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ISMP

Community/Ambulatory Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Putting Our BOOTS ON to kick off the 19th Annual ISMP CHEERS Awards

This month, ISMP rounded up an impressive group of individuals and organizations to honor with its 2016 **Cheers** Awards, which were presented at a gala dinner held on **December 6** at **Stoney's Rockin' Country** in Las Vegas. Please join us in congratulating the following medication safety trailblazers who have created best practices, programs, and resources that are helping to prevent medication errors and improve the quality of patient care.

One individual with significant career-long contributions to patient safety was honored with a special **Cheers**—the **2016 ISMP Lifetime Achievement Award**. **David Marx, JD**, is a true pioneer in the safety world, from developing human factors risk modeling methods to being the father of the "Just Culture" accountability model. He has more than two decades of experience in transforming workplaces in high-risk industries to achieve highly reliable outcomes and has brought lessons learned from aviation, aerospace, and transportation into the healthcare arena. Marx, who is currently CEO of Outcome Engenuity, has authored a patient safety guide for the National Institutes of Health and advises the US Agency for Healthcare Research and Quality (AHRQ) on safety issues. He also has authored two books on workplace accountability, *Whack-a-Mole: The Price We Pay for Expecting Perfection* and *Dave's Subs: A Novel Story about Workplace Accountability*.

During his acceptance speech, Marx described the pillars that are required to support patient safety in healthcare:

Systems Engineering: The interdisciplinary science of designing and managing the complex processes, equipment, interfaces, and the environment in healthcare, in a manner that maximizes patient safety and reliability.

Root Cause Analysis (RCA) and Causal Diagramming: Identifying the root causes that led to an actual or potential adverse outcome, and then creating a visualization of the relationship between the given outcome, all the behavioral and system factors that influenced the outcome, and the causes behind each behavioral or system factor.

Human Factors and Behavioral Economics: Understanding the psychological, social, cognitive, and emotional factors that drive human behavioral choices and cause human error, and using that information in the design of systems and processes to complement human capabilities, the implementation of change strategies, and the just management of staff behavioral choices.

Just Culture and the Law: A safety-supportive model of shared accountability where healthcare institutions are accountable for the systems they design; for sup-

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SAFETY briefs

"Ellipta"–it's not a drug. A pharmacist misread a prescription for **INCRUSE ELLIPTA** (umeclidinium), which was a new prescription for a patient upon discharge from a hospital, as "Increase Ellipta." The pharmacist was only familiar with **BREO ELLIPTA** (fluticasone and vilanterol) and had never filled a prescription for Incruse Ellipta prior to this incident. Because the patient was not using an "Ellipta" inhaler previously, the pharmacist called the prescriber's office to clarify the dose of what he thought was an order for Breo Ellipta. The prescriber confirmed the dose for Breo Ellipta as 100/25 mcg per inhalation, evidently overlooking the fact that he had prescribed Incruse Ellipta for this patient. When the patient was readmitted to the hospital several weeks later for an unrelated diagnosis, a pharmacist discovered the error while collecting a medication history from the patient and investigating why he was taking both **ADVAIR** (fluticasone propionate and salmeterol) and Breo Ellipta.

Incidentally, GlaxoSmithKline has marketed several different medication inhalers for asthma or chronic obstructive pulmonary disease (COPD) using the "Ellipta" trademark to identify their common inhalation delivery device. Breo Ellipta, used for COPD and asthma, was the first of these products, becoming available in 2013. Since then, several other "Ellipta" products have been marketed. These include **ANORO Ellipta** (umeclidinium and vilanterol) and **Incruse Ellipta** (umeclidinium), both for COPD, and **ARNUITY Ellipta** (fluticasone furoate), for asthma. We have received reports about "Ellipta" contributing to confusion and errors when pa-

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Provided to members courtesy of vizient.

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porting the safe behavioral choices of patients, visitors, and staff; and for responding to staff behaviors in a fair and just manner. In turn, staff are accountable for the quality of their behavioral choices (human error is not a behavioral choice) and for reporting hazards, errors, and system vulnerabilities. Legal reform may be necessary to better support patient safety, as our current legal system often punishes human error and supports a severity bias towards the outcome.

Socio-technical Probabilistic Risk Assessment (ST-PRA) and Model-based Risk Management: Prospective vulnerability analyses that link process failures with scientifically derived estimates of process failure rates, human error rates, and behavioral norms, yielding a more accurate picture of why and how often these failures affect patient outcomes. These analyses track all possible pathways that can lead to an adverse outcome and allow all combinations of tasks, behavioral choices, and system failures to be considered in combination with one another when formulating a risk-mitigation plan.

Cheers also rang out for the following winners:

- **Ascension**, the largest nonprofit health system in the US that includes 141 hospitals, for their impressive leadership commitment to comprehensive implementation of the **2014-2015 ISMP Targeted Medication Safety Best Practices for Hospitals**.
- The **American Society for Parenteral and Enteral Nutrition's (ASPEN) Parenteral Nutrition Safety Committee** for its cumulative and interdisciplinary efforts to advance safety in every facet of parenteral nutrition support.
- The **HCA Clinical Services Group** for its work to transform a pharmacy intervention program to ensure real-time clinical alerts and timely adjustments in patient care.
- The **Immunization Action Coalition (IAC)** for its vital role in immunization education and advocacy aimed at both healthcare professionals (www.immunize.org) and consumers (www.vaccineinformation.org).
- **Dr. Robert Stoelting**, President of the Anesthesia Patient Safety Foundation for nearly 20 years, for his tireless work to improve medication safety in the operating room and during the delivery of anesthesia.

One of the highlights of the evening was a presentation from the **Cheers Keynote Speaker**, **Daniel Budnitz, MD, MPH, Capt., USPHS,** about protecting young children from accidental overdoses. Dr. Budnitz directs the Medication Safety Program at the Centers for Disease Control and Prevention (CDC) and has authored more than 50 publications on medication safety, public health surveillance, and injury prevention. He presented a public health approach to reduce medication overdoses in children less than 5 years old, touching upon real-world successes such as the PROTECT Initiative, an innovative collaboration bringing together public health agencies, private sector companies, professional organizations, consumer advocates, and academic experts to develop strategies to keep children safe from unintentional overdoses.

Since the 1970s Poison Prevention Packaging Act, which required child-resistant caps for most medications, mortality from overdoses has declined dramatically in children less than 5 years of age. However, emergency department (ED) visits and hospitalizations due to overdoses in this age group increased between 2000-2011. To help address this, the industry has begun packaging some medications in unit doses, with each

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tients or health professionals refer to these products only by that name and not the drug brand name. It seems like the easiest and potentially most effective way to reduce confusion would be to remove the Ellipta modifier, in favor of using only the brand name. However, there is a potential risk of using only the drug brand name if the manufacturer decides to use the same name (or drug) in conjunction with a different delivery device. We have communicated our thoughts and concerns to the US Food and Drug Administration (FDA) for their consideration.

MTX topical pain patch. There's a new lidocaine/menthol over-the-counter (OTC) topical analgesic/antipruritic patch called **MTX PATCH (Figure 1)**. It's been marketed by Unik Pharmaceuticals, starting September 2016. The patch contains lidocaine 4% and menthol 1%. Given that MTX is sometimes used unsafely as an abbreviation for one of several cancer drugs, we think

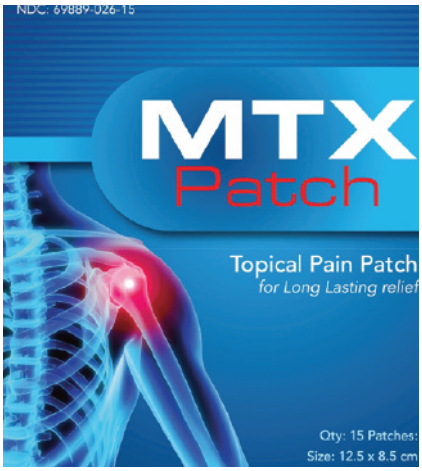

Figure 1. The MTX Patch (lidocaine 4%, menthol 1%) uses an unsafe abbreviation, MTX, which has caused confusion between several oncology drugs.

there's a potential safety concern due to the risk for confusion. The abbreviation MTX has been on our list of error-prone abbreviations for many years because it has led to dangerous mix-ups between methotrexate and mitoXANTRONE.

Both lidocaine and menthol are designated OTC drugs that have not been ap-

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oral solid dose in individual child-resistant packaging to prevent access to large quantities of unauthorized medications if the packaging is breached. The use of flow restrictors in bottles of oral liquid medications was also instrumental in reducing morbidity and mortality from unauthorized access to medications. Due to these packaging advances, along with metric-only dosing and dosing devices, and parent education about safe drug storage, ED visits due to unauthorized access to medications in children less than 5 years have decreased since 2011.

We would like to thank the organizations and individuals who attended and/or supported this year's **Cheers** Awards and helped us celebrate these extraordinary leaders. Visit www.ismp.org/Cheers for a list of contributors and winners, and visit www.ismp.org/support for ways you can help ISMP continue to fight against preventable medication errors. We look forward to another great year of working together to improve medication safety in 2017!

Potential issues with new basal insulin/GLP-1 fixed combinations

New safety challenges?

Two new fixed-ratio combination insulin/glucagon-like peptide-1 (GLP-1) receptor agonists were approved last month by the US Food and Drug Administration (FDA). They each combine a basal insulin with a GLP-1 agonist and are administered once daily. **SOLIQUA 100/33**, a Sanofi product (www.ismp.org/sc?id=2842), provides 100 units of insulin glargine per mL and 33 mcg of lixisenatide per mL in a 3 mL single-patient-use pen. Novo Nordisk's **XULTOPHY 100/3.6** (www.ismp.org/sc?id=2841) provides 100 units of insulin degludec per mL and 3.6 mg of liraglutide per mL, also in a 3 mL single-patient-use pen. Soliqua 100/33 and Xultophy 100/3.6 differ from other insulin-containing products and present new potential safety issues.

Mistaking the products as containing only insulin

One potential safety issue is that practitioners may mistakenly think that these products contain only insulin. This is one reason why computer system drop-down lists and pharmacy communications about these products should use the ratio expressions (i.e., Xultophy 100/3.6 and Soliqua 100/33), which hopefully will help to indicate to users that the products contain two different ingredients. The ratio expression is designed to express the ratio of insulin to GLP-1 agonist per mL (e.g., Soliqua 100/33 contains 100 units of insulin glargine and 33 mcg of lixisenatide per mL). In contrast to the ratios used for insulin-insulin combination products such as **NOVOLOG MIX 70/30** (insulin aspart protamine, insulin aspart) or **HUMALOG MIX 50/50** (insulin lispro protamine, insulin lispro), the ratio expressions for Soliqua 100/33 and Xultophy 100/3.6 do not sum up to 100%, which should also help practitioners differentiate them from insulin-only products.

If your system uses generic names, make sure both ingredients are displayed and not truncated. However, keep in mind, the first name practitioners will see is "insulin." This may contribute to practitioners mistaking these as insulin-only products. Using the brand names, ideally with a hover over presentation of the complete generic names, could reduce the risk of an error. Also, counsel patients when initiating Soliqua 100/33 and Xultophy 100/3.6 so they understand the products contain both insulin and a GLP-1 agonist.

Dosing is based on insulin units, not the GLP-1 agonist component

Dosing of these products is expressed based on the number of insulin units (the pen dials the dose in insulin units only). The package insert for each product has a table

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proved by the US Food and Drug Administration (FDA) by direct application but are legally marketed under regulations referred to as "OTC monographs" established through the FDA's OTC Drug Review. Monograph drugs are "generally recognized as safe and effective" for their intended uses. Thus, if they meet specifications in the monograph, companies can market certain OTC products like these without specific FDA approval of the product names. Still, due to the potential for confusion, we've asked FDA to look into this situation.

Beware of drug names that end in the letter "L." Potentially serious medication errors may occur when a lower case "L" at the end of a drug name is misread as the numeral "1." This happened in a case we reported in our January 2003 issue. An order for 300 mg of **TEGRETOL** (car**BAM**azepine) BID was misinterpreted as 1,300 mg BID. The letter "L" at the end of Tegretol had been written very close to the numerical dose of 300 mg on a prescription for the patient (Tegretol300 mg). The pharmacist was unfamiliar with the medication and the pharmacy computer did not alert him that the dose exceeded safe limits. The patient received only one dose in error before another pharmacist caught the mistake and the patient was informed. The single dose made the patient lethargic, but not seriously toxic.

Recently, we were reminded of this risk when we received a report involving a compounded topical cream that included menthol. The manner in which the prescription was written in the report placed the amount of menthol directly following the drug name (menthol5%). This could easily be misinterpreted as menthol 15% rather than the intended menthol 5%. Adequate spacing between the drug name and the dose also is crucial on electronic prescriptions and other electronic formats such as pharmacy computer selection screens, computer-generated medication labels and records, printed forms and communications, shelf labels, etc.

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that indicates the amount of GLP-1 agonist per insulin unit, but including the GLP-1 agonist dose is not recommended when prescribing these products. If an order is communicated without the ratio expression ("Soliqua 40 units" or "Xultophy 35 units"), practitioners could think it's a new insulin product and not recognize there is a GLP-1 agonist contained within. This could lead someone to prescribe a separate GLP-1 agonist to go along with what is thought to be the patient's insulin dose.

Not recommended for concurrent use with other products containing GLP-1 agonists

These products are not recommended for use in combination with any other product containing a GLP-1 agonist (**Table 1**) because of the risk of overdose. To help avoid this, consider testing your computer systems to see if a duplicate therapy alert is generated if one of the new combination products is entered along with another GLP-1 agonist containing product. Also, the package insert recommends using alternative antidiabetic products if patients require a Soliqua 100/33 daily dosage below 15 units or over 60 units. For Xultophy 100/3.6, use alternative antidiabetic products if patients persistently require less than 16 units or more than 50 units.

Table 1. Approved GLP-1 agonist containing products for type 2 diabetes mellitus.

Generic name	Brand name	Dosage form
insulin degludec and liraglutide	Xultophy 100/3.6	Pen
insulin glargine and lixisenatide	Soliqua 100/33	Pen
albiglutide	Tanzeum	Single-dose pen
dulaglutide	Trulicity	Single-dose pen or pre-filled syringe
exenatide	Bydureon	Single-dose pen or vial
	Byetta	Pen
liraglutide	Victoza	Pen
lixisenatide	Adlyxin	Pen
	Adlyxin Starter Pack	Pen

These errors that could occur when prescribing, dispensing, and administering these new products emphasize the importance for prescribers, diabetes educators, and pharmacists to provide patient education. All patients taking these products should be counseled before they are dispensed the product.

2016-2017 ISMP Fellows

ISMP welcomes **Staley Lawes, PharmD, BCPS**, the **2016-2017 ISMP Safe Medication Management Fellow**, supported in part by Baxter, Novartis Pharmaceuticals, and Fresenius Kabi; **Maximilian Straka, PharmD**, the **2016-2017 FDA/ISMP Safe Medication Management Fellow**; and **Celeste Karpow, PharmD**, also a **2016-2017 FDA/ISMP Safe Medication Management Fellow**. Staley previously worked as a clinical pharmacist at Geisinger Medical Center in Danville, PA and then CentraState Medical Center in Freehold, NJ where she designed and implemented a pharmacy position in the emergency department. She will spend an entire year at ISMP. Max and Celeste will rotate halfway through the year by spending 6 months at the US Food and Drug Administration (FDA) and 6 months at ISMP. Prior to the Fellowship, Max was a manager at Rite Aid Pharmacy for 2 years, and Celeste completed a PGY-1 residency program at Henry Ford Hospital in Detroit, MI. ISMP also welcomes **Ghadeer Banasser, PharmD, CPHQ**, our third international **ISMP Safe Medication Management Fellow**. Before joining ISMP for the year, Ghadeer worked as a Pharmacy Quality Management Specialist at King Abdulaziz Medical City-Jeddah, Saudi Arabia and served on the regional Medication Safety Program.

Special Announcements

ISMP webinar

Please join us on **January 25, 2017**, for our first webinar of the new year, ***Starting at the Top: Strategies to Enhance the Safety of Prescribing Practices***. Participants will learn about frequent harmful errors involving breakdowns in the prescribing process as reported to a state reporting program, along with first-hand observations of the organizational factors that contribute to prescribing errors and the challenges hospitals face making improvements. Our speakers will also outline key safety strategies for establishing a standardized approach for prescribing medications. For details, visit: www.ismp.org/sc?id=349.

Plan to attend a 2017 MSI workshop

If you were unable to join your colleagues at the **ISMP Medication Safety Intensive (MSI)** workshop at the December 2016 ASHP Midyear Clinical Meeting because it was sold out, sign up early for a program in 2017! Upcoming dates and locations for this unique hands-on program are: **March 23-24, 2017**, in **Austin, TX**; **September 21-22, 2017**, in **Hackensack, NJ**; and **December 1-2, 2017**, in **Orlando, FL**. For more information or to register, go to: www.ismp.org/sc?id=637.

To subscribe: www.ismp.org/sc?id=386

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Special Recognition…Our 2016 *ISMP Medication Safety Alert! Community/Ambulatory Care* Clinical Advisory Board

Production of this peer-reviewed newsletter would not be possible without the assistance of a reliable and talented clinical advisory board. As 2016 nears an end, we want to thank each of the following members of the advisory board for their dedication to making this newsletter a valuable medication safety resource for clinicians.

- **Kelly Besco, PharmD, FISMP, CPPS**, OhioHealth, Columbus, OH
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Happy Holidays…We wish you joy, health, and happiness this holiday season!

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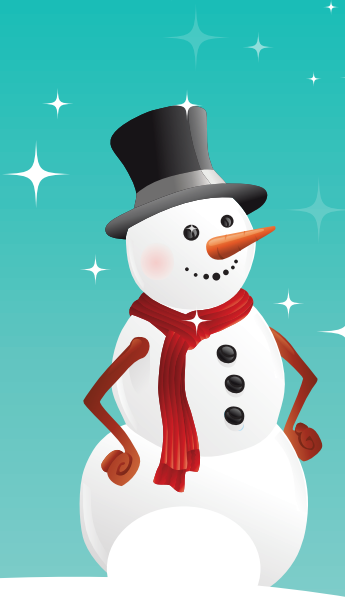

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Safe Medication Management Fellowships

ISMP is now accepting applications for two unique **2017-2018 Fellowship** programs

ISMP Safe Medication Management Fellowship

Location and Term: This 12-month Fellowship, sponsored by **Baxter International Inc.**, commences summer 2017 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 only. Now in its 25th year, the Fellowship allows the candidate to work collaboratively with practitioners in various healthcare settings to assess and develop interdisciplinary medication error-prevention strategies.

Sponsored by: Baxter

FDA/ISMP Safe Medication Management Fellowship

Location and Term: This 12-month Fellowship commences August/September 2017. 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, and 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, paid vacation, and health benefits are 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, 2017.