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ISMP
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Nurse AdviseERR®
Educating the Healthcare Community About Safe Medication Practices

Total systems safety supports practitioners in partnering with families to protect patients

The National Steering Committee for Patient Safety[1] was developed and coordinated by the Institute for Healthcare Improvement (IHI) and the Agency for Healthcare Research and Quality (AHRQ), which includes representation from ISMP and ECRI. In its National Action Plan to Advance Patient Safety (www.ismp.org/ext/1359), the Committee describes four interdependent foundations that are essential to achieving total systems safety:

- Cultivating leadership, governance, and cultures that reflect a deep commitment to safety
- Engaging patients and families as partners in designing and providing care
- Fostering a healthy, safe, and resilient environment for the workforce
- Supporting continuous and shared lessons learned to improve safety and quality of care and reduce the risk of harm

This total systems approach to advancing safety includes the design and implementation of a proactive, coordinated strategy to establish healthcare safety processes that impact patients, families, visitors, and healthcare workers across the continuum of care (**Figure 1**).[2] While the concept of including patients as safety partners is not new, practitioners might be more familiar with different terminology such as patient- and family-centered care (www.ismp.org/ext/1388).

Figure 1. Total systems safety includes culture, leadership, and governance; patient and family engagement; workforce safety and wellness; and learning system.

When it comes to keeping patients safe, family members are often keen observers who are highly motivated to ensure that the right treatments are correctly provided to their loved ones. They can help detect harmful or potentially harmful critical events before injuries occur, or mitigate the duration and severity of harm. We wrote about this in our acute care newsletter, *Partnering with families and patient advocates: another line of defense in adverse event surveillance* (www.ismp.org/node/10337). The article reflected on the numerous events that had been reported to ISMP in which a family member or patient advocate had noticed something unusual about their loved one and brought it to the attention of a healthcare practitioner who took action, thus avoiding a potentially catastrophic outcome. However, we continue to receive reports where practitioners did not seem to listen to patients, families, and caregivers when they voiced medication safety concerns, or critical information was not communicated to those who needed to take action, which resulted in harm.

Recent Event Reported to ISMP

Recently, the mother of a young teenager who has been receiving parenteral nutrition (PN) for several years, shared a story that highlights the struggles many patients and families experience regularly, especially during transitions of care. The mom, who happens to be a patient advocate, detailed the sequence of events from her child's hospital room as follows:

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SAFETY wires

Do not confuse these respiratory syncytial virus (RSV) products. Most patients who get respiratory syncytial virus (RSV), a lower respiratory tract infection, will have mild illness and will recover in a week or two. However, RSV can be dangerous for infants and young children, and for certain adults (e.g., older immunocompromised adults) (www.ismp.org/ext/1414). With all the publicity about new RSV products, and the fall and winter season coming when RSV is more prevalent, it is easy to confuse product names, dosages, and schedule differences between the two monoclonal products or confuse the three RSV vaccines. So, be prepared! *Beyfortus and Synagis are indicated for use in certain infants and children, while Arexvy, Abrysvo, and mRESVIA are indicated for use in certain adults.*

Pediatric RSV products. In July 2023, the US Food and Drug Administration (FDA) approved the monoclonal antibody **BEYFORTUS** (nirsevimab-alip), to prevent RSV infection in neonates and infants, and in certain children up to 24 months of age. Beyfortus is available in 50 mg/0.5 mL and 100 mg/mL single-dose prefilled syringes for intramuscular (IM) administration (**Figure 1**). See the prescribing information (www.ismp.org/ext/1235) for the recommended dose based on age, weight, RSV season, and for children who undergo cardiopulmonary bypass surgery. In October 2023, the Centers for Disease Control and Prevention

Figure 1. Beyfortus is available in 50 mg/0.5 mL (top) and 100 mg/mL (bottom) prefilled syringes.

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Day 1

- **6 pm:** The 14-year-old patient presented to the emergency department (ED) with what was later diagnosed as a viral infection. His home PN infusion bag had started infusing at 5 pm.
- **10 pm:** The patient was admitted to the hospital, and his home PN was discontinued per the organizational policy. The mom provided the patient's nurse with his current home PN order. The mom specifically mentioned that her son had renal tubular acidosis and required very high doses of potassium. A basic metabolic panel (BMP) was drawn upon admission, and his potassium level was 3.5 mEq/L (normal range is 3.5 to 5.2 mEq/L).
- **11 pm:** The prescriber ordered "standard" intravenous (IV) fluids (e.g., dextrose 5% and sodium chloride 0.45% with 20 mEq/L potassium chloride). The mom was told by his nurse, "he will be fine on this until PN can be made." The patient's mom objected to not continuing his home PN, particularly due to his high potassium requirements, but was overruled. He received the ordered IV fluids which contained much less potassium than his PN.

Day 2

- **9 pm:** The prescriber ordered PN for the patient based on his BMP laboratory results from the previous day, and the PN infusion was initiated. It is unknown what the patient's potassium level was at the time the PN began infusing.

Day 3

- **1 am:** The patient's mom noticed her child was experiencing bradycardia with 55-65 beats per minute, while his typical heart rate range is 95-110 beats per minute while sleeping. She spoke up because this was quite a deviation from his baseline, and was assured by the nurse that this was not alarming.
- **3 am:** The patient was found lethargic and bradycardic. The mom insisted that electrolyte levels should be drawn early to check what his potassium level was. Due to the mom's persistence, the prescriber ordered a BMP to be drawn 5 hours earlier than originally planned.
- **3:30 am:** The patient's potassium level came back critically low (2.1 mEq/L). A potassium infusion was ordered and administered.
- **12:30 pm:** The patient began to wake up and return to his baseline status.
- **2 pm:** A BMP was ordered which showed that the patient's potassium level was back up to 3.6 mEq/L.

Even though the patient's family communicated the child's high potassium requirement in his PN, this critical information did not seem to influence the patient's care plan which resulted in harm. This event left us with several questions: Why was the mom's request to provide her child with his typical potassium requirement seemingly ignored? Why was action not taken sooner when the mom notified the practitioner that her child's heart rate was drastically below his normal range? What might have been the outcome if the mom had not insisted that the patient's potassium level be checked early? How might this story have had a better outcome if the practitioners had a method to evaluate and document the patient's unique needs so that the appropriate practitioners could act upon the information that the family provided? Furthermore, while we advocate for standardization to minimize the risk of errors (e.g., "standard" IV fluid orders), how can hospitals also plan for deviation—the patient who requires something different or rare (e.g., high potassium requirement in home PN)? And how might a total systems safety approach be used?

Recommendations

Total systems safety intentionally includes patients and families with the ultimate aim of reducing preventable harm. To incorporate patients/families into systems and processes, and to appreciate the benefit of their expertise, organizations should consider the following:

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(CDC) distributed an advisory from their Health Alert Network, *Limited Availability of Nirsevimab in the United States—Interim CDC Recommendations to Protect Infants from Respiratory Syncytial Virus (RSV) during the 2023–2024 Respiratory Virus Season* (www.ismp.org/ext/1276) with interim recommendations for those who should receive the immunization. Based on manufacturing capacity and currently available stock, CDC recommends prioritizing the 100 mg/mL prefilled syringes for infants at the highest risk for severe RSV disease. Recommendations for using 50 mg/0.5 mL doses remain unchanged at this time. However, it is important to continually check the CDC website (www.ismp.org/ext/1413) for the most up-to-date recommendations as to which patient population meets the current criteria for receiving immunization against RSV.

Practitioners may be familiar with **SYNAGIS** (palivizumab), which was approved in 1998. Like Beyfortus, Synagis is a monoclonal antibody (**Figure 2**) but is only recommended for children less than 24 months with certain conditions that place them at increased risk for severe RSV disease (www.ismp.org/ext/1264). The dose of Synagis is 15 mg/kg IM, given once a month throughout the RSV season, which typically lasts for about 5 months, meaning 5 doses are needed.

Figure 2. Synagis is available in 50 mg/0.5 mL (top) and 100 mg/mL (bottom) single-dose vials for IM use.

Adult RSV products. In 2023, FDA approved two vaccines for RSV infection prevention in adults (www.ismp.org/node/110336). **AREXVY** (respiratory syncytial virus vaccine, adjuvanted) (**Figure 3**, page 3) was initially approved for active immunization of adults 60 years and older. However, in June 2024,

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Culture, Leadership, and Governance

- **Safeguard unique patient needs.** Develop a plan to care for patients who have medication needs that deviate from the "standard" therapy. Gather feedback and consider the workflow of all team members. As part of the total systems safety, determine how to communicate (e.g., electronic health record [EHR] documentation, handoff) a patient's special needs (e.g., high potassium requirement) to all applicable practitioners. Knowing that patients will be admitted at times when there are limited staff (e.g., night, weekend, holiday) to attend to complicated patient needs, prepare for circumstances when critical medications need to be addressed in a more timely manner and cannot wait until the following day (e.g., consider if there should be any exceptions for temporarily continuing home PN). Create a policy for continuing a patient's home medication.

- **Reconcile medications including home PN.** Add scripting to your medication reconciliation procedures that specifically asks patients about prescription medications, over-the-counter medications (including herbals and dietary supplements), non-enteral medications (e.g., infusions, including PN), and enteral nutrition. Obtain a copy of their home PN order and share this with the applicable practitioners (e.g., prescriber, pharmacist, dietician). If needed, follow up with the patient's primary care physician, specialty prescriber, outpatient pharmacy, and/or infusion pharmacy to ensure you have a complete and current medication list.

Patient and Family Engagement

- **Engage the patient and family.** Patient advocacy begins by including the family or an advocate in the patient's care and keeping them well informed so they know what to expect and can recognize if something is not right. Family members and patient advocates should be encouraged to speak up about any concerns or worries. They know the patient better than anyone on the medical team, so communication of their observations is extremely important. Many organizations have adopted bedside handoff processes for the nurses at change of shift. Some organizations invite family members to participate in medical rounds and include them on medication safety/quality committees or patient and family advisory councils. These inclusions acknowledge that the patient and the family are integral to high quality, safe and reliable care.

- **Listen to concerns and act when needed.** When family members and patient advocates do speak up, practitioners should take the time to actually listen and understand their concerns and then act in a manner that fosters true collaboration and empowerment. Some hospitals have recognized the important role family members and patient advocates can play in detecting untoward events in their loved ones by allowing the family and advocates to call a rapid response team if they suspect something is not right.

Workforce Safety and Wellness

- **Educate staff.** During orientation and annual competency assessments, educate practitioners about the role patients, families, and caregivers can have in preventing medication errors. Share close calls (i.e., good catches, near misses) where patient harm has been prevented due to practitioners partnering with patients, families, and caregivers.

Learning System

- **Encourage error reporting.** Certainly, the presence of family members and patient advocates during a loved one's hospitalization is not possible in all circumstances, but perhaps more could be done to encourage family members and/or patient advocates to be present and speak up to prevent errors. Engaging family members and patient advocates

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Figure 3. The Arexvy carton includes vials of lyophilized antigen (powder) and vials of adjuvant suspension (liquid). After reconstitution, a single dose is 0.5 mL.

Figure 4. The Abrysvo carton includes vials of lyophilized antigen (powder), prefilled syringes containing sterile water diluent, and vial adapters. After reconstitution, a single dose is 0.5 mL.

FDA expanded its approved use which now includes patients 50 years and older who are at increased risk. **ABRYSVO** (respiratory syncytial virus vaccine) (**Figure 4**) is for active immunization of pregnant individuals at 32 through 36 weeks gestational age, as well as individuals 60 years of age and older. Furthermore, in May 2024, FDA approved a third vaccine, **MRESVIA** (mRNA-1345) (**Figure 5**), to prevent RSV infection in adults 60 years and older. This vaccine is expected to be available for the 2024/2025 respiratory virus season. Both Arexvy and Abrysvo need

Figure 5. The mRESVIA carton includes 10 single dose (0.5 mL) prefilled syringes that must be thawed prior to use.

to be reconstituted and are administered IM as a single dose, without recommendations for revaccination with additional doses; while mRESVIA is supplied as a prefilled syringe that contains a frozen suspension

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as partners in identifying and reporting otherwise unrecognized errors and adverse events is a potentially promising approach for enhancing safety surveillance. Besides reporting at the hospital level, encourage patients to also report to external organizations including the following:

- ***ISMP Consumer Medication Errors Reporting Program*** (ISMP CMERP) (www.ismp.org/ext/1382)
- FDA's consumer reporting program (www.ismp.org/ext/1389)

■ **Share resources.** Share resources with practitioners and patients including the following:

- ISMP consumer website articles (www.ismp.org/ext/1384, www.ismp.org/ext/1385, www.ismp.org/ext/1386)
- The Joint Commission's Speak Up Campaigns (www.ismp.org/ext/1356)
- AHRQ's Engaging Patients and Families in Their Health Care (www.ismp.org/ext/1361)
- The World Health Organization (WHO) Global Patient Safety Action Plan 2021–2030 (www.ismp.org/ext/1362)
- WHO advocacy brief, Engaging patients for patient safety (www.ismp.org/ext/1287)

References

1) Institute for Healthcare Improvement. National Steering Committee for Patient Safety. IHI. Accessed May 20, 2024. www.ismp.org/ext/1387

2) Davila S. ECRI's top 10 patient safety concerns for 2024. ECRI blog. March 12, 2024. Accessed May 20, 2024. www.ismp.org/ext/1360

what's in a Name?

The "-ac" drug stem name

Medications with the suffix "-ac" belong to a class of drugs known as nonsteroidal anti-inflammatory drugs (NSAIDs) and can be further categorized as acetic acid derivatives. These medications provide anti-inflammatory and analgesic effects by inhibiting the cyclooxygenase (COX) enzyme preventing the formation of prostaglandins (hormone-like substances that affect several bodily functions, including inflammation, pain, and uterine contractions). There are two main types of COX enzymes, COX-1 and COX-2. COX-1 is expressed in most tissues and used in normal cellular activity such as protection of the gastric mucosa, platelet aggregation, and kidney function. However, COX-2 is expressed as a response to inflammatory stimulus. This category of NSAIDs is nonselective and therefore inhibits both COX-1 and COX-2 enzymes. So, although they are useful in treating pain and reducing inflammation, adverse effects to the gastric mucosa, kidneys, and cardiovascular and hematologic systems need to be closely monitored.

There are currently seven acetic acid derivatives and three combination products approved by the US Food and Drug Administration (FDA) (**Table 1**, page 5) for use in the United States. It should be noted that there are other drugs in this class that do not share the "-ac" stem and are not going to be discussed here. Most of these drugs are available as oral formulations; however, ketorolac and indomethacin are the only two available as parenteral preparations. One brand of ketorolac also is available as a nasal spray. A few of the drugs in this class also come as ophthalmic formulations, and another one is used as an intraocular irrigation. Finally, diclofenac is available topically in both prescription and over-the-counter (OTC) strengths to treat acute pain or osteoarthritis.

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that must be thawed prior to intramuscular (IM) administration.

Patients may also receive other vaccines (e.g., influenza, coronavirus disease 2019 [COVID-19]) at the same time as these RSV vaccines/immunizations. It is important to prepare each vaccine separately and clearly label the vaccine syringes (e.g., vaccine name, dose) once it is prepared. Ensure barcode scanning is used prior to administration. Educate staff about the differences in indication, storage locations, preparation, and dosage.

Only Priorix diluent was administered. **PRIORIX** is a measles, mumps, and rubella vaccine manufactured by GSK. It is available in cartons containing 10 single-dose vials of lyophilized antigen component and 10 single-dose prefilled syringes of sterile water diluent. The prefilled diluent syringes have luer tips to accommodate the attachment of needles to reconstitute the vials of lyophilized antigen and to administer the vaccine.

Recently, a patient arrived at a clinic for the measles, mumps, and rubella virus vaccine. It was a busy day in the clinic, and when the nurse went to retrieve and prepare the Priorix vaccine, they only removed a syringe of sterile water from the carton, leaving the vial of lyophilized antigen in the carton. They reported they did not see the vial containing the lyophilized antigen as it was "hidden" by the inside flap of the carton. The nurse administered the diluent alone and did not uncover the error until finding an extra vial of lyophilized antigen in the carton a couple of hours later. The patient was contacted and plans to return at a later date to receive the vaccine dose.

We warned practitioners in a February 2024 article, *Process for using Merck's new prefilled diluent syringe is error prone* (www.ismp.org/node/120212), that diluent syringes meant to reconstitute vaccines such as Priorix could be administered in error. To prevent preparation and administration errors with vaccines that come with prefilled diluent syringes, establish a process to keep vaccines and their corresponding diluents together if storage requirements do not

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Common side effects include nausea, abdominal pain, and headache while more serious adverse effects include bleeding, renal impairment, and skin reactions. Boxed warnings across all agents include serious cardiovascular thrombotic events with contraindications in the setting of coronary artery bypass graft surgery and serious gastrointestinal (GI) events including bleeding, ulceration, and perforation. Proton pump inhibitors can be co-administered with NSAIDs to reduce GI adverse events. Misoprostol, a prostaglandin analog, is combined with diclofenac (Arthrotec) to replace protective prostaglandins inhibited by NSAIDs, thus reducing GI side effects.

Table 1. List of NSAIDs, acetic acid derivatives available in the United States.

Generic Name(s)	Brand Name(s)	Formulation(s)
bromfenac	**BROMSITE**, **PROLENSA**	ophthalmic
diclofenac	generic	ophthalmic
	CAMBIA, **LOFENA**, **ZIPSOR**	oral
	LICART (patch), **PENNSAID** (solution), **PROFINAC** (solution)	topical
	ASPERCREME ARTHRITIS PAIN, FT ARTHRITIS PAIN, MOTRIN ARTHRITIS PAIN, PHARMACIST CHOICE DICLOFENAC, VOLTAREN ARTHRITIS PAIN	topical (gel) - OTC
diclofenac/lidocaine	**DICLONA** (gel), **DICLONA+** (patch)	topical
diclofenac/misoprostol	**ARTHROTEC**	oral
etodolac	**LODINE**	oral
ketorolac	**ACULAR**, **ACULAR LS**	ophthalmic
	generic	oral, parenteral
	SPRIX	nasal
ketorolac/phenylephrine	**OMIDRIA**	intraocular
nepafenac	**NEVANAC**	ophthalmic
sulindac	generic	oral

Specific boxed warnings for ketorolac include contraindications for intrathecal and epidural administration due to its alcohol content and should not be used in labor and delivery since it may adversely affect fetal circulation and inhibit uterine contractions. The use of ketorolac should be limited to managing moderate to severe acute pain requiring analgesia at the opioid level, and treatment (both oral and injection combined) should not exceed five days.

When using these medications, extra caution should be taken in certain groups of patients including those with renal impairment, a history of peptic ulcer disease, GI bleeding, or elevated risk such as older adults. Patients should be monitored for response to pain and inflammation, signs and symptoms of bleeding, skin rash, hypersensitivity, GI effects, hepatotoxicity, ototoxicity, and blood pressure at the beginning of therapy and periodically throughout use. Patients should also be counseled to self-monitor and report these adverse effects, as well as to avoid combining the use of NSAIDs. Oral agents should be taken with food to reduce GI effects.

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differ. Implement barcode scanning prior to preparing and administering vaccines. Configure the system to require scanning of both the vaccine and corresponding diluent barcodes. Provide vaccine-specific auxiliary labels to facilitate relabeling of the diluent syringe after the vaccine is reconstituted and withdrawn from the vial. Store the labels with the specific vaccine products. Document the national drug code (NDC) number, lot number, and expiration date of each container in the vaccination record or log before administration to confirm appropriate selection or preparation of both components. Documenting the actual administration of the vaccine should always occur after the vaccine is administered.

Vaccine registry not checked before administration. A nurse administered **TYPHIM VI** (typhoid vi polysaccharide vaccine) 0.5 mL injection to a clinic patient. When documenting the vaccine administration in the state registry, the nurse saw that the patient had previously received **VIVOTIF** (typhoid vaccine live oral Ty21a) capsules. Therefore, the patient should not have been reimmunized against typhoid fever for five years. The prescriber and patient were notified, and no harm was reported.

To help safeguard against errors with vaccines, verify the patient's immunization status in the state or local immunization information system, and the pharmacy computer system and/or electronic health record [EHR] prior to providing vaccines. Provide vaccinators with ongoing education and competency assessments including the need to verify immunization status in information systems prior to administration, as this can identify wrong timing and extra dose errors before reaching the patient. Encourage staff to report vaccine errors, and share close calls so that the organization can learn from events and improve processes.

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