

# Nurse AdviseERR®

Educating the Healthcare Community About Safe Medication Practices

## Accidental IV infusion of heparinized irrigation in the operating room

Accidental intravenous (IV) administration of a solution intended for bladder or wound irrigation is a repetitive error that has been the topic of numerous events published in our newsletters. These events typically involved confusion between unlabeled solutions on the sterile field, mix-ups between irrigation and par-enteral solution bags, or mix-ups between irrigation and venous access lines during connection or reconnection of the solutions. These errors have happened both inside and outside the operating room (OR).

Last year, ISMP's sister organization, ISMP Canada, published two similar events involving the inadvertent IV infusion of heparinized lactated ringer's solution intended for intraoperative irrigation.<sup>1</sup> These cases are being shared with US healthcare practitioners to raise awareness of the prevalence of this type of wrong-route error and the harm that can result.

### Medication incidents reported in Canada

A circulating nurse in the OR added 50,000 units of heparin to a 1,000 mL bag of lactated ringer's solution in anticipation of this solution being needed for intraoperative irrigation. The OR scrub nurse confirmed that the right drug, right dose, and right solution were used during preparation. Due to congestion in the workspace, the nurse was unable to access a red "Medication Added" auxiliary label, which was typically applied in this situation, and so, the bag was never labeled as containing heparin. This bag, only labeled by the manufacturer as containing lactated ringer's solution, was then stored on an IV pole outside the sterile field in the OR.

When the patient required fluid replacement during surgery, the mislabeled bag of heparinized lactated ringer's solution on the pole was retrieved by a different OR circulating nurse and given to the anesthesia provider who administered it IV. When the heparinized irrigation solution was requested by the surgery team, staff discovered it was missing and recognized the error. The patient was treated with protamine intraoperatively and recovered without complication.

In the second event, a circulating nurse in the OR used a small piece of gray tape to label a 1,000 mL bag of lactated ringer's solution to which 50,000 units of heparin had been added (**Figure 1**). The low contrast between the gray background and writing on the tape made it hard to read. The heparinized solution intended for irrigation was thought to be a plain bag of lactated ringer's solution and was subsequently infused via the IV route. When the patient was transferred from the OR, staff in the post-anesthesia care unit (PACU) recognized the error immediately and administered protamine as ordered. The patient was monitored carefully and recovered without sequelae.

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**Figure 1.** Gray tape label on bag of lactated ringer's (from Canada) with added heparin is poorly visible.

### check it out

Consider implementing the following strategies to prevent the accidental intravenous (IV) administration of irrigation solutions.

- ✓ **Pharmacy preparation.** Have the pharmacy prepare, label, and supply irrigation mixtures to the operating room (OR).
- ✓ **Use lowest standard concentration.** Use the lowest effective concentration of heparin in irrigation solutions, and standardize the strength and base solution so pharmacy can prepare the irrigation mixtures or they can be purchased commercially, if available.
- ✓ **Differentiate irrigation solution containers.** Purchase or prepare sterile solutions for irrigation in pour bottles or other route-specific packaging. Also, utilize fluid bags of a different size for solutions intended for irrigation (e.g., 2 L or 3 L bags). The container shape or bag volume can provide a visual cue to differentiate the route of administration.
- ✓ **Consider sodium chloride 0.9% for heparinized irrigations.** Sodium chloride 0.9% is available in **pour bottles** (which helps to differentiate it from IV bags) and is compatible with heparin. If heparinized irrigation solutions are required, consider mixing the heparin with sodium chloride 0.9% instead of lactated ringer's solution. Lactated ringer's solution may necessitate the use of an IV bag, which risks confusion as an IV solution.

- ✓ **Store safely.** Segregate products intended for fluid replacement from those intended for irrigation by storing them in different areas of the OR or in different sections of the warming cabinet. Prominently label these areas "IV Use Only" or "Irrigation Use Only."

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> **Irrigation**—continued from page 1

### Background

Irrigation solutions are not always available in ready-to-use packaging designed for irrigation. During surgical procedures, a sterile IV solution may be used as is, or it may be mixed with an additive for use with cell savers or for wound irrigations to remove debris.<sup>2</sup> The use of IV bags and tubing as a vehicle for this admixture creates a hazardous situation that can result in accidental IV infusion of the irrigation solution. The packaging of IV and irrigation solutions, both with and without additives, looks very similar, and the current compatibility of access ports intended for differing routes of administration makes misconnections and administration by the wrong route possible. Other contributing factors that can lead to mix-ups include: unlabeled or poorly labeled solutions; overreliance on the expected location of solutions on poles or the sterile field; a failure to read labels; repetitive task designs that foster automatic behavior with little conscious attention; a changeable, chaotic workspace; and problems with workflow.

The use of heparin in irrigation solutions can help prevent thromboses,<sup>3</sup> but unintended IV administration of the heparinized irrigation solution can increase the surgical patient's risk of bleeding. Unintended IV administration of plain hypotonic sterile water-based irrigation solutions, or those containing additives other than heparin (e.g., Dakin's solution<sup>4</sup> [diluted sodium hypochlorite]) have also resulted in patient harm. Thus, the potential for this type of error is a serious concern.

Several opportunities for reducing the risk of errors and/or mitigating the potential for patient harm were identified through analysis of the incidents described above. See the **check it out!** column to the right, starting on page 1, for recommendations on how to prevent the accidental administration of irrigation solutions via the IV route.

ISMP thanks ISMP Canada for allowing the reprint of this article, with minor edits for the US audience, which appeared in the August 30, 2016, ISMP Canada Bulletin.<sup>1</sup>

### References

- 1) ISMP Canada. Accidental intravenous infusion of a heparinized irrigation in the operating room. *ISMP Canada Safety Bulletin*. 2016;16(6):1-4.
- 2) Gabriel A, Windle ML, Schraga ED. Wound irrigation. Medscape: drugs and diseases. WebMD, LLC. October 5, 2015. <http://emedicine.medscape.com/article/1895071-overview>
- 3) Kruger A, Amon M, Abela-Formanek C, Schild G, Kolodjaschna J, Schauersberger J. Effect of heparin in the irrigation solution on postoperative inflammation and cellular reaction on the intraocular lens surface. *J Cataract Refract Surg*. 2002;28(1):87-92.
- 4) ISMP. Dakin's solution accidentally given IV. *Nurse AdviseERR*. 2011;9(2):2-3.

## Potential issues with new basal insulin/GLP-1 fixed combinations New safety challenges?

Two new fixed-ratio combination insulin/glucagon-like peptide-1 (GLP-1) receptor agonists were approved last November by the US Food and Drug Administration (FDA). They each combine a basal insulin with a GLP-1 agonist and are administered once daily. **SOLIQUA 100/33**, a Sanofi product ([www.ismp.org/sc?id=2842](http://www.ismp.org/sc?id=2842)), provides 100 units of insulin glargine per mL and 33 mcg of lixisenatide per mL in a 3 mL single-patient-use pen. Novo Nordisk's **XULTOPHY 100/3.6** ([www.ismp.org/sc?id=2841](http://www.ismp.org/sc?id=2841)) provides 100 units of insulin degludec per mL and 3.6 mg of liraglutide per mL, also in a 3 mL single-patient-use pen. Soliqua 100/33 and Xultophy 100/3.6 differ from other insulin-containing products and present new potential safety issues.

### Mistaking the products as containing only insulin

One potential safety issue is that practitioners may mistakenly think that these  
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> **check it out** continued from page 1

**Label immediately.** Label all irrigation solutions immediately when an additive is mixed into the solution. Ensure that the name and amount of any drug added to the irrigation solution is clearly visible on the labeled solution, along with the date/time of expiration. All required supplies (including labels) should be readily available in areas where medications or solutions are prepared.

**Affix auxiliary warning.** Affix a unique, prominent auxiliary label (Figure 2) stating "FOR IRRIGATION ONLY" to any irrigation solution (including plain irrigation solutions without additives), whether commercially available or mixed by pharmacy.

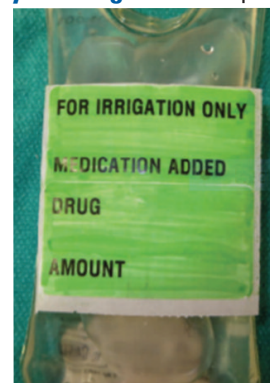


Figure 2. Example of a brightly colored auxiliary label indicating "FOR IRRIGATION ONLY."

**Use irrigation tubing, if available.** When preparing or dispensing solutions intended for irrigation, attach irrigation-specific connectors and tubing, if available, rather than IV connections and tubing, to prevent inadvertent IV administration. Place a label on the tubing, further designating that the solution is for irrigation only.

**Designate "irrigation" poles.** Use only designated "irrigation" poles if irrigation fluids must be hung for decanting. A mixture intended for irrigation is usually decanted into a sterile basin on the sterile field; the solution, pole, and the basin on the sterile field must all be labeled.

**Communicate during transitions.** Incorporate verbal communication tools such as a transition of care report when a patient is transferred from the OR to post-anesthesia care unit (PACU) and/or for staff relief during a case. In one of the incidents described in the newsletter, the procedure for transfer of care from the OR to the PACU  
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> **Challenges**—continued from page 2

products contain only insulin. This is one reason why computer system drop-down lists and pharmacy communications about these products should use the ratio expressions (i.e., Xultophy 100/3.6 and Soliqua 100/33), which hopefully will help to indicate to users that the product contains two different ingredients. The ratio expression is designed to express the ratio of insulin to GLP-1 agonist per mL (e.g., Soliqua 100/33 contains 100 units of insulin glargine and 33 mcg of lixisenatide per mL). In contrast to the ratios used for insulin-insulin combination products such as **NOVOLOG MIX 70/30** (insulin aspart protamine, insulin aspart) or **HUMALOG MIX 50/50** (insulin lispro protamine, insulin lispro), the ratio expressions for Soliqua 100/33 and Xultophy 100/3.6 do not sum up to 100%, which should also help practitioners differentiate them from insulin-only products.

If your computer system, including an electronic medication administration record, uses generic names, make sure both ingredients are displayed and not truncated. However, keep in mind, the first name practitioners will see is “insulin.” That may contribute to practitioners mistaking these as insulin-only products. Using the brand names, ideally with a hover over presentation of the complete generic names, could reduce the risk of an error. Also, counsel patients when initiating Soliqua 100/33 and Xultophy 100/3.6 so they understand the products contain both insulin and a GLP-1 agonist.

**Dosing is based on insulin units, not the GLP-1 agonist component**

Dosing of these products is expressed based on the number of insulin units (the pen dials the dose in insulin units only). The package insert for each product has a table that indicates the amount of GLP-1 agonist per insulin unit, but including the GLP-1 agonist dose is not recommended when prescribing these products. If an order is communicated without the ratio expression (“Soliqua 40 units” or “Xultophy 35 units”), practitioners could think it’s a new insulin product and not recognize there is a GLP-1 agonist contained within. This could lead someone to prescribe a separate GLP-1 agonist (e.g., albiglutide [**TANZEUM**], dulaglutide [**TRULICITY**], exenatide [**BYETTA/BYDUREON**], liraglutide [**VICTOZA**], lixisenatide [**ADLYXIN**]) to go along with what is thought to be the patient’s only insulin dose.

**Fixed ratios of insulin to GLP-1 agonist**

Both Soliqua 100/33 and Xultophy 100/3.6 may be used at doses containing less than the currently approved doses for the single ingredient GLP-1 component. For example, the Soliqua 100/33 starting dose is 15 units per day, which contains 5 mcg of lixisenatide. However, the recommended starting dose for single ingredient lixisenatide is 10 mcg daily. Converting between these products and the individual ingredients can be problematic since the dosing is not the same. For example, if a hospital stocks only Xultophy 100/3.6, the pen will not provide the same dose achievable with the individual ingredient components (e.g., insulin degludec pens and liraglutide pen).

**Not recommended for concurrent use with other products containing GLP-1 agonists**

These products are not recommended for use in combination with any other product containing a GLP-1 agonist because of the risk of overdose. The package insert recommends using alternative antidiabetic products if patients require a Soliqua 100/33 daily dosage below 15 units or over 60 units. For Xultophy 100/3.6, alternative antidiabetic products should be used if patients persistently require less than 16 units or more than 50 units.

*ISMP thanks Ariane O. Conrad, PharmD, BCACP, CDE, FISMP, at the US Food and Drug Administration (FDA) Division of Medication Error Prevention and Analysis, and Steven Meisel, PharmD, CPPS, at Fairview Health Services in Minneapolis, MN, for their assistance in preparing this article for publication.*

> **check it out** continued from page 2

included reconciliation and verification of all medications and fluids. This process worked as intended—the error was detected upon transfer, and the appropriate intervention was implemented promptly.

✓ **Establish protocols for reversal.** Establish standard protocols to manage the adverse effects of high-alert medications such as heparin. In both cases mentioned in the newsletter, the facilities had a protocol to manage heparin overdose/toxicity with administration of the reversal agent, protamine.

**SAFETY wires**

⚡ **Scanning difficult through IV bag overwrap.** We have received several complaints about the position of a seam on the protective overwrap of B. Braun heparin premixed solutions. Hospital staff often scan the barcode on heparin bags when restocking automated dispensing cabinets to ensure that the bags are placed in the correct stock location. The



**Figure 1.** Crimped seam on plastic heparin premixed bag overwrap interferes with barcode scanning.

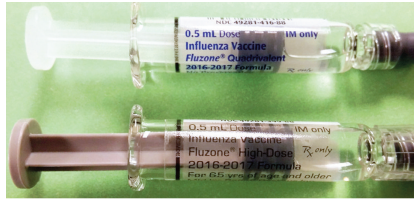
barcode that identifies the product is printed above the barcode for the lot and expiration date but behind a crimped seam on the clear overwrap (Figure 1), making it difficult or impossible

to scan the barcode without removing the bag from the overwrap. Removing the bag from the overwrap affects how long the bag can be stored and is not recommended until right before use. The bag should remain in the overwrap until it is used to avoid shortening the expiration date. This eliminates the possibility—continued on page 4—**SAFETY wires** >



## Plunger interferes with ability to read vaccine labels

With the Sanofi prefilled syringes of **FLUZONE QUADRIVALENT** (influenza vaccine) and **FLUZONE HIGH-DOSE** (influenza vaccine for patients 65 years and older), the plunger stopper interferes with the ability to read the label text (**Figure 1**). In particular, the words “High-Dose” are difficult to read on the product intended for older patients. This issue was reported to ISMP by a medication safety officer who was concerned enough about confusing these products that she sent out a health system-wide notice.



**Figure 1.** These influenza vaccine syringes look similar, but one (bottom syringe) is “High-Dose” and only for patients 65 years and older.

Also, the syringe label is not ideally positioned in relation to how most individuals would hold a syringe. Approximately 90% of the population is right-handed. So, most of us would pick up a syringe by the plunger, not the body of the syringe. When a right handed person picks up the Sanofi syringes by the plunger using his right hand, the label appears upside down. Labels should be oriented for the vast majority of people. In fact, we want people to pick up syringes by the plunger so they can easily read the label. We do not want them to pick up syringes by the body because the hand or finger may cover a portion of the label, risking that important information may be missed.

We recently asked Sanofi to look into this situation and to improve label visibility. Perhaps a white background could be placed on the syringe upon which the text could be printed, or a different color stopper could be used to provide contrast for the text. We also hope other individuals in the pharmaceutical industry who read this publication will take notice and avoid similar label visibility problems.

### → Special

## Announcements

**Don't forget to take our survey on verbal orders.** Please take a few minutes to take our survey on verbal orders before **March 3**. To take the survey and submit your responses, please visit: [www.ismp.org/sc?id=2851](http://www.ismp.org/sc?id=2851).

### Now accepting applications for ISMP and FDA/ISMP Fellowships

ISMP is now accepting applications for its **2017-2018 Fellowship** programs until **March 31**. One 12-month ISMP Fellowship position, funded by Baxter International, Inc., is open to a nurse, pharmacist, or physician with a least 1 year of postgraduate clinical experience, at the ISMP office in Horsham, PA. Two 12-month FDA/ISMP Fellowship positions for practitioners with similar qualifications are available at the offices of ISMP and FDA (Silver Spring, MD), with 6-month rotations at each site. Information and applications can be found at: [www.ismp.org/profdevelopment/](http://www.ismp.org/profdevelopment/).

### > SAFETYwires continued from page 3

bility of an important safety practice with this high-alert medication—barcode scanning. If the crimped seam was over the back of the bag, there would be no problem scanning it. No errors have been reported, but if the pharmacy must work around the problem and apply a barcode label to the bag, it introduces an opportunity for mix-ups. B. Braun told us that it is aware of this problem and is correcting the situation.



**Powdered surgical gloves.** The US Food and Drug Administration (FDA) asked us to remind healthcare personnel to check inventories to make sure powdered surgical gloves are no longer available. A rule that bans powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove went into effect on January 18, 2017. FDA notes that these products present unreasonable and substantial risk to healthcare providers. In aggregate, the risks of powdered gloves include severe airway inflammation, hypersensitivity reactions, allergic reactions (including asthma), allergic rhinitis, conjunctivitis, dyspnea, as well as granuloma and adhesion formation when exposed to internal tissue.

The act of banning a device is an important decision, and the FDA only takes this action on rare occasions when necessary to protect the health of the public. The FDA has only banned one other medical device, prosthetic hair fibers, in June 1983.

For more information on the ban of powdered surgical gloves and similar products, please review the final rule in the *Federal Register* at: [www.ismp.org/sc?id=2855](http://www.ismp.org/sc?id=2855).

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



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A BREAKFAST SYMPOSIUM CONDUCTED AT THE **AONE 2017 ANNUAL MEETING**

# Changing the Safety Paradigm on IV Medication Use: Recognizing the Risk and Taking Action

## Friday, March 31, 2017

**7:00 AM – 8:00 AM**

Breakfast Symposium  
Room 343-344, Baltimore Convention Center

Space is limited and pre-registration is encouraged. Pre-registration is for planning purposes only and seating will be available on a first-come, first-served basis. To register, please go to: [www.ProCE.com/AONE17](http://www.ProCE.com/AONE17)

### OVERVIEW

Errors involving IV medications can result in significant patient harm, given the immediate bioavailability and narrow therapeutic index of many of the drugs used. This symposium will address the multi-factorial risks associated with IV medications, along with the need for proven safety technologies, practice innovation, and educational strategies to enhance safety in all phases of the medication use process. Expert speakers will describe technologies available to support safe compounding and distribution practices with IV therapy, as well as the value of adopting barcoding technology and smart infusion pumps integrated with the electronic health record (EHR) to promote safe administration at the bedside.

### OBJECTIVES

The target audience for this activity includes nurses in health care settings. At the completion of this symposium, the participant will be able to:

- » Describe the system-based causes of IV medication errors.
- » Identify the most common unsafe practices and at-risk behaviors associated with the preparation and administration of IV medications.
- » Discuss several technologies designed to support safe practice with IV medication use.
- » Recognize the role of nursing leadership in the adoption of technology and practice changes to enhance the safety of IV medication use.

### TOPICS AND FACULTY

#### Risk Associated with IV Medication Use: Understanding Current Safety Challenges

Susan Paparella, MSN, RN, Vice President, ISMP

#### Advancements in Safe IV Medication Use: The Time Is Now

Michelle Mandrack, MSN, RN, Director of Consulting Services, ISMP

### ACCREDITATION

This CE activity is jointly provided by the Institute for Safe Medication Practices (ISMP), ProCE, Inc., and Wild Iris Medical Education, Inc. **This activity provides 1.0 contact hour of nurse CE credit.** Wild Iris Medical Education, Inc. is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. Continuing education credit is earned by attending courses that address a topic directly related to management practice and are offered by organizations other than the American College of Healthcare Executives (ACHE). We anticipate that this activity will qualify for ACHE self-reported credit. However, it is not pre-approved for ACHE credit.



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**For registration questions, contact ProCE at 1-800-748-7795.**

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