

# Acute Care

# ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

## Technology and error-prevention strategies: Why are we still overlooking the IV room?

Harmful or fatal errors that have occurred when compounding sterile intravenous (IV) preparations in the pharmacy—including simple IV admixtures—have been fodder for headline news during the past decade.<sup>1</sup> The 2012 meningitis outbreak that led to the death of 64 people from contaminated epidural solutions prepared by the New England Compounding Center (NECC) will long be remembered. There has been no shortage of sterile compounding errors in hospital pharmacies, either—from the accidental chemotherapy compounding error 9 years ago that claimed the life of 2-year-old Emily Jerry and eventually sent pharmacist Eric Cropp to jail, to the recent December 2014 compounding error in which a rocuronium infusion was prepared and dispensed instead of a fosphenytoin infusion, leading to the death of a 65-year-old woman.

Sterile compounding errors in hospital pharmacies have devastated the patients, family members, and healthcare practitioners involved in the events. Unfortunately, the lessons learned from these and other events have not been widely acknowledged, understood, and/or acted upon by pharmacies that were not involved in the tragic events.

The causes of sterile compounding errors are diverse, involving both sterility and other drug safety issues. ISMP visits dozens of hospitals and health systems each year for various reasons and has observed unsafe practices associated with sterile compounding in hospital pharmacies. Through our ISMP National Medication Errors Reporting Program and other reliable sources, we have compiled and analyzed many sterile compounding errors to determine the causes, and published our findings when possible in this newsletter. And late last month, an important report was released that mentioned the slow rate of adoption of pharmacy IV workflow technology with barcode scanning—only 6-7% of hospital pharmacies employ this technology despite its reasonable cost.<sup>2</sup>

To gain a wider perspective regarding the causes of sterile compounding errors and the slow adoption of technology and other error-reduction strategies, we recently held a discussion with our close colleague, sterile compounding expert **Eric Kastango**, president and CEO of Clinical IQ, LLC. Five entangled systems and behavioral causes surfaced as we discussed the issues: 1) depreciating importance of the compounding and dispensing processes in pharmacy practice, 2) lack of knowledge and standardization around best practices, 3) training based on traditions handed down from one pharmacist to another, 4) learned workplace tolerance of risk and routine practice deviations that persist, and 5) a reluctance to learn from the mistakes of others. These five causes are further described.

### Depreciating importance of the compounding and dispensing processes in pharmacy

During the last few decades, pharmacy practice has undergone a significant transformation into a more clinical realm. While we applaud the augmented clinical roles that pharmacists now play and their positive impact on patient safety, some of the core elements of pharmacy practice have been overlooked. *continued on page 2—Compounding >*

## HAZARDALERT

### Demonstration IV solutions administered to patients

The US Food and Drug Administration (FDA) again alerted healthcare professionals not to use Wallcur, LLC, simulated intravenous (IV) products in human or animal patients ([www.ismp.org/sc?id=472](http://www.ismp.org/sc?id=472)). These products are for training purposes only and should never be administered to humans or animals. Educators often utilize training products for simulations with students and want these items to look like the real solutions. However, there have been serious adverse events associated with misuse.



Figure 1. Products for training purposes only.

We learned via FDA's MedWatch that more than 40 patients actually received these solutions and developed chills and/or sepsis; 1 patient died. One of the products, Practi-0.9% Sodium Chloride (Figure 1) 100 mL, contains distilled water, not sterile saline, so hemolysis also might be an issue.

These events may be related in part to IV saline product shortages from B. Braun, Hospira, and Baxter. Purchasers looking for replacement supplies may have confused these training products with the real thing, and then ordered them through their distributors. Although distributor listings state that these are training products, purchasers may not recognize this. The solution *continued on page 2—HAZARDALERT >*



ISMP is asking all readers to send their *sterile compounding checklist* to us! For details, see the bottom of page 4.

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macy practice seem to have been lost or relegated to low priority status. Core practices such as sterile compounding and distribution do not receive the attention devoted to clinical pharmacy roles such as antibiotic stewardship, anticoagulation management, and disease state management. Many tasks associated with sterile compounding are carried out by pharmacy technicians, with minimal oversight by a pharmacist who may often rely on a woefully inadequate “syringe pull-back” method to verify the technician’s work.<sup>3</sup> Stated simply, sterile compounding is not very “sexy.”

**Lack of knowledge and standardization around best practices**

When it comes to sterile compounding, there is little confidence that pharmacists and technicians know what best practices look like. While the US Pharmacopeial Convention (USP) <797> provides proscriptive guidance on the sterility and quality components of the process, deficits abound amid unwarranted confidence that practices are on par with the standards. For other aspects of IV sterile compounding safety, there have been scarce resources for staff to consult. To help fill that void, in 2013 ISMP published a set of guidelines for safe preparation of sterile compounds ([www.ismp.org/sc?id=469](http://www.ismp.org/sc?id=469)). The guidelines, which were developed following a national summit, offer pharmacists and technicians a credible, peer reviewed resource on IV sterile compounding safety. While the guidelines provide consensus statements for many process steps involved in sterile compounding, the national summit did not delve into the details of some specific tasks, including the required components of an effective sterile compounding checking process.

Without standardization of best practices, there is clearly wide variability, even among staff in the same pharmacy, in completing the tasks associated with the compounding process—how the products are assembled for preparation, the size of syringes used during compounding, how the checking process is carried out and in what order, what constitutes a thorough check, when and where signatures are placed on labels, when and where labels are placed on the preparations, and so on. Further, despite USP <797> guidance on sterility, it appears that pharmacy staff are still getting it wrong. Suffice it to say that many do not understand all the necessary safety steps required during sterile compounding, why they are necessary, and what best practices look like.

**Training based on traditions**

New pharmacy graduates have often been shortchanged when it comes to learning the robust principles associated with IV sterile compounding. Schools of pharmacy typically do not adequately teach students sterile compounding, and new graduates are often immediately responsible for verifying compounded sterile preparations and overseeing processes they have never carried out themselves. Thus, it is not surprising that sterile compounding procedures are typically handed down from one pharmacist to another, often with little scientific merit. New pharmacists learn via tribal knowledge taught by a practicing pharmacist employing a well known mantra from medical school—see one, do one, teach one. Most training is prefaced with, “Here’s how I do it.” We have even heard of hospitals that maintain bound manuals of compounding procedure “legacies” or “legends” to pass on to new staff.

When training does occur, it is often hurried and without an explanation regarding why subtasks need to be carried out. Often, staff do not understand the rationale for certain steps that help ensure sterility and safety. Why must the checking process be carried out in a distinct order and manner? Why is it important to check the contents of some preparations before they are mixed? Why is a technology-aided checking system far superior to a manual checking system? Without explanatory information, practice change and long-term compliance is unlikely. There is virtually no support for more in-depth, unhurried

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tions may have then been misidentified upon arrival at the healthcare facility. Subsequently, internal distribution took place, and the fact that these were training products must have been overlooked. Since staff may be having trouble getting their usual IV products, they may not be suspicious of the unusual labeling. Although each product is labeled “for clinical simulation,” this may not always be recognized. (Also, “for clinical *simulation*” looks very close to “for clinical *situations*.”)

In a media release ([www.ismp.org/sc?id=470](http://www.ismp.org/sc?id=470)), Wallcur said it has recalled current products, including Practi-0.9% sodium chloride IV bags supplied in 50 mL, 250 mL, 500 mL, and 1,000 mL sizes, and the Practi-0.9% sodium chloride 100 mL IV solution bag with sterile distilled water. The extent of distribution of these products is not fully known, but inpatient and outpatient locations have received supplies. The company told us that about 90% of the distribution of training products is via independent medical distributors, including some drug wholesalers. Supplies can also be purchased through the company’s website, in which case they interact with the customer to assure use is for training purposes.

Wallcur is also working with FDA to identify ways to label these products to state more clearly that they are not to be used in humans or animals. The company has also notified its distributors and asked for their follow up. Please work with hospital educators, medical and nursing school affiliates, ambulatory surgical centers, and other inpatient and outpatient facilities in your health system to assure all are aware of this situation and taking action where appropriate.

If you suspect that any Wallcur training IV products (or training products from another manufacturer, such as Pocket Nurse Demo Dose) may have been administered to a patient, whether or not harm has resulted, please report it to FDA’s [MedWatch](http://www.fda.gov/medwatch) Adverse Event Reporting here: [MedWatch Online Voluntary Reporting Form](http://www.fda.gov/medwatch). FDA will continue to investigate and monitor this issue.

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training, perhaps because sterile compounding is increasingly overlooked and rarely featured as a prestigious aspect of pharmacy practice.

**Learned workplace tolerance of risk and routine practice deviations that persist**

Production pressure to get a compounded sterile preparation out the door has often adversely affected safety. The pressure leads to shortcuts that eventually become unsafe practice habits. Because these shortcuts have yet to result in a readily apparent adverse outcome, they become routine. These “successful” violations are often practiced and accepted by an entire pharmacy staff. Thus, what begins as small deviations from a safe sterile compounding preparation process becomes, with enough repetitions, normalized staff practice patterns (*normalization of deviance*).

Routine practice deviations are learned workplace behaviors that often persist regardless of knowledge or experience. Knowing an action could be harmful rarely controls behavioral choices; rather, it’s the immediate reward (e.g., getting the product out the door) from the behavior that controls the choices made (a bias known as *hyperbolic discounting*). Uncertain or delayed consequences, even potential patient harm, do not motivate behavioral choices. It is human nature to drift into at-risk behaviors—checking a sterile compounded solution on the fly, removing the mask when it becomes uncomfortable—while losing sight of the risk or mistakenly believing the risk is insignificant or justified. Thus, staff who engage in routine practice deviations are often singly focused on production, not safety, and possess little situational awareness regarding how their behavioral choices could lead to patient harm.

Even those overseeing sterile compounding preparations have become blind to unsafe practices, easily overlooking violations—a pharmacist who, using a camera, carefully verifies the additives but never notices that the technician’s face mask is below her chin and her bangs are hanging out of the cap, for example. The workplace has long tolerated the risks associated with sterile compounding, in part because there is little understanding regarding best practices and why certain steps are critical to safety. Instead of noticing the risks associated with behavioral drift and then “stopping the line” to resolve the risk, as staff would in highly reliable industries like aviation, these at-risk behaviors have continued unchecked, leading to perfect storms with adverse patient outcomes.

**Reluctance to learn from the mistakes of others**

Healthcare practitioners are often disinclined to learn from the mistakes of others, believing that if the adverse event hasn’t happened to them, the lessons do not apply. This belief stems from a variety of cognitive biases from which we all suffer, including: *conservatism* (tendency to insufficiently revise one’s belief when presented with new evidence); *normalcy bias* (refusal to plan for or react to a disaster which has never happened to you); *not invented here bias* (aversion to use standards and knowledge developed outside of a group); *ostrich effect* (ignoring an obvious problem); *Semmelweis reflex* (tendency to reject new evidence that contradicts what is known); *status quo bias* (tendency to like things to stay the same); and others. Thus, even the high-profile sterile compounding events in the past decade have not prompted all pharmacists and technicians to impartially reassess their own sterile compounding processes to see if similar vulnerabilities exist.

It has also been hard to change longstanding behaviors in the face of new evidence. For example, if a technician has been washing his hands for 15 seconds for the past 30 years without a known sterility issue, even when faced with USP <797> standards that call for 30 seconds of handwashing, the technician is unlikely to make a long-term change without understanding, and appreciating the significance of, the risks associated with his long-

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**SAFETY brief**



**Farxiga and Fetzima mix-ups.** The US Food and Drug Administration (FDA) is aware of several reported mix-ups due to name confusion between two medications—**FARXIGA** (dapagliflozin) and **FETZIMA** (levomilnacipran). Farxiga was approved in January 2014 to lower blood glucose levels in adults with type 2 diabetes when used along with diet and exercise. It is available in 5 and 10 mg tablets. Fetzima was approved in July 2013. It is a selective norepinephrine and serotonin reuptake inhibitor for major depressive disorder. The drug is available in 20, 40, 80, and 120 mg extended-release capsules.

Upon review of the 5 medication error reports received by FDA, it is believed that the errors can largely be attributed to the drugs being approved and marketed within 6 months of one another. Both drug names begin with the letter F and end with the letter A, and are of the same length and number of syllables. Prescribers and pharmacists may choose the wrong item from computer screens. Furthermore, the container labels might appear similar since both display the proprietary name of the product in red font (**Figure 1**).



**Figure 1.** Drugs have been confused due to name similarity.

We will be adding this name pair to the *ISMP List of Confused Drug Names*. The updated list will be available in February 2015. If these drugs are used in your hospital, consider adding computer alerts to verify the indication for these medications. Prescribers should include the indication with orders or prescriptions. Community

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standing practice. Keep in mind, changing to the new behavior—30 seconds of hand-washing, for example—requires acknowledging that one was doing it wrong for 30 years. As a profession, pharmacy practitioners must first acknowledge that the way they have been compounding sterile preparations may not be the best way, before they can learn from the mistakes of others, identify vulnerabilities in their own processes, and improve.

### Conclusions and next steps

Sterile compounding is a significant but perilous core pharmacy process in dire need of improvement. Variability in practices, a failure to identify and teach best practices, and a host of cultural issues associated with routine practice deviations and tolerance of risks have led to harmful and fatal errors that should serve as a call to action. It's time for pharmacy to "sweat the small stuff," contrary to the well known axiom, and examine every detail of every subtask involved in sterile compounding.

The details regarding how to perform each subtask associated with sterile compounding and why it is necessary are crucial and should be established and taught to all who are involved in sterile compounding, including pharmacy students. To date, USP <797> offers best practices associated with ensuring the quality of compounded preparations. However, these standards do not address processes for selecting and preparing the correct drug. We plan to update the ISMP sterile compounding guidelines to include additional details to better describe what needs to be done every time, why it is necessary, the best practices to achieve it, and how to teach it to those involved in sterile compounding. Our goal is to assist healthcare providers in: assessing their current sterile compounding processes; understanding the value of technology-assisted workflow; assessing pharmacy staffing requirements; establishing and implementing standard operating procedures and key technologies based on best practices; transferring knowledge to involved staff; evaluating staff knowledge, skills, and abilities; and monitoring ongoing performance.

To that end, ISMP is planning several initiatives in 2015 in which we hope newsletter readers will participate. Our first priority is to describe the sterile product checking process in detail, so we are asking newsletter readers to **send us any checklists (or other materials) you use to guide the steps in this process.** Please send the information via email to [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org) or by fax to 215-914-1492. We also plan to conduct several surveys on this topic and ask newsletter readers to participate to the fullest extent possible. Look for the first survey later this quarter. We look forward to working closely with interested healthcare professionals during 2015 on this important endeavor.

ISMP thanks **Eric Kastango** for sharing his observations and contributing to this article.

### References

- 1) Pew Charitable Trusts. U.S. illnesses and deaths associated with compounded medications (2001-present). April 15, 2013. [www.ismp.org/sc?id=468](http://www.ismp.org/sc?id=468)
- 2) Neuenschwander M, Fahmi J. In the clean room. A review of technology-assisted sterile compounding systems in the US. Bellevue, WA: The Neuenschwander Company. 2014.
- 3) ISMP. Syringe pull-back method of verifying IV admixtures unreliable. *ISMP Medication Safety Alert!* 2013;18(14):3.

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pharmacists should counsel all patients before dispensing these drugs to confirm the indication. Hopefully, as practitioners become more familiar with the two products, name confusion errors will diminish.

## Special Announcements

### ISMP webinars

Join us on **January 28** for **Strategies to Prevent Cancer Chemotherapy Errors: Focus on Oral Agents**. Oral chemotherapy agents can offer significant improvements for cancer patients, but also bring unique safety challenges. This program will explore the common causes of oral chemotherapy errors. Suggested best practices that all organizations can adopt to prevent errors will be highlighted.

Join ISMP on **February 10** for **Practical Approaches to Improving Medication Safety in the Perioperative Setting**. Learn about actual cases where errors occurred, relevant regulatory and/or accreditation requirements, and safe practices that need to be implemented to mitigate risk and ensure patient safety.

Join us on **March 19** for the **Evolution of Anticoagulants and the Effects on Patient Safety**. Learn about the significant changes in anticoagulation therapy, new anticoagulants on the market and their risks, contemporary use of prothrombin complex concentrates and common errors, and practical steps that can be taken to prevent errors.

For details, visit: [www.ismp.org/educational/webinars.asp](http://www.ismp.org/educational/webinars.asp).

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



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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 23<sup>rd</sup> 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/](http://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](mailto:fellowship@ismp.org).

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