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ISMP

Nurse AdviseERR®

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. ISMP is excited to announce the launch of 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*** (see **Table 1** on page 2). 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.

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.

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

continued on page 2—Self assessment >

SAFETY wires

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.

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

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.

Some of the auxiliary labels that automatically print 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

continued on page 2—SAFETY wires >

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> Self assessment—continued from page 1

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.

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
- USP

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 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 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

continued on page 3—Self assessment >

> SAFETY wires continued from page 1

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 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. In hospitals, nurses need to be 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.

Don't abbreviate drug names. A patient was being treated in a trauma bay after being seriously injured in a motor vehicle accident. The patient had initially been paralyzed with vecuronium for rapid sequence intubation. Several minutes later, a trauma surgeon verbally ordered more vecuronium, saying she needed "10 of vec" (10 mg of vecuronium). But this was misheard as **TENIVAC** (diphtheria and tetanus toxoids), a vaccine commonly given to trauma patients. Read back or repeat back of the verbal order either did not occur or was accomplished using the same abbreviated name and dose that the prescriber voiced, "10 of vec."

Although Tenivac was administered (and would have been ordered anyway), staff quickly recognized that vecuronium was needed for continued paralysis while the trauma team performed an emergency procedure. Lessons learned: don't abbreviate drug names—not even when communicating drug names verbally—and repeat back (or read back, if the receiving practitioner is physically able to transcribe the order immediately) all verbal orders, saying the full drug name, dose, and dosing units.

Unsafe procainamide packaging. Procainamide hydrochloride injection 1,000 mg/10 mL prefilled syringes should only be used to prepare IV infusions, but the label

continued on page 3—SAFETY wires >

> **Self assessment**—continued from page 2

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 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 other 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.

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:

continued on page 4—**Self assessment** >

> **SAFETY** wires continued from page 2

statement, "FOR THE PREPARATION OF I.V. INFUSIONS ONLY," may be missed (**Figure 1**). The risk of accidental bolus injection is high given that the prefilled syringe has a Luer connector. If stored in emergency supplies, this product might be selected instead of a vial of procainamide and used for preparing bolus loading doses. An accidental 1 g bolus dose of procainamide could lead to toxicity (the drug has known proarrhythmic properties). During the 1980s and 1990s, lidocaine 1 g and 2 g syringes, also meant for preparing infusions, were accidentally used for bolus dosing of lidocaine, resulting in more than 50 deaths before the syringes were taken off the market. A draft guidance from the US Food and Drug Administration (FDA), *Safety*

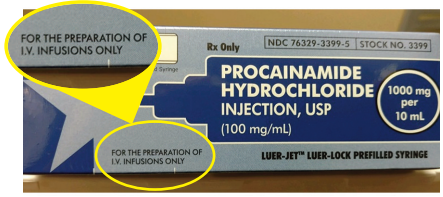

Figure 1. Label statement to use for the preparation of IV infusions is easy to miss.

Considerations for Product Design to Minimize Medication Errors (www.ismp.org/sc?id=2975), notes that products that require further dilution prior to administration should not be packaged in containers that could allow direct administration (e.g., a syringe is typically used for direct administration). ISMP recommends using 1 g vials for preparing procainamide bolus doses as well as infusions. We have notified FDA and the manufacturer, Amphastar, of our concerns.

what's in a Name?

The "-ciclovir" drug name stem

Medications that have the suffix "-ciclovir" are considered antiviral agents.[1] All antiviral agents have the stem "vir" in their drug names. Those with the suffix "-ciclovir" stop viral DNA synthesis by inhibiting DNA polymerases, a different mechanism from other antiviral agents. There are six "-ciclovir" antiviral agents available in the US (**Table 1**, page 4): aciclovir (International Nonproprietary Name [INN]) or acyclovir (United States Adopted Name [USAN]); valaciclovir (INN) or val**ACY**clovir (USAN); ganciclovir; val**GAN**ciclovir; penciclovir; and famciclovir. They

continued on page 4—*Name* >

Newsletter also partially supported by an educational grant from NEOMED®

> **Self assessment**—continued from page 3

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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what's in a Name? continued from page 3

are used to treat or prevent viral infections caused by herpes simplex virus, varicella zoster virus, and cytomegalovirus (CMV), such as cold sores, genital herpes, shingles, and CMV disease. They are **NOT** active against other viruses such as human immunodeficiency virus, influenza, and hepatitis.[2]

Table 1. Examples of US "-ciclovir" antivirals

Generic Name(s)	Common Brand Name(s)	Formulations
acyclovir	**ZOVIRAX**	Oral, Injectable, Topical
val**ACY**clovir	**VALTREX**	Oral
ganciclovir	**CYTOVENE, ZIRGAN**	Injectable, Ophthalmic
val**GAN**ciclovir	**VALCYTE**	Oral
penciclovir	**DENAVIR**	Topical
famciclovir	**FAMVIR**	Oral

Acyclovir, val**ACY**clovir, and famciclovir are generally well-tolerated with occasional headache and nausea.[2] Ganciclovir and val**GAN**ciclovir both can cause bone marrow suppression and are on the National Institute for Occupational Safety and Health (NIOSH) *List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings*.[3] Please check your organization's hazardous drug policy when handling these two medications. All "-ciclovir" antiviral agents are excreted renally, and their dosages should be adjusted in patients with impaired renal function (except for topical penciclovir).[2]

References

1) World Health Organization. The use of stems in the selection of International Nonproprietary Names (INN) for pharmaceutical substances. 2013. www.ismp.org/sc?id=3023
2) Razonable RR. Antiviral drugs for viruses other than human immunodeficiency virus. *Mayo Clin Proc*. 2011;86(10):1009-26.
3) NIOSH [2016]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O' Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016-161 (Supersedes 2014-138).