

Nurse AdviseERR®

Educating the Healthcare Community About Safe Medication Practices

Strengthen your resolve: 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. This time, the error involved the mix-up of two solutions in unlabeled containers on a sterile field. The strategies required to prevent this type of error 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 post-anesthesia care unit, and to other procedural areas including ambulatory surgery, radiology, invasive cardiac labs, labor and delivery rooms, emergency department, endoscopy units, treatment rooms, as well as patient care units where procedures may occur at the bedside.

In the recently reported error, 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 recommended that, in the future, 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 ISMP's earliest efforts to draw attention to unlabeled containers 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 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.

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check *it* out

To prevent errors with unlabeled containers, consider implementing the following recommendations.

✓ **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 (e.g., syringes, 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 (e.g., formalin, saline, Lugol's solution, 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.

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to the point | Kudos to nurses!

➔ **Nurses have again earned top honors in the annual Gallup poll on honesty and ethical standards when compared to other professions. Nurses ranked highest (80%) among the professions included—15 points higher than both pharmacists and medical doctors, who were tied for second place (www.ismp.org/sc?id=467).**

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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 **EPINEPH**rine injection instead of lidocaine with **EPINEPH**-rine 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 alike. One of the film's memorable 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 **EPINEPH**rine 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 healthcare professionals have basic knowledge of the risks associated with unlabeled containers. Unfortunately, repetition of this error also suggests that healthcare 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 would 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

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✓ **Confirm need.** 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.

✓ **Confirm medications during preparation.** 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.)

✓ **Reconfirm medications before use.** 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.

✓ **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.** Discard any unlabeled solution or medication

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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, 4 years later.

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Worth repeating...

Water for inhalation confused as IV solution

An emergency medical services (EMS) response team caring for a patient who had suffered a cardiac arrest accidentally began infusing a 1,000 mL bag of sterile water for inhalation instead of an IV solution. Given in substantial quantities, hypotonic sterile water solution can cause hemolysis and result in serious patient harm, including death. Fortunately, the patient was quickly transported to an emergency department (ED) where the ED staff noticed the error and replaced the bag of sterile water with 0.9% sodium chloride for injection. It is uncertain how the sterile water for injection found its way into the pre-hospital ambulance storage area reserved for IV solutions.

This was the second of two reports we received involving CareFusion sterile water for inhalation. The CareFusion sterile water for inhalation flexible bags (**Figure 1**) look very similar to IV solutions in 1,000 mL flexible bags, with similar black printing on the labels. While the word "inhalation" appears various times on the label, it is easy to misidentify the sterile water for inhalation as a standard IV solution, especially in an emergency situation.



Figure 1. Sterile water 1,000 mL bag for inhalation (CareFusion) looks similar to 1,000 mL IV solutions.

ISMP first wrote about this type of error in our January 2004 newsletter. Since then, we have periodically learned of other errors, involving other manufacturers, including an event in 2011 in which an inpatient received a large quantity of sterile water for inhalation instead of lactated ringer's solution. This patient was not receiving high-flow oxygen treatments nor on a ventilator—conditions that might warrant the use of respiratory sterile water. However, respiratory staff were using the sterile water bags for another ventilated patient on the unit, and a bag of sterile water was misplaced in the storage area with IV solutions.

If your hospital uses sterile water for inhalation, consider using rigid plastic bottle containers or 2,000 mL bags to better differentiate the sterile water and traditional IV bags containing 1,000 mL. Also review the need for ventilators in your facility that require humidification via infusion of sterile water.

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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.


✓ **Communicate expectations.** Be clear with staff that labeling all products on the sterile field is a duty you expect all clinicians to uphold, and if circumstances arise where this strategy cannot be implemented, they must report it immediately.

✓ **Confirm competency.** Include accurate and complete labeling of all medications and solutions in the sterile field as a core competency in initial and ongoing performance evaluations.

✓ **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.

✓ **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 that ensure accurate and complete labeling.

SAFETY wire

 **Glucagon label contributes to confusion.** A nurse gave orange juice to a patient with a blood glucose level of less than 50 mg/dL, but it did not raise the glucose level much, so he administered a dose of IV **GLUCAGON EMERGENCY** (glucagon) per policy. When the patient's blood glucose was checked about 30 minutes later, the glucose level was still less than 50 mg/dL. Orange juice was given again, but 20 minutes later, the patient's glucose level remained less than 50 mg/dL. Another glucagon injection was given, which raised the blood glucose into the 50s. More oral carbohydrates were given until, finally, the patient's blood glucose returned to normal.

Later, the nurse who administered the glucagon injections mentioned that he had continued on page 4—**SAFETY wire** >

VARIZIG dilution problems reported

An issue came to our attention regarding varicella zoster immune globulin (VARIZIG), indicated for post-exposure prophylaxis against chickenpox in high-risk individuals, such as children and adults who are immunocompromised. The product is available as a kit (Figure 1) that contains a single vial of diluent along with a vial of 125 units of lyophilized powder (labeled as IU for international units, which is an unsafe and unnecessary expression that is sometimes misread as IV). The diluent is packaged as a single-dose vial containing 8.5 mL. VARIZIG is approved in the US for IM use only but approved in Canada for IM or IV use. According to the US label, only 1.25 mL of diluent is needed to reconstitute the 125 unit vial for IM use, resulting in a solution of 100 units per mL. In Canada where IV use is approved, 2.5 mL of diluent must be added to the vial. But in neither case should the full volume of diluent—8.5 mL—be used.

Recently, in a US hospital emergency department (ED), a 5-year-old pediatric patient was to receive 125 units IM. However, a nurse misunderstood the instructions and used the entire volume of diluent (8.5 mL) to reconstitute the product. Rather than waste the dose, the nurse decided to divide the dose into two 3 mL injections and one 2.5 mL injection—for a total of 3 IM injections, which is bound to be traumatizing, particularly for a 5-year-old child. It is unclear why the instructions were misunderstood, but since only a fraction of the diluent (1.25 of the 8.5 mL) is necessary, it is likely that the packaging contributed to the error. We could also foresee a situation where the entire diluent is used to reconstitute the powder, and the practitioner assumes this provides the labeled 100 units per mL concentration, which would lead to a subtherapeutic dose.



Figure 1. Lyophilized VARIZIG and diluent.

The product is distributed in the US by Emergent Biosolutions and manufactured by its subsidiary, Cangene Biopharma, in Canada. According to Emergent Biosolutions, the diluent vial presently contains 8.5 mL because higher doses were originally used in Canada, and stability studies were conducted with larger diluent volumes. The company told us that Cangene has a new liquid form of the drug under development that will not require reconstitution. For now, if you stock the lyophilized product, consider adding an auxiliary label reminding practitioners to reconstitute with 1.25 mL per 125 unit vial, which provides 100 units per mL, and then to discard the remaining diluent.

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So, the question is, will the next victim be in your hospital? Or, will you improve your labeling practices? 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. Consider the recommendations in the **check it out** column (starting on page 1, right column) to help prevent these errors from occurring in your organization.

Pass this article on to risk managers; OR, emergency department, and radiology managers; and other appropriate individuals and leadership in your organization for action.

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administered a dose measured in units because the label on Lilly's Glucagon Emergency Kit (Figure 1) and vial indicates the dose is "1 mg (1 unit)." The nurse was new and had never administered glucagon. He said he used a U-100 insulin syringe to administer the 1 unit dose each time. He did not realize that "1 unit," in this case, meant a full mg as indicated by the marking on the syringe contained in the kit. The patient had received only 1/100 of the required dose, even though a pharmacy label on the product said, "Inject 1 mg (1 unit) subcutaneously every 15 minutes as needed if blood glucose is less than 60 mg/dL and patient unable to take glucose products by mouth." Apparently, the nurse became confused when he saw "1 unit" and used an insulin syringe to measure each dose.



Figure 1. Lilly's Glucagon Emergency kit.

While the likelihood of a similar error occurring again is small, we did ask Lilly to look at the product labeling to consider whether the dose in units is needed. **GLUCAGEN HYPOKIT** (glucagon), distributed by Novo Nordisk, lists the dose only in mg (1 mg) on the primary display panel. According to Lilly's Glucagon Emergency Kit directions, the syringe that contains the diluent is to be used to withdraw the dose (to the 1 mg mark on the syringe) and then also to inject it. Instructions can be found here: <http://pi.lilly.com/us/rglucagon-ppi.pdf>. The facility is also committed to improving staff training on the topic of glucagon administration.

If you would like to subscribe to this newsletter, visit: www.ismp.org/sc?id=384



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Safe Medication Management Fellowships

ISMP is now accepting applications for two unique Fellowship programs

ISMP Safe Medication Management Fellowship

Location and Term: The 12-month Fellowship commences summer 2015 at the Pennsylvania (near Philadelphia) office of ISMP. Relocation to the Philadelphia area is required.

Description: The Fellowship **offers a nurse, pharmacist, or physician with at least 1 year of postgraduate clinical experience** an unparalleled opportunity to learn from and work with some of the nation's experts in medication safety. Now in its 23rd year, the Fellowship allows the candidate to work collaboratively with practitioners in various healthcare settings to assess and develop interdisciplinary medication error-prevention strategies.

FDA/ISMP Safe Medication Management Fellowship

Location and Term: The 12-month Fellowship commences summer 2015. The Fellow will spend 6 months at the Pennsylvania (near Philadelphia) office of ISMP and 6 months at the Maryland (near Washington, DC) office of the US Food and Drug Administration (FDA). Relocation to the Philadelphia and Washington, DC, area is required.

Description: The Fellowship, **open to a healthcare professional with at least 1 year of postgraduate clinical experience**, is a joint effort between ISMP and FDA's Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, and Division of Medication Error Prevention and Analysis. The Fellowship allows the candidate to benefit from ISMP's years of experience devoted to medication error prevention. At FDA, valuable regulatory experience is gained by working with the division focused on medication error prevention.

A competitive stipend, 2 weeks paid vacation, and health benefits are provided with all Fellowship Programs.

How to Apply

Information and applications can be found at: www.ismp.org/profdevelopment/. Applications can also be requested by calling 215-947-7797.

Speak to ISMP's Current Fellows

Please join us on **February 11, 2015, at 2:00 p.m. ET** for a special, live conference call about the Fellowship programs. Current and past Fellows will describe their Fellowship experiences as well as their post-Fellowship careers. They will also be available to answer any questions you may have about the Fellowship. To attend, please send an email to: fellowship@ismp.org.

The application deadline for all Fellowship Programs is March 31, 2015.