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ISMP
An ECRI Affiliate

Community/Ambulatory Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

It is time for a change: Respond to consumers' error concerns with empathy and honesty

Last month, ISMP identified poor and inappropriate responses to consumers' error concerns as one of the ***Top Five Medication Safety Concerns*** from 2021. Unfortunately, we continue to receive reports from consumers that describe unprofessional and at times callous responses from pharmacists when errors or potential errors are brought to light. It is time for a change in how we interact and treat patients. It is time that we respond to consumers' error concerns with empathy and honesty, avoiding defensive and sometimes flippant responses. Below are recent examples reported to the ***ISMP Consumer Medication Errors Reporting Program*** (ISMP CMERP):

I got my son's prescription. I gave him his medicine the next day. I thought the pill looked different but trusted the pharmacist. The second day my son and I looked at the bottle and the description of the pill did not match the actual pill. I took the bottle to the pharmacy where the pharmacist saw my exasperated/concerned demeanor and said, "of course it's anxiety." EXCUSE ME?! He said the pills are correct and so I asked him why the label didn't describe their appearance. He sighed at me and put a new corrected sticker and also a green sticker stating the pill changed. He said, "I put a new label on since it matters that much." Again, excuse me?? I have every right to know what I put in my child's body and to be able to verify without having to rush to the pharmacy in a panic because of mislabeling. And then being mocked and belittled. Reprehensible behavior.

The pharmacy filled my RX and put the wrong instructions on the label. When my daughter picked it up, she overheard them discussing that they could not contact the doctor to confirm the prescription instructions, yet they filled it anyway and didn't explain anything to us; the instructions were wrong. For about three weeks I have tried to get someone from the pharmacy to call me to tell them what happened; they refused to call me back. The pharmacy on several occasions has refused to call me back for over a month. XXXXXX is the complaint number they finally gave me in our last communication when they guaranteed someone would call me that was almost a week ago.

I was given the wrong birth control. I called to let the pharmacist know and she argued with me that it was right, I KNEW it was not. Took it to another pharmacy and I was told the sticker was right, but the drugs were not, and it had ingredients that could have been dangerous to me.

Plan and Practice How to Respond to an Error

When medication errors happen, especially those that result in patient harm, practitioners can experience extreme stress and anxiety. This is on top of the stress and anxiety practitioners are already feeling related to workload, staffing shortages, and the coronavirus disease 2019 (COVID-19) pandemic. Stress combined with the fear that an error may impact job security and lead to litigation may cause healthcare practitioners to view the patient as a threat. When this happens, the organization's and practitioner's first inclination may be to deflect, deny, and defend. Unfortunately, this

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Azithromycin packaging confusion. To treat an acute bacterial exacerbation of chronic obstructive pulmonary disease (COPD) or acute bacterial sinusitis, the recommended dose of azithromycin is 500 mg orally once daily for 3 days. Some companies supply azithromycin 500 mg tablets in a single blister card of three tablets, packaged within a carton. However, some of these companies also supply cartons holding three blister cards containing three tablets each, presumably in case additional courses of therapy are warranted. With the three-card cartons, pharmacists may not realize they are providing three courses (nine tablets) of therapy if the entire carton is dispensed.

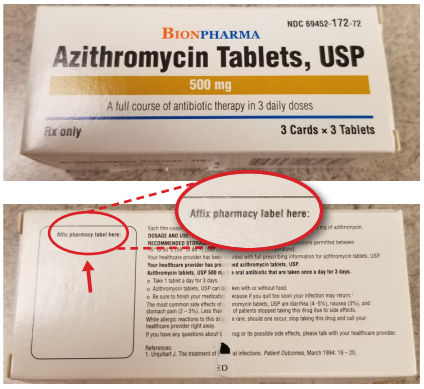

Figure 1. Front (top) and back (bottom) carton labels for azithromycin from BionPharma. Red arrow points to a statement, "Affix pharmacy label here."

For example, one generic manufacturer, BionPharma, includes dedicated space on the back of the carton for affixing a pharmacy label (**Figure 1**, bottom) even though the carton holds three treatment courses and the pharmacy label would likely mention the dose and directions for a single course of therapy. Furthermore, the principal display panel for this product mentions, "A full course of antibiotic therapy in three daily doses" (**Figure 1**, top), making it seem as if the carton holds a single course of therapy. This is misleading

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approach will often alienate patients and close the organization's eyes to the risks that contributed to the event and patient response.

Instead, it is imperative that organizations and practitioners plan ahead and prepare staff to respond to victims of errors with transparency, honesty, and empathy. This approach puts the patient's safety and interests in focus. It encourages open communication about errors and supports system improvements.

Every pharmacy should have written policies and procedures for responding to medication errors, including a defined process to follow-up with patients to provide investigation results. Policies on disclosure and apology to patients and caregivers (and others as necessary) are also a must. Review and discuss these policies and procedures with the entire pharmacy team so that the process is clearly understood. Regularly review the procedures for appropriateness. The policies and procedures should contain specific guidance on what to say and do, what not to say or do, who should be contacted, particularly when all the facts of the case may not be immediately known, and who will follow up. Practice and role-play possible scenarios with all staff using your established procedures and guidelines.

It is also critical that pharmacies learn from errors and engage employees in helping to implement high-leverage risk-reduction strategies. To maximize these efforts, establish a continuous quality improvement (CQI) program to detect, document, and assess errors as a means to determine the causes, develop an appropriate response, and implement strategies to prevent future errors. Share and discuss events, prevention strategies, and procedural changes with staff.

Conclusion

Whether the error is obvious or still a remote possibility, focus on the patient and respond immediately with compassion, empathy, and honesty. The concern demonstrated to the patient and family through the acknowledgement that a mistake has occurred as well as follow-up discussion of what will be done to prevent future occurrences can help maintain healthy and compassionate communications and achieve an amicable and fair resolution for all parties. Most importantly, it is the right thing to do.

For additional recommendations, see our article *Excuse me, I think there is an error with my prescription: Practitioners should respond with empathy and honesty* (www.ismp.org/node/23867) published in the February 2021 issue of this newsletter.

Look-alike cartons: Potential for wrong specialty product to be dispensed

In a February 2021 ***SAFETY brief***, we described an error in which a pharmacy dispensed three **ACTEMRA ACTPEN** (tocilizumab) prefilled pen devices and one **ACTEMRA** prefilled syringe. Actemra is an interleukin-6 (IL-6) receptor antagonist used to treat rheumatoid arthritis and other inflammatory conditions. While there are similarities between these products, the administration instructions differ for the pen and syringe, so there is a risk the patient may not know how to administer the medication if they receive the incorrect device. Fortunately, in this case the patient noticed the error, called the pharmacist, and received education about using the prefilled syringe. Similarities between the products likely contributed to this error.

Recently, a pharmacist shared with us that two other specialty drug products are packaged in cartons that look similar and could contribute to errors. **SIMPONI** (golimumab) is a tumor necrosis factor (TNF) blocker used to treat moderate to severe rheumatoid arthritis and active psoriatic arthritis alone, or in combination with methotrexate; active

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because, with typical dosing for an individual patient, only one card, not three, is needed. Patients also may misunderstand the packaging and use all three cards (i.e., take nine tablets).

We have asked BionPharma to consider removing the "Affix pharmacy label here" statement from the carton. They agreed and are currently revising the graphics to remove the space for the pharmacy label from the back of the carton. Still, with these products, it would be safer and less confusing if cartons only held a single treatment course.

Do not dilute gray-capped Pfizer-BioNTech COVID-19 vaccine! ISMP is concerned about the potential for practitioners to accidentally dilute the new prediluted form (gray cap) of the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine (**COMIRNATY**) ever since we received word about its availability late last year. We mentioned the risk of further diluting this prediluted vaccine most recently in our January 2022 newsletter. Soon afterwards, we received a report in which normal saline was erroneously added to the gray-capped Pfizer-BioNTech COVID-19 vaccine vial. Fortunately, a pharmacist caught the mistake before syringes of the vaccine were used.

The purple-capped vaccine (available under an emergency use authorization [EUA] and as the brand product, Comirnaty) requires dilution prior to use. Now that practitioners are accustomed to diluting the purple-capped vaccine, and both the gray- and purple-capped vaccines are simultaneously available, it is predictable that the prediluted form (gray cap) and the vaccine that requires dilution (purple cap) will be confused during preparation. This will result in erroneously diluting the gray-capped vaccine or not diluting the purple-capped vaccine.

We understand that Pfizer-BioNTech intends to eventually supply only the gray-capped prediluted vaccine for ages 12 years and older. To avoid dilution errors, we recommend switching entirely to the gray-capped prediluted vaccine vials as

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ankylosing spondylitis; and moderate to severe ulcerative colitis with an inadequate response or intolerance to prior treatment or requiring continuous steroid therapy. It is available in 50 mg/0.5 mL and 100 mg/mL prefilled syringes and prefilled autoinjectors. The cartons in which they are packaged look very similar (**Figure 1**). However, the syringes and autoinjectors have different directions for use, so a mix-up between the two could lead to patient self-administration errors.

Figure 1. Simponi prefilled syringes (top) and autoinjectors (bottom) are available in the same concentrations and similar looking cartons.

The other product with similar-looking cartons that the pharmacist reported was **SKYRIZI** (risankizumab-rzaa). Skyrizi is an interleukin-23 (IL-23) antagonist indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy as well as active psoriatic arthritis in adults. Like Actemra, the cartons for the Skyrizi prefilled syringes and prefilled pen device look nearly identical (**Figure 2**) with similar blue waves at the bottom of the panel and the concentration highlighted in black. If a patient received the wrong device, they may not be educated on how to properly use the device, they could have a device misfire and waste the medication, or they may use the device incorrectly and not receive their full dose.

Figure 2. Skyrizi prefilled syringes (top) and pen device (bottom) are available in the same concentrations and similar looking cartons.

When adding products to your inventory for the first time, test, and update as necessary, your dispensing software to make sure the barcodes on the products scan accurately. To reduce the risk of errors, print and affix a label to each package dispensed. Scan each carton's barcode during production instead of scanning one carton multiple times. Ideally, pharmacy computer systems will prompt or require each product's barcode to be scanned. Enhance the computer system to alert the pharmacist during product verification if barcode scanning was bypassed during production. Apply an auxiliary label or circle the dosage form on these cartons when received from the supplier to differentiate the autoinjectors and pen devices from the prefilled syringes.

Worth repeating...

Safeguards needed when copying an old prescription

ISMP continues to receive reports that describe dispensing errors that occurred when a patient's previous prescription was copied and edited in the pharmacy computer system. Copying old prescriptions is often thought of as a way to expedite the dispensing process; however, care, hopefully with the assistance of technology, is needed when entering and verifying these prescriptions.

In a previous case, a patient was given a new prescription for oxy**CODONE** 5 mg. A few months earlier, this same patient had received a prescription for oxy**CODONE** 30 mg. The pharmacist chose to copy the previous oxy**CODONE** 30 mg prescription but failed to edit and select the correct dosage strength. The patient received oxy**CODONE** 30 mg and used this strength for a month.

In another case, a community pharmacy dispensed **ADDERALL XR** (dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine sulfate and amphetamine aspartate monohydrate extended release) 20 mg to a patient instead of the prescribed Adderall

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soon as possible so you do not have both purple- and gray-capped vaccines in stock. Be sure that labels and preparation instructions do not provide directions to dilute the gray-capped vaccine. If you stock prediluted vaccine (gray cap) simultaneously with purple-capped vaccine vials that require dilution, do not store them together in the refrigerator during or after thawing (e.g., use separate shelves). Require an independent double check of the preparation process. Educate pharmacy and vaccination staff regarding this type of error. Provide those who prepare the vaccines with an updated *Fact Sheet* for the EUA vaccines (www.ismp.org/ext/842, www.ismp.org/ext/813) or the package insert for Comirnaty (www.ismp.org/ext/843). Verify the competency of each practitioner involved in vaccine preparation.

Nonspecific PRN medication administration. If a medication is ordered "QID PRN," might a practitioner or patient interpret this to mean that all four allowable doses that day could each be given at any frequency interval, let's say just 1 hour apart? What if oxy**CODONE** was ordered that way? Or ibuprofen? Technically, the answer is yes! Practitioners or patients have interpreted "QID PRN" to mean that four doses a day (QID) could be given at any frequency interval (as needed [PRN]) as long as it is administered just four times a day. And, if you are servicing or practicing in a setting that utilizes an electronic health record (EHR) system, the EHR might allow these doses to be documented as such. However, this may not be the prescriber's intended meaning of the medication frequency and may not be safe for patients depending on the medication involved.

Frequencies such as BID PRN, TID PRN, and QID PRN do not provide clear directions regarding the interval between doses of a medication. They allow ambiguity that can foster practitioner-to-practitioner and patient-to-patient variability in interpretation and may result in harmful outcomes. Such errors have been reported to ISMP.

We recommend eliminating the use of nonspecific PRN frequencies in all care

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XR 10 mg. The patient discovered the error at the point-of-sale when he looked at the pharmacy label. The patient had previously taken Adderall XR 20 mg, but his doctor was switching him to Adderall XR 10 mg. One of the factors contributing to this error was the computer system's functionality that allows the person conducting order entry to copy a previous prescription for the same drug.

In a more recent case, a patient received a new prescription for chlordiaze**POXIDE** 10 mg capsules. The patient had previously been taking chlordiaze**POXIDE** 25 mg capsules. The technician generated a "new from old" prescription when the new one was dropped off but did not change the capsule strength from 25 mg to 10 mg. As a result, chlordiaze**POXIDE** 25 mg capsules were dispensed. The prescriber discovered the error and contacted the pharmacy inquiring about the lower dose of medication. She informed the pharmacy that the patient was very drowsy and out of it, and that is why she lowered the dose.

Evaluate your computer system's prescription copy or linking functionality. Some systems may actually prompt the user to link the new prescription to an old prescription already on the patient's profile. While this functionality can increase order entry efficiency, any changes on the new prescription may be missed. If this functionality is utilized, review the workflow, process, and prompts when copying or linking to old prescriptions. Examine ways to have the computer system guide the person conducting order entry to verify that each piece of information (e.g., drug name, drug strength, suffix, quantity, directions) on the new prescription matches the one already on the patient's profile before accepting the "copy." Even if your computer system can't incorporate this change, the manual process used to verify prescriptions should include these additional steps. Educate practitioners about the importance of verifying each piece of information.

Additionally, when using this functionality to place a prescription on hold, it is critical that the order entry undergoes the same verification process used when a prescription is actually dispensed. This includes conducting a double check of the order entry by comparing the prescription information entered into the computer system to that contained on the original prescription. Then, when the prescription is eventually dispensed, verification against the original prescription or its scanned image should be done again. Of course, final verification also should include a review of the patient's profile and a prospective drug utilization review. Engaging the patient as a final check at the point-of-sale can help catch errors.

Customized ISMP consulting services

ISMP's nationally recognized experts are here to support you! Our multidisciplinary consulting team can offer medication safety solutions for healthcare facilities of all sizes, virtually or in person. Whether you need assistance getting your medication safety program started, identifying potential issues, or solving ongoing problems, we can help. Our consulting team can provide you with an unbiased analysis of the medication-use process and a customized roadmap for improvement to help you reduce the risk of medication errors. For information on services tailored to your specific needs, visit: www.ismp.org/node/23650.

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settings (e.g., inpatient, long-term care, other outpatient settings). Instead, the prescriber should specifically define, within the order, the minimum time (e.g., hours) between PRN doses. Frequencies such as "every 8 hours PRN" or "every 12 hours PRN," for example, provide specific directions regarding when medications can be administered by clearly defining the amount of elapsed time between doses. Prescribing and EHR systems should not allow nonspecific PRN frequencies as part of an order. Also, all PRN medication prescriptions should include the purpose for the drug and the specific dosing parameters.

Both prescribers and pharmacists also should provide patients with clear, specific directions both verbally and in writing. When counseling a patient about a medication, use the teach-back method to verify that they understand the information and will be able to use the drug correctly.

Special Announcements

Become an ISMP Fellow

ISMP is accepting applications until **March 13, 2022**, for three unique Fellowship programs that will begin in the summer of 2022. For descriptions of the Fellowships, candidate qualifications, brochures, program outlines, and to apply online, please visit: www.ismp.org/node/871.

Virtual MSI workshops

Don't miss the opportunity to register for one of our unique 2-day, virtual ***ISMP Medication Safety Intensive (MSI)*** workshops being offered in 2022. Our next workshop is scheduled for **March 31 & April 1, 2022**. For details, more dates in 2022, and to register, please visit: www.ismp.org/node/127.

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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