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ISMP

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

# ISMP launches the first high-alert medication safety self assessment for inpatient and outpatient facilities

Without a doubt, we consider the series of ***ISMP Medication Safety Self Assessment***® tools (www.ismp.org/selfassessments/) to be among the most important activities we've undertaken to help advance medication error prevention efforts. This week, ISMP is excited to announce it is launching a groundbreaking new medication safety self assessment that will help hospitals, long-term care facilities, and certain outpatient facilities evaluate their best practices related to high-alert medications, identify opportunities for improvement, and track their experiences over time. Many key professional and accrediting organizations have endorsed the new ***ISMP Medication Safety Self Assessment® for High-Alert Medications*** (**Table 1**). Participation in the new self assessment will help healthcare organizations analyze how they are meeting requirements for managing high-alert medications from regulatory and accrediting agencies, such as the Centers for Medicare & Medicaid Services (CMS) and The Joint Commission.

**Table 1.** Organizations endorsing the *ISMP Medication Safety Self Assessment® for High-Alert Medications*

- American Association of Colleges of Nursing
- American Hospital Association
- American Nurses Association
- American Society for Healthcare Risk Management
- American Society for Parenteral and Enteral Nutrition
- American Society of Health-System Pharmacists
- Anesthesia Patient Safety Foundation
- Association for the Advancement of Medical Instrumentation Foundation
- Association of periOperative Registered Nurses
- ECRI Institute
- Health Care Improvement Foundation
- Infusion Nurses Society
- Institute for Healthcare Improvement
- National Committee for Quality Assurance
- National Patient Safety Foundation
- Pediatric Pharmacy Advocacy Group
- Society of Critical Care Medicine
- The Joint Commission

High-alert medications, a term first coined by ISMP in 1997, are defined as those drugs that bear a heightened risk of causing significant patient harm when used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients.

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# Transition adapters for ENFit syringes can defeat the purpose of ENFit itself

Some hospitals have finally begun converting to ENFit tubing, syringes, and administration sets for enteral feedings and medications to prevent misconnections with vascular access sites. But, in case hospitals and/or patients are not yet using ENFit feeding tubes, manufacturers are still distributing ENFit administration sets with transition adapters (**Figure 1**, page 5). These transition adapters can be removed to expose an ENFit connector for patients who have an ENFit feeding tube, or can remain in place if the patient has a legacy feeding tube with a Luer connector. This temporary measure is necessary to assure compatibility with either system. The transition adapters will eventually be eliminated when all are using feeding tubes with an ENFit connector.

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## SAFETY briefs

**CycloSPORINE oral solution error.** A 10-fold overdose of modified cyclo**SPORINE** oral solution (100 mg/mL) was administered to a child. The physician prescribed 0.5 mL (50 mg), and the pharmacy dispensed a sealed package of the medication (100 mg/mL), which contained a 5 mL oral syringe (**Figure 1**) provided by the manufacturer, AbbVie, that was calibrated in 1 mL increments, with hash marks between each mL. The child's parent gave 5 mL (500 mg) instead of 0.5 mL to the child for several days.

Patients who received solid organ transplant or allogeneic hematopoietic stem cell transplants are required to take long-term immunosuppressant drugs to prevent rejection and graft-versus-host disease. The dosages of immunosuppressants are usually individualized based on the type of transplant, target blood level, body weight, drug-drug interactions, and the risk of rejection or toxicity. Many transplant centers use oral solution formulations of immunosuppressant agents to allow greater flexibility in dosage adjustments, especially for pediatric patients. Since immunosuppressant agents have significant interpatient dosing variability, dosage delivery devices need to be selected specifically for each patient, and one-size does not fit all. In this case, the 5 mL


**Figure 1.** Package contains 5 mL oral syringe marked in 1 mL increments, with hash marks between mL markings. Pediatric doses may require measurement of less than 1 mL of medication.

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## Overview of the New Self Assessment

**Targeted high-alert medications.** The new ***ISMP Medication Safety Self Assessment® for High-Alert Medications*** is being funded through a contract with the US Food and Drug Administration (FDA) Professional Affairs and Stakeholder Engagement/Safe Use Initiative, and will focus on best practices for high-alert medications in general, along with eleven specific medication categories:

- **Neuromuscular Blocking Agents**
- **Concentrated Electrolytes Injection**
- **Magnesium Sulfate Injection**
- **Moderate Sedation in Adults and Children, Minimal Sedation in Children**
- **Insulin, Subcutaneous and Intravenous**
- **Lipid-Based Medications and Conventional Counterparts**
- **Methotrexate for Non-Oncologic Use**
- **Chemotherapy, Oral and Parenteral**
- **Anticoagulants**
- **Neuraxial Opioids and/or Local Anesthetics**
- **Opioids**

Several changes have been made to this particular self assessment as compared to our other self assessments to make the tool easier to use. Participants can choose one or more of the high-alert medication sections to assess. They can complete the tool in phases, responding to just the sections on the high-alert medication categories used in their facilities. They can even submit their findings anonymously to ISMP as each section is completed. More details about this process follow.

**Organizations that will benefit.** Healthcare organizations that can benefit from the new self assessment include hospitals, health systems, long-term care facilities, and some outpatient facilities, such as ambulatory surgery centers, emergency/urgent care facilities, oncology clinics, treatment centers, dental surgery centers, endoscopy centers, and diagnostic testing centers. A separate set of general demographic questions are provided for inpatient and outpatient facilities, and the self-assessment items are designed for diverse healthcare settings that use any or all of the targeted high-alert medications.

**Self-assessment items.** When developing the assessment for high-alert medications, ISMP worked with an expert Advisory Group to ensure that the systems and practices most crucial for patient safety were included, and that the recommendations were achievable in a broad range of healthcare facilities. Keep in mind that ISMP is not a standards setting organization. As such, the self-assessment items do not represent a minimum standard of practice and should not be considered as such. In fact, some of the self-assessment items represent innovative practices and system enhancements that are not widely implemented in healthcare facilities today. Their value in reducing errors is grounded in scientific research and/or a collaborative agreement by the expert Advisory Group regarding items included in the assessment.

**Weighted scores.** Healthcare organizations can use this unique tool in their own medication safety efforts. However, only organizations that submit their assessment findings to ISMP anonymously via a secure internet portal by **December 15, 2017**, will be able to obtain weighted scores based on their assessment, so they can compare themselves to demographically similar organizations nationally. To determine a weight for each self-assessment item, ISMP used a standard process to independently evaluate each item to determine its impact on patient safety and its ability to sustain improvement. Most of the self-assessment items are weighted in a way that

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syringe size was significantly larger than each intended dose and did not facilitate accurate measurement and delivery of the prescribed dose.

Upon product dispensing, pharmacists should evaluate the appropriateness of the dosage delivery devices included in the package. A 2016 study (Yin HS, Parker RM, Sanders LM, et al. Liquid medication errors and dosing tools: a randomized controlled experiment. *Pediatrics*. 2016;138[4]) found that parents made fewer errors when measuring oral liquid medications for their children with oral syringes compared to dosing cups. However, the error rate with using oral syringes was still 16.7%. The researchers also found that providing dosing devices that closely matched the prescribed volume per dose offered the greatest reduction of errors (Yin HS, Parker RM, Sanders LM, et al. Pictograms, units and dosing tools, and parent medication errors: a randomized study. *Pediatrics*. 2017;140[1]). Healthcare professionals should ask patients/caregivers to show them how they will properly measure oral liquid medications using their dosage delivery device. (If the pharmacy that dispensed the cyclo**SPORINE** had done this, the dosing error might have been avoided.) The manufacturer and the US Food and Drug Administration (FDA) were notified about this event, and a recommendation was made to investigate including a smaller syringe for pediatric patients in the package.

HIGH-ALERT

**Textbook errata.** Elsevier has notified us of a potentially harmful dosage error in the *Harriet Lane Handbook*, 21st edition. On page 915 of the print version of the book, lines 5-6, the dose for **HYDRO**morphone is listed incorrectly as weight-based for children and adolescents above 50 kg. It states the dose as 0.2-0.6 mg/kg Q2-4 hours PRN. In fact, the doses are not weight-based. The dose should be listed as 0.2 mg-0.6 mg per dose, not per kg. This error has already been corrected in the e-book and all other digital versions of the content. Please make the correction in your print copy, or you can order an erratum sticker by completing the online form at: www.ismp.org/sc?id=3019. Please contact Elsevier Customer Service at 1-800-545-2522 or USBKInfo@elsevier.com with any questions.

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results in no numerical score (zero value) unless there is partial or full implementation of the item. However, some of the self-assessment items are weighted in a way that results in no numerical score unless there is full implementation of the item throughout the organization.

**Protection of anonymous results submitted to ISMP.** Although demographic information is collected as part of the assessment process, ISMP will NOT be able to identify individual facilities that have entered and/or submitted information. In addition, ISMP is a federally certified patient safety organization (PSO), which affords an even higher level of protection when clinicians and organizations choose to submit error data and other patient safety work to ISMP. If self-assessment information is collected within the organization's patient safety evaluation system and submitted to ISMP as patient safety work product, the information is granted protection from discovery in connection with a federal, state, or local civil, administrative, or disciplinary proceedings. No contract with ISMP is required for this legal protection.

## Details on Participation

**Obtaining the free assessment tool.** The new assessment tool is now available on the ISMP website at: www.ismp.org/selfassessments/saham. The tool (workbook) is available for download, and directions for creating a free account to use the online self-assessment form are available at this site. The online form can be used to record responses, and information entered can be saved and revisited for later completion. If using the online form to complete the assessment, the general demographics section and the general high-alert medications section will need to be completed and submitted to ISMP in order to gain access to all sections of the assessment. The online form is also used to submit your results to ISMP anonymously.

**Choosing the medications for assessment.** Again, to gain access to all sections, organizations need to complete the first section of the assessment covering general high-alert medications. Then, other sections can be used to evaluate systems and practices associated with specific high-alert medications. Not all the targeted high-alert medications included in the assessment may be used in every inpatient or outpatient facility, so each facility can choose one or more of these high-alert medications upon which to focus. However, ISMP strongly encourages all facilities to complete the assessment for every high-alert medication category used in their facility.

**Assessing as a team.** ISMP recommends that healthcare organizations establish interdisciplinary teams to work on the assessment, which include facility leaders; staff nurses, physicians, and pharmacists; information technology (IT) staff; medication safety or patient safety officers; and risk management/quality improvement professionals. The assessment workbook contains instructions for establishing and convening teams, selecting high-alert medications for analysis, and submitting information to ISMP online.

**Please note: Because medication use is a complex, interdisciplinary process, the value and accuracy of the self assessment is significantly reduced if it is completed by a single person or a single discipline.**

It is also important for each facility in a health system to complete the assessment individually and submit its information separately. Although standardization across a health system is desirable, practices often differ. For an accurate assessment, the tool requires information that can only be provided by practitioners who work in the facility. Each facility will truly benefit from completing the assessment individually and obtaining its own individual set of scores to focus on vulnerabilities that may vary from facility to facility. Corporate-level assessment invalidates the tool's effectiveness and usefulness.

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**Patients should not swallow AcipHex Sprinkle capsules!** ACIPHEX SPRINKLE (RABEprazole sodium) delayed-release capsules are used to treat gastroesophageal reflux disease in children 1 to 11 years for up to 12 weeks. Although the product is a capsule, it must **not** be swallowed whole or chewed, nor should the granules be crushed. AcipHex delayed-release tablets for adults should be swallowed whole, not crushed or chewed. But for the sprinkles, patients or caregivers should open the capsule and sprinkle the granule contents on a spoonful of soft food or liquid, and take the entire mixture within 15 minutes of preparation. AcipHex Sprinkle is the only capsule formulation proton pump inhibitor (PPI) that **cannot** be swallowed whole. All other PPI capsules, such as omeprazole, esomeprazole, and lansoprazole, can be swallowed whole, although patients who have difficulty swallowing can also open these capsules and sprinkle the pellets over a tablespoon of applesauce. Other sprinkle capsules, such as topiramate sprinkle capsules, divalproex sodium delayed-release sprinkle capsules, and KLOR-CON sprinkle capsules (potassium chloride extended-release), can be swallowed whole or opened and sprinkled over soft food.


**Figure 1.** Auxiliary labels printed with AcipHex Sprinkles prescription label are confusing. AcipHex Sprinkles should NOT be swallowed whole.

Unfortunately, some of the auxiliary labels that automatically print along with pharmacy labels for AcipHex Sprinkle capsules may be interpreted to mean that the capsules can be swallowed whole (**Figure 1**). If applied to the prescription bottle, the labels can cause confusion and increase the risk of incorrect administration if older children try to swallow the capsules.

ISMP contacted the manufacturer's medical information group, and the company could not comment on the clinical and safety outcomes if patients swallow the AcipHex Sprinkle capsule whole. Retail pharmacies

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**Submitting findings to ISMP.** We strongly encourage all healthcare facilities completing any section of the assessment to submit their results to ISMP anonymously by **December 15, 2017**. This will help create a baseline of national efforts to enhance safety with high-alert medications, identify and prioritize opportunities to reduce patient harm, and help ISMP create tools associated with identified areas of vulnerability that can help improve medication safety. Your participation in this study is crucial to ensure we have the best data upon which to base our decisions regarding the most valuable use of our collective resources.

As explained in the workbook, findings from any or all of the assessment sections can be submitted to ISMP using the online form after creating a free account at: https://ismpassessments.org/high_alert/. Organizations that submit results to ISMP must complete general demographic questions and the general high-alert medications assessment items before navigating to any of the targeted high-alert medication categories. This information is necessary to provide aggregate information back to participating facilities that can be used for comparison to like facilities, and to ensure a representative sample of US healthcare facilities participates in our study.

**Viewing a report of your results.** After a self-assessment section for a high-alert medication category has been submitted to ISMP, participants can generate a report showing their weighted scores in that section. The report can then be used to identify and prioritize opportunities for improvement as part of the organization's medication safety action plan.

**Comparing your results to like facilities.** After the data collection period ends, ISMP will prepare and publish a preliminary aggregate results workbook for the general high-alert medications and each of the targeted high-alert medications, with comparative reports of the safety practices in US facilities based on the data submitted. Facilities that submit information to ISMP will be able to access these aggregate comparative reports by logging into the account that was used to enter and submit their self-assessment information.

**Aggregating results for collaborative efforts.** Large health systems or organizations with large participating groups can contact ISMP (selfassess@ismp.org) to obtain a group code that can be used to aggregate the online submission results of their participating facilities, which will allow a collaborative effort to develop an action plan based on the group's self-assessment results. The code should be obtained before participants submit data to ISMP.

## Value to the Healthcare Community

As with the data submitted by thousands of organizations in response to prior ISMP medication safety self assessments, ISMP will use the aggregate findings to plan additional educational curricula, tools, and resources to help healthcare practitioners enhance safety when using high-alert medications. Several national medication safety initiatives have been based on data from ISMP's previous self assessments, and other countries have adopted the assessment tool to gather information and to set goals for their own medication safety efforts. An analysis of the aggregate results also will be submitted for publication in a professional journal to detail national baseline efforts to reduce the risk of errors and prevent patient harm associated with high-alert medications.

Please help ISMP make this assessment tool a valuable medication safety resource representative of US hospitals, long-term care facilities, and outpatient facilities by participating in this important effort. For more information, visit: www.ismp.org/selfassessments/saham, email selfassess@ismp.org, or call 215-947-7797.

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should evaluate the medical information pamphlet and auxiliary labels programmed to print with AcipHex Sprinkle prescriptions to be sure they reflect the correct administration method. Hospital pharmacies also need to make nurses aware of the correct administration either through built-in administration instructions in the electronic medical record or other drug information resources. We also contacted all major drug information vendors so they can make any necessary changes to auxiliary warnings they provide in their content for pharmacies.

**More on contrived prescriptions to "test" insurance coverage.** Once again, we've learned of a situation where a contrived "test claim" was submitted to a pharmacy benefits manager or insurance company to determine coverage. Doing so has sometimes resulted in a patient getting an unintended medication that does not match the patient's actual need. In most cases it's been a prescriber trying to learn whether a certain medication will be covered for the patient. In the most recent case, a pharmacy technician submitted the claim after a patient requested information to determine whether **GENVOYA** (cobicistat, elvitegravir, emtricitabine, and tenofovir), which was not yet prescribed, would be covered. This patient's insurance approved the medication and a label was printed, resulting in the prescription being filled and dispensed to the patient. The patient called his physician about the medication, and the drug was cancelled before the patient took the medication.

In response to a 2016 *Safety Brief* about the risks associated with sending "test" prescriptions to a patient's pharmacy to determine insurance coverage, Surescripts, the company that routes prescriptions electronically to pharmacies, sent a *Customer Bulletin* to pharmacy and electronic health record [EHR] vendors, warning them about errors. In these instances, prescribers did not intend for the pharmacy to dispense the "test" medications. To improve patient safety and support adherence to correct electronic prescribing practices, Surescripts has asked that EHR vendors and their end-users (physicians and pharmacy personnel) ensure that no "test" prescriptions are sent in the live environment. Prescribers should only transmit electronic prescriptions that are intended for the pharmacist to dispense to the patient.

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In addition to the above, we've recently learned that other types of adapters have now become available to facilitate a connection between legacy oral syringes and the new ENFit connectors on feeding tubes. Alarmingly, some of these adapters even fit parenteral syringes that have a Luer-slip or Luer-lock tip (**Figure 2**).

ISMP has long advocated prohibiting preparation of any oral liquid medication in a parenteral syringe. If this unsafe practice occurs, these add-on adapters would need to be applied *after* the dose has been prepared in the parenteral syringe. If this step is omitted, and the adapter is not applied to the parenteral syringe, the oral liquid would be in a syringe that could be connected to an intravenous (IV) port, allowing for the possibility of administration by the IV route.

In addition to the risk of inadvertent IV injection of oral liquids or suspensions when using these adapters with a parenteral syringe, the adapters may also be a choking hazard if left at the bedside, similar to caps from syringes that have been left at the bedside or lost in the bed sheets during administration (www.ismp.org/sc?id=3002).

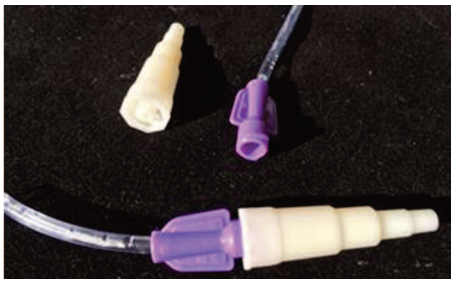

**Figure 1.** Transition adapter now accompanies enteral feeding administration sets. It can be removed for use with feeding tubes that have an ENFit connection, or left in place to use with legacy feeding tubes that have a Luer connector.

Furthermore, these add-on adapters can undermine the low dose ENFit syringe tip (on ENFit syringes of 5 mL or less) that was specially designed to minimize the dead space and associated volume retention during drug administration. The add-on devices appear to have significant dead space that will allow the accumulation of fluid during administration, which will never reach the patient. Thus, these adapters can cause inaccurate liquid dosing of small volume liquids in neonates and pediatric patients, and in adults who are receiving drugs that have a narrow therapeutic index. For more information about the low dose tip, please visit: www.ismp.org/sc?id=3001.

**Figure 2.** Above, oral syringe with add-on adapter to make it compatible with ENFit connector on feeding tube. Bottom, same add-on adapter fits on a parenteral syringe.

ISMP stands behind the need for full conversion to ENFit devices to reduce the risk of accidental connection of syringes and administration sets meant for other routes of administration. Transition adapters *for feeding tubes* must be considered a temporary measure only. Adapters *for syringes* add risk, especially when the adapter allows compatibility between Luer-tip syringes that should never be used for preparing or administering oral liquids or suspensions. As soon as possible, full conversion should occur to feeding tubes and administration sets that use only integrated ENFit connectors. In the meantime, all risks, even if temporary, should be fully explained and outlined to staff.

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The patient, prescriber, or a hospital-assigned individual should instead call the insurance company or pharmacy benefits manager (PBM) to inquire about coverage, submit preauthorizations, or check plan formularies available online. The *Customer Bulletin* referred to above is no longer available on the Surescripts website. Any questions about the issue should be directed to Surescripts at: http://surescripts.com/contact-us.

## Special Announcements

### ISMP webinar

Join us for our **October 5** webinar, *Medication Safety Practitioners: Leading, Innovating, and Improving Healthcare*. To register, visit: www.ismp.org/sc?id=349.

### ISMP Medication Safety Intensive

Join us on **December 1-2** in Orlando, FL, for our highly acclaimed 2-day **Medication Safety Intensive** workshop, where you will gain practice in error analysis, evaluate the root causes of errors, learn about various data collection methods to identify medication risks, and so much more! Nurses and pharmacists will also earn 12 hours of continuing education. To register, visit: www.ismp.org/sc?id=637.

### Opioid safety symposium at ASA *(Share with Anesthesiology Department)*

An ISMP symposium on opioid safety is being held at the **American Society of Anesthesiologists (ASA)** meeting on **October 22, 2017**, in **Boston**. Please encourage your anesthesiology department to attend, as anesthesia providers are in a key position to support improved understanding of the risks associated with opioids. Discussions will center around the potential leadership role for anesthesiologists in error prevention. To register, visit: http://surveys.ismp.org/s3/freseniuskabi-ANES17.

If you would like to subscribe to this newsletter, visit: www.ismp.org/sc?id=382

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**Editors:** Judy Smetzer, BSN, RN, FISMP; Michael Cohen, RPh, MS, ScD (hon), DPS (hon); Ann Shastay, MSN, RN, AOCN; Russell Jenkins, MD; Ronald S. Litman, DO. ISMP, 200 Lakeside Drive, Suite 200, Horsham, PA 19044. Email: ismpinfo@ismp.org; Tel: 215-947-7797; Fax: 215-914-1492.