November 2025 | Volume 24 ■ Issue 11

ISMP Institute for Safe Medication Practices
An ECRI Company

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

Patient readmitted to hospital after taking only diluent from vancomycin kit

Problem: A patient diagnosed with *Clostridioides difficile* (*C. diff*), formerly known as *Clostridium difficile*, colitis was prescribed **FIRVANQ** (vancomycin) oral solution. To facilitate reconstitution, the product comes in a carton containing a bottle of vancomycin powder and a bottle of diluent. Prior to dispensing, the contents of the drug powder in one of the bottles must be reconstituted with the diluent from the other bottle. However, in this case, the Firvanq kit was dispensed to the patient without mixing the diluent with the vancomycin powder. At home, the patient took "doses" from the diluent bottle and therefore did not receive any active drug. The patient's *C. diff* infection progressed into sepsis, and they required hospitalization.

The brand name, Firvanq, is displayed on both the powder and diluent bottles. ISMP has previously received reports in which pharmacy staff read "Firvanq" on the diluent label and missed that it was just the diluent. At the time, they dispensed the diluent bottle thinking it contained active drug. In response to these error reports, the manufacturer, Azurity Pharmaceuticals, revised the diluent bottle container label. They made the word "Diluent" more prominent and deemphasized the brand name, Firvanq, to help practitioners recognize the bottle contains diluent only. However, if the diluent bottle is mistakenly dispensed to patients, they may not understand what the term "diluent" means and assume the bottle contains active drug.

Safe Practice Recommendations: To reduce the risk of errors with both the brand and generic vancomycin for oral solution kits (and other medications that require reconstitution), consider the following recommendations.

- Standardize the process used to store, prepare, and dispense vancomycin kits. Upon receipt of the kits into the pharmacy inventory, consider placing a warning label on the carton alerting staff that the vancomycin kits **MUST** be reconstituted prior to dispensing. Do not dispense just the diluent bottle to the patient, or the kit (both bottles) with the powder not reconstituted with the diluent.
- Add a distinct visual cue to the prescription receipt indicating that the medication needs to be reconstituted prior to dispensing.
- Incorporate technology at the point of sale to alert pharmacy staff that the prescription needs to be reconstituted. Explore options to utilize an interactive alert, for example, one that requires a pharmacist to confirm that the medication has been reconstituted.
- In the will-call area, do not place the actual carton or product containers in the same bag with other prescriptions for the patient as this can make it easier to miss that the product needs to be reconstituted.
- Provide an appropriate metric-only dosing device which corresponds to the instructions on the label.
- Give the reconstituted product to a pharmacist. Open the bottle with the patient or caregiver to check that the contents have been reconstituted.
- Use the teach-back method to educate patients and/or caregivers about the medication. Have the them demonstrate how they will measure and administer the dose to validate comprehension.
- Monitor patients and encourage them to contact their providers if a medication is not working as intended.

Adapted from the article, *From the CAMER Database: Patient Readmitted to Hospital with Sepsis After Taking Only Diluent from Vancomycin Kit*, which appeared in the November 2025 issue of The Script published by the California State Board of Pharmacy, Department of Consumer Affairs.

SAFETY briefs

HIGH-ALERT

Proper patient education and dosing syringes needed for sirolimus oral solution. A pediatric patient was discharged from the hospital with a prescription for the immunosuppressant agent sirolimus oral solution (1 mg/1 mL). The prescribed dose was 0.1 mL (0.1 mg) orally once daily. During routine follow-up, it was found that the patient's sirolimus level was unexpectedly high. The patient's parents then realized that they had been administering 1 mL for each dose. The parents had mistaken the 1 mL marking on the oral syringe provided with the sirolimus carton for 0.1 mL (**Figure 1**), thus administering a tenfold overdose with each dose.

Figure 1. The 1 mL marking on the 3 mL oral syringes included in sirolimus oral solution cartons was mistaken as a 0.1 mL dose, a tenfold overdose.

Sirolimus oral solution is available in cartons that contain a 60 mL bottle of medication, an oral syringe bottle adapter, and 30 oral syringes and syringe caps. The oral syringes can accommodate doses in 0.1 mL increments. However, only the markings denoting half and full mL doses are labeled with numbers.

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Join us for **ISMP's 28th Annual Cheers Awards** (page 4), Tuesday, **December 9, 2025**, at the House of Blues, Las Vegas, NV, at 6:00 pm or consider making a donation. For support opportunities or to register for the dinner, visit: ISMP Cheers Awards.

Alpha-gal syndrome—evaluate active and inactive ingredients

Problem: Alpha-gal syndrome is a potentially life-threatening allergic condition that can occur after a patient has been bitten by a tick. It is named for a molecule, galactose-alpha-1,3-galactose, which is found in most mammals, but not humans. Symptoms may then occur after the patient eats red meat or is exposed to other products made from mammals (e.g., gelatin, dairy products). A hospital reported that a patient with alpha-gal syndrome received beef broth with their food tray despite a special diet order in the electronic health record (EHR) stating the patient cannot have beef or pork products. During an event investigation, the hospital identified deficiencies in the EHR that included how drug-food allergies do not cross over into the diet restrictions and not having a mechanism to screen for inactive ingredients in medications and vaccines (e.g., gelatin, glycerin, magnesium stearate, bovine extract) or animal-derived products (e.g., monoclonal antibodies, heparin, certain antivenoms) which may be contraindicated for patients with alpha-gal syndrome (see Products That May Contain Alpha-gal).

We discussed a similar concern with inactive ingredients in our April 2022, newsletter article, Hidden Pork Content in Colace Capsules. Some medications, including the **COLACE** brand of docusate sodium, have gelatin capsules sourced from pigs, but product labeling does not state that. People with food allergies or those who want to avoid animal products need to know the origin of the ingredients contained in their medications. We contacted Avrio Health, the manufacturer of the brand product Colace, and confirmed that the gelatin used is sourced from pigs, which is not specified in the labeling. It appears that, under current regulations, the product label is not required to detail the animal source of the gelatin.

Safe Practice Recommendations: There is a good chance that staff may be unaware of alpha-gal syndrome and how patients with this condition may react to certain medications and inactive ingredients. Refer them to resources such as the Centers for Disease Control and Prevention (CDC) website. Consider building an alert to notify practitioners when you become aware of a patient with food allergies, or someone known to have alpha-gal syndrome.

Evaluate your EHR and/or pharmacy dispensing systems' functionality to determine if an alert would fire if a patient with alpha-gal syndrome had a documented allergy to an animal-derived product or an inactive ingredient known to trigger this allergy. During transitions of care, specifically ask patients about any reactions they have had from foods, medications, or inactive ingredients, and document the details of the reaction in the EHR and/or pharmacy dispensing system. If patients have concerns about the inactive ingredients contained in a medication, the pharmacy should review the package/label and prescribing information or contact the manufacturer for more information. Additional resources include the following: *What medications are contraindicated with an alpha-gal allergy? What mammal by-products could be listed as inactive ingredients on the package insert (i.e., magnesium stearate, gelatin)?* (InpharmD.com) and Alpha-gal Syndrome (VEGANMED.org).

Special Announcements

Virtual MSI workshop

Join us for our last ***ISMP Medication Safety Intensive (MSI)*** workshop of the year, which will be held **December 4 and 5, 2025**. For more information and to register, click here.

Midday symposium at ASHP Midyear

If you are attending the 2025 ASHP Midyear Clinical Meeting and Exhibition in Las Vegas, NV, join us on **December 9, 2025**, for our midday symposium, ***Safety Considerations for IV Push Amid Drug Shortages***. Speakers will review adverse drug events associated with intravenous (IV) push medications and present safe practice guidelines and system-level strategies to prevent errors. For more information and to register, click here.

>SAFETY briefs

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Consider providing 1 mL oral syringes for doses less than 1 mL or 0.5 mL oral syringes for doses less than 0.5 mL. These smaller syringes may be more accurate and easier to use for such small doses. Mark prescriptions for sirolimus oral solution for mandatory counseling. Leverage technology in the pharmacy dispensing and point-of-sale systems to prompt mandatory patient education, including for patients to whom the medication may be shipped. Pharmacists should mark the syringe to indicate the volume to be measured and administered. You may consider affixing an auxiliary label that provides a visual clue as to where the caregiver should measure the dose. Use the teach-back method to educate patients and/or caregivers how to measure and administer this medication in order to verify their understanding. Require pharmacists to provide patients with educational material on reading syringe markings and how to measure the ordered dose.

HIGH-ALERT

Look-alike Semglee and Kirsty insulin pens. We have received multiple reports about the potential to mix up Biocon Biologics' new **SEMGLEE** (insulin glargine-yfgn) long-acting insulin and **KIRSTY** (insulin aspart-xjhz) rapid-acting insulin prefilled pen devices. The body and cap of each pen are the same blue color and each has a light-colored pen label. While each pen label includes a colored band (i.e., orange for Kirsty and purple/lavender for Semglee) that corresponds to the color of the device's push button, the look-alike nature of the pen bodies and caps may contribute to errors when the pens are removed from their cartons.

We have written about the potential to confuse insulin pens in the past, particularly for patients with impaired vision. To help prevent mix-ups, teach patients and their caregivers ways to help differentiate the various insulin types they may have in their homes. Some potential strategies include using adhesive tape, a rubber band, or hair ties wrapped around one of the pens. Perhaps affixing auxiliary labels denoting 'long-acting' and 'rapid-acting' to the pens or storage containers could also help. Since insulin does not need to be kept in

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Your *Reports* at *Work*

In July 2025, the US Food and Drug Administration (FDA) approved a new formulation of **SHINGRIX** (zoster vaccine recombinant, adjuvanted) in a prefilled syringe by GSK. Unlike the current two-vial system that requires reconstitution before use, the prefilled syringe is ready-to-administer. ISMP had been in contact with GSK in the past to lobby for such a product. We have previously written about preparation and administration errors with two-component vaccines that require reconstitution. In these cases, practitioners have used the wrong diluent to reconstitute the lyophilized powder component, or the liquid component alone was administered to the patient. In fact, from August 2024 to August 2025, there were six events reported to the ISMP National Vaccine Errors Reporting Program (ISMP VERP) in which practitioners only administered the adjuvant suspension (liquid component) from the two-component Shingrix formulation. The new Shingrix prefilled syringe formulation aims to mitigate this risk. GSK anticipates discontinuing production of the two-vial system once the prefilled syringe formulation is available.

According to the prescribing information, the prefilled syringe formulation has the same indications as the two-component Shingrix formulation. It is used for the prevention of herpes zoster (shingles) in adults aged 50 years and older, and in adults aged 18 years and older who are at increased risk of shingles due to immunodeficiency or immunosuppression caused by known disease or therapy. The dosing schedule also remains unchanged. Two intramuscular doses are required. After the first dose, a second dose is administered 2 to 6 months later. The prefilled syringes must be stored in the refrigerator and protected from light. Once removed from the refrigerator, the prefilled syringe should be used as soon as possible but may be kept for up to 72 hours at room temperature.

We highly recommend switching your pharmacy inventory to this product as soon as it becomes available. Hopefully, vaccine manufacturers are looking at ways to do the same with other two-component vaccines. We sincerely appreciate organizations continuing to report medication and vaccine errors to us so that we can work together to prevent patient harm.

New white paper: Optimizing ADC safety

Med Safety Board (MSB), an ISMP company, recently published a white paper, Optimizing ADC Safety: Research Insights into Storage Configurations and Processes That Minimize Errors and Delays, which summarizes the results of a survey, conducted earlier this year, regarding storage configurations, error risks, and medication access concerns with automated dispensing cabinets (ADCs), along with findings from other collected data sources, including errors reported to ISMP. The white paper also provides recommendations for both healthcare organizations and ADC manufacturers/vendors.

The survey found that nearly two-thirds of the 156 respondents reported an error(s) occurring within the past year with multiaccess compartments (67%), such as matrix drawers or towers, and single-access compartments (66%), such as locked-lidded pockets. Most respondents (96%) perceived that storing medications in single-access compartments minimizes the risk of error, and 86% agree that storing medications in multiaccess compartments contributes to errors. Furthermore, practitioners also believe that they do not have enough single-access compartments (49%) compared to multiaccess compartments (22%) in ADCs within their organizations. The most common error reported with multiaccess compartments was finding the wrong medication in a compartment intended for a different drug (43%).

Refer to the white paper for additional details, including the impact of ADC malfunctions. Review the recommendations provided in the white paper to optimize safe ADC storage, minimize errors, and limit access concerns from ADC malfunctions. Thank you to all practitioners who participated in this survey enabling us to learn more about the safe use of ADCs.

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the refrigerator after opening, the pens can be stored in the specific physical locations where they will be administered, such as the bedroom for long-acting Semglee, and the kitchen (away from moisture or high-heat sources) or dining room for rapid-acting Kirsty. However, always remind patients to safely and securely store their medication up and away and out of sight of children.

HIGH-ALERT

Needlestick risk: EPINEPHrine auto-injector without retractable needle. A pediatric emergency department nurse reported that an **EPINEPH**rine single-dose prefilled auto-injector (Amneal) does not automatically retract and shield the needle post-injection. According to the prescribing information, Amneal's **EPINEPH**rine auto-injector requires the user to manually slide a cover over the needle after administration, increasing the risk of a needlestick injury. Other products (e.g., **EPIPEN** [Mylan], generic [Mylan]) have a mechanism that automatically covers the needle after administration or the needle automatically retracts (e.g., **AUVI-Q** [Kaleo]).

We have notified the manufacturer about this concern and recommended that the syringe needs engineering controls that protect people against needlestick injuries. Amneal has escalated our concern for further follow-up. Organizations should consider purchasing products with automatic mechanisms to prevent needlestick injuries. Report issues with devices that do not have this safeguard to ISMP, FDA, and the manufacturer.

To subscribe: www.ismp.org/ext/1369

ISMP Medication *Safety Alert!* Community/Ambulatory Care (ISSN 1550-6290)

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

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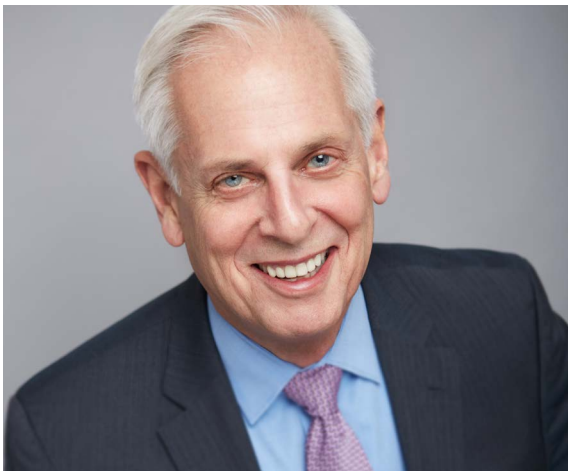
SHARING A SAFETY MISSION

ISMP 28TH ANNUAL CHEERS AWARDS

Tuesday, December 9, 2025

House of Blues – Las Vegas, NV 6:00 pm



The 28th Annual ISMP Cheers Awards will celebrate individuals and organizations on a mission to make strides in medication safety. Support ISMP's ONLY annual fundraising event or attend the awards dinner to honor them and advance our shared goal of preventing errors and protecting patients!

For support opportunities and/or to register for the dinner, visit: https://home.ecri.org/pages/cheers-event

The Michael R. Cohen Lifetime Achievement Award Winner:
Martin J. Hatlie, JD
Founding Member, Director for Policy & Advocacy, Patients For Patient Safety US

ISMP will be at the 2025 ASHP Midyear Clinical Meeting
Educational Sessions with ISMP Speakers:

Sunday, December 7, 2025

How Smart Are Smart Infusion Pumps in Preventing Medication Errors?
9:00 am – 10:15 am PT

ISMP Medication Safety Update 2025
3:30 pm – 5:00 pm PT

Tuesday, December 9, 2025

A Winning Strategy: Confronting the Top 10 Patient Safety Challenges of 2025 with ISMP
10:00 am – 11:00 am PT

Symposium: Safety Considerations for IV Push Amid Drug Shortages
11:30 am – 1:00 pm PT
Mandalay Bay Convention Center - South Pacific D - Lower Level
Preregister here: https://home.ecri.org/blogs/ismp-upcoming-events/safe-iv-push-practices-amid-drug-shortages

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