November 29, 2018 ■ Volume 23 Issue 24

ISMP

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

Are national efforts to reduce drug name confusion paying off?

Introduction

One in every 1,000 medication orders in a hospital, and one in every 1,000 prescriptions in a pharmacy, have been associated with selecting the wrong drug while prescribing, transcribing, dispensing, or administering medications.[1-4] Drug name similarities are a primary cause of these errors.[5] Orthographic (spelling) factors that increase visual resemblance among drug names include similarities in the length of the names and the number of groups of similar or the same characters within the names.[6] Phonological (sound) factors that increase auditory resemblance among drug names include similarities in the number of syllables, the stressed syllable, the initial or terminal syllable, and the stressed vowel.[6] Other factors that increase the risk of drug name confusion include similarities in strength, dosing, route of administration, dosage forms, indication, and other factors, such as the environment in which the drugs are used, the frequency of use, and product labeling.[7]

Sources of name confusion. Sources of drug name confusion errors include: memory, perceptual, and motor control errors.[6] Memory errors can arise when practitioners make a mistake during recall or recognition of a drug name. Perceptual errors occur when practitioners misread or mishear a drug name. Motor control errors occur upon selection of a drug. For example, this type of error occurs when an adjacent drug with a similar name is selected in error from a list, such as a drop-down set of choices on a computer screen.

Drug naming processes. Generic (nonproprietary) drug names are based upon a collection of standard stems used as prefixes, suffixes, and infixes to identify the pharmacologic property and/or chemical structure of the medication. In the US, generic names are assigned by the United States Adopted Names (USAN) Council. In the global arena, the World Health Organization (WHO) International Nonproprietary Name (INN) members work with international naming authorities like USAN to harmonize generic names between different countries. Proposed generic names are released for public review and comment. Sometimes, the drug name stems embedded in generic names contribute to mix-ups among names with the same stem. However, the stem helps position an unfamiliar drug with others in a class and provides clues as to its use and effects.

Brand (proprietary) names for drugs are selected by the manufacturer. As part of the drug product approval process, the US Food and Drug Administration (FDA) reviews the proposed brand name and determines its acceptability. Brand names are intended to be unique and memorable to identify products and distinguish one manufacturer's product from its competitors. However, brand names that look or sound alike can contribute to name confusion errors.

Name safety testing. For generic drug names, USAN Council members (one each from the American Medical Association, USP, American Pharmacists Association, FDA, and a member at large) conduct an evaluation during the naming process to reduce the risk of similarities with existing brand or generic drug names. One of the guiding principles associated with the USAN Council naming process includes criteria that the name should not conflict, mislead, or be confused with other nonproprietary or proprietary drug names.

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SAFETY briefs

HIGH-ALERT

Generic EPINEPHrine autoinjectors. **EPINEPH**rine is dosed by weight when used to treat an allergic reaction or anaphylaxis, not by whether the patient is an adult or child. Thus, generic brands of the **EPINEPH**rine autoinjector do not use the abbreviation "Jr" for the 0.15 mg dosage strength (**Figure 1**). The abbreviation "Jr" is already part of the **EPIPEN** trademark used for that strength. However, given that dosing is weight-based, please be sure staff are aware that generics will list the metric strength only, 0.3 mg or 0.15 mg. Patients 30 kg (approximately 66 pounds) or heavier should use a 0.3 mg injector. Those who

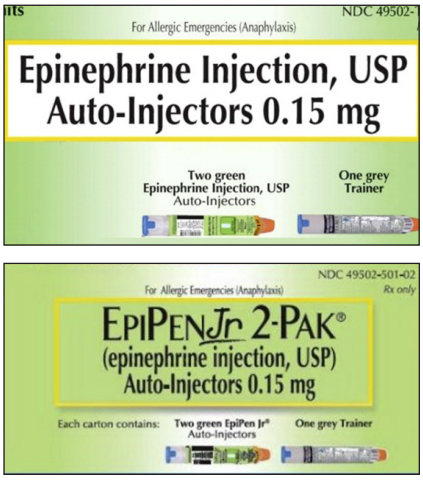

Figure 1. Generic **EPINEPH**rine autoinjectors (top) do not refer to the 0.15 mg strength as "Jr" as does the brand version, EpiPen Jr (bottom). Other generics also will not designate the 0.15 mg strength as "Jr."

weigh between 15 to 30 kg (33 pounds to 66 pounds) need to use a 0.15 mg injector. Both strengths should be available for treatment in healthcare facilities. A pharmacist expressed concern that practitioners unfamiliar with **EPINEPH**rine dosing may confuse the strengths if they are accustomed to seeing the "Jr" designation.

Simulation products look real. Medications used for educating healthcare practitioners during simulation exercises, also known as demo medications, often appear

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Over the past decade or more, the pre-market safety evaluation of proposed brand names has become more extensive and structured. FDA issued voluntary proprietary naming guidances in 2008[8] and 2014,[9] and the role of regulatory authorities in the review of brand names has increased significantly.[10] Today, before launching a new drug, many pharmaceutical companies voluntarily use external safety testing companies to evaluate potential risks associated with proposed brand names, including name similarities. MedERRS, a wholly owned subsidiary of ISMP, is one of the companies that conducts this testing. The testing, which often involves practicing healthcare practitioners who may prescribe, dispense, and/or administer the new drug, identifies similarities with existing drug or medical product names, medical terms, and abbreviations that may lead to confusion. A computer software program, POCA (phonetic and orthographic computer analysis), is also used by external safety testing companies and FDA to evaluate name similarity.

It is important to note that pharmaceutical companies are NOT required by regulation to test and evaluate their proposed brand names for potential name similarities, so many pharmaceutical and biotech companies, including generic manufacturers and distributors, have not adopted this practice. According to FDA, in 2017, only 57% of the submissions for new drug approvals were accompanied by testing and evaluation results supporting the proposed new brand name.[11] Still, the FDA Division of Medication Error Prevention and Analysis (DMEPA) evaluates ALL brand names presented with products submitted for approval using practitioner name simulation studies, POCA results, and input from the FDA review team for that product. DMEPA conducts this independent evaluation of brand name similarity, even if the company conducts its own safety evaluation of a brand name and submits the results to FDA.

Is name confusion declining? With more than 27,000 drug products currently on the US market, creating new drug names that are not similar to existing drug names is challenging.[10] But, has a decade of efforts to evaluate brand names for possible name confusion prior to launch made a difference? Have significant advances in technology, including electronic prescribing, barcoding, and other practices during this time contributed to fewer errors associated with name confusion? Because little is known about the true incidence of drug name confusion,[6] ISMP conducted a retrospective analysis of name-related medication errors voluntarily reported to ISMP to examine the percent of change in reporting over time to begin to answer these important questions.

Methods

Since 1994, ISMP has operated the voluntary, practitioner-based *ISMP National Medication Errors Reporting Program* (ISMP MERP). Today, the ISMP MERP receives more than a thousand medication-related error reports annually from physicians, pharmacists, nurses, and other healthcare practitioners who prescribe, dispense, and/or administer medications to patients in a wide variety of settings, including hospitals, long-term care facilities, infusion centers, community pharmacies, and other treatment locations.

Two chronological samples of ISMP MERP error reports (submitted between 2000 and 2004, and between 2012 and 2016) were extracted for analysis and compared to determine whether drug name confusion reports had increased or decreased between the two time periods, and whether the types of name confusion reports had changed over time. The narrative in each report was reviewed, and based on the description of the hazard or error, the reports in each data set were categorized into four groups: 1) name confusion between two proprietary drug names (brand-brand); 2) name confusion between a proprietary and nonproprietary name (brand-generic); 3) name confusion between two nonproprietary drug names (generic-generic); and 4) all other reports that were not associated with drug name confusion (other reports). Errors associated with labeling and packaging (not related to name confusion), drug name modifiers (e.g., LA, ER, XL), brand name extensions, or differences in formulations were categorized as other reports. Reports involving the same name pair were each included separately.

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very similar to the actual medication. The names on some simulation products contain the same letters as the real drug name with a few characters left out, as in the case of "AUGMENTN" (**Figure 1**), an example we recently encountered. Practitioners often look at labels and read only the first few letters before their brain decides what the label says. This is an example of confirmation bias, which leads individuals to "see" information that confirms their expectations, rather than information that contradicts their expectations. Once the first few letters in a drug name are confirmed, a practitioner may not recognize the subtle differences between the simulation and actual product, even with careful inspection.

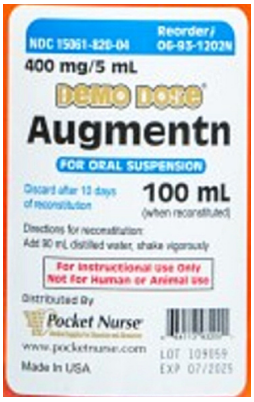

Figure 1. Simulation product from Demo Dose. Note the intentional misspelling of **AUGMENTIN** (amoxicillin/clavulanic acid), which may be overlooked.

Simulation products may also bear the actual product name. Some even contain a fluid vehicle such as 0.9% sodium chloride. However, because they are produced for training purposes only, they are nonsterile and not meant for patient use.

We first described a mix-up between an actual and a simulation product in our November 28, 2013 newsletter, where a carton of "EPINEPHRN" was placed in a crash cart instead of actual **EPINEPH**rine. In an emergency, a practitioner could have failed to notice that it was a simulation product. In 2015, we learned from the US Food and Drug Administration (FDA) that more than 40 patients were administered a simulated intravenous (IV) fluid and developed adverse reactions including fever, tremors, and chills. This led to hospitalization for some and, in one instance, death (www.ismp.org/node/552). FDA (www.ismp.org/ext/113) and the Centers for Disease Control and Prevention (CDC) (www.ismp.org/ext/114) have also warned about simulated medications.

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A Pearson's Chi-squared test of independence with Yates' continuity correction was used to test: 1) whether the frequency of name- and non-name-related error reports was different between time periods; and 2) whether the frequency of the three different types of name-related reports (brand-brand, brand-generic, and generic-generic) differed between time periods. The Pearson's Chi-squared test of independence was used to assess if observed frequencies deviated from expected, random frequencies for categorical data. The Yates' continuity correction conservatively estimates the P values in Chi-squared analyses, and is recommended when analyses have low degrees of freedom, as in this study. Pearson's residuals in post-hoc tests were also calculated to assess which of the specific associations in each Chi-squared test was statistically significant. The null hypothesis for the first test was that there was no association between name- and non-name-related error reports and the time period. The null hypothesis for the second test was that there was no association between the type of name-related error reports and the time period.

Results

A total of 4,091 reports were submitted between 2000 and 2004, of which 816 were related to drug name confusion and 3,275 were classified as other types of events (**Figure 1**). A total of 6,206 reports were submitted between 2012 and 2016, of which 603 were related to drug name confusion and 5,603 were classified as other types of events. Among the 816 reports of drug name confusion submitted between 2000 and 2004, 507 involved brand-brand name confusion, 91 involved brand-generic name confusion, and 218 involved generic-generic name confusion (**Figure 2**). Among the 603 reports of drug name confusion submitted between 2012 and 2016, 183 involved brand-brand name confusion, 51 involved brand-generic name confusion, and 369 involved generic-generic name confusion.

Figure 1. Counts of name-related confusion and all other types of events reported in 2000-2004 and 2012-2016

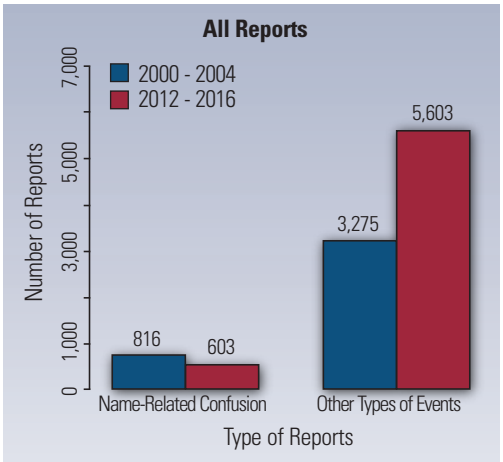
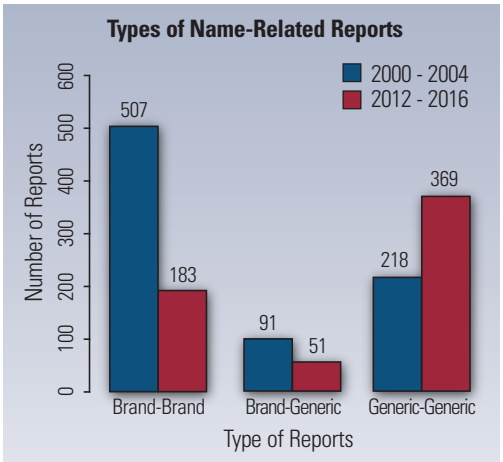


Figure 2. Counts of three different types of name-related confusion reported in 2000-2004 and 2012-2016



We found strong evidence that name-related reports were significantly less common in 2012-2016, while all other types of reports significantly increased over this time span (**Figure 1**). There were 52% more total reports in the 2012-2016 period than in the 2000-2004 period. Name-related reports declined by 26% in the years 2012-2016, but the number of non-name-related reports increased by 71%. There was a significant association between the reporting frequency of name- and non-name-related reports and the time period ($\chi^2 = 216.31$; df = 1; $P < 2.2 \times 10^{-16}$). The Pearson's residuals (**Table 1**, page 4) indicated that the reporting frequency of name-related reports was significantly lower than expected in 2012-2016 (R = -8.62), and significantly greater than expected in 2000-2004 (R = 10.62). Furthermore, there were significantly fewer non-name-related reports than expected in 2000-2004 (R = -4.24).

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As the above incidents have shown, steps must be taken to ensure that simulation products do not enter the supply chain, where they could be used in real patient care situations. Simulation products should only be stored in non-patient care areas such as classrooms and other educational simulation areas. Instructors should account for each demo product at the end of class to ensure they do not travel outside the room in someone's pocket. Alert healthcare practitioners to the nearly identical product labeling often used on these products and their proper use and storage.

Clinical practice guidelines available. Our safety partner, ECRI Institute, recently announced availability of ***The ECRI Guidelines Trust*** (www.ismp.org/ext/144), which provides open access to clinical practice guidelines. The guidelines were previously available through the National Guideline Clearinghouse (NGC) at the Agency for Healthcare Research and Quality (AHRQ), which ended in July due to funding cuts. ECRI had developed and maintained the NGC website for 20 years, vetting the guidelines for trustworthiness. An initial set of guidelines are again freely available, preventing what would have been a huge loss for the promotion of evidence-based care.

LevOCARNitine packaging leads to errors. We have received several complaints about the way levOCARNitine tablets are packaged in blisters, which we originally mentioned in our February 27, 2014 newsletter. LevOCARNitine is used to prevent and treat carnitine deficiency in patients with kidney disease who are on dialysis. In a recent event, a patient received a single dose of 3 tablets (990 mg) of levOCARNitine instead of 1 tablet (330 mg) three times daily, causing an overdose. Adverse effects with an overdose include nausea, vomiting, abdominal cramps, diarrhea, or serious adverse reactions such as seizures.

The barcodes on the levOCARNitine blister pack from the manufacturer, Hi-Tech Pharmacal, do not line up with the individual tablets, so each tablet does not have its own corresponding barcode (**Figure 1**, page 4). While the pharmacy dispensed 3 tablets that had been cut from the blister pack, each tablet had not been separated individually. Thus, the nurse administering the

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We also found strong evidence that reporting of brand-brand name-related confusion significantly *decreased* over time, while reporting of generic-generic name-related confusion significantly *increased* over time (**Figure 2**, page 3). There were 26% less name-related reports submitted in 2012-2016 than in 2000-2004, primarily due to drops in brand-brand name and brand-generic name reports, which declined by 64% and 44% respectively. In contrast, generic-generic name-related reports increased by 69%. There was a significant association between name-related reports and time period (χ^2=174.20; df = 2; $P < 2.2 \times 10^{-16}$). Specifically, there was a lower proportion of brand-brand name confusion reports than expected in 2012-2016 (R = -6.43), and a greater proportion of generic-generic name confusion reports than expected in 2012-2016 (R = 7.57). However, the proportion of brand-generic name confusion reports did not differ from expectation in 2012-2016 (**Table 2**).

Discussion

Similarity between drug names has been a frequent cause of medication errors. As expected, all types of drug name confusion—brand-brand name, brand-generic name, and generic-generic name—were reported in all the years studied. However, we observed a decrease in the reporting of all types of name confusion in 2012-2016 when compared to 2000-2004. We are unable to determine the reason for the change in reporting frequency between the two time periods. However, it is unlikely that practitioners were less motivated between 2012-2016 than between 2000-2004 to report name-related confusion and errors to ISMP. So it may be plausible that the overall reduction in the reporting of name confusion errors of all types in 2012-2016 is due to national efforts to reduce drug name-related confusion, including advances in technology such as electronic prescribing (which eliminates handwritten prescriptions that risk misinterpretation) and barcode scanning (which can help detect and correct an error due to drug container name confusion). Practice improvements such as reducing verbal orders, tagging problem name pairs in computer databases to aid clinical decision support, expanding the use of tall man letters, and including an indication on prescriptions, also may have impacted the occurrence (and subsequently the reporting) of drug name confusion.

Table 1. Pearson's residuals for analysis of name- and non-name-related reports. Pearson's residuals greater than 4 indicate a statistically significant positive association, and those less than -4 indicate a statistically significant negative association.

Time Period	Name-Related Reports	All Other Reports
2000 - 2004	**10.62**	**-4.24**
2012 - 2016	**-8.62**	3.45

Table 2. Pearson's residuals for analysis of name-related report types. Pearson's residuals greater than 4 indicate a statistically significant positive association, and those less than -4 indicate a statistically significant negative association.

Time Period	Brand-Brand	Brand-Generic	Generic-Generic
2000 - 2004	**5.53**	1.03	**-6.51**
2012 - 2016	**-6.43**	-1.20	**7.57**

We also found that name-related confusion reporting appears to have switched from predominantly brand-brand name confusion in 2000-2004, to predominantly generic-generic name confusion in 2012-2016. The change from brand-brand to generic-generic name confusion error reporting may be due to the evolution of FDA and manufacturer testing of brand names prior to approval to ensure they have a low potential for confusion and are safe to use in the healthcare environment. The ever-increasing market share for generic medications, which accounts for the bulk of outpatient prescriptions in the US, also may have played a role in the increased reporting of generic-generic name confusion. In 2002, only about half of outpatient prescriptions were for generic medications; in 2016, generic medications accounted for 90% of all outpatient prescriptions.[12] Other factors that may have contributed to an increase in generic-generic name confusion reporting include an increase in the use of generic drug names, the expanding number of generic drug names that utilize the same stem within a therapeutic class, assignment of similar stem names (e.g., -umab and -ximab), and the use of longer USAN stems.

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levOCARNitine thought that the 3 tablets comprised a single dose, especially since only one barcode was visible on the part of the blister pack containing the 3 tablets. After not being able to locate the patient's next dose, another nurse discovered that all 3 doses had been administered as a single dose. Thankfully, the patient was unharmed.

Previously, Hi-Tech Pharmacal told us it would not be changing the packaging. (An additional problem is that the lot and expiration date are embossed, difficult to read, and located at the very top edge of the blister-pack sheet.) However, Leadiant Biosciences, which manufactures a brand of levOCARNitine, CARNITOR, is the new drug application (NDA) holder and has revised the Carnitor packaging earlier this year. Authorized generic manufacturers must package their products in the same way as the NDA holder. However, the problem continues because the packaging change did not address all problems. The drug name, dose,

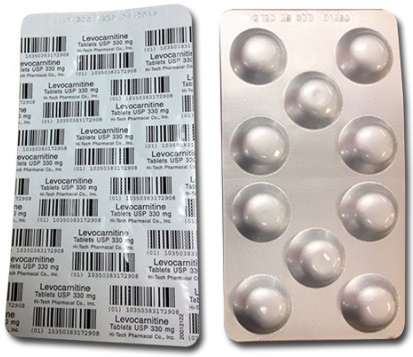

Figure 1. Lev**OCARN**itine barcodes do not line up with each tablet. Also, the lot and expiration date are embossed, difficult to read, and only located at the very top edge of the blister-pack sheet.

and barcode still do not properly align over the individual tablets. No further packaging changes are planned, and it appears that the US Food and Drug Administration (FDA) will not require our suggested changes.

If you stock the Leadiant or Hi-Tech product shown in **Figure 1**, we recommend relabeling each tablet blister individually and adding a barcode. Do not repackage the product as this can compromise the integrity of the tablets. We hope you will take every opportunity to contact Leadiant, Hi-Tech, and other companies that package medications like this, as pharmacy relabeling increases the risk of errors and decreases efficiency. Please also contact ISMP and we will inform FDA about your report.

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Managing the risks associated with name similarity is an industry-wide obligation. It begins with pharmaceutical companies that propose generic and/or brand names, and with regulatory and standards organizations that approve the names. The increase in reporting of generic-generic drug name confusion suggests possible vulnerabilities in the way generic drug names are assigned, evaluated, and approved. While USAN has remained open to changing the generic name of a product if post-marketing surveillance shows harmful or potentially harmful confusion with another generic drug name, changing a name is a complex and lengthy process and should not be relied upon as a risk mitigation strategy. Instead, FDA, USP, and USAN should work with industry leaders to develop a more robust, standard evaluation method for nonproprietary names to be employed *prior* to generic name assignment. Growth in generic drugs and biopharmaceutical products will likely require new funding methods to allow for computerized screening of proposed generic names and field testing with practitioners.

Although FDA evaluates brand names prior to drug approval, requiring ALL pharmaceutical companies to use an independent source to test proposed brand names to identify and remedy potential look- and sound-alike confusion with existing drug names, and to submit their results to FDA when seeking new drug approval, can further reduce name similarities that may cause serious errors. In addition, there should be a consistent and standardized approach regarding the methods employed to determine the acceptability of a brand name.[10] Furthermore, FDA should require companies to develop a risk management program that includes a name change provision for newer brand names if post-marketing surveillance (including error reports) shows harmful or potentially harmful confusion with an existing brand or generic name.

Healthcare providers can also reduce the risk of drug name confusion by implementing strategies to prevent errors (e.g., indication-based prescribing, computer listing of both brand and generic names, separate storage, tall man letters, electronic alerts for look- and sound-alike names). Accreditors should provide assistance to ensure this is successful.

Limitations

This study examined the differences in reporting of name confusion to the voluntary, practitioner-based ISMP MERP during two different time periods. The data sets did not include all name confusion events occurring in the US during the study time periods. Thus, our study was only able to detect variations in the voluntary reporting of name-related confusion events to ISMP, and our results are not generalizable to all US reporting programs. We were also limited in our ability to determine why the changes in reporting occurred. Thus, plausible explanations for the changes were based upon expert opinion and not scientific evidence.

Conclusion

The volume of medication error reporting to the ISMP MERP has increased over time. While the reporting of drug name confusion of all types, particularly brand-brand name confusion, has decreased over time, the reporting of generic-generic drug name confusion has increased and is likely to continue increasing as the US market share of generic medications rises. Future work should attempt to reduce the risk of generic-generic drug name confusion through better pre-market evaluation of generic names along with post-market monitoring and action if serious or potentially serious drug name confusion errors occur.

Acknowledgements

*ISMP thanks **Alexander Radovanovich**, PharmD, Medication Safety Fellow at Novartis Pharmaceutical Corporation, for analysis of the data while on rotation at ISMP. We also extend our appreciation to **Dorothy Linvill-Neal**, Global Head, Name Creation & Regulatory Strategy at Novartis for suggestions made regarding this project.*

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Join ISMP on Tuesday evening, **December 4, 2018**, at 6:00 p.m. for the **21st Annual Cheers Awards** at **Bowlmor Anaheim** in Anaheim, CA. The gala will celebrate an impressive group of healthcare leaders who are in their own league when it comes to best practices and programs that prevent medication errors and protect patients.

Your donation or attendance at the awards dinner helps bring attention to safety advances and enables ISMP to continue the core of its lifesaving work—preventing medication errors. To make a donation or register for the dinner, please visit: www.ismp.org/cheers-awards.

Keynote Speaker:
Ana McKee, MD,
Executive Vice President and Chief Medical Officer of The Joint Commission

Lifetime Achievement Award Winner:
Timothy S. Lesar, PharmD,
Director of Clinical Services and Pharmacy Residency Director, Albany Medical Center in Albany, NY

ISMP Activities at the 2018 ASHP Midyear Meeting in Anaheim

(all at the Anaheim Convention Center [ACC North] unless otherwise specified)

Workshop *(preregistration required - please call 215-947-7797)*

Friday, November 30 & Saturday, December 1: **Medication Safety Intensive,** Maggiano's Little Italy, 3333 Bristol Street, Costa Mesa, CA

Symposia *(preregister at www.ismp.org/ashp-activities)*

Sunday, December 2
Balancing Unpredictable Intravenous Medication Supply with the Demand for Safe Injection Practices
9:00 a.m. – 10:00 a.m.; Doors open at 8:15 a.m.
Room 225

Monday, December 3
Hidden Perioperative Medication Safety Risks: A Time for Pharmacy Involvement
11:30 a.m. – 1:00 p.m.; Doors open at 10:45 a.m.
Room 261

Tuesday, December 4
Transforming Smart Infusion Pump Safety: Are You Ready?
11:30 a.m. – 1:00 p.m.; Doors open at 10:45 a.m.
Room 258

Wednesday, December 5
Addressing Risks Associated with IV Push Medication Use in Adults
11:30 a.m. – 1:00 p.m.; Doors open at 10:45 a.m.
Room 253

Educational Sessions with ISMP Speakers

Sunday, December 2
In Your Spare Time: Addressing Medication Safety Practices Without a Dedicated Medication Safety Practitioner
3:30 p.m. – 4:30 p.m.
Room 210b

Monday, December 3
Three's Good Company: Three Strategies for Improving Safety Through Effective Event Response
4:00 p.m. – 5:15 p.m.
Room 303b

Tuesday, December 4
Strategies to Eliminate Errors in IV Compounding
(Live Webinar)
5:45 a.m. – 7:45 a.m.
Hilton Anaheim

Wednesday, December 5
ISMP Medication Safety Update for 2019
8:00 a.m. – 9:30 a.m.
Room 154

Visit ISMP at www.ismp.org and Exhibit Booth #151