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ISMP An ECRI Affiliate

Acute Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

PATH to NEW BEGINNINGS

ISMP 24TH ANNUAL CHEERS AWARDS

This month, ISMP celebrated its 24th Annual **Cheers Awards**, which recognize individuals, organizations, and groups that have demonstrated extraordinary commitment to advancing the science and practice of patient safety. This year's winners were honored at a virtual awards ceremony on **December 7, 2021**. Please join us in congratulating this year's **Cheers Awards** winners, an impressive group of leaders and organizations that have left their footprints on the **Path to New Beginnings** by developing innovative best practices and programs that prevent medication errors and protect patients.

Cheers Awards Winners

City of Hope Cancer Center's Protocol Content Administrators Team has promoted patient safety and research integrity by ensuring the accuracy of all elements of investigational treatment plans. The City of Hope Cancer Center, located in Duarte, California, typically has more than 700 clinical trials open at a time. The team conducts a comprehensive review of every clinical trial protocol, lab manual, and pharmacy manual, looking for discrepancies and vulnerabilities that could lead to medication errors. They also review and customize each patient's treatment plan in the electronic medical record to help prevent errors and increase transparency, efficiency, and continuity of care. As of July 2021, the protocol content administrators team has made 493 clarifications, mostly in protocols. More than 20% of those clarifications have had a positive impact on patient safety. Additionally, the team collaborates with internal and external investigators and research personnel and has created standardized and safe protocol templates for investigator-initiated trials.

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Perioperative assessment: Final extension is February 11, 2022!

Because of the ongoing resurgence of the coronavirus disease 2019 (COVID-19) pandemic, we understand that healthcare providers are extremely busy. Thus, we have again extended the deadline for submitting your findings from the ***ISMP Medication Safety Self Assessment® for Perioperative Settings*** to **February 11, 2022**. This is the last data submission extension that we will be able to provide, given the overall timeline for completing the self assessment project before June 2022. However, we want to give facilities more time to participate in the assessment, particularly since more than 1,000 sites have expressed an interest in participation and have created accounts in the online format. We also have nearly 500 facilities that have already submitted their demographic data, but more than half of these facilities still need to submit their full assessment findings. If you are a US hospital that offers peri-operative services, a free-standing ambulatory surgery center (ASC), or another facility that performs medical and/or surgical procedures under sedation, please take advantage of this opportunity to evaluate your systems, identify challenges, and document regulatory compliance by visiting: www.ismp.org/node/18027. See **page 6** for details.

NANALERT

Age-related COVID-19 vaccine mix-ups

On December 6, a ***National Alert Network*** (NAN) alert was issued (www.ismp.org/node/28619) about the ongoing mix-ups between the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine for children ages 5 through 11 years and the vaccine formulation for individuals 12 years and older. ISMP has been receiving a steady stream of reported age-related COVID-19 vaccine mix-ups, which have likely impacted thousands of people. Even though these errors are not expected to cause serious adverse events, and children and adults receiving underdoses can be revaccinated, we do not want mix-ups to raise more concerns about vaccine hesitancy (www.ismp.org/ext/804) and further undermine the efforts to vaccinate as many children as possible. We have previously published information about these age-related COVID-19 vaccine mix-ups in this newsletter on November 4, 2021 (www.ismp.org/node/28303) and November 18, 2021 (www.ismp.org/node/28633). Some errors are happening due to vial or syringe mix-ups. In other errors, healthcare providers incorrectly thought it was acceptable to give a smaller or diluted dose of the formulation intended for individuals 12 or older to children ages 5 through 11. Vaccine vials for individuals 12 and up (purple cap) should never be used to prepare doses for younger children.

SAFETY briefs

Onpattro requires a 0.45 micron filter for preparation. **ONPATTRO** (patisiran lipid complex injection) is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. A hospital recently reported two sterile compounding errors involving the lack of using an appropriate filter during preparation.

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Provided to members courtesy of vizient

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Inova Health System's Intravenous Insulin Team has shown extraordinary persistence in improving the safety of intravenous (IV) regular insulin administration. Inova is a nonprofit healthcare provider in northern Virginia. The system's pharmacy medication safety team has collaborated with other disciplines to implement error-reduction strategies, including requiring IV push regular insulin prescribing via order sets with dosing limits and linking the orders to ensure the dispensing of an appropriate needleless, Luer lock insulin syringe for proper measurement and administration. The team also ensured that orders for IV push regular insulin include an image of the appropriate syringe to be used in the medication administration record. Many ISMP tools and guidelines were utilized during the process, and a significant reduction in severe hypoglycemic events has resulted over the last year.

The **KIDs List Collaborators** developed the first available list of drugs that should be avoided or used with caution in pediatric patients. In 2017, the Pediatric Pharmacy Association (PPA) commissioned seven pediatric pharmacists to compile a list of drugs potentially inappropriate for use in pediatric patients. Those pharmacists were **Rachel S. Meyers**, PharmD; **JenniferThackray**, PharmD; **Kelly L. Matson**, PharmD; **Christopher McPherson**, PharmD; **Lisa Lubsch**, PharmD; **Robert C. Hellinga**, PharmD; and **David S. Hoff**, PharmD. The goal was to improve the safe use of medications in pediatric patients and to inspire future medication safety research in children. After 3 years of literature reviews and gathering expert opinions, the KIDs List was published in the April 2020 issue of the *Journal of Pediatric Pharmacology and Therapeutics* (www.ismp.org/ext/459). The KIDs List will be updated at least every 5 years, and the team intends to include other healthcare disciplines in the development of future versions.

The St. James's Hospital **Medication Safety Minute** team, based in Dublin, Ireland, created an innovative system of delivering weekly micro-learning sessions related to safe medication prescribing. The team developed a two-slide presentation for each bite-size "safety minute" that physicians can access at their convenience. Initially, the goal was to provide medication safety education in 60 seconds or less for physicians, who have limited time due to multiple competing priorities. Considerable evidence exists that key information provided in short, easily digestible units of learning increases the reader's recollection and receptiveness to changing behaviors. From the start, the safety minutes have been made available to a wider audience. They are used by 24 additional hospitals in Ireland, shared with undergraduate and postgraduate students at local colleges, and shared on social media with a dedicated Twitter handle. Over the last 4 years, the team has created and distributed 126 weekly Medication Safety Minutes, most of which are available in a free online resource as a digital flipbook (www.ismp.org/ext/820).

Raymond J. Muller, RPh, MS, FASHP received a Volunteer Award for decades of altruistic service to ISMP as a clinical advisor on oncology-related medication errors. He has helped address dozens of potentially harmful issues, particularly with medication packaging and labeling and look-alike drug names. Ray was instrumental in helping ISMP to publish a series of newsletter articles on significant product-related issues with investigational drugs and to develop practical recommendations and solutions for the US Food and Drug Administration (FDA), clinical trial sponsors, and clinical trial practice sites. In addition, he joined ISMP in influencing FDA to recommend minibag administration of vin**CRIS**tine and to remove syringe administration as an option from the prescribing information to prevent inadvertent and deadly intrathecal administration. He has been a steadfast advocate of this safe practice and will never give up until accidental intrathecal administration of vin**CRIS**tine no longer occurs.

Tabba Heart Institute in Karachi, Pakistan, was honored for launching a proactive international initiative in a low- to middle-income country to eliminate concentrated electrolytes from floor stock and patient care units. The pharmacy department embarked on the project after another hospital in Pakistan experienced an event in which a

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According to the package insert, the product requires a 0.45 micron filter to be used during compounding, although one is not supplied. Hospitals may not routinely stock the 0.45 micron filter and may need to special order this item, as was the case at the reporting institution.

On two occasions, the need to use a 0.45 micron filter for preparation was missed. On the first occasion, the pharmacist misread the instructions and gave a 5 micron filter to the compounding technician to prepare the product. On the second occasion, no filter was used during compounding. The technician misunderstood the directions and assumed the 0.45 micron filter was required during drug administration since that size filter was not commonly used during compounding. The hospital contacted the company to determine if it was possible to filter the medication after it was diluted in 0.9% sodium chloride, and the company said that the lipid complex would be altered if filtered after further dilution. This resulted in wasting the drug.

As mentioned above, the required filter for compounding the product is not included in the packaging. For other medications that require a specific filter, such as **AMBISOME** (amphotericin B liposome for injection), the manufacturer (Astellas Pharma) provides the filter with the medication. Additional factors that contributed to not filtering the medication included high workload volumes and unfamiliarity with the product, as it was not commonly used. Also, the technicians involved in both cases did not routinely compound sterile products, but were assisting due to the increase in workload.

Pharmacy staff are working to update the compounding instructions to clarify that filtration with a 0.45 micron filter is necessary for Onpattro. They are also putting the filter together with the drug in a kit for use when needed. ISMP has also asked the manufacturer, Alnylam Pharmaceuticals, to consider including a 0.45 micron filter with the product, as this is a specialty item that is generally not used for other medications.

Prasugrel unavailable in unit dose packaging. Last year, Eli Lilly discontinued production of unit dose packaging for the

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9-month-old baby girl died after receiving the wrong drug, potassium chloride for injection concentrate, which was available in vials on the patient care unit. Hospital leadership fully supported and funded the initiative despite significant challenges, including the fact that commercially available premixed IV fluids containing potassium chloride are not available in Pakistan. Instead, costly pharmacy revisions were necessary for pharmacists to prepare and dispense potassium-containing solutions. The initiative's success helps increase awareness of the need for similar efforts among international healthcare providers and for increased availability of affordable premixed solutions around the globe.

LIFETIME ACHIEVEMENT AWARD Winner

One of the highlights of the evening was the presentation of the 2021 ISMP LIFETIME ACHIEVEMENT AWARD, which is given in memory of ISMP's late Trustee, David Vogel, PharmD. The award honors individuals who have made ongoing contributions to patient safety throughout their career. This year's honoree, **Patricia (Patti) Kienle, RPh, MPA, BCSCP, FASHP**, has served as an outstanding leader and role model throughout her longstanding commitment to medication safety.

Patti Kienle is one of the nation's foremost experts on medication management as well as accreditation and regulatory issues, especially in the areas of sterile compounding, hazardous drugs, and radiopharmaceuticals. She has almost a half century of experience helping healthcare administrators develop and execute comprehensive medication management programs in acute and non-acute care environments, and currently is the Director of Accreditation and Medication Safety for Cardinal Health.

Kienle is a former board member of ISMP and the American Society of Health-System Pharmacists (ASHP) and has served as president of the Pennsylvania Society of Hospital Pharmacists. She is a current member and past vice-chair of USP's Compounding Expert Committee and has served on The Joint Commission's Medication Compounding Technical Advisory Panel. She has earned numerous state and national awards, including the ASHP Award for Distinguished Pharmacy Leadership, the ASHP John W. Webb Lecture Award, and the USP Award for Outstanding Contributions to the Standards.

In her acceptance remarks, Kienle stressed that medication safety is a "team sport" that involves almost all healthcare disciplines. She encouraged everyone in the healthcare community to consider what they can do as individuals, within their organizations and in the broader world of health policy, to advance safe medication use. She highlighted that practitioners and healthcare systems can do more to advance patient safety. Pharmacists and nurses can do more to provide each other with valuable insight into how medication errors occur. Healthcare systems can do more to share best practices and involve practitioners with a fresh set of eyes to identify possible risks. She emphasized that we each should have a singular focus to share our knowledge of processes with our colleagues and to learn from each other. And finally, she urged everyone to commit to promoting efforts to keep patients safe in our home states, provinces, and countries.

THANKS AND LOOKING FORWARD

We would like to express our sincere gratitude to all of the organizations and individuals who attended and/or supported this year's CHEERS AWARDS. For a list of contributors and winners, please visit: www.ismp.org/node/25784, and for ways you can join us on the path to a brighter future for medication safety, please visit: www.ismp.org/support. If you were not able to attend the virtual CHEERS AWARDS this year, you can view a recording of the event posted on the ISMP website at: www.ismp.org/node/25784.

ISMP wishes you a happy, safe, and peaceful holiday, and we look forward to continuing to work together on preventing errors and keeping practitioners and patients safe in 2022.

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antiplatelet drug, prasugrel (**EFFIENT**), leaving only 30-count bulk bottles of 5 mg or 10 mg tablets of the branded product for purchase. For safety reasons, this is discouraging for hospitals since almost all drugs are dispensed in unit dose packaging with a barcode on the label. Unit dose packaging also allows for the medication to be safely loaded in an automated dispensing cabinet (ADC); for example, cardiac catheterization labs often need a 60 mg loading dose (6 x 10 mg tablets) emergently for patients with acute coronary syndrome.

Because prasugrel is prone to oxidative and moisture-based degradation, the medication must be kept in its original container, which has a desiccant. The drug could be dispensed from the pharmacy when needed urgently, such as to cardiac catheterization labs, but this may lead to delays in care when emergent treatment is necessary. The cardiac team would have to contact the pharmacy and wait for the medication to be delivered. Another option would be to load an entire 30-count bottle in an ADC, but this could increase the potential for dosing errors if someone accidentally gives more or less than the recommended dose.

One hospital developed a workaround process they wanted to share in order to help other hospitals that may only receive 30-count bottles. This hospital decided that the safest action might be to dispense the bottle and desiccant after first removing 24 tablets (and disposing them since they cannot be repackaged) and leaving 6 x 10 mg (60 mg) in the bottle for the loading dose. The bottle is then labeled with a barcode repackaging label, covering the manufacturer's barcode. Since the drug is available from several companies, contracted pricing may make this a cost-effective option.

The brand, Effient, is now marketed in the US by Daiichi Sankyo, having been acquired from Lilly earlier this year. However, unit dose packaging remains unavailable. Several generic manufacturers also provide prasugrel, but again, most do not provide the drug in unit dose packaging. We confirmed with one company, Aurobindo, that they have unit dose packages of prasugrel, and we recommend purchasing this product. ISMP has asked Daiichi Sankyo to consider re-introducing unit dose packaged tablets.

ECRI Institute for Safe Medication Practices PSO
Learn how ECRI and the ISMP Patient Safety Organization can assist with your patient safety efforts at: www.ecri.org/pso.

Potential problem opening imported Hexatrione ampules

Due to the discontinuation and resulting shortage of **ARISTOSPAN** (triamcinolone hexacetonide) by Sandoz, the US Food and Drug Administration (FDA) has authorized Medexus Pharma to temporarily import **HEXATRIONE** (triamcinolone hexacetonide), which is manufactured and marketed in France by Ethypharm Laboratories. Aristospan was approved for the short-term treatment of acute gouty arthritis, acute and subacute bursitis, acute nonspecific tenosynovitis, epicondylitis, rheumatoid arthritis, and synovitis of osteoarthritis. While FDA has authorized the importation of Hexatrione, it is important to know that it is not an FDA-approved product, and as with other imported products, it has unique packaging and labeling characteristics that may contribute to confusion and errors.

While Hexatrione is available as a 20 mg/mL (2%) injectable suspension, just as Aristospan was, it is packaged in a glass, prescored, "free-breaking" One Point Cut (OPC) ampule, with a faint white dot printed on the bulbous part of the ampule to indicate the position of the score and to help practitioners identify the correct breaking point (**Figure 1**). Similar to other ampules, there is a risk for pieces of glass to enter the suspension if the glass shatters or splinters, especially when the proper breaking technique is not employed. ISMP has received two specific inquiries as well as reports of the risk of glass fragments in the medication after opening ampules of Hexatrione.

Commonly, a filter needle is used to withdraw medication from opened ampules to reduce the risk of drawing up glass shards and injecting them into a patient. However, Hexatrione is a milky white suspension, and due to its formulation properties, a filter needle is not recommended. When filter needles are used with certain medications, such as suspensions and liposomal formulations, they can remove important active ingredients that are suspended in the vehicle.

FDA released a Dear Health Care Provider (DHCP) letter from Medexus dated March 25, 2021, to accompany a translated package insert for US healthcare providers to reference. Absent from the DHCP letter dated March 25, 2021, are detailed instructions for the proper technique of opening an OPC ampule. ISMP contacted FDA and Medexus to inquire about the availability of instructions for opening the ampule to help practitioners minimize the risk of the glass splintering. The company provided the instructions for use, which can be found here: www.ismp.org/ext/822. When preparing to open the ampule, make sure that no medication is in the neck of the ampule. This will help you visualize the faint white dot. If the ampule shatters or splinters, the medication should be discarded, and a new ampule should be accessed.

Figure 1. Hexatrione 2% carton and One Point Cut (OPC) ampule. Note the white dot (red arrow) indicating where the person's thumb should be placed to open the ampule.

During our discussions with FDA about this concern, we advocated for the inclusion of the ampule opening instructions within the product packaging and the DHCP. On December 9, 2021, following discussion with ISMP, FDA updated the DHCP letter (www.ismp.org/ext/824) with the instructions for opening the Hexatrione ampules, a statement about not recommending use of a filter needle, and instructions to not use the medication if glass particulates are observed. FDA also posted the updated DHCP letter on its drug shortages webpage. Please be sure healthcare providers in your facility receive and read the updated DHCP letter from December 9, 2021. If healthcare practitioners have any additional questions regarding the technique for opening this ampule, they should contact Medexus per the DHCP letter.

Special Announcements

Become an ISMP fellow

ISMP will soon be accepting applications for three unique Fellowship programs that will begin in the summer of 2022. For brief descriptions of the Fellowships, candidate qualifications, brochures, and program outlines, visit: www.ismp.org/node/871. More information will be provided early in 2022!

FREE ISMP webinar

On **January 25, 2022**, ISMP is presenting a **FREE** webinar on the high-alert medications, **heparin**, **concentrated electrolytes**, and **magnesium**. Faculty will review the safety characteristics of these high-alert medications and identify opportunities for improvement and effective risk-reduction strategies. Continuing education (CE) credit will be provided. For details, visit: www.ismp.org/node/28440.

Virtual MSI workshops

Don't miss the opportunity to register for one of our unique 2-day, virtual ***ISMP Medication Safety Intensive (MSI)*** workshops being offered in 2022. Our first workshop is scheduled for **January 27-28, 2022**. For details and more dates in 2022, visit: www.ismp.org/node/127.

Virtual ISMP mentorship

Take advantage of ISMP's ***Practitioner in Residence (PIR)*** mentorship program during the online session to be held early in 2022. The program will consist of five sessions held weekly on Tuesdays, from **February 1** through **March 8, 2022** (no session February 22, 2022). For details, visit: www.ismp.org/node/28657.

To subscribe: www.ismp.org/node/10

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Production of this peer-reviewed newsletter would not be possible without the assistance of a reliable and talented **Clinical Advisory Board**. As 2021 nears an end, we want to thank each of the following members of the **Clinical Advisory Board** for their dedication to making this newsletter a valuable medication safety resource for clinicians.

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Surgery sites have more time to participate!
Final deadline extension: February 11, 2022

ISMP Medication Safety Self Assessment®

for Perioperative Settings

Due to the ongoing resurgence of the coronavirus disease 2019 (COVID-19) pandemic, we have **extended the deadline** to submit your assessment findings to ISMP until **February 11, 2022**!

If you have any questions while conducting the assessment, refer to the **Frequently Asked Questions** (www.ismp.org/node/18027) or **contact ISMP** at: selfassess@ismp.org.

Take part in the ***ISMP Medication Safety Self Assessment® for Perioperative Settings***

- ✓ Download the assessment workbook and/or the Excel file
- ✓ Follow the instructions for completing the assessment
- ✓ Access the online assessment and create a login
- ✓ Submit your findings by: **February 11, 2022**
- ✓ www.ismp.org/node/18027

Participate in a **unique opportunity** for **collaborative groups** to pool members' assessment results! Collaborative codes can be added to your login account **after** submitting your findings to ISMP. For information, contact: selfassess@ismp.org.

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