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ISMP 25 YEARS ADVANCING MEDICATION SAFETY

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

ISMP calls on FDA— No more syringes for vinca alkaloids!

Since January 2019, ISMP has learned about 4 children who received vin**CRIS**tine erroneously by the intrathecal route of administration, each suffering a very painful death. Three of the children were from Guyana, and one was from Norway. The child from Norway had a brain tumor and was just 6 years old when vin**CRIS**tine was injected into the spinal fluid via an intraventricular catheter instead of methotrexate (www.ismp.org/ext/191). The three children from Guyana were just 3, 6, and 7 years old (www.ismp.org/ext/190).

The most effective way to prevent patient harm is to supply **all** vinca alkaloids in minibags, thus avoiding the risk of confusion with syringes. ISMP has strongly advocated this practice since 2001. Dispensing vin**CRIS**tine (and other vinca alkaloids) in a minibag of compatible solution, and not in a syringe, was among the very first ISMP ***Targeted Medication Safety Best Practices for Hospitals*** (www.ismp.org/node/160) released in 2014. Other accrediting and professional organizations have helped promote this practice, including The Joint Commission (TJC), National Comprehensive Cancer Network (NCCN), Oncology Nursing Society (ONS), American Society of Clinical Oncology (ASCO), and many others.

Internationally, the World Health Organization (WHO) has promoted dilution of vinca alkaloids in minibags since 2007, and in Norway, where one of the latest events happened, this practice had been widely implemented for children during treatment of leukemia, but not consistently for treatment of other cancers using vinca alkaloids. According to Andrew Seger, a pharmacist from Boston's Brigham and Women's Hospital who tracks vin**CRIS**tine errors from around the world, 5 years ago the total number of fatalities and neurological devastation from intrathecal vinca alkaloid administration worldwide was 120 (44 in the US and Canada)—all involving vinca alkaloids in syringes (www.ismp.org/node/624). Today, the total is 135, and as far as we know, **none** of these cases involved vinca alkaloids prepared in minibags.

Most practitioners in the US dilute vin**CRIS**tine (and other vinca alkaloids) in a minibag prior to administration. According to a 2017 ISMP survey of US hospitals, 86% of 338 hospital respondents have fully adopted this practice. This represents a steady increase in compliance since 2014, when only half of respondents reported this practice. Also, in our recent 2018 ***ISMP Medication Safety Self Assessment® for High-Alert Medications***, 81% of almost 500 hospital respondents reported full adoption of this practice. Although the latest tragic events have occurred internationally, the error could still happen in the US given that 19% of our 2018 assessment respondents reported that they still use syringes to administer vinca alkaloids. Furthermore, even though the US official prescribing information includes directions to dilute the drug in a flexible plastic container to reduce the risk of wrong route errors, the labeling still *allows* for administration of vinca alkaloids via a syringe and even provides explicit directions for this alternative yet unsafe method of administration.

ISMP calls upon the US Food and Drug Administration (FDA) to lead the way internationally by requiring the removal of administration by syringe from the prescribing information

continued on page 2—No more syringes! >

SAFETY briefs

HIGH-ALERT

Neuromuscular blocker storage. We recently learned of a close call in which vancomycin was prescribed, but a vial of vecuronium was used to prepare a dose in the pharmacy. The error was identified during a quality control check of the prepared intravenous (IV) admixture. Investigation found that vecuronium was stocked right next to vancomycin in the IV area (**Figure 1**). Vecuronium was normally kept in a storage bin with a lid, but the lid was missing. Vecuronium has since been moved to a different shelf to separate the two drugs,

Figure 1. Unsafe storage of vecuronium and vancomycin next to each other. Also, warnings on the vecuronium container are worn and hard to read.

and a new lidded container was ordered. In areas where they are needed, neuromuscular blockers should be segregated and sequestered from other medications, such as placing them in a lidded bin or rapid sequence intubation (RSI) kit. Also, the barcode on drugs used for IV admixture should be scanned using IV workflow technology to ensure correct product selection.

In **Figure 1**, also notice the curled warning labels on the vecuronium storage bin. Warning labels that are affixed to heavily used storage containers can easily become worn, loosened, and soiled, making them difficult to read. This defeats the purpose of a warning label—to effectively communicate a hazard and incite safe action (see our article on warnings at: www.ismp.org/node/1483). If warning labels are used, inspect them regularly and replace them as soon as signs of wear are recognized. We

continued on page 2—SAFETY briefs >

> No more syringes!—continued from page 1

for all vinca alkaloids. Administration by syringe has been at the root of all reported errors associated with vinca alkaloids given by the intrathecal route and should NOT be an approved method of preparation for administration. The cost in human lives has been high—it is an error for which death is almost certain. It is time for FDA regulatory action, which we hope will lead to similar global changes. If FDA commits to taking regulatory action, ISMP and the International Medication Safety Network (IMSN) will have the support needed to continue vigorously advocating for other countries to do the same.

Don't miss a persuasive article by David Marx—*Reckless Homicide at Vanderbilt? A Just Culture Analysis*

David Marx, the Chief Executive Officer at Outcome Engenuity, has written an article on the criminal indictment of RaDonda Vaught, a nurse from Vanderbilt University Medical Center who was involved in a fatal medication error (see our January 17, 2019 [www.ismp.org/node/1326] and February 14, 2019 [www.ismp.org/node/1389] newsletters for details). Marx's article is available in PDF (www.ismp.org/ext/183) and audio (www.ismp.org/ext/184) formats.

The article first explores Tennessee law to help readers understand the charge of reckless homicide against RaDonda, making it clear that she is not being prosecuted because she made a mistake (i.e., administered the wrong medication) but rather for the behavioral choices she made (e.g., obtained the medication from an automated dispensing cabinet via override, did not monitor the patient after drug administration). Marx notes that RaDonda is facing prosecution for the healthcare equivalent of a drunk driver who runs a red light, killing a pedestrian in the crosswalk.

Marx also explores the differences between reckless and at-risk behaviors, and the role of our risk monitor, that little voice that knocks on the door of our conscious thoughts and lets us know that we are endangering the lives of those around us. Marx concludes that, on the day of the event, RaDonda's risk monitor was likely silent as she moved through an otherwise normal day. He notes, "Why would she, in direct view of a nurse she was training, engage in choices she thought were reckless? Could her decisions and practices on that day be consistent with what she did on many other days? Could it be her conscious brain never recognized the significant and unjustifiable risk she was taking? The answer here is yes, if you are open to recognizing our natural propensity to drift into at-risk behaviors."

While Marx acknowledges that RaDonda knowingly deviated from safe practices, he points out that, if we criminally prosecuted every healthcare provider who has knowingly deviated from a safety protocol, a large portion of providers would be in jail. He asks the reader to imagine charging every nurse who has obtained a medication via override with reckless endangerment. Now he asks the reader to imagine a very empty hospital—and a very full prison.

Marx points out that to drift into unsafe practices is part of our human nature, and that these at-risk behaviors, along with system design, should be the primary focus of a patient safety program. The inescapable human error is less the issue. That said, he notes that this requires some intellectual honesty about our propensity to drift. While it is one thing to publicly disclose that people make mistakes, it is wholly another to disclose that healthcare providers choose to violate rules. Admitting at-risk behaviors exist is messy and taboo. Instead, it becomes easier to judge the behaviors of those involved in an adverse event as either human error or reckless behavior. Too often, there is no middle ground to recognize and address at-risk behaviors. Marx comments, "If it's an inadvertent violation, it's for the safety professional; if it's a choice to violate, off to the human resources office (or prosecutor) you go."

continued on page 3—Reckless homicide? >

> SAFETY briefs

cont'd from page 1

also hope providers will consider other recommendations we made in our recent article on preventing neuromuscular blocker errors (www.ismp.org/node/1326).

Diluent given without vancomycin. Oral vancomycin is available from CutisPharma in an oral solution kit containing bottles of vancomycin powder for oral solution and a grape-flavored diluent. Prior to use, the powder must be reconstituted with the diluent. Though the manufacturer recommends reconstitution by a pharmacist, some pharmacies without 24-hour service make the kit available in the emergency department (ED) and/or patient care units.

In 2016, after reports of administering the diluent alone, we were pleased with labeling changes made by CutisPharma for vancomycin oral solution (FIRST-Vancomycin) compounding kits. At that time, the new label emphasized the word "Diluent" in large bold font on the diluent label, without mentioning the vancomycin concentration, and "Powder" was emphasized on the vancomycin powder bottle (**Figure 1**). But that product was discontinued in April 2018 after CutisPharma received approval for a newly branded product, **FIRVANQ** (vancomycin) (**Figure 2**, page 3). Unfortunately, the Firvanq diluent label includes the brand name and concentration, and the powder label no longer emphasizes "Powder," so the containers are hard to tell apart.

We recently learned of a case where a patient received 3 doses of the Firvanq diluent alone. It was thought that the technician

continued on page 3—SAFETY briefs >

Figure 1. Former product labeling uses bold font and color to emphasize "Diluent" on the diluent label and "Powder" on the vancomycin powder label.

> Reckless homicide?—continued from page 2

Marx ends his article by answering the question, did RaDonda's choices rise to the level of recklessness? The nurse's mission was to administer a drug to a patient undergoing a positron emission tomography (PET) scan. Marx asks, "Did she, by conscious choice (or developed habit), deviate from safety standards? Yes. In doing so, did her risk monitor fire? Did it creep into her conscious thought that she was taking a substantial and unjustifiable risk with her patient? Was she reckless? Likely not, if we are intellectually honest about how we operate as human beings." Marx points out that in a Just Culture, RaDonda would have likely been consoled around the human error of administering the wrong drug to the patient and coached around a series of at-risk behaviors. "It is unlikely, given the facts that we know today, that RaDonda did anything reckless."

Importantly, Marx suggests that this event should have been prevented in the first place. He notes that we tend to turn a blind eye to both risky systems and risky choices, believing everyone is safe if bad outcomes don't occur. "And then when a bad system and/or an unlucky nurse's choices do cause harm, we rise to the occasion with termination of employment and a criminal prosecution." Marx concludes that tragedy has once again been followed by injustice.

Top 10 Tips for keeping pets safe around human medications

Most people are aware of the need to keep medications out of children's reach, but they don't necessarily realize that similar rules apply when it comes to keeping pets safe. Pets can also get into medications that are not intended for them, which could cause harm. One case in point was recently reported.

After an outing at the park with his two dogs, a man picked up his monthly prescription refills from the pharmacy and placed the bag on the passenger's seat in the car. Before returning home, he headed to the grocery store to pick up some forgotten items. While he was in the grocery store, one or both of the dogs got into the pharmacy bag containing his medications. The dog(s) took a prescription bottle containing 90 tablets of lisinopril 5 mg into the back seat and chewed the bottom of the bottle open. The man returned to the car, did not notice a prescription bottle was missing from the bag, and drove home. When he brought the pharmacy bag into the house and put his medications away, he did not notice the lisinopril was missing. When he returned to the car several hours later, he noticed that the lisinopril tablets were strewn all over the back seat and floor. He was only able to find 70 of the 90 tablets.

Both dogs were taken to an emergency veterinarian, who examined the dogs and called the Animal Poison Control Center run by the American Society for the Prevention of Cruelty to Animals (ASPCA). Fortunately, the toxic dose of lisinopril for either 50-pound dog was well above the missing amount of lisinopril (100 mg), and the dogs suffered no adverse effects. However, luck certainly played a role in this fortunate outcome. Had the dog(s) chosen a different medication from the pharmacy bag full of refilled medications, the outcome could have been tragic.

To keep your four-legged family member safe, follow the recommendations in our **Top 10 Tips**:

1. Store all medications out of your pet's reach. Most dogs can quickly chew a bottle open to get to the medications inside.

2. Don't leave medications on tables or nightstands where your pet can reach them.

3. If you drop any medications on the floor, immediately pick them up. Pets are likely to mistake dropped medications as dropped food scraps and eat them before realizing they're not tasty treats.

continued on page 4—Keeping pets safe >

> SAFETY briefs

cont'd from page 2

preparing the doses may have seen only the drug name and concentration on the new diluent label.

We have contacted CutisPharma and hope the company will de-emphasize the brand name and concentration, and better emphasize "Diluent" in large bold font, on the diluent label.

Figure 2. Newer labeling with brand name (Firvanq) and concentration (50 mg/mL) printed on both the powder and diluent bottles.

If you plan to stock and/or dispense this kit, keep the bottles together in their carton until the product is reconstituted. Since the diluent bottle does not have a barcode, preparing the diluent alone would not allow a verification scan of the product, which may reduce the risk of an error.

HIGH-ALERT

Package insert mistaken as label. A pharmacy technician nearly placed a package of bupivacaine 0.25% into a bin of bupivacaine with **EPINEPH**rine. It was later determined that the technician identified the drug by a package insert that was in a clear overwrap on the top of the packing box. The package insert displayed both plain bupivacaine and bupivacaine with **EPINEPH**rine (**Figure 1**, page 4). The US Food and Drug Administration (FDA) allows a single package insert for both products. The technician read both names on the insert and mistakenly thought he had bupivacaine with **EPINEPH**rine in hand. The error was caught when the barcode scanner was used to restock an automated dispensing cabinet. Hospira packages lidocaine and lidocaine with **EPINEPH**rine in the same

continued on page 4—SAFETY briefs >

> Keeping pets safe—continued from page 3

4. Keep human medications and pet medications separate. Although pets may often be treated with the same medications as people, the doses are usually vastly different, and confusing the doses can be fatal. Also, keep medications intended for different species of pets separate to prevent mix-ups. Medications for animals can have different, and often undesirable, effects when used for a different species. For example, some flea medications intended for dogs are highly toxic to cats.

5. Don't let pets come in contact with or eat medication patches (e.g., nicotine patches, fenta**NYL** patches) prescribed for you. Also, if pets are prescribed a medication patch, be sure they do not lay next to heat sources that could potentially enhance the medication's absorption and lead to an overdose.

6. Don't let pets come into contact with or lick your skin where medical creams (e.g., sports creams, topical nonsteroidal anti-inflammatory creams [www.ismp.org/ext/165], fluorouracil topical cream [www.ismp.org/ext/166]) have been applied.

7. If a pet sitter or someone unfamiliar with your pet's medicines will be giving medications to your pet, leave clear written instructions to prevent confusion and dosing mistakes.

8. Never give pets human medications (including over-the-counter [OTC] medications and weight loss products) without consulting your veterinarian. Medications that may seem innocuous, such as ibuprofen, can be fatal for pets.

9. Properly dispose of expired medications in pet-safe containers.

10. Always contact the ASPCA Animal Poison Control Center (888-426-4435) or your veterinarian if your pet has ingested any medications that were not prescribed for them. A $65 consultation fee may apply when you call the Animal Poison Control Center.

We hope errors never happen, but if they do, please report any veterinary-related medication errors to the US Food and Drug Administration (FDA) (www.ismp.org/ext/167). You can also report errors to ISMP (www.ismp.org/MERP) and we will forward them to the FDA Center for Veterinary Medicine.

Additional resources

- FDA Center for Veterinary Medicine (www.ismp.org/ext/167)
- ASPCA list of poisonous household products, human medications, and cosmetics (www.ismp.org/ext/168)
- American Veterinary Medical Association list of 10 "poison pills" for pets (www.ismp.org/ext/93) and important information about your pet's medications (www.ismp.org/ext/169)

If you would like to subscribe to this newsletter, visit: www.ismp.org/node/10

Report medication and vaccine errors to ISMP: Please call 1-800-FAIL-SAF(E), or visit our website at: www.ismp.org/MERP or www.ismp.org/VERP. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

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> SAFETY briefs cont'd from page 3

manner, with a package insert listing both product names, so mix-ups can happen with these products, too.

The package insert should not be placed in a way that it may be confused as the package label. We have reached out to FDA and Hospira with a recommendation to flip the package insert text-side down to avoid the risk of confusion. Meanwhile, continue to barcode scan these products, and remind staff about the risk of mix-ups and to look at the side panels that contain the official label on the carton for proper drug identification.

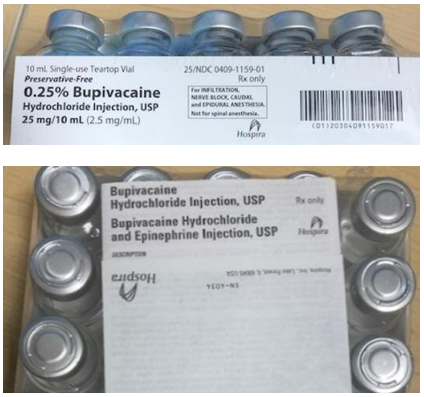

Figure 1. A package of 0.25% bupivacaine vials (top) was mistaken as bupivacaine with **EPINEPH**rine vials because the package insert, which lists both product names, is on the top of the packing box (bottom image).

Special Announcements

Deadline extended for IV push GAT

The submission deadline for the ISMP ***Gap Analysis Tool (GAT) for Safe IV Push Medication Practices*** has been extended to **April 30** to give organizations more time to participate in the **FREE** assessment. Participants who submit their findings anonymously to ISMP will receive a gap analysis score and have access to aggregate data. For details, visit: www.ismp.org/node/1188.

FREE symposia at TSHP Annual Seminar

If you are attending the Texas Society of Health-System Pharmacists (TSHP) Annual Seminar in **Frisco, TX**, don't miss ISMP's lunch symposia, ***Improving Intravenous Drug Delivery Safety*** on **April 12**. The program, sponsored by Fresenius Kabi, will be offered at other pharmacy meetings later this year. For details, visit: www.ismp.org/node/1469.