February 2021 ■ Volume 20 Issue 2

ISMP An ECRI Affiliate

Community/Ambulatory Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Excuse me, I think there is an error with my prescription Practitioners should respond with empathy and honesty

ISMP frequently receives reports of medication errors directly from patients. Often these reports describe errors that occurred in community pharmacies. While they are understandably concerned about the errors, the patients who report to us are usually more upset about the response, or lack of response, from the pharmacist or pharmacy management team than with the actual error itself. Based on what we hear from patients and caregivers, all too often pharmacy staff, managers, and corporate personnel are leaving patients dissatisfied when addressing patients' concerns and responding to medication errors. Below are some actual cases reported to the ISMP Consumer Medication Errors Reporting Program (CMERP):

- *I picked up a prescription for temazepam to help me sleep. The pills didn't work, and I actually felt worse taking them. Over the course of four days, I only slept about five hours total. I had heart palpitations, chest tightness, and feelings of panic and agitation. Concerned, I brought the medication back to the pharmacy and the pharmacist identified the pills as Adderall, not temazepam. The pharmacist immediately became defensive and refused to answer questions about what I should do. He just told me I need to switch pharmacies. I called my doctor who told me to go to urgent care, where I learned my heart rate and blood pressure were elevated. The pharmacist at the store refused to file an incident/liability claim to pay for my out of pocket costs, which aren't significant, but they should do the right thing.*

- *Prescription for azithromycin 100 mg/5 mL - take 1 tsp PO first day, then 1/2 tsp daily for next 4 days. Received bottle from pharmacy with label - take 5 mL PO first day, then 2.5 once daily on days 2-4. I noted that there was not enough volume to last for 5 days and that they had only put on the label to use for 4 days. I called the pharmacy concerned that the overall concentration would be higher if the entire dose was distributed over 5 days instead of 4. The answer I received from the pharmacist was that "we don't make mistakes." When I pointed out that the label was indeed wrong from the printed prescription, she asked me what I wanted; another bottle and proceeded to tell me that she wouldn't be able to give it to me anyways. My concern is: 1. The pharmacist was in denial of ever making a mistake. With this mindset, they will never be aware or open to learning from mistakes made. There is such thing as human error; but the outcome of error should be learning from it. 2. My daughter did not suffer harm. However, had this been a dose sensitive drug, she (or the next patient) could have suffered. 3. I was not looking for replacement medication. Not being as familiar with the medication in its use in babies, I was fearful of the dosage being wrong. The pharmacist was not concerned about my fears as a mother and either reassuring me that the changed directions would still be safe, nor did she guide me. Instead, she was defensive regarding the fact that "we don't make mistakes here."*

- *I received a call this morning from the pharmacy to inform me that my prescription was ready for pickup. I called the store and was told that the prescription was for amoxicillin. I told the pharmacist that I was allergic to that and she made an oops noise and said she would return it. No explanation. No apology. No responsibility.*

continued on page 2 — Empathy and honesty >

SAFETY briefs

Wrong Actemra device dispensed.

ACTEMRA (tocilizumab) is an interleukin-6 (IL-6) receptor antagonist used to treat rheumatoid arthritis and other inflammatory conditions. It is available in vials (used to prepare intravenous infusions) as well as a prefilled syringe and a prefilled pen (**ACTEMRA ACTPEN**) for subcutaneous injection. Depending upon the indication and other factors, the drug may be administered subcutaneously every 1, 2, or 3 weeks. Recently, a pharmacy dispensed the wrong device. The patient was to use one Actemra ACTPen weekly. However, the pharmacy dispensed three Actemra ACTPens and one Actemra prefilled syringe. 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, the patient called the pharmacist and was taught how to use the syringe.

Similarities between the products likely contributed to this error. Both the Actemra ACTPen and prefilled syringe are available in the same concentration (162 mg/0.9 mL). Both cartons look similar with vertical purple bars and green boxes highlighting the concentration (**Figure 1**). To save time, a technician or pharmacist may scan one box multiple times rather than scanning each box dispensed. This bypasses the safety check provided by the barcode scanning system.

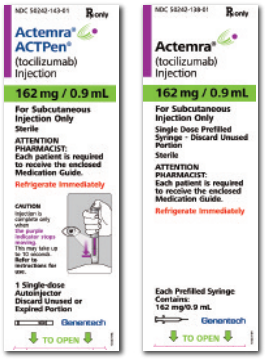

Figure 1. Actemra ACTPens (left) and Actemra prefilled syringes (right) are available in the same concentration and similar looking cartons.

continued on page 3 — SAFETY briefs >

> Empathy and honesty — continued from page 1

Responding to a dispensing error

When medication errors happen, especially those that result in serious patient harm, practitioners can experience extreme stress and anxiety. Fear of litigation may cause healthcare organizations and practitioners to view the patient as an adversary or threat. When this happens, the organization or practitioner's first inclination may be to deny and defend. Unfortunately, this approach can alienate patients and close the organization's eyes to the risks that contributed to the event and patient response.

Instead, responding to victims of errors with transparency and honesty puts the patient's safety and interests in focus. It encourages open communication about errors and supports system improvements. Most importantly, it's the right thing to do.

When a patient thinks a mistake has been made and brings it to the attention of a staff person, how is it handled? Who is contacted? What is the response to the patient? Are errors, including harmful events, handled with transparency, sincerity, and empathy? Does your pharmacy or organization have a policy and process for handling these situations?

Plan how to respond to an error

Every pharmacy should have written policies and procedures for handling medication errors and, more importantly, these procedures need to be reviewed and discussed with the pharmacy team, including part-time, float, and newly hired staff, so that the process is clearly understood. Regularly review the procedures for appropriateness to the specific workplace and update them to reflect changes in workflow and additions of technology. The policies and procedures should contain specific guidance about 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. General principles include:

Staff Roles

- Define staff roles in response to a possible or actual medication error
- Define how management should respond and investigate the cause of an error
- For reports communicated by phone, define to whom the call should be routed and how the report is communicated internally for investigation and follow-up

Disclosure and Communication

- Have a written policy on disclosure and apology to patients and caregivers (and others as necessary) that is agreed upon and followed by management and staff
- Define when others (e.g., prescriber) should be notified of an error
- Whether the error is obvious or still a remote possibility, respond immediately with concern, compassion, and empathy
- Remedy the immediate situation with truth and honesty
- Be direct and open with the patient reporting the error; the goal is to correct the error and minimize any harm or negative impact to the patient
- Assure the patient reporting the event that it is important and a priority
- Define a process to follow-up with patients and staff to provide investigation results

Documentation and Reporting

- Document the event and response, include the date, time, and details of the event
- Make a note in the patient's profile so that staff is aware, especially when the patient returns to the pharmacy
- Define how and when to notify supervisors as well as risk and upper management

continued on page 3 — Empathy and honesty >

Dr. Allen Vaida retiring, Dr. Rita Jew joins staff

ISMP has announced that Executive Vice President **Allen Vaida, PharmD, FASHP**, will be retiring at the end of March 2021. Dr. Vaida has been an integral part of the ISMP team for decades and has had an immense impact on patient safety, the practice of health-system pharmacy, and ISMP. He has been ISMP's representative on numerous committees and influential healthcare groups, including the inaugural USP Safe Medication Use Expert Committee, US Food and Drug Administration (FDA) committees on risk management and pharmacy compounding, and the Accreditation Council for Graduate Medical Education's Patient Safety Task Force. He has worked with healthcare accrediting bodies, regulators, and professional organizations both nationally and internationally, and has given presentations on medication safety around the world.

"Allen has been an invaluable asset," says ISMP President Michael Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP. "He will be sorely missed for his vision, collaborative spirit, and integrity. He has helped ISMP build a reputation as the gold standard for medication safety information and served as a mentor and role model for countless healthcare professionals."

Dr. Vaida will be succeeded by **Rita Jew, PharmD, MBA, BCPPS, FASHP**, as ISMP's new Vice President of Operations. Dr. Jew has an MBA from the Wharton School of the University of Pennsylvania and is a nationally recognized pharmacy executive and expert in hospital technology, medication management strategy, and operations. She was most recently a principal in her consulting practice and, prior to that, she held leadership positions at several well known acute care institutions, including University of California San Francisco (UCSF) Health, Children's Hospital of Orange County, and Children's Hospital of Philadelphia. Dr. Jew has received numerous awards, including a Distinguished Service Award from the American Society of Health-System Pharmacists (ASHP) Section of Clinical Specialists and Scientists. Please join us in welcoming Rita to ISMP (info@ismp.org)!

> **Empathy and honesty** — continued from page 2

- Report the event using the pharmacy's internal reporting system
- Report errors to licensing bodies as required
- Report the event confidentially to ISMP (www.ismp.org/report-medication-error), when appropriate, to help notify others of errors that have occurred and help prevent similar errors

Staff Support

- Support staff who are involved in the incident
- Console staff and offer those involved with the error access to employee assistance programs when necessary

Staff Training

- Consider training everyone involved in responding to an error to use statements such as: "Please let me explain what we believe happened and how we plan to fix it" or "At this point, I can't answer how this happened but I will look into it, get back to you, and let you know what we are doing to prevent this in the future"
- Practice and role-play possible scenarios with all staff using your established procedures and guidelines. Discuss how you might respond to the following incidents:
  - A patient returns to the pharmacy counter, after just paying for his prescription, and says, "This does not look like what I got last month!"
  - While counseling a patient on their warfarin dose change, you discover that the strength on the label and the tablets in the vial don't match
  - A patient calls the pharmacy and reports that they have received less medication than was prescribed
  - A patient calls or returns to the pharmacy reporting that they have received someone else's medications

To help healthcare organizations and practitioners avoid adversarial type responses to harmful events, the Agency for Healthcare Research and Quality (AHRQ) published the *Communication and Optimal Resolution* (CANDOR; www.ismp.org/ext/648) toolkit. The CANDOR process is designed to help organizations and practitioners respond to harmful events in a thorough and just manner, emphasizing transparent disclosure of adverse events and a more proactive method to achieving a fair resolution for the patient, practitioners, and organization. The process is also designed to support organizations' efforts to fully investigate and analyze harmful events, improve safety and quality of care, and prevent patient harm. The toolkit includes multiple modules, including a disclosure checklist, to help guide organizational discussion and implementation of the CANDOR process.

When any error happens, it is critical that pharmacies learn from them and implement high-leverage strategies to reduce or eliminate future medication errors. To maximize these efforts, establish a continuous quality improvement (CQI) program to detect, document, and assess prescription errors in order 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. It is only through analysis and investigation of root causes and contributing factors of errors that strategies to improve the medication use process and prevent future events will be identified.

Conclusion

Practitioners should approach all patients reporting actual or potential medication errors with transparency and empathy. Keep in mind that the attention and concern demonstrated to the patient and family through the admission and apology for an error as well as follow-up discussion of what will be done to prevent future occurrences can help achieve an amicable and fair resolution for all involved.

> SAFETY briefs

cont'd from page 1

To reduce the risk of errors, scan each carton 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 Actemra ACTPen cartons when received from the supplier to differentiate them from the prefilled syringes. ISMP has contacted the manufacturer, Genentech, and asked them to better differentiate these products.

Syringes with trailing zeros. A pharmacist was completing a medication history and education session with a patient who used injectable methotrexate for psoriasis. The patient stated that she draws her methotrexate injection "up to the 10" on the syringe, but she did not know the dose in milligrams. The patient was using a 25 mg/mL injectable product, so 10 mL (250 mg) would have been too high of a dose for psoriasis, which is typically 10 to 25 mg once weekly. Upon further probing, the patient confirmed that she draws the medication "up to the little 10." The pharmacist considered the possibility that the patient had been using an insulin syringe, as this is the only type of small syringe that has markings for whole numbers including a "10." This was also concerning. If the patient had been withdrawing methotrexate up to the "10 units" mark on an insulin syringe, this would have been only 0.1 mL (2.5 mg) of methotrexate, which would have been an underdose. The pharmacist con-

Figure 1. TB syringe with error-prone measurement marks that do not include a leading zero (e.g., .2, .3) and include a dangerous trailing zero (i.e., 1.0).

continued on page 4 — SAFETY briefs >

Error-prone concentrations of ibuprofen suspensions

Parents who are told to give their child or infant over-the-counter ibuprofen oral suspension may not be aware that there are two different concentrations available. An infant's formulation (for infants 6-23 months or weighing 5.5-10.5 kg) contains 50 mg/1.25 mL (40 mg/mL). This is more concentrated than the children's formulation (for children 2-11 years or weighing 10.9-43.1 kg), which contains 100 mg/5 mL (20 mg/mL). Also, the labeling and packaging of the two concentrations can sometimes look similar.

Staff at pediatric hospitals and clinics might be familiar with this and have told us about mix-ups that sometimes occur after an encounter. For one, patient instructions for oral liquids typically present the dose in a metric volume to help parents measure each dose using a dosing cup or oral syringe. However, the concentration parents might purchase or already have at home is often unknown.

One hospital reported a close call involving a child who was discharged from an ambulatory surgery unit. The child's mother was concerned because she was familiar with giving her 8.6 kg child less than 2 mL of ibuprofen, as per the manufacturer's label instructions. However, the discharge instructions said to give 4.3 mL, or 86 mg of the 100 mg/5 mL concentration. After confirming with the mother that she had the 50 mg/1.25 mL concentration at home, the hospital was able to tell the mother the appropriate volume of ibuprofen to administer to her child for each dose.

In another case, a child was prescribed ibuprofen 70 mg every 6 hours. The child's mother was told to give 3.5 mL of the medication for each dose, with the expectation that the 100 mg/5 mL suspension would be used. However, the child's mother purchased 50 mg/1.25 mL concentration and gave her child 3.5 mL per dose as instructed. Instead of receiving 70 mg, the child received 140 mg per dose. Fortunately, we are not aware of any serious adverse outcome as a result of this 2-fold overdose, but the possibility of side effects is likely increased. An overdose might lead to nausea, vomiting, diarrhea, headache, stomach bleeding, and kidney damage.

This situation is similar to an issue that has since been resolved with oral liquid acetaminophen products, which, for many years, existed in two concentrations: a more concentrated liquid (100 mg/mL) for infants, and a less concentrated liquid (160 mg/5 mL) for children. When the 100 mg/mL concentrated product was accidentally administered to children in volumes appropriate for the 160 mg/5 mL product, there were accidental deaths and serious injuries to children. Faced with this evidence, manufacturers voluntarily withdrew the more concentrated infant's product and agreed to only provide the 160 mg/5 mL concentration (some manufacturers also have products available in a 500 mg/15 mL concentration intended for patients 12 years and older).

We have interacted with the US Food and Drug Administration (FDA) and asked the agency to look into the matter to determine if the more concentrated product is truly necessary. One of the children's hospital nurses who we spoke with queried colleagues about this, and the overwhelming response was, "Why isn't there just one concentration of liquid ibuprofen similar to acetaminophen?" Ideally, Johnson & Johnson Consumer Health, the sponsor of infant's and children's **MOTRIN** (ibuprofen), would standardize to the children's concentration, as was done for acetaminophen, with other ibuprofen manufacturers to follow. For now, healthcare providers should counsel parents about the availability of the two liquid ibuprofen strengths, and that the 100 mg/5 mL strength includes "children's ibuprofen" in the name, while the more concentrated 200 mg/5 mL (50 mg/1.25 mL) strength is often referred to as "concentrated infant drops." Ensure parents understand that the dose in mL must be based on which concentration they are using.

> SAFETY briefs cont'd from page 3

tacted the dispensing pharmacy, which confirmed that they had dispensed tuberculin (TB) syringes to the patient. The pharmacist noticed online that some TB syringe scales use a trailing zero after the decimal point (i.e., 1.0 for 1 mL), and a few failed to include a leading zero before a decimal point (e.g., .1, .2, .3) (**Figure 1**, page 3).

Fortunately, this patient had been drawing up the correct 1 mL amount (25 mg) but thought she was drawing the medication up to the "10," as she did not see the decimal point in the "1.0" syringe marking. This could have resulted in a serious medication error if the pharmacist had entered "10 mL" into the patient's health record, or if the patient had indeed been taking the wrong dose. The pharmacist was able to counsel the patient regarding the correct dose.

It is important for pharmacists to educate patients about the medication, prescribed dose, and proper dose measurement using the teach-back method. Pharmacies should proactively evaluate the syringes they purchase and take steps to only stock syringes without error-prone markings. For decades, ISMP has recommended avoiding trailing zeros and including leading zeros for decimal doses, and we recently began repeating this recommendation to various manufacturers in reference to syringes.

To subscribe: www.ismp.org/node/126

ISMP An ECRI Affiliate

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

Report medication and vaccine errors to ISMP: Call 1-800-FAIL-SAF(E), or visit our website at: 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.