented in all areas of the organization. Take for example an error that involved the mix-up of 2 solutions in unlabeled containers on a sterile field. The strategies required to prevent these errors are straightforward and relatively simple — accurate and complete labeling of containers for all solutions and medications on the sterile field, in every procedural area, every time. This applies not only to the operating room (OR) and anesthesia, but also to the holding area and postanesthesia care unit and to other procedural areas including ambulatory surgery, radiology, invasive cardiac labs, labor and delivery rooms, emergency department, endoscopy units, treatment rooms, and patient care units where procedures may occur at the bedside.

In a recently reported event, a woman undergoing a stereotactic breast biopsy in a procedural area outside of the OR had her breast injected with formalin instead of lidocaine 1%. Both the lidocaine, intended for local anesthesia, and the formalin, intended to preserve the extracted breast tissue, were placed in basins on the same tray to be used by the physician during the case. Neither basin was labeled to identify its contents. The physician inadvertently drew up formalin instead of lidocaine and injected it into the patient's breast. The patient complained of severe pain following the injection, and the physician quickly realized the error. The biopsy was stopped and rescheduled, and the patient recovered. During investigation of the error, the root cause analysis team determined that formalin does not belong in a basin on the sterile field at the beginning of any procedure and could be provided outside the sterile field in a container once the specimen has been extracted.

One of our earliest efforts to draw attention to unlabeled containers appeared in the July 1989 Medication Error Reports column in *Hospital Pharmacy*.

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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 the spinal fluid that had been removed to reduce cerebral pressure during the procedure. 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.

Early in the inaugural year of ISMP's acute care newsletter (January 31, 1996), we reported the death of a 7-year-old boy during what should have been routine surgery to remove scar tissue and a benign tumor from his left ear. The child accidentally received an injection of undiluted epinephrine injection instead of lidocaine with epinephrine 1:100,000 due to mislabeled specimen cups on the sterile field. This tragic story was featured in our short documentary film, *Beyond Blame* (www.ismp.org/sc?id=440), which describes how medication errors affect practitioners and patients. One of the film's stand-out scenes features the anesthesiologist present during the event saying, "Now I will bet any dollar that I have, that this has happened before, multiple times, same type of scenario, and I'll bet it's going to happen again." Well, he was right! Since then, ISMP and others have repeatedly published cases of mix-ups between unlabeled solutions or medications on the sterile field, including but not limited to the following examples:

- A woman was injected with hydrogen peroxide instead of lidocaine 1% for local anesthesia when both were on the sterile field in unlabeled cups. The patient suffered no adverse reaction (www.ismp.org/sc?id=443).
- A man was injected with lidocaine 2% instead of contrast media during angiography; both were on the sterile field in unlabeled syringes. He suffered a grand mal seizure but recovered (www.ismp.org/sc?id=443).
- A caustic germicidal solution (pH of 13) was mistakenly applied to the genitals of a 37-year-old male patient instead of vinegar during surgical removal of genital warts, causing severe burns (www.ismp.org/sc?id=443).
- A patient's face was injected with ethyl alcohol instead of lidocaine prior to a surgical procedure. Both of the clear solutions were in unlabeled basins. The patient suffered partial facial paralysis (www.ismp.org/sc?id=445).

- A patient had an injection site infiltrated with contrast media from an unlabeled basin instead of lidocaine for local anesthesia prior to angiography. Local tissue damage resulted (www.ismp.org/sc?id=443).
- A 60-year-old woman undergoing coil placement via cerebral angiography to repair a brain aneurysm was accidentally injected with the skin prep solution, chlorhexidine, instead of contrast media. Both clear solutions were on the sterile field in unlabeled basins. Severe chemical injury to the injection site in the patient's groin led to leg amputation, which resulted in a stroke, organ failure, and death (www.ismp.org/sc?id=444).
- A patient under general anesthesia had his knee injected with epinephrine found in an unlabeled syringe on an OR prep table, which was mistaken for bupivacaine. The patient experienced a heart attack, pulmonary edema, and died (www.ismp.org/sc?id=441).

High-profile cases like these and the national attention given to unlabeled medication and solution containers by The Joint Commission, the Centers for Medicare & Medicaid Services, the US Food and Drug Administration, ISMP, and others suggest that most health care professionals have basic knowledge of the risks associated with unlabeled containers. Thus, repetition of this error suggests that health care providers have lost the perception of risk associated with unlabeled products, mistakenly believe the risk is insignificant or justified, or have forgotten to implement effective prevention strategies in all procedural areas. First, *normalcy bias* may cause some to falsely believe that an error will never happen to them. This leads to the mistaken belief that labeling is not always necessary or the rationalization of faulty strategies. These faulty strategies may include identifying products by where they are placed on the sterile field and overreliance on immediate use before the container leaves one's hands. Or, unlabeled containers may be considered "someone else's problem," a phenomenon similar to bystander apathy that causes people to ignore a problem because they believe it is not relevant to them, unlikely to happen, something they can't fix, or someone else's responsibility to fix. Additionally, some may believe they have implemented the perfect labeling procedures only to find partial compliance because the task is tedious, error-prone, or impractical without system changes.

Results from the 2011 ISMP Medication Safety Self Assessment for Hospitals ($N = 1,310$ hospitals)

showed that 1% of participating hospitals never labeled containers of solutions or medications on the sterile field, 24% labeled containers inconsistently, and only 73% reported full compliance with this important safety practice. Compliance may not be significantly better today, 3 years later.

Will the next victim be in your hospital? Or, will you improve your labeling practices? Although 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. Consider the following:

Provide labels. Make labeling easy by purchasing sterile markers, blank labels, and preprinted labels prepared by the facility or a commercial vendor that can be opened onto the sterile field during all procedures in all areas and used effectively on syringes, basins, bowls, and cups. 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.

Require labels. In all patient care areas, require labels on all medications, medication containers (eg, syringes, medicine cups, basins), and 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 (eg, formalin, saline, Lugol's solution, and radiocontrast media) that are used in perioperative and procedural units or in other units where procedures might be performed.

Differentiate look-alike names and 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.

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 at the time of preparation, before another medication is prepared.

Confirm medications and labels. Before preparing a medication or solution listed on a physician's preference list, verify with the physician that it will be required for the procedure and needed on the sterile field. When preparing the medication or solutions for the procedure, require the scrub person, the circulating nurse, or a second practitioner involved in the procedure 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 or other nurse should verify the medication/solution with the licensed professional performing the procedure.) During the procedure, when passing a medication to the licensed professional performing the procedure, again 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 has concluded.

Prepare and label syringes. If the solution or medication must be drawn into a syringe from a bowl or cup for use during the procedure, consider preparing the syringe immediately before use and follow the same process for labeling and verifying the product as was done when adding to the bowl. This will help prevent the accumulation of unlabeled syringes during the procedure.

Limit access. To the extent feasible, provide solutions or medications on the sterile field only as needed to limit accidental access. For example, tissue preservatives should be provided only after tissue extraction and may not require entry onto the sterile field if the cup is held by a circulating nurse as the tissue specimen is dropped into it.

Reverify with relief staff. At shift change or relief for breaks, require the arriving and departing personnel to concurrently note and verify all medications and solutions 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) or procedural areas and report the event as a hazardous condition. Nothing should leave the hand or be used unless it is labeled.

Conduct walk-arounds. Perform regular safety rounds in perioperative and procedural areas to observe labeling, promote consistency, and inquire about barriers to implementing this important safety practice. Establish close ties between pharmacists and the OR staff (via satellites or regular on-site presence) and other staff in areas where sterile procedures are performed (eg, emergency department, radiology) to help motivate practice changes that are needed to improve labeling on the sterile field.

No tolerance of unlabeled products. Tell memorable stories to staff about tragic mix-ups that have occurred in other facilities when medications and solutions were unlabeled on the sterile field to demonstrate the risk and help motivate practice changes

Policies related to patients bringing medications from home should prevent patients' use of these medications until they are first identified by a pharmacist. These medications must be stored securely and never commingled with hospital floor stock medications. Pharmacists should work with the purchasing department to develop a list of manufacturer's kits that contain medications. Before these are purchased, pharmacists should analyze their safety and test the barcodes for proper scanning when possible. Also, saving unused vials from manufacturer's kits as floor stock should be prohibited, and nurses should be provided with clear directions regarding the disposition of leftover vials. Pharmacists and nurses should be alert to the risk of medications from external sources and look for these products during routine medication storage assessments. ■