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ISMP 25 YEARS ADVANCING MEDICATION SAFETY

Acute Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

SPEAK UP for Medication Safety: September 17, 2019 The first World Health Organization World Patient Safety Day

No one should be harmed while seeking care. And yet, every day, too many people in the world suffer avoidable harm or are put at risk of injury while receiving healthcare. According to the World Health Organization (WHO) (www.ismp.org/ext/294):

- As many as 1 in 10 patients is harmed while receiving hospital care, contributing to at least 2.6 million deaths around the world annually.
- The occurrence of adverse events due to unsafe care is one of the 10 leading causes of death and disability across the world.
- 15% of hospital expenses can be attributed to treating patient safety failures in the 36 global OECD (Organisation for Economic Co-operation and Development) countries (including the US).
- Unsafe medication practices and medication errors harm millions of patients and cost $42 billion globally every year.

Recognizing patient safety as a global health priority, the World Health Organization's (WHO) Member States established **September 17** as **World Patient Safety Day**. Through this global campaign WHO urges patients, healthcare workers, policymakers, academics, researchers, professional networks, and the healthcare industry to "Speak up for patient safety!" to make healthcare safer for patients. To spotlight patient safety and to increase awareness and engagement, the WHO will officially launch the first **World Patient Safety Day** by lighting up a prominent landmark in the city of Geneva, the Jet d'Eau fountain, in orange at sunset on **September 17**.

Other cities around the world will join WHO (www.ismp.org/ext/294) by lighting up monuments in orange, holding key patient safety conferences, and carrying out other planned patient safety events on **September 17** using the WHO's posters and campaign materials (www.ismp.org/ext/304). To cite a few examples:

- In Canada, various safety organizations have partnered to host a live screening of *To Err is Human*, followed by a panel discussion and a networking event of senior healthcare leaders.
- In the US, the Institute for Healthcare Improvement (IHI) will host a social media campaign about speaking up for patient safety and air a podcast of the National Steering Committee for Patient Safety panel discussion about progress in patient safety, challenges that remain, and areas of ongoing focus. The Zakim Bridge in Boston will also be lit in orange (September 18) in honor of World Patient Safety Day.
- In Ghana, the Health Service is holding a National Patient Safety and Healthcare Quality Conference (PSHQC) to contribute to the global effort in achieving quality universal health coverage by 2030.

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Ring that remains after removing tamper-evident cap may fall off. Many hospitals use plastic, tamper-evident caps for oral and parenteral syringes containing controlled substances. These may also be used by some 503B outsourcers or compounding pharmacies for both controlled and non-controlled drugs. The syringe caps are useful in reducing the risk of tampering and diversion of controlled drugs. Unfortunately, they can also introduce unexpected problems should loose rings fall off the syringe (**Figures 1-3**).

During an abdominal surgical procedure, a surgeon prepared an irrigation solution in a basin using 1 g per 10 mL ceFAZolin syringes provided by QuVa, a 503B compounding pharmacy. The company uses red tamper-evident caps on most of its syringe products, including ceFAZolin. Other outsourcers may use the same or similar tamper-evident caps. When the surgeon poured the solution into the patient's abdominal cavity, he saw a plastic ring floating around in the solution. The ring was originally connected to the tamper-evident cap on the ceFAZolin syringe. Fortunately, the detached ring was noticed. Had

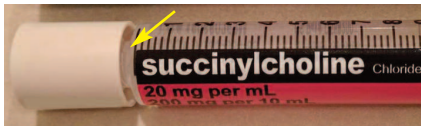

Figure 1. Example of white tamper-evident cap on syringe. In the case described above, the caps were red.

Figure 2. Outer cap removed with clear inner stopper intact and white plastic ring retained.

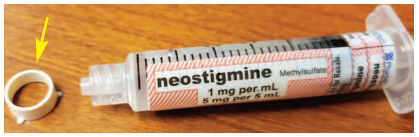

Figure 3. Plastic ring can easily fall off.

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- In England, Loughborough University will hold presentations about how the National Health Service (NHS) has improved 'patient safety alerts' to reduce the risk of incidents leading to harm, followed by a networking event.

- In Scotland, several agencies have partnered to hold a social media campaign with a theme of 'Why does safety matter to you?' to raise awareness of World Patient Safety Day and to highlight some of the key achievements and learning from more than 10 years of the Scottish Patient Safety Programme.

- In Sudan, staff from the Fedail Hospital in Khartoum will conduct on-the-job training for staff members in medication safety, hold panel discussions with the hospital's senior providers, and host a social media campaign and several radio and TV shows on patient safety related topics and stories.

- In Afghanistan, the Ministry of Public Health of Afghanistan, along with the WHO Afghanistan Country Office, will participate in a National Patient Safety Conference covering important patient safety topics, including medication safety, global patient safety, and root cause analysis of medical errors.

- In India, the Indian Alliance of Patient Groups, International Institute of Health Management Research, and the National Thalassemia Welfare Society will celebrate the first World Patient Safety Day with a workshop on patient safety.

- In Singapore, the Health Services staff will host an event highlighting the importance and role of patient safety research for nurses.

Embracing this year's theme of "Speak up for patient safety," ISMP encourages all US healthcare organizations and practitioners to support the WHO's **World Patient Safety Day** by encouraging patients to speak up about medication safety during their hospitalization. To assist with this effort, ISMP has provided **10 Medication Safety Tips for Hospitalized Patients** on page 5, which can be used as a handout for hospitalized patients. Each of these 10 tips should also be embedded in patient education materials (e.g., patient admission materials, intranet educational offerings while hospitalized) and reinforced by healthcare professionals who prescribe, dispense, and administer medications, as well as during review of the patients' home medications upon admission and discharge. You, too, can improve global patient safety by encouraging patients to be actively involved in their own care, to ask questions, and to work with their healthcare providers to ensure patient safety. Healthcare providers should also encourage patients to have an advocate or caregiver accompany them to help with understanding and adherence to the prescribed plan of care. Safe healthcare starts with good communication, and we all have a responsibility to promote patients', advocates', and caregivers' voices.

Nearly identical methotrexate and folic acid tablet appearance

We do not usually highlight errors due to the look-alike color of the tablets, but in the case of methotrexate and folic acid, which are often used together to lessen toxicity of the former, there is reason to do so. We recently received a report involving an accidental mix-up between these two medications. The mix-up resulted in the patient taking methotrexate daily for 6 days of the week and only taking folic acid once a week. It should have been the opposite.

The prescriber had reminded the patient to take the methotrexate once weekly using the mnemonic, "Take **m**ethotrexate on **M**onday." However, in this case, a friend helped set up the patient's medications in a weekly pill container. The friend did not realize the difference between the methotrexate and folic acid because both tablets looked similar; both were

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it not been noticed, the ring could have been retained in the patient's abdominal cavity, perhaps risking a serious long-term problem. ISMP received no similar reports previously.

Our March 8, 2018, newsletter included a SAFETYbrief warning that these tamper-evident caps for oral syringes could be a choking hazard if the ring enters the mouth or is left at the bedside where someone might later place it in their mouth. The caps are available in multiple colors for parenteral syringes, including blue and red but also white, which may make the ring less noticeable if it falls off. In the 2018 SAFETYbrief, we also mentioned how important it is for providers to be aware of the issue.

International Medical Industries (IMI), a manufacturer of these caps, recommends discarding the ring after removing the cap and before administering the medication. However, this information is in printed material that doesn't accompany the syringe and may not be seen by those administering the medication. Nurses and other healthcare providers who frequently use these products are likely aware of the syringe rings. However, they should be reminded of the potential hazards of a fallen ring and to remove and dispose of the ring prior to administering the syringe contents. Healthcare providers should also be aware that not all 503B outsourcers provide syringes with caps that are tamper-evident or that will have the retained rings.

Watch for overfill with Xolair single-use vials. XOLAIR (omalizumab) is an immunologic agent indicated for moderate to severe treatment-resistant asthma and chronic idiopathic urticaria (CIU). For the treatment of asthma, doses ranging from 75 mg to 375 mg are administered by subcutaneous injection every 2 or 4 weeks. The dose and dosing frequency are determined by body weight and total immunoglobulin E (IgE) serum levels measured before the start of treatment. The drug is available in both prefilled syringes (75 mg and 150 mg) and single-use vials as a lyophilized powder (150 mg) requiring reconstitution.

Healthcare practitioners have been telling us that they are confused by the vial's outer carton principal display panel that states

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round and yellow (**Figure 1**). The friend accidentally interchanged the days the patient was supposed to take the methotrexate and folic acid. That led the patient to take the folic acid on Mondays and the methotrexate tablets daily. The error continued until the patient presented to an emergency department with severe thrombocytopenia. The patient was hospitalized for treatment and monitoring and was later discharged. Google image searches show that many methotrexate and folic acid tablets are various shades of yellow, with some looking essentially identical.

Figure 1. Methotrexate 2.5 mg tablets (left) and folic acid 1 mg tablets (right) may look almost identical.

For years, ISMP has written about the potential for error when weekly methotrexate doses are accidentally administered daily (www.ismp.org/node/1141; www.ismp.org/node/394). Preventing the inadvertent daily dosing of oral methotrexate for non-oncologic conditions has been one of the **Targeted Medication Safety Best Practices for Hospitals** (TMSBP) since 2014, and the International Medication Safety Network (IMSN, www.intmedsafe.net/) recently published a similar global TMSBP earlier this year (www.ismp.org/ext/289). Despite these efforts, errors with oral methotrexate used for the treatment of non-oncologic conditions continue to occur, and multiple root causes have been identified.

It is critical to provide clear instructions for weekly dosing of methotrexate, utilizing auxiliary labels to draw attention to the once-weekly frequency. Practitioners should provide all patients with a copy of ISMP's free high-alert medication consumer leaflet on oral methotrexate (www.ismp.org/ext/290). Additionally, Teva Women's Health manufactures methotrexate in various colors and strengths (green [5 mg], blue [7.5 mg], pink [10 mg], purple [15 mg]), marketed as **TREXALL**. If the patient's insurance allows use of this brand product, which is packaged in a way that guides weekly administration, it would allow the dispensing of smaller quantities and reduce the risk of confusion with yellow, round folic acid tablets. Dispensed quantities should always be limited to a 4-week supply, and patients should be encouraged to keep methotrexate tablets in their original packaging rather than combining them with daily medications in pill containers. If patients are taking concurrent folic acid, additional education about the purpose of folic acid and the differences between the medications is necessary. Practitioners should also be aware of the potential for errors where patients confuse "Monday" with "morning." That may lead patients to take a dose of methotrexate every morning if written as an abbreviation (e.g., "q Mon" may be seen as "q Morn" [or q month]).

Methotrexate instead of metOLazone

We recently learned about a fatal mix-up between met**OL**azone and methotrexate through various media reports (www.ismp.org/ext/292). A patient in an assisted living facility died after mistakenly receiving methotrexate instead of met**OL**azone, a thiazide diuretic. The pharmacy had accidentally sent the wrong prescription to the facility, and the error was not identified. The assisted living facility staff then administered the wrong medication to the patient who eventually began experiencing severe pain and discomfort. The patient died about 1 month after the daily methotrexate was started. In 2016, ISMP wrote about a similar error that occurred in which methotrexate was dispensed instead of met**OL**azone, resulting in the death of a patient. Mix-ups between these drugs have also resulted in met**OL**azone being dispensed instead of methotrexate.

One of the most common error reports involving drug name mix-ups that we receive these days is where the first few letter characters bring up multiple drug names on the screen. The risk of a selection error increases when the drugs share similar strengths and dosage forms. In this example, these drug names share the first three letters (M-E-T), and both are available in 2.5 mg (generic) and 5 mg (generic met**OL**azone and

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each vial holds 150 mg (**Figure 1**). In reality, each vial holds 202.5 mg of Xolair. Users are instructed in the labeling to reconstitute the drug with 1.4 mL of sterile water for injection. The resulting solution includes overfill to facilitate dose preparation, so only 1.2 mL (150 mg) should be drawn into the syringe for subcutaneous injection, not the total amount within the vial after reconstitution. This mismatch between what is listed on the carton label and the actual contents of the vial after reconstitution can be confusing and could lead to dosing errors.

The risk of excess dosing with the Xolair vial compounds as the dose increases, requiring multiple vials to prepare each dose. For example, a patient who should receive a 300 mg dose could receive up to 105 mg

Figure 1. Carton label indicates the single-use vial contains 150 mg. Flip the carton over and instructions note the vial contains 202.5 mg of omalizumab, for reconstitution with 1.4 mL of sterile water for injection.

more drug than intended if the total contents of two 150 mg vials (405 mg) are administered. It should be noted that toxic doses of Xolair have not yet been determined. According to the prescribing information, single intravenous doses up to 4,000 mg have been administered in clinical trial settings, with no evidence of dose-limiting toxicity.

Incidentally, this situation is similar to a problem we noted with **NUCALA** (mepolizumab) in our June 28 and September 6, 2018 *SAFETY*briefs. With Nucala, an add-on maintenance treatment for adult patients with severe eosinophilic asthma, some pharmacy staff have been confused by the vial label statement, "100 mg/vial," when each vial actually contains approximately 144 mg of the drug to facilitate dose preparation.

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brand methotrexate, **TREXALL**) tablet strengths. When only M-E-T is typed, meth**IMA**zole, met**OL**azone, and methotrexate all appear and list a 2.5 mg oral solid dosage form. The similarities seem to make it easier to select the wrong item. Other drug names such as methamphetamine, methergine, methylphenidate, methyl**PREDNIS**olone, metoclopramide, metoprolol, and metro**NIDAZOLE**, may also appear on screen. For a long time, ISMP has recommended typing at least 5 letter characters (see the ISMP **Guidelines for Safe Electronic Communication of Medication Information**, www.ismp.org/node/1322) to reduce the number of different drugs that might appear on screen. In reality, though, it may require more than 5 letters to eliminate all but the intended drug.

Including the indication with all prescribed drugs may also help avoid errors (see our November 17, 2016 article, *Is an indication-based prescribing system in our future?*, www.ismp.org/node/190). Although indication-based prescribing systems are not currently available commercially, just including the intended purpose in the directions when prescribing drugs might be enough to prevent errors—for example, "For fluid retention: met**OL**azone 2.5 mg" or "met**OL**azone 2.5 mg daily (for fluid retention)."

ISMP also recommends using tall man letters for met**OL**azone to help differentiate it from methotrexate, and employing a hard stop in prescribing and dispensing software to prevent daily methotrexate from being entered without an appropriate cancer indication. Prior to dispensing methotrexate to any patient, verification of the dose, frequency, and indication is required, and education/counseling is required. This will also provide an opportunity for the pharmacist to recognize an error if the wrong drug is being dispensed. As a safe practice, consider establishing a system to ensure review of all methotrexate prescriptions that have been dispensed for patients within the past 24 hours. Please also see our August 9, 2018, article on strategies to prevent prescriptions for inadvertent daily methotrexate (www.ismp.org/node/1141).

Special *Announcements*

Get intensive about medication safety

Don't miss our last ***Medication Safety Intensive*** (MSI) workshop of the year being held in **Las Vegas**, NV, on **December 6-7**! You won't want to miss this unique opportunity to maximize your error prevention efforts and learn to look at your organization through the eyes of leading safety experts. For information and to register, visit: www.ismp.org/node/127.

Attend ISMP program at the CSHP meeting

Will you be at the ***California Society of Health-System Pharmacists*** conference in Anaheim this **October**? If so, register now for a **FREE** ISMP breakfast seminar, supported by Fresenius Kabi, on ***Improving Intravenous Drug Delivery Safety***, which will be held on Friday, **October 18**. Program speakers will discuss the primary safety issues, at-risk behaviors, and ISMP guidelines and best practices associated with intravenous (IV) drug therapy. For more information and to register, visit: www.ismp.org/node/1482.

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Healthcare professionals generally expect that the amount of drug listed on the label is the amount contained in the vial. Such confusion could lead to an unintentional overdose of these medications if the entire amount within the vial after reconstitution is drawn into a syringe and administered.

All staff who prepare Xolair and Nucala should be aware of the preparation procedure to reconstitute and remove the proper amount of drug from each vial.

BD 60 mL syringes will soon measure only 50 mL. BD announced a measurement scale change for its 60 mL plastic disposable syringe. The scale mark is being reduced to 50 mL, and the product will be sold as a 50 mL syringe. No other changes to syringe components are being made. This involves BD Luer-Lok Tip, Luer Slip Tip, Eccentric Tip, and Catheter Tip syringes, in both oral and enteral syringe categories. According to BD, one reason for the change is to help drive safe sterile compounding practice by preventing overfill of medications. These changes will occur before the end of the year, with the revised catheter tip syringes becoming available as soon as late September. Additional information can be found at: www.ismp.org/ext/305.

Many facilities, especially pediatric facilities, use syringe pumps and may have built drug dilutions based on a total syringe volume of 60 mL. This change may require modifications in syringe pump drug libraries (e.g., dispense volumes, size of syringes). The total volume may be in the drug library or with the drug name as a default setting. The change may also require modifications in recipe listings or compounding formulas, and may impact adult dosing. Other areas where protocols might need to be rebuilt include your intravenous (IV) workflow system. We do not have any information from other syringe vendors regarding possible changes.

Editors: Judy Smetzer, BSN, RN, FISMP; Michael Cohen, RPh, MS, ScD (hon), DPS (hon); Ann Shastay, MSN, RN, AOCN; Russell Jenkins, MD; Ronald S. Litman, DO. ISMP, 200 Lakeside Drive, Suite 200, Horsham, PA 19044. Email: ismpinfo@ismp.org; Tel: 215-947-7797; Fax: 215-914-1492.

10 Medication Safety Tips

for Hospitalized Patients

1. **Keep an up-to-date list and know your medicines.** Know the full names of your prescribed and over-the-counter medicines. Be sure you know your medicines' generic names if brand products are used. Because medicine names and doses are hard to remember, always keep an up-to-date list of all your medicines. This list should include all medicine doses, instructions, and why you take the medicine. Keep the list with you in your wallet, purse, or digitally on an app to share with your healthcare provider. Expect that your healthcare provider will review the list with you and/or a family member upon hospital admission.

2. **Observe healthcare providers (and others) washing their hands.** Make sure anyone who brings you medicine (or who enters your room) first washes or sanitizes his or her hands. If you do not directly observe the handwashing, don't be afraid to speak up and ask the healthcare provider about handwashing.

3. **State your name and date of birth and get your identification bracelet scanned.** The entire process of safely administering medicine to you begins by verifying your identity. Although your healthcare providers may know you well, it is important for you to provide anyone who brings you medicine with your full name and date of birth. If barcode scanning is available, be sure they also scan the barcode on your identification bracelet to confirm your identity before giving you any medicine. Don't let the process proceed until this has been done.

4. **Where the technology is available, observe healthcare providers scanning barcodes on your medication packages before opening them.** Watch anyone who brings you oral medicine to ensure they scan the barcode on the outer package (just like grocery packages) before opening the medicine and giving it to you. Most oral medicine packages can be scanned in your room or at your bedside, after your identification bracelet has been scanned. Ask nurses to show you the actual package within which the medicine is available. Refuse to take unlabeled medicines (e.g., loose tablets, liquid poured into an unlabeled dosing cup, unlabeled syringe of medicine).

5. **Know the reason for taking each medicine.** Ask your healthcare provider the reason for each medicine given to you and be sure it makes sense to you, given your health conditions. Possible mistakes can be detected if you speak up when the reason for taking the medicine does not make sense to you based on your health conditions.

6. **Speak up about any differences in the appearance of your medicines.** If the medicines given to you in the hospital look different than what you usually take at home, speak up! If the color, shape, or number of tablets or capsules is different, or the volume of a liquid medicine is different, tell your healthcare provider. While the hospital may be using a different generic or brand of the medicine that looks different than your usual medicine, don't hesitate to ask to see the medicine in its outer wrapper. That way, you can verify the name and dose of the medicine if it looks different to you.

7. **Ask about side effects.** When your healthcare provider prescribes a new medicine, ask him or her about any anticipated side effects that you may expect and should report. Depending on the side effect, you may also want to ask your healthcare provider for tips to lessen or avoid certain side effects.

8. **Know your discharge medicines.** Ask your healthcare provider to review with you the medicines prescribed to you upon discharge, including over-the-counter medicines. If a new medicine has been prescribed at discharge, specifically ask if it replaces a previous home medicine that should be discontinued. If a previous home medicine has not been prescribed, specifically ask about it to learn if you should continue or stop taking it.

9. **Let your healthcare provider know if the cost of the medicine is an issue.** If you find out after discharge that you cannot afford to pay for your prescribed medicine, don't be embarrassed. Talk to your healthcare provider. Do not simply avoid filling the prescription. Your doctor may be able to prescribe a different medicine or provide you with samples temporarily, or your pharmacist may be able to find manufacturers' coupons, to help cover the cost.

10. **Talk with your pharmacist when picking up your discharge medicines.** When you pick up your prescription medicines at the pharmacy, open the bag, review the medicines, and ask to speak with the pharmacist. Although you may not have any specific questions for the pharmacist, ask him or her to review each of the prescribed medicines with you, including the dose, how to take each dose, and the reason for taking the medicine. Many reported medication errors have been prevented when this important step was taken.

Institute for Safe Medication Practices (ISMP)
200 Lakeside Drive, Suite 200
Horsham, PA 19044-2321

Tel: 215-947-7797
www.consumermedsafety.org
www.ismp.org