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ISMP
An ECRI Affiliate

Community/Ambulatory Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Ensuring the safe use of automated dispensing technology: We need your input!

Recently, a pharmacy that was using automated dispensing technology (e.g., vial dispensing robot) was in the process of refilling one of the cassettes (cells) with tra**ZOD**one 50 mg tablets. The person refilling the machine retrieved two 500-count medication bottles from a storage shelf, but without realizing it, one of the containers held topiramate 50 mg, not tra**ZOD**one 50 mg. Both medications are manufactured by Zydus Pharmaceuticals and look nearly identical (**Figure 1**), and one bottle was sitting right behind the other where they were stored. Both tablets are round, white, and about the same size. The tra**ZOD**one tablet is scored and has a tablet code on one side. However, the reverse side is smooth and without any markings. Topiramate tablets look very similar but are not scored (**Figure 2**). Thus, it is not only the bottles that look alike, but so do the tablets. Fortunately, before anyone received the wrong medication, a pharmacist caught the filling error while verifying a prescription for tra**ZOD**one 50 mg when she recognized that the two drugs appeared to be mixed together in the prescription vial.

The pharmacist who reported this error told us that the automated dispensing technology software her pharmacy uses requires barcode scanning, but unless you scan each stock bottle individually, the technology can be bypassed by scanning just one bottle. That is, if you are trying to add 1,000 tablets and the medication comes in a 500-count bottle (which is how both above medications are supplied), you can scan just one of the bottles, then pour both bottles (one being the incorrect medication in the unscanned bottle) into the dispensing robot cell. After this event, the pharmacy now only permits using one bottle at a time to restock the robot.

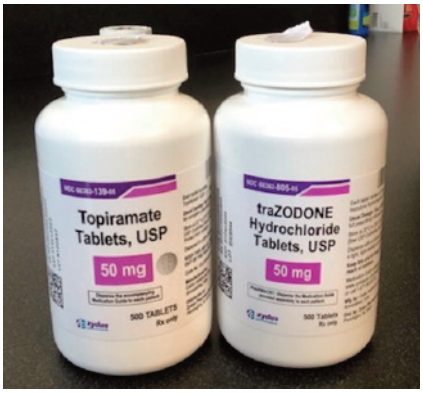

Figure 1. Look-alike containers of topiramate and tra**ZOD**one from Zydus.

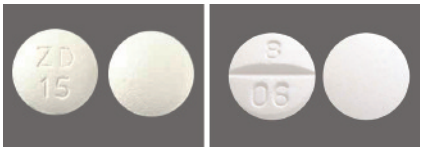

Figure 2. Topiramate 50 mg and tra**ZOD**one 50 mg tablets also look alike.

Pharmacies with robotic dispensing capabilities need to address situations in which multiple bottles of tablets are used to refill a cassette. Visual checks are important, but as described above, cannot be solely relied upon for proper identification of bottle contents. Check with your technology manufacturer to learn what is recommended to address situations in which multiple bottles are used to refill a cassette. Ideally, the filling process should require a scan of the barcode printed on the label of *each stock bottle* before it is added. Pharmacies should engage their staff and establish standard work practices to barcode scan each stock bottle. Use only unopened stock bottles to ensure the national drug code (NDC) number, lot number, and expiration date match for all tablets (2D barcodes would be needed). Completing the entire process of filling one cell before moving to the next cell and

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SAFETY briefs

Update on need for a pegfilgrastim formulation for pediatric dosing. A *Safety Brief* in our July 2021, newsletter discussed error reports involving pediatric patients who required pegfilgrastim (**NEULASTA**) as outpatients. The product is only available in a 6 mg (0.6 mL) prefilled syringe from the sponsor, Amgen, and biosimilar manufacturers. Although the package insert includes a table for weight-based dosing of pediatric patients under 45 kg who need less than 6 mg (0.6 mL), there is no vial to withdraw such a dose, and the prefilled syringe has no graduation marks to aid in measurement. Parents are often instructed to withdraw a partial dose from the prefilled syringe using an empty sterile syringe and needle. However, in some cases, this is not done correctly, and some children have been given the entire contents of the syringe.

We recently learned that, in October 2019, the US Food and Drug Administration (FDA) issued an "Order Letter" to the sponsor of Neulasta for a post-marketing commitment that includes the development of an appropriate formulation that can be used to administer Neulasta directly and accurately to pediatric patients who require doses less than 6 mg. FDA also sent similar letters to the pegfilgrastim biosimilar manufacturers. FDA called upon these companies to conduct any necessary human factors studies to evaluate the ability of practitioners and/or caregivers to measure the appropriate doses. In the letter, FDA stated that a pediatric presentation, such as a vial or a pediatric-sized, prefilled syringe (with a suitable concentration) would be an "appropriate formulation" alternative.

Confusing syringe scale. Caregivers and long-term care facility staff might be confused when measuring liquid medica-

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corresponding drug bottle(s) is critical to ensure that bottles used to refill different cells are not mixed up after barcode verification. Privileges to make modifications, adjustments, or changes in the bin contents of automated dispensing systems should be restricted to properly trained staff members. Pharmacy managers and/or regional personnel for chain pharmacies should periodically perform quality control checks by observing the processes involving robotics and automation to ensure adherence to the standardized work practices. If at-risk behaviors, such as scanning only one bottle or scanning the same bottle twice, are observed, coach staff to see the potential for error and the importance of scanning each bottle. Finally, share stories like this with staff who use this type of automation to emphasize best practices such as the scanning of each bottle (rather than one bottle multiple times).

It is also undeniable that look-alike product labeling and packaging was one of the root causes of the mix-up. We do recommend reading medication labels three times at different points in the product selection and dispensing processes—when obtaining a drug from storage, during use, and when discarding the container or returning it to stock. However, the need for companies to prevent container labels from looking similar across multiple items within a company's product line is among the topics included in draft guidance for industry from the US Food and Drug Administration (FDA), *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (www.ismp.org/ext/473). We asked Zydus to revise the product labeling that contributed to this error and also to look at all of their product labels for such safety issues.

We hope to address the safe use of automated dispensing technology more globally. In order to do that, we need to hear from you. We ask that you share with us any identified limitations or barriers you have experienced in the safe use of your automated dispensing technology, including limitations in the barcode scanning process. We would also like to learn about the strategies you and your automated dispensing technology vendor(s) have in place to reduce the risk of medication errors and ensure the correct drug is added to the correct cell. Please contact us at: ismpinfo@ismp.org.

Close calls—a sign of resilience or vulnerability? Odds are higher that vulnerabilities are reported

In the January 2021 issue of *The Joint Commission Journal on Quality and Patient Safety*, Jung et al. examined how the proximity of a close call to the averted failure (reaching the patient) impacted healthcare workers' psychological safety and willingness to report the event.[1] A close call (also referred to as a near miss) is an event, situation, or error that took place but was captured before reaching the patient. To cite one example of a close call, the wrong drug was dispensed by the pharmacy, but a nurse caught the error before it was administered to the patient.

Jung et al. note that reports of close calls contain contrasting clues or associations that highlight either *resilience*—we managed to avoid the failure and were successful in terms of the outcome—or *vulnerability*—we nearly failed in what transpired right before the averted outcome. They found that close calls that were caught early in the process were often perceived as successful because they were further away from the averted failure, thus underscoring a sense of *resilience*. In contrast, close calls that were caught later in the process were often perceived as near failures, thus underscoring a sense of *vulnerability*.

The authors emphasized that close calls were not processed and treated equally. They found that the likelihood of reporting close calls seems dependent not only on the degree of psychological safety felt by the worker in reporting the event, but also

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tion doses using the syringe scale printed on Covidien's Monoject 3 mL enteral (ENFit) syringes. The scale is marked as ½, 1, ½, 2, ½, 3 mL (**Figure 1**). This can easily be misunderstood, reading the intended 1½ mL or 2½ mL as just ½ mL. The confusion could lead to preparing and administering the wrong medication dose for a patient or resident. We have let the company know the syringe scale should be revised as it is not safe to use. Syringe scales should never indicate doses using fractions but should indicate the entire volume using decimals (0.5, 1.5, 2.5). You may want to stock and dispense an alternate syringe brand.

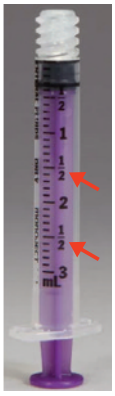

Figure 1. Syringe scale using fractions could easily confuse people, as 1½ mL or 2½ mL could be read as just ½ mL.

Confirm correct mg and mL dose based on product concentration supplied. A discharge prescription for testosterone cypionate 100 mg/mL in oil for intramuscular (IM) injection included directions to administer 0.5 mL (50 mg) into the muscle every week. However, in the outpatient pharmacy, testosterone cypionate in oil was only available in a 200 mg/mL strength from the pharmacy wholesaler. A pharmacy technician selected the only strength listed in the computer and prepared a 200 mg/mL vial for dispensing. However, the technician mistakenly used the original prescription directions to "inject 0.5 mL" into the muscle every week. A pharmacist verifying the medication did not catch the error. The directions should have been changed to inject 0.25 mL for a 50 mg dose.

Ideally, given the prevalence of electronic prescribing and increasing interoperability, pharmacy computer systems should alert the verifying pharmacist if a different concentration of a product was selected during order entry compared to what was received with the electronic prescription. The alert should prompt the pharmacist to check the concentration as well as the new mg and mL doses. However, in the meantime, pharmacists should contact the prescriber if a prescribed concentration does not match the

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whether the close call was caught early (evidence of *resiliency*) or later (evidence of *vulnerability*) in the process.

While psychological safety is important to feel comfortable reporting a close call, Jung et al. found that the odds of reporting were higher if it was caught later in the process, was discerned as a *vulnerability* or near failure, or was felt to be an event that "nearly happened" rather than "could have happened." The willingness to report the event seemed to be related to a strong outcome bias and how close the event came to harming the patient. On the other hand, the odds of reporting a close call were lower if it was caught earlier in the process, deemed a chance success or a sign of *resilience*, or was felt to be an event that "could have happened" rather than "nearly happened." Healthcare workers were less inclined to report close calls that seemed to be distant to patient harm or have a weak or neutral outcome bias.

Prior research suggests that the perceived severity of a close call may reduce psychological safety and thus reduce the willingness to report the event. However, these recent findings suggest that another variable that predicts the likelihood of reporting close calls is whether the event is perceived as a failure or *vulnerability* rather than a success or a sign of *resilience*. Jung et al. point out that close calls that are identified early in the process may resemble an ordinary, everyday occurrence, more so than a reportable incident. These early mistakes may not be regarded as sufficiently important to report.

Although the study was done in a radiation oncology setting, the lessons are ones that can be shared in any practice setting. The authors suggest that educating healthcare workers about the dual nature of close calls, which can demonstrate either *vulnerability* or *resilience*, may aid appropriate recognition of all close calls as learning opportunities. Healthcare workers should be encouraged to report all types of close calls, including seemingly minor ones that occur early in the process. There is much that can be learned about both the *vulnerability* and *resilience* of your systems from all close calls.

Reference

1) Jung OS, Kundu P, Edmondson AC, et al. Resilience vs. vulnerability: psychological safety and reporting of near misses with varying proximity to harm in radiation oncology. *Jt Comm J Qual Patient Saf*. 2021;47(1):15-22. www.ismp.org/ext/713

Infection transmission risk with shared glucometers, fingerstick devices, and insulin pens

The Centers for Disease Control and Prevention (CDC) has issued several warnings regarding unsafe practices that might result in the transmission of hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), and other infectious diseases during assisted blood glucose monitoring and insulin administration (www.ismp.org/ext/714). Assisted blood glucose monitoring is when a healthcare worker assists or performs glucose testing. Often times, the healthcare worker uses a shared glucometer (as opposed to self-blood glucose monitoring with the patient using their own glucometer). This typically occurs in long-term care settings, correctional facilities, senior centers, health fairs, hospitals or clinics, ambulatory care settings, and schools or camps.

Outbreaks associated with assisted blood glucose monitoring have been identified with increasing regularity in various inpatient and outpatient healthcare settings where blood glucose monitoring equipment is shared. Failure to follow the most basic principles of infection control contributed to most of these outbreaks.

Most frequently, the unsafe practices that have contributed to the transmission of infections include the following:

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available product concentration. As a result of this error, pharmacy technicians at this pharmacy now communicate both the mL and the mg amounts to the pharmacist to confirm the dose in mg and mL during the final product verification. Keep in mind though that the patient instructions printed on the pharmacy label should include the dose in the unit of measure used for administration, which in this case would be mL. Printing both the mg and mL on the pharmacy label can increase the risk of confusion for the patient. Finally, discuss and document any changes in strength or concentration with the patient.

Confusing labeling on a two-dose blister. Aprepitant capsules are often administered with dexamethasone and a 5-HT_3 antagonist antiemetic like ondansetron to manage moderately or highly emetogenic chemotherapy. On day 1 of the chemotherapy treatment, the aprepitant dose is 125 mg. On days 2 and 3, the dose is 80 mg each day. The 80 mg capsules are available in a single-capsule unit dose package and in a two-dose blister, intended for days 2 and 3 of chemotherapy. However, these two-dose blisters are labeled as 80 mg (**Figure 1**) and may be confused with the unit dose package, even though the total amount of medication in the package is 160 mg. Furthermore, the barcode on the two-dose blister scans as 80 mg, not 160 mg.

Figure 1. Aprepitant two-dose blister package should be labeled as 160 mg (two 80 mg capsules).

In a recently reported event, a nurse initially believed that both capsules (160 mg total) were supposed to be given together for the 80 mg ordered dose. But she checked further and learned that each 80 mg capsule was to be given by itself on days 2 and 3. With the two-dose blister, the package label does not clearly indicate anywhere that there is 80 mg "per capsule" or that the package holds

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- Using fingerstick devices, also called lancing devices, for more than one person
- Using a blood glucometer for more than one person without cleaning and disinfecting it after every use
- Failing to change gloves and perform hand hygiene between fingerstick procedures
- Using insulin pens for more than one person risks infection transmission

Although some fingerstick devices have been previously approved and marketed for multi-patient use and require the lancet and disposable components to be changed between each patient, CDC recommends **never** using these devices for more than one person due to failures to change the disposable components, difficulties with cleaning and disinfection after use, and their link to multiple HBV infection outbreaks. Single-use fingerstick devices are disposable and prevent reuse through an auto-disabling feature.

Whenever possible, blood glucometers should **not** be shared. If they must be shared, each device should be cleaned and disinfected after every use, per the manufacturer's instructions. The glucometer must be cleaned before it can be disinfected, which might require the repeated application of an approved cleaning agent following the manufacturer's recommendations. If the manufacturer does not specify how the device should be cleaned and disinfected, then the glucometer should not be shared. Organizations have the responsibility to verify with the manufacturer that the glucometers are, in fact, approved to be used for multiple patients.

Using insulin pens for more than one patient is an ongoing medication safety risk we have previously discussed in our newsletters and during consultations and live presentations, starting as early as 2008. Since then, ISMP and others have chronicled large-scale, potential exposures to bloodborne pathogens caused by using insulin pens for multiple patients even after changing the needle. Insulin pens should **never** be used for more than one patient.

Additionally, The Joint Commission (TJC) has found that knowledge gaps among providers and leaders associated with assisted glucose monitoring and insulin administration via a pen device have resulted in unsafe practices and subsequent escalation to an *Immediate Threat to Health or Safety*. TJC has released an informational video that examines some of the more common mistakes witnessed by surveyors when staff administer insulin via a pen or perform glucose monitoring using a shared glucometer (www.ismp.org/ext/715). Additionally, the May 2021 issue of *Perspectives* details helpful information on compliance with standards related to glucose monitoring and insulin administration (The Joint Commission. Consistent Interpretation. Joint Commission surveyor's observations of staff competency related to blood glucose monitoring and insulin administration. *Perspectives*. 2021;41[5]:38-41).

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2 doses (capsules). The package insert contains this information, but nurses often do not have the package insert available to them when administering medications. Aprepitant is also available in a 40 mg dose for the prevention of post-operative nausea and vomiting. There is also a tri-pack with one 125 mg capsule and two 80 mg capsules.

ISMP has reported similar situations before, including with the chemotherapy agent, venetoclax (**VENCLEXTA**), and the antiemetic, rolapitant (**VARUBI**). In the past, ISMP has discussed these labeling problems with the US Food and Drug Administration (FDA), and enhancements have been made to products such as Venclexta and Varubi. FDA should work with sponsors to assure label clarity for aprepitant and other products in the future where there may be confusion in what appears to be a unit dose package but might contain multiple doses.

Special Announcements

Two-day program for industry

Healthcare practitioners who work in the pharmaceutical industry are invited to join us on **October 13 and 14, 2021**, for a live, virtual program entitled, ***FDA, ISMP, and Industry Partners: Symbiosis for Medication Safety***. The program will provide an understanding of how products are impacted during dispensing and administration through the use of technology. Examples of safety issues will be presented as well as a discussion on how human factors contribute to product-related errors. At the completion of this program, participants will have a greater understanding of the importance of safe product design. For more information, and to register, please visit: www.ismp.org/node/25772.

Accepting Cheers Awards nominations

Not much time is left! Nominations for CHEERS AWARDS will be accepted through **September 10, 2021**. To submit a nomination, visit: www.ismp.org/node/1036.