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Community/Ambulatory Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

A problem that still needs "ironed" out: Label improvements needed for iron products

PROBLEM: A practitioner reviewing an elderly patient's home medication list learned that the patient's daughter had been giving him 5 tablets of ferrous sulfate daily to equal the 325 mg dose recommended by her father's physician. The ferrous sulfate she had purchased at a pharmacy was only labeled with the amount of elemental iron in each tablet, 65 mg. The label provided no indication that each tablet was equivalent to ferrous sulfate 325 mg. The patient's daughter thought she was supposed to give her father five 65 mg tablets for each 325 mg dose. The patient experienced severe constipation and stopped taking the iron after 2 days but was soon hospitalized for other reasons, where the error was discovered.

This is not a new problem. Longstanding lack of standardization for iron product labeling has led to frequent dispensing and administration errors. A total of 67 reports concerning iron were submitted to the ISMP National Medication Errors Reporting Program (MERP) between 1998 and 2017. Forty percent of these reports were due to confusing product labeling on both the outer package of multi-dose containers and on individual unit dose packages.

We have even heard from practitioners who have similarly misinterpreted iron supplement labels. For example, after receiving a product labeled "Iron (as ferrous sulfate) 65 mg," a nurse in a skilled nursing facility calculated that 5 tablets were needed for a single dose of ferrous sulfate 325 mg. Fortunately, she realized that 5 tablets per dose

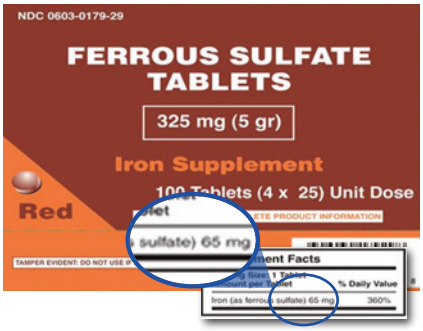

Figure 1. Primary display panel lists the strength of ferrous sulfate as a salt, while the same product's Supplement Facts panel lists the strength as elemental iron.

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Apply now for an ISMP fellowship

ISMP is accepting applications until **March 31** for two unique yearlong fellowship programs commencing mid- to late-summer 2018:

- The **ISMP Safe Medication Management Fellowship** offers a pharmacist, nurse, or physician an opportunity to learn from the nation's experts in medication safety at the Horsham, PA, office of ISMP.

- The **FDA/ISMP Safe Medication Management Fellowship** offers a healthcare professional an opportunity to work with medication safety experts at ISMP in Horsham, PA, for 6 months, and the US Food and Drug Administration (FDA) Division of Medication Error Prevention and Analysis in Silver Spring, MD, for 6 months.

All candidates must have at least 1 year of postgraduate clinical experience and relocate to the area. For details, visit: www.ismp.org/profdevelopment/.

SAFETY briefs

Some drug look-up codes are too short. Order entry errors often happen when just the first few letter characters and an associated strength are used to search and select a medication from on-screen computer listings. For example, again and again, errors are reported with LEV500 (levo**FLOX**acin or lev**ETIRA**cetam), MET500 (metro**NIDAZOLE** or met**FORMIN**), and many others. Just recently, we learned of another case. A pharmacist was manually entering oxybutynin extended release 10 mg daily into the computer system. When doing so, the pharmacist used the computer system's "quick key" functionality, which searches for the first 3 letters of the generic name and the strength of the drug. In this case, the search was for "oxy10." Products such as oxybutynin extended release 10 mg and oxy**CODONE** extended release 10 mg appear on the screen when the search is completed. Inadvertently, the pharmacist chose "oxycodone SR 10 mg." Luckily, the error was caught before reaching the patient. Typing at least 5 letter characters (unless the drug name contains 4 or fewer letters) along with the drug strength most

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Data submission extended for assessment until March 16

We are extending the date from February 28 to **March 16** for healthcare facilities to submit their findings to ISMP for the *ISMP Medication Safety Self Assessment for High-Alert Medications* (www.ismp.org/sc?id=3032). This month, we received numerous requests from organizations for a short extension of 2 weeks by which data must be submitted to ISMP. We hope the additional 2 weeks will provide facilities with sufficient time to participate in the full assessment and submit their data.

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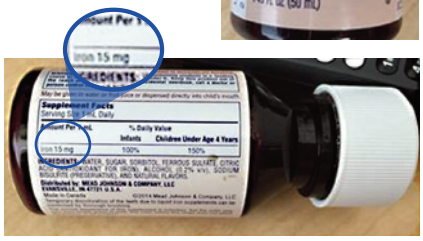
seemed unusual and a call to the facility's pharmacist helped prevent a serious medication error. But these are a small fraction of the errors that may go undetected leading to patients receiving unintended amounts of elemental iron.

Over-the-counter (OTC) iron products are regulated as food supplements by the US Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN). So, a *Supplement Facts* panel appears on the label instead of a *Drug Facts* panel. Unfortunately, we have observed tremendous variability in the labeling of OTC iron products, many of which do not match with how providers often order these products based on their salt form (e.g., ferrous sulfate 325 mg daily).

Figure 2. Fer-In-Sol front panel label lacks any mention of strength, while the Supplement Facts label lists only the amount in terms of elemental iron.



We have seen container labels of some iron products that express only the amount of elemental iron in each tablet. Other iron products express the amount of iron in salt form on the primary display panel and a differing amount of iron, the elemental form, in the *Supplement Facts* panel (**Figure 1**, on page 1). Some iron supplements do not include the amount of iron on the primary display panel and instead list the dose of elemental iron only on the *Supplement Facts* panel (**Figure 2**). In the latter example, one must search under the ingredients section to find that the iron is from ferrous sulfate. Finally, some products may list the apothecary strength (5 gr) which can also lead to confusion.

Safe Practice Recommendations: Since most iron supplements are available OTC, patients may purchase products in any type of store or online, including a pharmacy, without a pharmacist's assistance. In order to minimize the likelihood of errors with iron supplements, consider the following:

- Do not refer to the supplement as "iron" but, instead, as "elemental iron" or the appropriate ferrous salt, especially when communicating dosage information.
- Despite its OTC status, prescribers should provide patients with a prescription for iron supplements in order to facilitate patient counseling by a pharmacist. Prescribers should also encourage patients to seek assistance from a pharmacist when selecting iron supplements, especially liquid formulations.
- Ideally, all dosages should be expressed in terms of milligrams of elemental iron. However, because prescribers often express doses in terms of the ferrous salt form, while some package labeling indicates strength in terms of elemental iron, both should appear in all forms of communication (e.g., patient charts, prescriptions, pharmacy labels, medication administration records [MAR], manufacturer labels, drug references). For example, ferrous sulfate 325 mg (elemental iron 65 mg).
- Ensure that staff understands that iron-containing products are available in salt forms such as ferrous gluconate, ferrous sulfate, and ferrous fumarate. It is also important for them to know that, respectively, only 12%, 20%, and

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often limits similar names from appearing together on the same screen; work with your information technology staff and computer vendor to implement this strategy in the order entry system. Use of tall man letters can also help differentiate similar drug names if practitioners are faced with a list of drug names.

Vaccine error potential with new herpes zoster vaccine. **SHINGRIX** (zoster vaccine recombinant, adjuvanted), referred to as "RZV" by the Centers for Disease Control and Prevention (CDC), was approved for use by the US Food and Drug Administration (FDA) last October. For over a decade, the medical community has been accustomed to the storage and administration requirements of Merck's **ZOSTAVAX** (zoster vaccine live, or ZVL), the only herpes zoster vaccine on the market at that time. But Shingrix and Zostavax have different storage requirements, components/diluents, and routes of administration.

GlaxoSmithKline, the manufacturer of Shingrix, has received a small number of error reports involving differences between the vaccines. Both components of the Shingrix vaccine, its lyophilized gE antigen component and its adjuvant suspension component, should be stored under refrigeration, both before and after reconstitution (see package insert for details). If the lyophilized component or its adjuvant suspension are improperly stored in a freezer, they must be discarded. The storage requirements for Zostavax differ: the lyophilized vaccine (attenuated varicella-zoster virus) should be stored in a freezer, and the Merck-supplied sterile water diluent can be stored in a refrigerator or at room temperature. The product components are not interchangeable. A system should be employed to ensure the Shingrix lyophilized component and adjuvant suspension vials are stored with one another to reduce the risk of using a diluent from another vaccine. Finally, Shingrix is given

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33% of each dose is elemental iron. Educate patients about the difference between elemental iron and its salt forms.

- Store iron supplements behind the pharmacy counter and require a pharmacist to provide counseling regarding dosing instructions. If this is not possible, place products near the pharmacy checkout in plain view of the pharmacist to capture an important counseling opportunity. At minimum, use "shelf-talkers" near these products that instruct patients to ask for a pharmacist's help when selecting iron supplements.
- Pharmacists should verify that the prescribed dosage falls within the guidelines for iron-replacement therapy for the patient's age and weight.
- Pharmacists and nurses should clarify prescriptions that contain only the volume to be administered for liquid iron products. Use the teach-back method to ensure that patients understand how to measure the proper dose.
- All practitioners should stress the importance of keeping these products up, away, and out of the reach of children. If an accidental ingestion occurs, recommend calling the Poison Help number (800-222-1222) immediately (encourage patients and caregivers to store this number in all their phones, including cell phones). It may only take a few tablets to cause serious toxicity in children.
- Manufacturer package labels should clearly express dosage strengths in terms of both elemental iron and the ferrous salt form. Pharmacists should affix a pharmacy label that clarifies dosing instructions. In addition, pharmacies should not purchase products found to have ambiguous labeling.

ISMP has discussed this issue with CFSAN and continues to advocate for them to work with manufacturers to "iron" out this confusion.

Improper use of insulin pen safety needles

Although our October 12, 2017 National Alert Network (NAN) publication about standard insulin pen needles involved patients at home who failed to remove the needle cover before injection (www.ismp.org/sc?id=3033), problems in long-term care (LTC) facilities during insulin administration can also happen when using safety needles.

An elderly woman with type 1 diabetes and dementia was recently admitted to an extended care facility. Prior to admission, the resident had good glycemic control. During the first 2 weeks at the facility, she required five visits to an emergency department (ED) for hyperglycemia and a hospital admission for diabetic ketoacidosis. The cause of the hyperglycemia and ketoacidosis was found to be improper use of the **BD AutoShield Duo** insulin pen needle, which resulted in numerous failures to deliver insulin during administration.

Figure 1. Red indicators appear on the BD AutoShield Duo (left) and NovoFine Autocover (right) after injection when the system locks.

The facility required the use of the BD AutoShield Duo pen needles to prevent needlesticks. They have a sliding sleeve encircling the needle that retracts when the pen and needle are pressed against the patient's skin. Afterwards, the shield

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intramuscularly, and Zostavax is given subcutaneously.

Please pass on this information to providers who manage vaccine programs or administer vaccines at your practice site. The CDC Advisory Committee on Immunization Practices recently published recommendations for use of herpes zoster vaccines in *Morbidity and Mortality Weekly Report (MMWR)* January 26, 2018; 67(3);103–8 (www.ismp.org/sc?id=3100). The American Pharmacists Association also has a table describing the differences: www.ismp.org/sc?id=3102.

Updated vaccine labels from CDC. Earlier this month, the Centers for Disease Control and Prevention (CDC) updated its vaccine label storage safety tool to help reduce some of the most frequent causes of vaccine errors. The labels (www.ismp.org/sc?id=3101) may help reduce some of the common errors reported to the *ISMP National Vaccine Errors Reporting Program (VERP)*, such as age-related errors. These labels can be placed in an organized fashion on individual containers or bins, or permanent vaccine shelving units where vaccines are stored.

Optimal use of antibiotics for UTIs in LTC facilities. Antibiotics are one of the most commonly prescribed medications in long-term care (LTC) facilities. However, up to 75% of antibiotics used in LTC facilities, particularly to treat urinary tract infections (UTIs), are prescribed incorrectly. Overuse and misuse has led to the emergence of antibiotic-resistant bacteria and *Clostridium difficile* infection. The Pennsylvania Patient Safety Authority conducted a 30-month study of reported events involving broad-spectrum antibiotic use associated with antibiotic resistance and *C. difficile*, that were prescribed to treat UTIs in LTC facility residents (www.ismp.org/sc?id=3025). The findings revealed significant deviance from national guidelines, signaling an urgent need for immediate adoption of best practices

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slides back over the needle, locks into place, and a red indicator becomes visible (**Figure 1**, on page 3). In this case, some staff members were not pressing hard enough for the cover to retract, and others injected the insulin at an angle that did not allow the retraction mechanism to work properly, resulting in no insulin delivery. Current insulin delivery recommendations note that the pen needle must be injected into the skin at a 90 degree angle, with no skinfold pinch for 4-5 mm needles, or with a skinfold pinch for longer needles. Administration failures can also occur if the needle makes contact with the skin but is then moved to another site, as the needle mechanism will lock upon initial contact with the skin.

In another case published in the literature, an elderly resident in a LTC facility experienced hyperglycemia and diabetic ketoacidosis requiring multiple hospitalizations (Yu CHY. "Safety" technology: a hidden cause of diabetic ketoacidosis. *CMAJ*. 2012;184[5]:557-8). The healthcare team confirmed that the patient's soft, redundant abdominal tissue was impeding the retraction of the pen needle's sleeve. Standard, nonretractable pen needles were then used, which resulted in resolution of the extreme glucose fluctuations. When the patient presented to a hospital again with ketoacidosis 20 days later, it was learned that the LTC facility had exhausted the box of nonretractable needles and had resumed use of the safety needles.

These safety issues can exist with both the BD AutoShield Duo and the NovoFine Autocover systems. If either of these needle systems are used, proper staff training is critical, including a requirement to look for the red indicator post-injection. While there may be little need for patients to use the more costly safety needles in the home unless someone else is injecting the insulin, patients and family members who may be using these systems will also need to be educated.

Medication safety officers: Join MSOS and attend free bimonthly webinars and more

If you are a medication safety officer or planning a career that focuses on medication safety, we hope you consider joining our Medication Safety Officers Society (MSOS). The mission of MSOS is to advance and encourage excellence in medication safety by providing communication, leadership, direction, and education for its members. MSOS offers an open forum for information sharing and collaboration. **Membership in the MSOS is currently free** and open to US and international professionals. Webinars, which are free to members, are held every other month. During the webinars, members share lessons learned and implementation strategies on specific topics of interest to the group. ISMP also provides a brief update on current issues and activities. To learn more about the MSOS, visit: www.medsafetyofficer.com.

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for treating UTIs in the elderly. The authors offer a number of recommendations LTC facilities should consider, including empowering clinicians to withhold antibiotic therapy for asymptomatic bacteriuria, and improving communication between nursing, prescribing staff, and other healthcare practitioners across the continuum of care. Successful antibiotic stewardship requires a team effort. Long-term care and consultant pharmacists are key players on that team. Consultant pharmacists, pharmacies that supply medications to LTC facilities, and prescribers should team up with facility staff to provide staff education and tools to operate an antibiotic stewardship program and differentiate broad-spectrum from narrow-spectrum antibiotics. The Centers for Disease Control and Prevention (CDC) has a number of resources (www.ismp.org/sc?id=3105), including *Core Elements of Antibiotic Stewardship for Nursing Homes*, you can share with your LTC facilities.

Special Announcement

"Intensive" training in medication safety

The last **Medication Safety Intensive (MSI) Workshop** sold out quickly! Act now to avoid being put on the waiting list for our **April 5-6** workshop in **Philadelphia**—you won't want to miss this unique opportunity to maximize your error-prevention efforts. For details and to register, please visit: www.ismp.org/sc?id=637.

If you would like to subscribe to this newsletter, visit: www.ismp.org/sc?id=386

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

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Safe Medication Management Fellowships

ISMP is now accepting applications for two unique **2018-2019 Fellowship** programs

ISMP Safe Medication Management Fellowship

Location and Term: This 12-month Fellowship commences summer 2018 at the Horsham, Pennsylvania (near Philadelphia) office of ISMP. Relocation to the Horsham/Philadelphia area is required.

Description: The Fellowship **offers a nurse, pharmacist, or physician with at least 1 year of postgraduate clinical experience** an unparalleled opportunity to learn from and work with some of the nation's experts in medication safety. This Fellowship is open to US citizens (or applicants with a valid US visa). Now in its 26th year, the Fellowship allows the candidate to work collaboratively with practitioners in various healthcare settings to assess and develop interdisciplinary medication error-prevention strategies.

FDA/ISMP Safe Medication Management Fellowship

Location and Term: This 12-month Fellowship commences August/September 2018. The Fellow will spend 6 months at the Horsham, Pennsylvania (near Philadelphia) office of ISMP and 6 months at the Silver Spring, Maryland (near Washington, DC) office of the US Food and Drug Administration (FDA). Relocation to the Horsham/Philadelphia and Silver Spring/Washington, DC, area is required.

Description: The Fellowship, **open to a healthcare professional with at least 1 year of postgraduate clinical experience**, is a joint effort between ISMP and FDA's Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis. This Fellowship is open to US citizens only. The Fellowship allows the candidate to benefit from ISMP's years of experience devoted to medication error prevention. At FDA, valuable regulatory experience is gained by working with the division focused on medication error prevention.

A competitive stipend is provided with all Fellowship programs.

How to Apply

Information and applications can be found at: www.ismp.org/profdevelopment/.
Applications can also be requested by calling 215-947-7797.

The application deadline for all Fellowship Programs is March 31, 2018.