

| Issue | Problem | Recommendation | Organization Assessment | Action Required/ Assignment | Date Completed |
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| Clear instructions and patient education key for the direct oral anticoagulant XARELTO (rivaroxaban) | | | | | |
| 09/18  agenda safety icon-alert | Xarelto is approved for several indications, including the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), where the patient initially takes 15 mg twice daily with food. After 21 days on this dose, the patient switches to 20 mg once daily with food for the remainder of treatment. However, patients have been dispensed and taken both doses concurrently. A few factors that have contributed to the reported events include: 1) insufficient patient education; 2) the labeling of the 20 mg daily prescription did not clearly indicate that the medication should not be taken until the 15 mg twice daily prescription was completed; and 3) limited use of manufacturer’s starter pack that guides patients to proper dosing for the first 30 days of treatment. | Prescriptions for the 20 mg daily dose should not be communicated to the pharmacy until a few days before it is to start. If prescribers must prescribe both dosing regimens at the same time, provide clear prescription directions and discharge instructions to the patient that the 20 mg tablets are to be started when the 15 mg tablets are finished and ensure they are understood. The statement, “Begin taking after [date]” should be included in the Xarelto 20 mg directions. Ensure the patient has received these explicit instructions verbally and in writing. Patient education by pharmacists for selected high-alert drugs, such as anticoagulants, should be mandated. Improved, effective computer warnings that are not easy to bypass are also required. |  |  |  |
| Reconstitution error with SHINGRIX (zoster vaccine recombinant, adjuvanted, or RZV) vaccine | | | | | |
| 12/18 | Shingrix is comprised of two components, a lyophilized gE antigen component and an adjuvant suspension component. The lyophilized component must be reconstituted with the adjuvant suspension before administration. Recently, a pharmacist mistakenly administered only the Shingrix adjuvant suspension. He failed to use the adjuvant to first reconstitute the lyophilized gE antigen component of the Shingrix vaccine. As a result, the patient was left unknowingly vulnerable to disease. | Employ a system to ensure the Shingrix lyophilized component and adjuvant suspension vials are stored with one another to reduce the risk of administering only the adjuvant suspension or using a diluent from another vaccine. The Centers for Disease Control and Prevention (CDC) provides information about proper storage, administration, and handling of both zoster vaccines, Shingrix and ZOSTAVAX, along with strategies to prevent administration errors (www.ismp.org/ext/22). |  |  |  |
| Reporting and second-order problem solving can turn short-term fixes into long-term remedies | | | | | |
| 11/18 | Practitioners who are repeatedly challenged by unexpected work system failures that hinder patient care have become proficient in working around these failures to get the job done. These quick fixes, called first-order problem solving, are often considered to be signs of resourcefulness. However, these quick fixes, transfer problems to another time, person, or place. Failure to use second-order problem solving (i.e., report problems, understand why they exist, correct the problem) hinders long-term remedies. The culture often emphasizes quick fixes above learning from failures and improving system reliability. | To promote organizational learning, create an environment of psychological safety that fosters open reporting, active questioning, and frequent sharing of insights and concerns. Encourage practitioners to both handle the unexpected problem and then report it so steps can be taken to address its underlying causes. Create capacity for second-order problem solving to occur as close as possible to when and where the problem occurred. Once a problem has been identified and the underlying causes examined, proper attention must be paid to reducing its recurrence by developing an action plan to address the systems’ weak points |  |  |  |
| Container label changes for vitamin A, D, and E | | | | | |
| 10/18 | The US Food and Drug Administration (FDA) published a final rule that requires listing the absolute amounts of vitamins and minerals in mg or mcg in addition to the percent daily value (% DV) on the label. Packages of over-the-counter fat-soluble vitamins A, D, and E have already started to reflect this change. Unfortunately, there is no equivalency expressed on the labeling from the old format to the new (international units to metric weight). | Educate patients and practitioners about this change and how it will affect dosing if they use these vitamins. ISMP has requested consideration of public announcement about this change and supports requiring manufacturers to include the strength on container labels and Supplement Facts panels in both mg or mcg as well as international units in parentheses to allow for safe transition to metric weight labeling. |  |  |  |
| Generic EPINEPHrine 0.15 mg autoinjectors do not use the abbreviation “Jr” | | | | | |
| 11/18  agenda safety icon-alert | Brand **EPINEPH**rine autoinjectors, **EPIPEN** (0.3 mg) and **EPIPEN JR** (0.15 mg), make it easy to determine which should be used for an adult or a child. Generic autoinjectors list only the metric strength (0.15 mg, 0.3 mg) and do not use the “Jr” designation for the 0.15 mg strength. | When dispensing or using generic **EPINEPH**rine autoinjectors, educate practitioners and consumers about the lack of “Jr” designation on the 0.15 mg strength product and which strength should be used based on patient weight. |  |  |  |
| Similar or same names lead to confusion and wrong long-term care (LTC) resident errors | | | | | |
| 09/18 | ISMP regularly receives reports of wrong LTC resident errors that occur when pharmacy staff enter a medication order into the wrong resident’s profile. This erroneous order entry subsequently appears on the wrong resident’s pharmacy-prepared medication administration record. Similar or the same last names of residents are at the root of many of these errors. Errors also happen when medications for a resident in one LTC facility are accidentally entered into the profile of a resident in another facility. | Clearly print the resident’s name on the order. Use at least two resident identifiers (i.e., full name and date of birth) to verify resident identity. If these identifiers are not available or illegible, pharmacy staff should contact the LTC facility to collect and verify the information. Employ alerts to warn staff about possible name confusion when residents have the same or similar last names, particularly if residing in the same LTC facility. |  |  |  |
| Entire bottle of sublingual nitroglycerin was administered to a patient | | | | | |
| 11/18 | An inexperienced nurse administered the entire bottle of nitroglycerin tablets to a patient. She had scanned the barcode on the bottle, which confirmed the correct medication without an alert. The new nurse was familiar with unit dose dispensing and thought the small bottle contained a single dose for the patient. | Ensure the medication administration record and automated dispensing cabinet screens include instructions to administer 1 tablet sublingually (with additional doses as prescribed). Package the nitroglycerin bottle in a plastic bag or pharmacy vial and affix a label with detailed directions for use. Remind all long-term care practitioners when preparing or administering a medication that If they need more than 3 of any dosage form, call the pharmacy. |  |  |  |
| Confusion between placebo and active pills can happen with various birth control packs | | | | | |
| 10/18 | There is a risk of confusion between the week 1 active tablets and the week 4 placebo tablets of **TRI-ESTARYLLA** (norgestimate and ethinyl estradiol), **TRI-LINYAH,** and other therapeutically equivalent products. Some products utilize different color tablets for weeks 1 and 4 compared to the others. This is of concern, especially for patients who switch products. This difference in color confused a patient. Thankfully she called the pharmacy before taking the wrong tablets at the wrong time of the month. | Alert patients of the change when products are substituted. To avoid confusion, for therapeutically equivalent products, manufacturers should work with the US Food and Drug Administration (FDA) to standardize tablet colors with the original brand. Standardization can help patients use the product correctly and help them recognize if they have been dispensed a wrong drug that is not therapeutically equivalent. |  |  |  |