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ISMP

Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Key vulnerabilities in the surgical environment: Container mix-ups and syringe swaps

Medication errors in the perioperative area received widespread media attention last week with the publication of an ahead-of-print article in the journal, *Anesthesiology*.[1] The perioperative area is one of the most medication-intensive locations in a hospital, often with more medications, particularly high-alert medications, administered per patient when compared to other patient care units. Yet, this area of the hospital often operates with fewer medication safety strategies in place than most other patient care units. For example, the anesthesia provider often selects, prepares, labels, and administers medications without the benefit of electronic clinical decision support, pharmacy review of medication orders prior to administration, barcode scanning of products prior to administration, and other secondary checks by other healthcare providers.[1,2] This lack of normal checks and balances, along with the use of multiple medications, time-sensitive tasks, complex and stressful working conditions, distractions, and fatigue all contribute to making the perioperative area particularly error-prone when medications are administered.

While there are many opportunities for anesthesia providers to make medication errors in the perioperative area, two specific tasks are especially vulnerable to errors.[3] The first task is selecting a drug container from which a medication dose must be withdrawn. The anesthesia provider could accidentally pick up the wrong vial or ampul, especially if it looks similar to another container or is placed near another medication on the anesthesia tray or cart. For example, ISMP recently reported container mix-ups between **VAZCULEP** (phenylephrine) and **BLOXIVERZ** (neostigmine) by anesthesia providers. The second task is selecting the prepared syringe for administration, which can result in a "syringe swap" in which an anesthesia provider accidentally administers the wrong medication from a different syringe than intended. Given that, in many hospitals, most anesthesia syringes are prepared in the surgical suite by the anesthesia provider, the tasks associated with selecting the medications, preparing the syringes, and administering the medications by a single practitioner can be a source of significant iatrogenic patient harm,[3] as described in the medication errors that follow.

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Warning: Don't confuse idarucizumab with IDArubicin

HIGH-ALERT

Last month the US Food and Drug Administration (FDA) granted accelerated approval to **PRAXBIND** (idarucizumab) for use in patients who take **PRADAXA** (dabigatran) and suffer a life-threatening bleeding event. Hospital pharmacies may stock Praxbind if dabigatran patients are treated in the hospital or seen in the emergency department. Unfortunately, the drug's nonproprietary name, idarucizumab, shares its first five letters with the antineoplastic drug **IDA**rubicin. This might lead to the selection of the wrong drug from a computer system dropdown menu or selection of the wrong container from its storage location, since both drugs are refrigerated solutions.

This past week we received a report of a close call at a hospital where idarucizumab was pulled from stock instead of **IDA**rubicin. The hospital had just purchased the reversal

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SAFETY briefs

Confusing volume on vial. **OBIZUR** (antihemophilic factor [recombinant], porcine sequence) was recently approved for treating patients with acquired hemophilia, a rare autoimmune disorder that occurs when the immune system produces antibodies that mistakenly attack clotting factors, most often factor VIII. The product is available as a lyophilized powder in a vial that is prominently labeled "3 mL" (**Figure 1**). The full dose in each vial is labeled nominally as 500 units. A prefilled 1 mL syringe of sterile water for injection is provided as a diluent for reconstitution. An incident with Obizur occurred recently that involved a misunderstanding about the "3 mL" notation on the vial label and how Obizur should be administered after reconstitution.

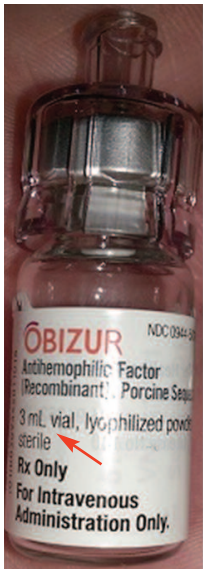

Figure 1. Vial label misled staff into believing volume after reconstitution was 3 mL.

A dose of 10,300 units had been ordered for a 51.5 kg patient (200 units per kg) during the evening with directions to administer the drug the following day. The pharmacy had never dispensed this new drug, so the pharmacists who were verifying the order and preparing the IV preparation directions for the next day weren't familiar with the drug. Observing that only 1 mL of diluent was needed to reconstitute each vial, the pharmacists incorrectly assumed that the final volume in the vial after reconstitution would swell to 3 mL given the prominent labeling of "3 mL" on each vial. While they thought this was odd,

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Medication Errors

A 68-year-old woman undergoing a total knee replacement received tranexamic acid intrathecally instead of the intended bupivacaine and morphine. The surgeon had planned to irrigate the open knee with tranexamic acid to minimize blood loss, and the anesthesiologist had intended to administer bupivacaine and morphine intrathecally for pain control. The pharmacy had dispensed 10 mL vials of both the tranexamic acid (100 mg/mL) and bupivacaine (2.5 mg/mL) to the surgical suite for staff to prepare in syringes just prior to administration (morphine was available in unit stock). The vials looked similar in size, and despite label dissimilarities, the anesthesiologist picked up a 10 mL vial of tranexamic acid believing it was bupivacaine. He added this vial to his anesthesia tray and later administered the drug intrathecally, believing he had prepared the syringe using a vial of bupivacaine. Apparently, he had quickly glanced at the label and never noticed that he had grabbed the wrong 10 mL vial when setting up the medications required for this patient's anesthesia. There was no opportunity to barcode scan the medication before preparation and administration.

The patient immediately developed myoclonus of her lower extremities and seizures. The surgical procedure was stopped, and the patient received 300 mg of intravenous (IV) fosphenytoin. She continued to experience seizures and self-terminating runs of ventricular tachycardia. She was intubated and placed on a ventilator while receiving a neuromuscular blocker. She required treatment in the intensive care unit, and after 23 days of hospitalization, the woman was finally discharged to a skilled nursing facility for physical rehabilitation.

A search of the literature easily found nearly a dozen additional foreign cases of mix-ups between tranexamic acid and bupivacaine in which tranexamic acid was inadvertently administered via the intrathecal route of administration. Four of the cases in the literature resulted in fatalities.[4-7] One fatality reported in the 2010 *Anesthesia Patient Safety Foundation (APSF) Newsletter* involved a 21-year-old woman pregnant with twins, who was scheduled for a cesarean section due to vaginal bleeding and placenta previa.[4] The anesthesiologist decided to administer spinal anesthesia and asked a technician for bupivacaine. The technician accidentally opened and handed the anesthesiologist an ampul of tranexamic acid instead of bupivacaine, which the anesthesiologist administered after confirming free flow of cerebrospinal fluid. Within minutes, the patient complained of severe pain from her waist to lower extremities. She became dysphoric and dizzy, and after emergency delivery of her twins, she required mechanical ventilation, experienced severe myoclonus and seizures, and developed tachycardia that required treatment with antiarrhythmics. She later developed ventricular tachycardia and then ventricular fibrillation refractory to treatment.

In this case, both bupivacaine and tranexamic acid were available in look-alike containers with the same volume of medication and red font print on the label. While tranexamic acid was not typically used in the surgical suite, it had been used several weeks prior to the event to control nonobstetric bleeding. Residual, unused product had been added to the medication supplies instead of sending it back to the pharmacy.

Another fatal error happened while performing spinal anesthesia on a 55-year-old woman undergoing orthopedic surgery.[7] Tranexamic acid rather than bupivacaine was injected intrathecally, and the patient experienced immediate, severe burning pain in her lower extremities. She subsequently developed myoclonic twitching of the facial muscles, hypotension, and became unconscious. She was intubated and mechanically ventilated but died after 10 hours due to ventricular fibrillation refractory to treatment.

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nothing in the package insert or labeling led them to believe differently. Since the total volume was thought to be 60 mL (10,300 units/500 units per vial = 20 vials; 3 mL per vial x 20 vials = 60 mL), the directions instructed the technician to place the final product in a minibag since 60 mL would be too much volume for a 60 mL syringe.

The next day, different pharmacists started the process of preparing the medication. The vials of Obizur were taken into the preparation area, and while the technician began preparing the product, a pharmacist called the patient care unit to tell nurses that the total volume would be 60 mL, to infuse the medication over 30 minutes, and to utilize a "basic infusion" mode with the smart pump since no entry existed in the pump's drug library for this new drug. Shortly after this conversation, the hematologist who had ordered the drug told the nurse that the volume of medication should be around 20 mL, which could be administered via IV push over 10 minutes. When the nurse conveyed the conflicting message she had received from the pharmacist, the hematologist called the pharmacy to clarify the order. By then, the technician reconstituting the vials also had realized that each vial only contained 1 mL of solution, not the 3 mL listed on the vial label. In the end, the correct volume (20 mL) and dose of medication was dispensed in a syringe and administered IV over 10 minutes. But had the volume in the preparation instructions remained 60 mL, and had the technician gained access to additional vials of the medication to add more drug to the bag to equal 60 mL, the patient could have received a 3-fold overdose. Or, a technician unfamiliar with the process might use 60 mL of sterile water in order to achieve the total volume on the pharmacy label; the impact of overdilution on drug stability is uncertain.

We reported to the manufacturer, Baxalta, how pharmacy staff had been misled by the "3 mL" designation on the vial. According to the company, the "3 mL" designation refers to the vial's size, not how much volume the vial will contain after reconstitution.

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Incidence and Causes of Perioperative Errors

While the literature is sparse on perioperative medication errors and consists mostly of self-reported events, the results of a recently published prospective study found that about 1 in 20 perioperative medication administrations and half of all surgical procedures resulted in a medication error and/or adverse drug event.[1] This error rate is higher than reported in many retrospective surveys, even though the large hospital involved in the study was often using a barcode-assisted syringe labeling system that scans drug containers, prints a syringe label, and provides audio and visual feedback regarding the drug name and concentration. All of the medication errors and 80% of the adverse drug events were deemed preventable. More than one-third of the medication errors led to actual patient harm, and the remaining two-thirds had the potential to cause harm. While more than half of all errors occurred within the first 20 minutes of anesthesia induction, procedures longer than 6 hours or requiring 13 medications or more had higher error rates. The most common errors were associated with absent or incorrect labeling, wrong doses, a failure to act, omitted doses, and wrong medications. The least frequent errors were related to inadvertent boluses of medication remaining in the tubing and wrong timing of medications.

Common causes of perioperative medication errors can often be linked to both human and system causes. Examples of human causes may include unlabeled syringes when medication labeling is regarded as desirable but not mandatory; overreliance on the expected location of medications and syringes on the cart or tray; overreliance on color-coded labels; failure to carefully read labels; and repetitive task designs that foster automatic behavior with little conscious attention required.[8] Examples of system causes may include a failure to standardize medication concentrations; a changeable, chaotic anesthesia work area; a hodgepodge of medication storage; sound-alike and look-alike medication names, containers, and labels; workflow problems; use of a distal instead of proximal port to inject medications; and compatibility of access ports intended for differing routes of administration.

Recommendations

In 2010, the Anesthesia Patient Safety Foundation (APSF) proposed a paradigm to reduce medication errors causing harm to patients in the surgical suite based on **Standardization, Technology, Pharmacy/Prefilled/Premixed, and Culture (STPC)**.[8] Five years later, some of these and numerous other recommendations listed below remain a challenge in many hospitals. Please note, these recommendations move beyond the important but traditional emphasis on label format and the admonishment to "always read the label," to more robust system- and technology-based strategies.[8]

Standardization and Storage

- Standardize the concentrations of all high-alert medications used in the perioperative area, such as phenylephrine and **EPINEPH**rine, so that they can be prepared in the pharmacy as often as possible.[8]
- Standardize the anesthesia workspace, especially the locations where medications are stored.
- Set up storage in anesthesia carts or automated dispensing cabinets (ADCs) so that the labels on vials and ampules are readily visible (instead of the caps).
- Organize anesthesia carts and trays to avoid the proximity of sound-alike or look-alike medications, or look-alike packaging and labeling.
- Reduce the number of multiple-dose vials, and use single-dose or single-use vials as much as possible.
- Limit the types and quantities of medications in the perioperative area to those

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Baxalta told us that a 3 mL vial is needed to facilitate swirling of the contents after reconstitution (complete instructions and diagrams are available in the package insert). Since the vial size after reconstitution is of no consequence, as long as it is large enough to accommodate the swirling, we're not sure why it needs to be listed on the vial instead of the final volume after reconstitution, as with other medications.

HIGH-ALERT

U for units with insulin. Thank you to those who've been pointing out the use of the abbreviation "U" in the advertising and labeling for two of the newly launched insulin products, a potentially dangerous practice when describing medication strengths and dosages measured in units. It has been disappointing to see Sanofi and Lilly advertisements use this error-prone abbreviation when promoting their new insulin products, particularly after all the years and attention given to this issue. However, as mentioned in our June 4 newsletter, when we brought this issue to Sanofi, the company agreed to revise its advertising and official product labeling for **TOUJEO** (insulin glargine) **SoloStar** from 300 U/mL to 300 units/mL. We have also had recent conversations with Lilly and hope the company will do the same with its new U-200 insulin lispro product, **HUMALOG KwikPen** (**Figure 1**). The US Food and Drug Administration (FDA) should add specific recommendations to avoid the use of this abbreviation to appropriate guidance documents for industry that touch on unsafe labeling practices. The FDA *Draft Guidance on Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (www.ismp.org/sc?id=185) notes that certain abbreviations, acronyms, and symbols are dangerous and should not be used, and refers the industry

Figure 1. Labeling for new insulin product uses error-prone abbreviation "U" for units.

to The Joint Commission's "Do Not Use" list, as well as the *ISMP List of Error-Prone Abbreviations, Symbols, and Dose Designations*, which both include "U" for units.

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necessary at the anesthesia workspace or cart until refill within 24 hours.
- Regularly review and remove rarely used or no longer needed medications from the anesthesia workspace, ADCs, and drug storage carts.
- Remove used and unused medications from the anesthesia workspace when a case is completed to prepare for the next case.
- When available, use only standardized, route-specific connectors for tubing that will not allow misconnections to an unintended route (e.g., IV, arterial, epidural).

Technology
- Deliver all medication infusions via a smart pump with activated dose error-reduction software with dose-checking capabilities.
- Employ a barcode scanning system to identify medications before preparing and/or administering them.[8]
- Provide a standardized, machine-readable barcoded label on all drug containers and/or syringes dispensed to the perioperative setting, or employ a similar just-in-time labeling system that can be used in the surgical setting.[8]
- Employ an electronic mechanism to provide feedback, decision support, and documentation of important data during the perioperative encounter.[8]
- Provide large and loud visual and auditory stimuli to target multiple senses to verify drugs and concentrations, and to communicate important alerts.

Pharmacy/Prefilled/Premixed
- Require the use of commercially available, outsourced, or pharmacy-prepared prefilled or premixed syringes and infusions rather than anesthesia provider-prepared syringes and infusions. Use premade medication kits or drug trays by case type when feasible.[2,8]
- If it is impractical for pharmacy to dispense all prefilled syringes for all medications used in all perioperative locations, employ the use of a barcode-assisted, automated syringe label printer that will visually and audibly aid in the verification of medications prepared and administered by an anesthesia provider.[8]
- Consider locating a satellite pharmacy in the perioperative area to help maintain medication surgical case trays and to dispense ready-to-administer medications.
- Include clinical pharmacists with enhanced specialty training on the perioperative team or make them available as perioperative consultants.[8]
- Consider establishing a pharmacy liaison who works in the perioperative setting to drive safe medication use and implementation of error-reduction strategies, disseminate drug information, control the formulary, identify contraindications (e.g., allergies), and work with the dispensing pharmacy to ensure products are provided when feasible in a ready-to-administer form.
- Provide dedicated anesthesia ADCs in operating rooms and procedural areas that communicate with the pharmacy and its information management system when medications are removed.
- Establish a practice to keep all used syringes and drug containers until each case has concluded.

Culture
- Establish an environment which promotes reporting, learning, just culture, and interdisciplinary respect and cooperation in the perioperative setting to promote teamwork and safety.[8]

*ISMP thanks **Cathy A. Miller**, MPH, BSN, from the Division of Medication Error Prevention and Analysis (DMEPA), US FDA, for suggesting this topic and assisting with a literature search.*

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ISMP comments on nonproprietary naming of biologicals. ISMP submitted comments last week regarding the US Food and Drug Administration (FDA) draft guidance on *Nonproprietary Naming of Biological Products; Draft Guidance for Industry* (www.ismp.org/sc?id=634). ISMP agrees with FDA that use of a unique suffix for each biological product is warranted. The manufacturing processes for biosimilar and interchangeable products are different from the reference biological product. This could result in a different adverse event profile that may not initially be recognized, given the relatively small number of patients receiving the product in clinical trials prior to FDA approval. The ISMP letter can be viewed at: www.ismp.org/sc?id=635. Other comments can be viewed at: www.ismp.org/sc?id=636.

2015-2016 ISMP Fellows

ISMP welcomes **Liz Hess, PharmD, MS**, the **2015-2016 ISMP Safe Medication Management Fellow**, sponsored by Express Scripts Foundation. Liz joins ISMP from the University of North Carolina Medical Center (UNCMC) where she completed a PGY-1/PGY-2/MS in Health-System Pharmacy Administration. Liz received a BS in biology in 2009 and her Doctor of Pharmacy in 2013 from The Ohio State University. She earned a Masters in Pharmacy Administration in 2015 from UNC Eshelman School of Pharmacy. Her interests include patient and medication safety, pharmacy operations and automation, and emergency preparedness.

Liz is joined by **Bryan Bailey, PharmD, BCPS**, also a **2015-2016 ISMP Safe Medication Management Fellow**. Bryan joins ISMP as part of the US Army Medical Department's Training with Industry program. He is an active duty officer who holds the rank of major. Bryan has served in a variety of pharmacy administration and clinical positions during his 10-year military career. He received his Doctor of Pharmacy from Southwestern Oklahoma State University in 2003 and completed a PGY-1 pharmacy practice residency in 2009. He is currently working on a Masters in Health Ad-

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agent when the close call incident occurred. The idarucizumab carton was in the refrigerator next to a bag containing **IDA**rubicin, which was being readied for a patient. A vial of idarucizumab was spiked with a closed system transfer device, but fortunately, a pharmacist noticed the error before any drug was actually administered.

As noted, many hospitals may already stock or are planning to stock idarucizumab in case it is needed, although cancer hospitals may not see a need to stock the drug. (There is already a risk of bleeding in many oncology patients undergoing treatment.) Once an order is entered electronically, barcode scanning of the drug vials will prevent a mix-up if it's done prior to sterile compounding. Computer alerts and the use of tall man letters for computer selection screens (idaru**CIZUMAB** and **IDA**rubicin) should also be considered for these drugs. Of course, neither drug should be dispensed or administered without confirming patient need.

Vials of **IDA**rubicin should not be stored near idaru**CIZUMAB** vials. In fact, the proposed US Pharmacopeial Convention (USP) chapter (<800>) states that refrigerated antineoplastic hazardous drugs must be stored in a dedicated refrigerator, so separate refrigerators will be needed for each drug. Also, consider adding auxiliary labels to idaru**CIZUMAB** containers to alert staff who may access the drug. Since the error could also happen the other way around, it's not a bad idea to inform staff and use an auxiliary label for **IDA**rubicin, too. Praxbind is a colorless to slightly yellow, and clear to slightly opalescent, solution. Once the drugs are removed from their vials, staff will notice an obvious color difference between idaru**CIZUMAB** solutions and orange-red, clear **IDA**rubicin solutions. But as in the case just reported, this might not always act as a deterrent, especially when the drugs aren't used very often.

ISMP has notified Boehringer-Ingelheim, the manufacturer of Praxbind, about the mix-up and has also contacted appropriate world authorities that impact the development and ultimate safety of nonproprietary names. Please report any other events like this to ISMP by going to: www.ismp.org/MERP, and we'll automatically notify FDA.

References—continued from page 4

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ministration through Ohio University. His interests include patient and medication safety, and organizational leadership.

ISMP and the US Food and Drug Administration (FDA) also welcome **Briana Rider, PharmD**, as the **2015-2016 FDA/ISMP Safe Medication Management Fellow**. Briana joins ISMP from the Office of Disease Prevention and Health Promotion (ODPHP) of the Office of the Assistant Secretary for Health at the US Department of Health and Human Services in Washington, DC. While there, she completed a 16-month ORISE Health Policy Fellowship where she coordinated efforts to reduce healthcare-associated adverse outcomes. Briana received her Doctor of Pharmacy from Wilkes University Nesbitt College of Pharmacy and Nursing in Wilkes-Barre, PA, in 2014. Her interest in medication safety spans from pre- to post-market drug approval and includes human factors engineering, regulatory standards, health policy, and pharmacovigilance.

Announcements

ISMP webinar

Join us on **November 18** for our webinar, ***Oops, Sorry, Wrong Patient: Taking Steps to Improve the Identification and Prevention of Wrong Patient Errors in Electronic Systems***. Our speaker, Dr. Jason Adelman, will describe the use of an automated "retract and reorder" measure to discover wrong patient errors not visible in most facilities. For details, visit: www.ismp.org/sc?id=349.

ISMP programs at ASHP Meeting

ISMP is holding five **symposia** and a pre-conference **workshop** during the *ASHP Midyear Clinical Meeting*. For details, please **see page 6** or visit www.ProCE.com/ISMP2015 and www.ismp.org/sc?id=637.

If you would like to subscribe to this newsletter, visit: www.ismp.org/sc?id=382

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ISMP Activities at the **2015 ASHP Midyear Meeting in New Orleans**

VISIT ISMP AT EXHIBIT BOOTH 2327

ISMP Medication Safety Intensive

Friday and Saturday, December 4 & 5

Conference Center at Pan American Life Center
Register online at: ***www.ismp.org/educational/msi/default.asp***

Symposia

Register for ISMP symposia online at: ***www.ProCE.com/ISMP2015***

Sunday, December 6

Preparing to Manage Medications Across the Continuum of Care
Breakfast 8:30 a.m. – 9:00 a.m.
Symposium 9:00 a.m. – 11:00 a.m.
Hilton New Orleans Riverside, Grand Salon A&B

Monday, December 7

Medication Safety in Radiology: Often Unrecognized Issues
Breakfast 6:15 a.m. – 6:45 a.m.
Symposium 6:45 a.m. – 8:45 a.m.
Hilton New Orleans Riverside, Grand Ballroom D

Making Smart Pumps More Intelligent Using Technology Integration and Pooled Data Analysis
11:30 a.m. – 1:00 p.m.
New Orleans Convention Center, Room 384
[Will be simulcast as a concurrent webinar; register at same link given above]

Tuesday, December 8

Improving the Safety of Compounding Sterile Products
11:30 a.m. – 1:00 p.m.
New Orleans Convention Center, Room 293

Wednesday, December 9

Advancing Medication Safety for Adult Patients Receiving IV Push Therapy
11:30 a.m. – 1:00 p.m.
New Orleans Convention Center, Room 384

Educational Sessions with ISMP Speakers

Tuesday, December 8

The Pharmacist's Role: Identifying Medication Use Risk Points Outside of Pharmacy
8:00 a.m. – 9:30 a.m.
New Orleans Convention Center
Room 244

Tuesday, December 8

Concentrated Insulin: Safe Use in the Hospital and Transitions of Care
11:30 a.m. – 1:00 p.m.
New Orleans Convention Center
Room 391
Register at: ***www.ProCE.com/ISMP2015***

Wednesday, December 9

Key Strategies for Improving Medication Safety: An ISMP Perspective for 2015
2:00 p.m. – 4:00 p.m.
New Orleans Convention Center
La Nouvelle Ballroom C

For more information, visit: **www.ismp.org** or call **215-947-7797**.