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ISMP An ECRI Affiliate

Community/Ambulatory Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Workflow vulnerability leads to missed drug-drug interaction

Problem. A patient called their specialty pharmacy to set up delivery of **COSENTYX** (secukinumab), a monoclonal antibody that blocks interleukin-17A (IL-17A). Consentyx is used to treat ankylosing spondylitis, axial spondyloarthritis, enthesitis-related arthritis, plaque psoriasis, and psoriatic arthritis. A technician set up delivery and placed the order in the pharmacists' verification queue within the dispensing software.

When speaking to the pharmacist over the phone, the patient indicated that they started taking **XELJANZ** (tofacitinib) samples from the provider the previous month. Xeljanz is a Janus kinase (JAK) inhibitor used for ankylosing spondylitis, polyarticular course juvenile idiopathic arthritis, psoriatic arthritis, rheumatoid arthritis, and ulcerative colitis. Xeljanz is not recommended to be used in combination with biologic disease-modifying antirheumatic drugs (DMARDs), biologic therapies (for ulcerative colitis), or with potent immunosuppressants like Cosentyx. The pharmacist attempted to contact the provider to confirm the treatment plan, but the provider was not immediately available. So, the pharmacist had to leave a message for the provider.

In the meantime, a different pharmacist saw the prescription in the verification queue and verified it. The order was then filled and shipped to the patient. When the dispensing error was discovered, the pharmacy again called the provider's office. The pharmacy confirmed that the patient was no longer supposed to be taking Cosentyx.

Contributing factors

The pharmacy identified several factors that contributed to this error: 1) the provider did not inform the pharmacy that the patient should stop taking Cosentyx, or that the patient had started Xeljanz; 2) the patient was unaware that they should no longer be taking Cosentyx; 3) two separate pharmacists were working on this order—one spoke with the patient and the other verified the order; 4) the second pharmacist did not realize that the Cosentyx should not be filled because the first pharmacist did not note or communicate this; 5) there was a delay in resolving the issue and confirming the correct treatment plan with the provider because the first pharmacist was not able to speak with the provider right away; and 6) although the pharmacist who spoke with the patient entered Xeljanz into the patient's medication history in the dispensing software it did not prompt a drug utilization review (DUR) alert for duplicate therapy or the drug-drug interaction because the prescription was already in the DUR/verification queue.

Safe Practice Recommendations. To help prevent this type of error at your pharmacy, explore ways to electronically mark or flag that a prescription is awaiting pre-

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Last call for Cheers Awards nominations!

Nominations for this year's ISMP Cheers Awards will be accepted through **September 9, 2022**. The Cheers Awards honor individuals, organizations, and groups that have demonstrated an exemplary commitment to medication safety. To submit a nomination by September 9, 2022, please visit: www.ismp.org/node/123.

SAFETY briefs

Look-alike Menactra and MenQuadfi packages. **MENACTRA** and **MENQUADFI** (meningococcal [groups A, C, Y, and W-135] conjugate vaccines) are approved for active immunization against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135. Both vaccines are manufactured by Sanofi Pasteur and have similar-looking carton and vial labels (**Figures 1** and **2**) but are not equivalent. Menactra is indicated for patients 9 months through 55 years and contains 4 mcg of each meningococcal polysaccharide per 0.5 mL. MenQuadfi is indicated for patients 2 years or older (including people over 55 years old, the age limit for Menactra) and contains 10 mcg of each meningococcal polysaccharide per 0.5 mL. Like all biolog-

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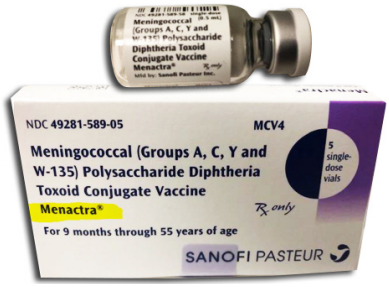

Figure 1. The Menactra carton and vial are prominently labeled as meningococcal polysaccharide diphtheria toxoid conjugate vaccine and are indicated for patients 9 months through 55 years.

Figure 2. The MenQuadfi carton and vial are prominently labeled as meningococcal conjugate vaccine and are indicated for patients 2 years and older.

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scriber and/or patient follow-up. Ideally, the pharmacy computer system would not allow the prescription to be dispensed until the issue was marked resolved. Another option suggested to ISMP is to explore ways to move orders out of the workflow if there is an issue to prevent another team member from completing the order. Be sure to think through potential implications (e.g., if removed from the workflow, where will the order "reside;" how will pharmacists track where in the process the prescription is; which pharmacist is responsible for finalizing any follow-up) and conduct an assessment, such as a failure mode and effects analysis, to identify potential failure points in the redesigned workflow. Establish a process to communicate issues with orders including adding system notes or direct communication with colleagues. Update the patient's profile with any new drugs the patient is taking so the pharmacy computer system will alert the pharmacist to drug-drug interactions and duplicate therapy (if the prescription has not yet moved to the DUR/verification queue). Test your pharmacy computer system at various stages of the workflow to determine if DUR alerts will fire when a patient's medication history is updated.

Encourage providers to share therapy changes including new therapies or discontinued therapies with the pharmacy. The CancelRx transaction in electronic prescribing systems can be used to communicate to the pharmacy the discontinuation of a medication.

Enlist the help of your patients by asking them to show or notify you of any medication samples they have received. Pharmacy staff can then enter the medication into the pharmacy system so that pharmacists can perform the important DUR checks. Finally, it is a good idea to advise patients to check the expiration date of any sample medications.

Take a tour of ISMP's updated consumer website: ConsumerMedSafety.org

We are delighted to announce the official launch of our newly updated consumer website, ***ConsumerMedSafety.org***. In 2009, *ConsumerMedSafety.org* went live as the only website designed by a nonprofit organization exclusively to bring the message of medication error prevention directly to the consumer. Our updated website (**Figure 1**) demonstrates our commitment to providing the most up-to-date information that is easy to navigate.

ConsumerMedSafety.org has a newly branded logo, and the website has a modern and clean look. It remains advertisement free. We hope you will share this updated resource with your patients. We've highlighted some of the changes below:

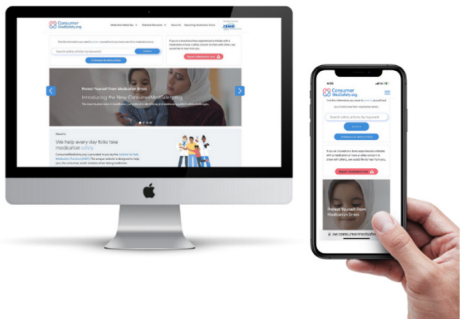

Figure 1. *ConsumerMedSafety.org* has a fresh, new look, and consumers can access the site via the internet on any computer, tablet, or smart phone.

Scrolling marquee. The first feature that consumers will notice on the website is a scrolling marquee, which provides vital and newly posted content, including the latest drug safety warnings and advice from experts. Current examples include an article on how to avoid confusing "concentrated ibuprofen infant drops" with "children's ibuprofen," and a "buyer beware" warning about vaping products.

Search engine. The robust search engine helps locate safety topics of interest. Above the scrolling marquee, use the search feature to locate safety articles by entering a keyword. Or click the "browse all safety articles" button to scroll through hundreds of medication safety topics and breaking news about safety-related issues with medications.

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ical products, the proprietary (brand) name is printed below the nonproprietary (generic) name and does not stand out. It is recommended (not required) that the same product be used for all doses.

When we reached out to Sanofi Pasteur to suggest differentiating these products, they told us that Menactra will be phased out when the supply is fully depleted, which they anticipate will be mid-2022. For now, if your organization purchases both products, store these products separately and use barcode scanning to prevent dispensing and administration of the incorrect product.

Pfizer and FDA respond to Paxlovid error reports. In an August 5, 2022, letter to healthcare providers, Pfizer and the US Food and Drug Administration (FDA) communicated about wrong-dose medication errors associated with the prescribing, dispensing, and administration of **PAXLOVID** (nirmatrelvir and ritonavir) (www.ismp.org/ext/967). ISMP previously published a special alert about Paxlovid errors on January 3, 2022 (www.ismp.org/node/29033), soon after FDA issued an Emergency Use Authorization (EUA) for Paxlovid on December 22, 2021. ISMP also published an analysis of wrong-dose Paxlovid errors reported to both ISMP and FDA in our June 2022 newsletter.

As mentioned in the Pfizer and FDA letter, as well as in the ISMP publications, prescribing and dispensing errors are occurring widely. However, many wrong-dose errors have also occurred during patient self-administration and generally involved patients incorrectly taking the wrong combination of nirmatrelvir and ritonavir tablets from blister cards. In their letter, Pfizer noted that they had revised the *Fact Sheet for Patients, Parents, and Caregivers* to address wrong-dose errors that might occur during patient self-administration. The revised *Fact Sheet* (www.ismp.org/ext/968) shows how the medication is labeled and informs the patient how to correctly take Paxlovid. Each dispensed prescription of Paxlovid should include a *Fact Sheet for Patients, Parents, and Caregivers*. It is also critical to educate the patient at the time of dispensing.

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Report medication errors. Consumers are invited to share their stories about errors or safety issues with medications by clicking on the red button that says, "**Report a Medication Error**."

Medication Safety Tips. In the toolbar at the top of the website, the first navigation drop-down menu is named **Medication Safety Tips** (**Figure 2**). This drop-down menu lists three different sections. Each section features articles and/or tools that are specific for certain topics or situations. For example:

- In the *Safety with Medicines* section, you will find teaching sheets on different high-alert medications, such as opioids and insulin products. There is also information about over-the-counter (OTC) medications as well as safety information about vaccines and medication patches.
- In the *Safety by Location* section, you will find safety tips that are useful while at the pharmacy, doctor's office, hospital, home, and others.
- In the *Safety by Population* section, you will find safety tips for various age groups such as older adults and children, and even medication safety with pets.

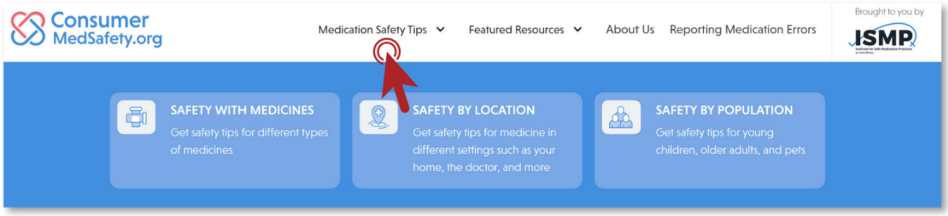

Figure 2. Navigation to **Medication Safety Tips** provides safety information for different types of medications, locations of care, and at-risk populations (older adults, children, pets).

Featured Resources. The next navigation button in the toolbar at the top of the website is **Featured Resources** (**Figure 3**), which has a drop-down menu that lists the following six different sections:

- **Insulin Safety Center**
- **Over-The-Counter (OTC) Medicines** section
- **Top 10 Tips Lists**, a section that features different lists related to safety with medications. For example, one list describes the *Top 10 Steps Parents Should Take to Prevent Medicine Mishaps* when giving medications to a child.
- **FDA Alerts**, a section dedicated to delivering the latest updates on medications and products regulated by the US Food and Drug Administration (FDA), drug recalls, drug shortages, and *Medication Guides*.
- **Additional Resources**, a section that features specific topics related to safety with medications. Here you can find information about how to read a prescription, prepare for a disaster, measure liquid medications, and more.
- **General Medication Safety**, a section that addresses general safety tips with medications, such as information about what you can do at home, while in the hospital, and while at a doctor appointment.

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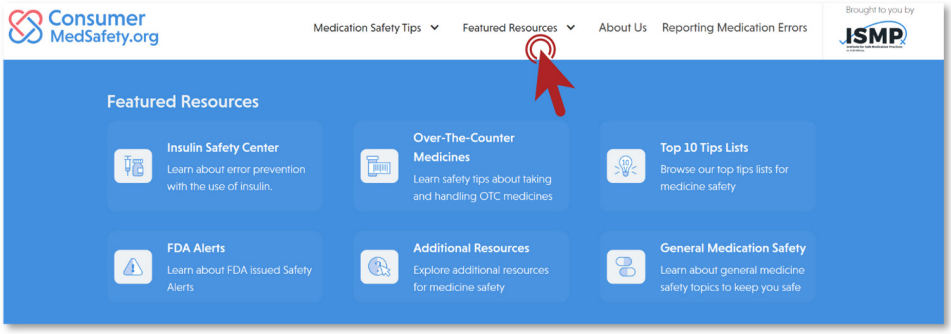

Figure 3. The **Featured Resources** section provides information grouped into six different categories that can be selected from the drop-down menu.

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It is mandatory for practitioners to report to FDA errors with medications authorized under an EUA (www.fda.gov/medwatch/report.htm). But please take a moment to report any Paxlovid errors to ISMP, as well (www.ismp.org/report-medication-error).

HIGH-ALERT

Risk of prescribing an overdose in athenahealth's EHR. We recently received reports of issues with athenahealth's electronic health record (EHR), which is used mostly in ambulatory care. For a period of time in July 2022, if a dose less than 1 was entered without a leading zero for a new prescription, the decimal was removed (disappeared), leaving the dose 10-fold greater than intended. For example, if the intended dose of 0.2 mg was entered as .2 mg (without a leading zero), the dose would be saved as 2 mg! In addition, if a dose of medication less than 1 was entered with an ending (redundant) zero (e.g., in the hundredth position), the decimal was removed but the ending zero remained, which could result in a 100-fold overdose! So, if an intended dose of 0.2 mg was entered as .20 mg, the dose would be saved as 20 mg! This could lead to overdoses, patient harm, or even death with some high-alert medications, such as morphine. We are uncertain if placing a zero before the decimal point (0.20 mg) would alleviate the problem with adding a redundant zero after the decimal point at the end of the dose.

The initial fix for this technology safety flaw was weak: practitioners had to *remember* to always enter a leading zero and to avoid entering a trailing (redundant) zero. Another strategy was to select a prepopulated option from the dose field drop-down menu to ensure the correct dose was ordered. When we reached out to the vendor, they notified us that this issue had been resolved as of July 28, 2022. However, we encourage athenahealth users to test their systems to ensure this safety flaw has been corrected in their EHR. If it has not been corrected, please reach out to athenahealth, and also send us an email to report the problem.

ISMP has received reports involving serious errors with other EHR software systems. To ensure that proper notice is given to the field, and follow-up is accomplished by

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We hope that you will encourage your patients and families to visit the new *ConsumerMedSafety.org* website to learn more about safety with medications. Having knowledge and understanding about safe medication practices and being involved in care decisions is an excellent way for your patients to prevent an error from happening. Please also consider making a charitable donation to ISMP (www.ismp.org/node/754). With your help, we will be able to continue our work to keep consumers safe and lead efforts to improve the medication use process.

Meet our three new 2022-2023 Fellows

Tyler Nichols, PharmD, BCPS, is the **2022-2023 ISMP International Medication Safety Management Fellow**, supported by Novartis, Name Creation & Regulatory Strategy. He completed his Doctor of Pharmacy degree at Albany College of Pharmacy and Health Sciences in Albany, NY. Prior to the fellowship, Tyler spent 12 years working in health-system pharmacy, most recently as an inpatient pharmacy manager with a focus on sterile compounding practices at the Albany Med Health System. Tyler hopes to use his time as an ISMP international fellow to gain a broader perspective on global safety initiatives and to work closely with subject matter experts across multiple organizations and disciplines to improve his ability to deliver safe and effective care.

Jose P. Nery, PharmD, is the **2022-2023 ISMP Safe Medication Management Fellow**, supported by Baxter International, Inc. He completed his Doctor of Pharmacy degree at the University of Pittsburgh School of Pharmacy in Pittsburgh, PA. Prior to the fellowship, Jose practiced as a Lead Pharmacist at the UPMC Children's Hospital of Pittsburgh, with primary oversight of medication error analysis. It is in this role that his passion for process improvement and medication safety was ignited. Jose's desire to gain mastery in the field of medication safety ultimately led him to pursue a fellowship with ISMP.

Sadik Owolewa, PharmD, is the **2022-2023 FDA/ISMP Safe Medication Management Fellow**. He completed his Doctor of Pharmacy at Northeastern University School of Pharmacy in Boston, MA. Before the fellowship, Sadik worked at a Rite Aid pharmacy as a staff pharmacist. It was while working in the retail pharmacy setting that he discovered his passion for medication safety, which led him to a fellowship role with ISMP. After his fellowship, Sadik hopes to use his skills in medication safety in a regulatory agency or in the pharmaceutical industry.

If you would like to subscribe to this newsletter, visit: www.ismp.org/node/126

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

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vendors, reporting such issues to agencies like ISMP, ECRI, and the US Food and Drug Administration (FDA) is critical (ISMP shares error reports with FDA). Government agencies such as the FDA and the Office of the National Coordinator for Health Information Technology need to have programs in place to learn from reporting programs and screen EHR software to prevent issues like this that could lead to a large-scale tragedy.

Accidental needlestick with Evenity prefilled syringe. A nurse in an outpatient infusion setting experienced an accidental needlestick injury when administering a subcutaneous injection of an **EVENITY** (romosozumab-aqqg) 105 mg per 1.17 mL prefilled syringe from Amgen. Evenity is used for the treatment of postmenopausal osteoporosis in patients who are at high risk for fracture, or in patients in whom other available osteoporosis therapy has failed or cannot be taken. Two syringes and two subcutaneous injections are needed to administer the total dose of 210 mg, which should be administered by a healthcare provider. The needles lack a safety guard and are not retractable or removable, so users are not able to change the needle to one that has a safety guard. Other organizations reported the same concern about accidental needlesticks with this product.

Similar concerns have been reported with other prefilled syringes that do not come with a needle safety guard, including **KINERET** (anakinra) and **HUMIRA** (adalimumab). Even with prefilled syringes intended for self-administration, family members, other caregivers, long-term care staff, and physician practice/clinic staff often administer these medications. Also, these products could make their way into garbage bins and other forms of common waste, exposing children, animals, and others to unintended needlestick injuries. We have notified the US Food and Drug Administration (FDA) and the manufacturer of this concern and recommended the addition of a needle safety guard for all prefilled syringes with an attached needle to prevent accidental needlesticks. The manufacturer has escalated our concern for further follow-up.