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

ISMP National Vaccine Errors Reporting Program 2022-2023 analysis: New vaccines, new errors

Problem: Though immunization is one of the greatest public health achievements, continued success relies on the appropriateness with which vaccines are prescribed, dispensed, stored, and administered. We recently reviewed 1,987 events reported to the ***ISMP National Vaccine Errors Reporting Program*** (ISMP VERP) from January 1, 2022 through December 31, 2023, which showed that most of the reported events reached the patient (82%). The full analysis has been included in the recently published *2022-2023 Bi-Annual Report, The ISMP National Vaccine Errors Reporting Program (VERP)*.

Unfortunately, vaccine errors are a widespread issue, especially in outpatient settings where barcode scanning prior to vaccine administration is often lacking. As vaccination programs seek to achieve a high immunization rate, more needs to be done to reduce the risk of vaccination errors as they can lead to inadequate immunity, increased cost, and reduced confidence in the healthcare delivery system. For this reason, the 2024-2025 ISMP ***Targeted Medication Safety Best Practices for Hospitals*** *Best Practice #22*, calls for organizations to safeguard against errors with vaccines administered in the inpatient and associated outpatient settings. In addition, the ISMP ***Targeted Medication Safety Best Practices for Community Pharmacy*** *Best Practice #1*, calls for pharmacies to use a standard protocol to verify a patient's identity, utilizing at least two patient identifiers, prior to administering vaccines; and *Best Practice #2* encourages the use of barcode verification during vaccine dispensing and administration in the outpatient setting.

Our analysis of the reports during the 24-month timeframe showed that the most frequent types of vaccine events reported were as follows:

- Wrong vaccine (25%)
- Expired vaccine or contamination/deterioration (20%)
- Wrong dose (overdosage and underdosage events) (12%)
- Wrong age (10%)
- Extra dose (9%)
- Wrong time or interval (7%)
- Vaccine/component omission (only the diluent or a single component of a two-component vaccine was administered) (4%)
- Wrong route (2%)
- Wrong patient (1%)
- Other (10%)

Since most vaccines are administered in the outpatient setting, most reported events occurred in those settings: medical clinics (43%), public health immunization clinics (18%), doctors' offices (17%), or community pharmacies (9%). Only 2% of the events occurred in inpatient settings, and 11% occurred in other settings. Forty-eight percent of the events involved medical assistants, 27% involved registered nurses, 19% involved licensed vocational nurses or licensed practical nurses, and 13% involved pharmacists. Other healthcare providers, such as physicians, nurse

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Weathering the storm—

Safety considerations during fluid shortages

Problem: As most readers are aware, on September 29, 2024, Baxter announced that their North Cove, NC manufacturing plant was temporarily closed due to damage from Hurricane Helene. This facility is the production site for several intravenous (IV), parenteral nutrition (PN), peritoneal dialysis (PD), and cardioplegic fluids/solutions. The closure has resulted in the need for Baxter to invoke product allocations to healthcare organizations. ISMP has been in communication with Baxter, the US Food and Drug Administration (FDA), the American Society of Health-System Pharmacists (ASHP), and several other organizations to advocate for safe fluid conservation practices. ASHP and the University of Utah are providing ongoing updates to their *Small- and Large-Volume Fluid Shortages – Suggestions for Management and Conservation* resource. In addition, on October 9, 2024, the FDA announced it is working to temporarily import some products to help meet patient needs.

As organizations implement strategies that work best for their institution, we recognize that any change to compounding procedures, workflows, or needing to procure new products because of the shortage may increase the risk of error. The following represent safety concerns and unsafe practices that must be addressed and avoided.

- ☐ Manipulating fluid bags (e.g., preparing smaller aliquots from a fluid bag into syringes) outside of the pharmacy's sterile compounding area without IV workflow management systems (IVWMS)
- ☐ Storing vials of concentrated 23.4% sodium chloride injection outside of the pharmacy for compounding solutions of 0.9% sodium chloride for injection

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practitioners, physician assistants, and students (e.g., medical, nursing, pharmacy) were also involved in the events.

We completed a similar analysis between June 2020 and December 2021 and shared the results in our September 22, 2022 newsletter. While the vaccine event types have not changed, additional vaccines have been marketed since and, in some cases, are indicated for vulnerable patient populations such as infants, pregnant women, and elderly patients. Therefore, the focus of this article will be on the newer vaccines.

In 2023, the US Food and Drug Administration (FDA) approved two vaccines for respiratory syncytial virus (RSV) infection prevention in adults (ISMP. Do not confuse these RSV products. *ISMP Medication Safety Alert! Acute Care*. 2023;28[24]:1-3). **AREXVY** (respiratory syncytial virus vaccine, adjuvanted) was first approved for active immunization of adults 60 years and older. In June 2024, the FDA expanded its approved use, which now includes patients 50 through 59 years old who are at increased risk. **ABRYSVO** (respiratory syncytial virus vaccine) is indicated for active immunization of pregnant individuals at 32 through 36 weeks gestational age, as well as individuals 60 years of age and older. Although not available for inclusion in this 2022/2023 data analysis, in May 2024, FDA approved a third vaccine to prevent RSV infection, **MRESVIA** (respiratory syncytial virus vaccine, mRNA), to protect adults aged 60 years and older. This is expected to be available for the 2024/2025 respiratory virus season. Each year there are also updated formulas for the coronavirus disease 2019 (COVID-19) and influenza vaccines made by a variety of manufacturers. In addition, Merck now has a prefilled sterile diluent syringe used for reconstituting the **M-M-R II** (measles, mumps, and rubella), **VARIVAX** (varicella), and **PROQUAD** (measles, mumps, rubella, and varicella) live virus vaccines which has also led to errors.

Wrong Vaccine Events

Events related to patients receiving the incorrect vaccine continue to be the most frequently reported error type. The top underlying causative factors associated with wrong vaccine mix-ups noted by the reporters included the following:

- Similar vaccine container labels/package (22%)
- Similar brand names (22%)
- Products stored near one another (21%)
- Similar vaccine abbreviations (15%)

Consider these recent vaccine event reports involving the new RSV vaccines:

Case 1: In anticipation of a high volume of patients, a nurse prepared vaccine doses for multiple patients in a clinic. One patient was prescribed Arexvy; however, the nurse mistakenly prepared and administered **SHINGRIX** (zoster vaccine recombinant, adjuvanted) prescribed for a different patient. Barcode scanning was not available in the clinic. Both vaccines are made by GSK and have a similar font and orange color on their labels (**Figure 1**).

Figure 1. A patient was supposed to receive Arexvy (top), but a nurse prepared and administered Shingrix (bottom) in error.

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- ☐ Storing 1,000 mL bags of sterile water outside of the pharmacy
- ☐ Lack of understanding of how to administer medications via IV push that were previously administered by infusion (e.g., uncertain rate of antibiotic administration)
- ☐ Mix-ups due to look-alike product packaging/labeling when new products are purchased from an alternative manufacturer or imported (which may present unforeseen labeling and nomenclature issues)
- ☐ Bypassing barcode medication administration (BCMA) systems due to missing or unscannable barcodes (e.g., imported products)
- ☐ Administering an expired product due to confusion about the product's extended expiration date

Safe Practice Recommendations: When implementing fluid conservation strategies, consider the following recommendations.

Evaluate systems. Evaluate all systems impacted by workflow or product changes due to the shortage. Review order sets and treatment protocols and make changes based on available products (and likewise when shortages end). Review and update order sets to remove automatic orders for fluids, when possible. Consider changes in the electronic health record (EHR) to allow the use of either dextrose or saline for the admixture of drugs compatible with both solutions (considering any critical carbohydrate or sodium restrictions that the patient may have). Use EHR alerts or forcing functions when a drug is compatible with only one diluent. Confirm existing smart infusion pump drug libraries are up to date to ensure safe and consistent practices. If a new medication concentration will be used, evaluate all systems and refer to our previous newsletter article, *A comprehensive, proactive plan is needed to mitigate risk when changing drug concentrations*, published June 16, 2022.

Maximize the use of IVWMS. Use IVWMS in the pharmacy when manipulating or compounding all products. IVWMS should also be used when aliquoting from large containers to smaller "unit-dose" containers (i.e., large-volume parenteral [LVP] to a syringe).

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Case 2: A mother brought her 4-day-old infant to a clinic for a newborn health examination. A prescriber gave a verbal order for the nurse to administer "the RSV vaccine" to the infant. The prescriber was confused about the new RSV products available and intended to prescribe a monoclonal antibody indicated to prevent RSV infection in infants, as opposed to an adult vaccine. The nurse administered Abrysvo, the only RSV vaccine available in the clinic. The nurse later identified that Abrysvo is not indicated for infants and notified the prescriber and parent.

Case 3: A prescriber mistakenly ordered Arexvy rather than Abrysvo for a patient who was 36 weeks pregnant. The error was not identified by the pharmacist during order verification or by the nurse prior to administration. The prescriber later identified that, unlike Abrysvo, Arexvy is not indicated for pregnant patients. The prescriber reported concerns that the new RSV vaccines share similar brand and generic names, and are both referred to as the "RSV vaccine" which contributed to the error.

Wrong Dose Events

The most common contributing factors associated with underdosage and overdosage events included the following:

- Age-dependent formulations of the same vaccine (39%)
- Lack of familiarity with dosing of vaccines (24%)

Examples of wrong dose errors occurred with the 2023-2024 Moderna COVID-19 vaccine (25 mcg/0.25 mL) (**Figure 2**), indicated for patients 6 months to 11 years of age under an emergency use authorization (EUA):

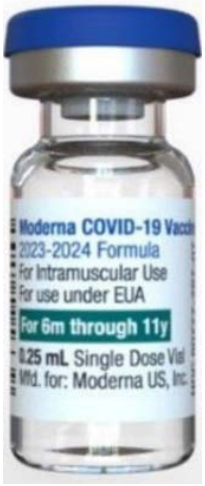

Figure 2. The label on the Moderna COVID-19 vaccine (2023-2024) for patients ages 6 months through 11 years states, "0.25 mL Single Dose Vial," but practitioners have administered the entire contents, which can contain up to 0.5 mL.

Case 1: A nurse was preparing the Moderna COVID-19 vaccine for an 8-year-old using a 25 mcg/0.25 mL vial. The nurse withdrew the entire contents from the single-dose vial into a syringe, but she did not confirm the amount in the syringe. When preparing a dose for a second patient, the nurse realized there was overfill (0.5 mL total volume) in the single-dose vial rather than the expected amount of 0.25 mL.

Case 2: A pediatric clinic reported that more than 200 children were administered the full vial of the Moderna COVID-19 vaccine before the error was identified. The vial is labeled as a 0.25 mL single-dose vial, but it contains double the dose as overfill. The dose of Moderna's **SPIKEVAX** (COVID-19 vaccine) for patients 12 years and older is 50 mcg/0.5 mL, and the volume (0.5 mL) is similar to several other childhood vaccines which could have also contributed to this event.

Vaccine/Component Omission Events

Errors have been reported where only the diluent (without the vaccine antigen) or a single component of a two-component vaccine was administered. The most common contributing factor was practitioners' lack of familiarity with how to prepare products (57%). Prefilled syringes that are not ready-to-administer may contribute to omission errors and create an increased risk of other errors.

Case 1: An outpatient clinic reported concerns with Merck's prefilled sterile diluent syringes (packaged separately) (**Figure 3**, page 4) for reconstituting a lyophilized powder vial of M-M-R-II, Varivax, and Proquad vaccines. The syringes are labeled "STERILE DILUENT FOR RECONSTITUTION OF MSD LIVE VIRUS VACCINES," but the instructions do not mention the need to relabel the diluent syringe with the vaccine name after reconstitution and prior to administration. The clinic

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Conduct a proactive safety analysis. When a new product is procured (i.e., from an alternative manufacturer or imported) conduct a review to identify potential risks with the product's design, including look-alike labeling and packaging concerns with other products in use within the organization. Store look-alike products separately, and consider the use of signage in storage locations, or other warnings such as auxiliary labels. Do not store 1,000 mL bags of sterile water for injection, irrigation, or inhalation in patient care areas, and follow recommendations in the ISMP ***Targeted Medication Safety Best Practices for Hospitals***, archived *Best Practice #10*. Test all product barcodes in the pharmacy prior to distribution to identify and mitigate any issues. For more information, see our previous article, *Safety considerations during expedited product approval*, published in the April 6, 2023 issue.

Safeguard IV push practices. If switching from an infusion to IV push when the patient's clinical status and drug properties (e.g., pH, osmolarity) allow, follow the recommendations listed in the ***ISMP Safe Practice Guidelines for Adult IV Push Medications***. The pharmacy should prepare and dispense medications that may be administered IV push in ready-to-administer concentrations in appropriate syringes. The syringe of diluted medication should be labeled with the patient's name, drug name, strength, dose, rate of administration (e.g., slow IV push over 5 minutes), and the beyond-use date/time. The medication administration record (MAR) should also include the rate of administration. Ensure practitioners administering medications have access to IV push policies and guidelines and have been trained and are competent in administering medications via IV push.

Monitor expiration dates. If FDA approves an extended expiration date for a product, implement a process (e.g., make staff aware and update the expiration date on the label) to ensure staff know when the product will expire.

Educate practitioners. Communicate changes to policies and practices, systems, and when new products are purchased, so staff are aware of any potential safety concerns. Be prepared for times like these by providing

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reported concerns that someone could inadvertently pick up and inject an unmixed diluent syringe. A separate risk is if a practitioner does not know that a syringe was already used to reconstitute a vaccine, it could be used for reconstitution again, and a patient could get a double dose or two different vaccine products.

Figure 3. Prefilled diluent syringe for use with Merck vaccines must be relabeled with the vaccine name after reconstitution.

Wrong Diluent Events

Among the "other" event types, wrong diluent events were also reported. This could include using the wrong diluent, using a diluent instead of a vaccine liquid component to reconstitute its lyophilized powdered component, or reconstituting one vaccine with another vaccine. Here is one example:

Case 1: An elderly patient was to receive both Abrysvo and Fluzone High-Dose vaccines. During reconstitution, the nurse inadvertently connected the Fluzone High-Dose luer lock syringe with the Abrysvo powder for reconstitution (instead of the intended sterile water diluent for Abrysvo) (**Figure 4**). The error was caught prior to administration.

Figure 4. Rather than using an Abrysvo diluent syringe (bottom), a nurse connected the Fluzone High-Dose syringe (top) to the Abrysvo vial via an adapter for reconstitution.

Safe Practice Recommendations: Review the new 2024-2025 ISMP ***Targeted Medication Safety Best Practices for Hospitals*** *Best Practice #22* and consider the following recommendations to prevent vaccine errors, foster herd immunity to prevent disease outbreaks, limit costly overvaccination and re-vaccination, and enhance the public's confidence in vaccines and the healthcare delivery system.

Maximize technology

- Utilize standard orders based on the Centers for Disease Control and Prevention (CDC) immunization schedules to guide prescribers to the appropriate formulation based on the patient population (e.g., age, pregnancy status).
- Require an order prior to administration of any vaccine.
- Utilize the full generic name and brand name (if applicable) in the electronic health record (EHR) and outpatient pharmacy systems. Avoid the use of vaccine abbreviations.
- Confirm that clinical decision support will provide an alert if a practitioner orders a vaccine for a patient in an age group or documented pregnancy status outside of its approved indication.
- Use barcode scanning technology to verify the correct vaccine and dose are being administered to the correct patient prior to vaccine administration. Expand the use of barcode scanning beyond inpatient care areas to offer a greater layer of protection to ensure the patient receives the correct vaccine, as recommended in the 2024-2025 ISMP ***Targeted Medication Safety Best Practices for Hospitals*** *Best Practice #18*.

Ensure safe storage

- Store vaccines in separate bins or containers based on name and formulation.
- Store the components of each two-component vaccine together where storage requirements permit.

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competency assessments related to impacted technologies (e.g., BCMA, IVWMS), including a broad spectrum of scenarios (e.g., incorrect drug alert upon scanning) that staff might encounter. If a medication barcode will not scan, the practitioner must confirm the product's identity prior to administration. Develop an escalation process when a medication barcode will not scan. The process should include when and how to report close-call events, barcode-related issues, why it is dangerous to use a proxy scan, and who is responsible for monitoring barcode issues. Gather staff feedback about safety concerns related to shortages during huddles.

Report errors and share lessons learned. Report medication errors, close calls, and hazards, including those related to shortages, to ISMP. Share lessons learned within your organization and externally with others.

Additional Resources.

1) ECRI: *Patient safety nonprofit releases guidance for navigating medical supply chain disruptions caused by Hurricane Helene*

2) End Drug Shortages Alliance: *Resources*

SAFETY brief

Using an irrigation syringe results in an overdose. A neonate was brought to a children's hospital's emergency department (ED) when the parents realized their baby's oral **PHEN**obarbital elixir, which was prescribed to treat seizures, ran out faster than expected. The parents were concerned they had administered higher than intended doses. The parents showed the ED nurse the irrigation syringe (**Figure 1**, page 5) that they were using to measure the doses of medication. A practitioner had given them the syringe upon their baby's discharge from a different hospital. At the first hospital, the practitioners had drawn a line on the irrigation syringe to mark the intended volume of medication needed for the parents to measure the dose.

Irrigation syringes are typically used for dental cleanings or to irrigate wounds and

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- Separate adult and pediatric vaccine storage on different shelves in bins properly labeled with the corresponding age formulation.
- Do not store vaccines with similar names or abbreviations, or overlapping components (e.g., diphtheria, tetanus, and/or pertussis vaccines [DTaP, Tdap, TD, Td]) right next to each other.
- Assign a staff person to go through the contents of the vaccine bins on a regular schedule (e.g., monthly), opening each carton and making sure no vaccines were incorrectly returned to stock, confirming the vaccine formulations are still stored separately, and checking that the vaccines have not expired. Ensure vaccines that expire soonest are stored closest to the front to be used first.

Verify identity, age, and vaccine(s) requested

- Verify a patient's immunization status (in the EHR as well as in state and/or local immunization information systems) prior to providing vaccines.
- Ask patients and/or caregivers to bring up-to-date vaccination records/cards to their appointment so they may be reviewed and compared to the EHR.
- If multiple patients are being vaccinated at the same time, separate them into distinct treatment areas; bring only one patient's vaccines into the treatment area at a time.
- When checking in a patient scheduled to receive a vaccine(s), ask the parent, caregiver, or patient to provide at least two patient identifiers—their full name and date of birth. Verify the patient's actual age with the patient, parent, or caregiver, and ask which vaccine(s) they have requested. Repeat this process immediately prior to vaccination.

Prepare and label syringes

- Use manufacturer prefilled syringes when available. If not available, prepare each vaccine dose immediately prior to administration and, if not administered immediately to the patient, label with the vaccine name, dose, and if appropriate, the indicated age range before it is set down.
- Prepare and label only one vaccine at a time.
- To facilitate labeling, print patient-specific labels with barcodes or provide practitioners who prepare the vaccines with strips of preprinted labels that differentiate adult or pediatric formulations and doses for each vaccine.

Engage the patient

- Involve the parent, caregiver, or patient in verifying the vaccine, formulation, and dose by reviewing the label to confirm the correct vaccine.
- Provide patients, parents, and/or caregivers with vaccine information (e.g., Vaccine Information Statement [VIS]) in their preferred language prior to vaccination. Providing the VIS and reading the medication name and age formulation in the patient's preferred language can provide an additional opportunity for both parties to stop and question if something does not seem right.

Document the vaccine(s)

- Document the vaccine's national drug code (NDC) number, lot number, and expiration date prior to administration; this is often the step during which healthcare workers detect an error that can be mitigated.
- Document administration afterward in the EHR, on vaccination records, and in state or local immunization information systems.

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should never be used to prepare or administer medications. During event investigation, a nurse drew up water to the marking on the irrigation syringe and transferred it into an oral syringe to determine the actual volume/dose of medication the parents were administering to their baby. This confirmed that the parents were administering 20 mg (5 mL) twice daily instead of the prescribed dose of 8 mg (2 mL) twice daily.

Figure 1. An irrigation syringe with a hand drawn marking to measure **PHEN**obarbital doses.

Unmarked devices including irrigation syringes should never be used to prepare or administer medications to patients. Pharmacy staff should always dispense oral/ENFit syringes with all oral liquid medication prescriptions. Ensure that the oral/ENFit syringe provided is an appropriate size based on the dose of medication needed and use the teach-back method to make sure the patient or parent knows how to measure the proper dose.

Special Announcement

New white paper released

Polypharmacy is common among older adults and age-related changes in medication metabolism can lead to side effects and adverse drug events. In ECRI's new white paper, *Reducing Inappropriate Polypharmacy through Deprescribing*, our experts explore how to reduce polypharmacy risks in older adults and provide steps for healthcare leaders to take to protect patients now. To obtain a copy, click here.

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Educate practitioners

- Provide vaccinators with ongoing education and competency assessment about vaccines and their appropriate storage, selection, preparation, administration, and monitoring.
- When bringing in new vaccine products, including during shortages, educate staff about the new vaccine product, highlighting its storage location, packaging, indication, and the intended patient population including age and pregnancy status.
- In locations where vaccines are prescribed, dispensed, and administered, provide resources that list the indication and schedules for routine and catch-up vaccinations.
- Share impactful stories and recognize staff for good catches, describing how the event was averted to prevent future close calls or actual events.

Report vaccine-related errors

- Report vaccine errors internally as well as to ISMP VERP, and the Vaccine Adverse Event Reporting System (VAERS) operated by the FDA and CDC.

Additional resources

- Please see the main articles in past newsletter issues (September 22, 2022; June 28, 2018; February 23, 2017; July 28, 2016; March 26, 2015; May 22, 2014; March 13, 2014) for additional recommendations to prevent vaccine errors.

Recommendations for FDA and manufacturers

- We encourage manufacturers to review labeling strategies to reduce the risk of vaccine mix-ups. More can be done by regulators and manufacturers to reduce errors.
- For vaccines and other biologics, government regulations require manufacturers to place the product's proper (generic) name above the brand name. The font size and typeface of the proper name must be at least as prominent as the font size and typeface used in designating the trademark and trade name. However, when reading a label, people generally start from the top, and once they think they have identified the product, they tend to stop reading. Thus, healthcare workers can overlook critical information, including the vaccine's brand name. For vaccines that have different brand names for vaccine formulations, displaying the brand name prominently and higher on the carton label and vial could help differentiate the various formulations when vaccines have similar generic names.
- Manufacturers should always look to produce vaccines in ready-to-use prefilled syringes. For vaccines that do not come in ready-to-use prefilled syringes, manufacturers should provide preprinted labels (in the carton) that include the vaccine name, dose, and intended age group, so that syringes can be easily labeled once the vaccine is prepared.
- We also encourage manufacturers to develop innovative packaging for component vaccines in order to prevent errors where only the diluent or a single component of a two-component vaccine are administered.

Welcome our newest staff members

Director of Consulting and Education

We are pleased to announce that **Jana O'Hara**, MSN, RN, CPHQ, CPPS has joined ISMP as the Director of Consulting and Education. Jana has worked in a variety of clinical quality, safety, and leadership roles. Most recently, she served as the Director of Marketplace Operations for a healthcare staffing company, leading clinical and non-clinical teams that support clinical staff across the country. Prior to that she served as the Director of Patient Safety for University Health in San Antonio, TX, overseeing patient safety across the entire healthcare system including inpatient, ambulatory, ambulatory surgery centers, dialysis, and correctional facilities.

2024-2025 FDA/ISMP Safe Medication Management Fellow

Desire' Johnson, PharmD, is the ***2024-2025 FDA/ISMP Safe Medication Management Fellow***. She received her Doctor of Pharmacy degree at Mercer University College of Pharmacy in Atlanta, GA and completed a PGY-1 acute care residency at AdventHealth Altamonte Springs in Altamonte Springs, FL. She will spend the first 6 months of her Fellowship at ISMP and the second half of the year at the US Food and Drug Administration (FDA). Desire' aspires to become a servant leader in medication safety and aims to increase awareness of the importance of establishing safe medication-use processes.

Please join us in welcoming our new staff members!

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