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

Use barcode scanning to prevent errors with enteral nutrition feedings

Problem: The safe use of enteral nutrition (EN) in the hospital setting is often taken for granted. However, when viewed closely, the process is often fraught with potential failure points. Challenges exist for patients of all ages, from neonates to older adults. Preterm and critically ill infants and children often require additional calories, protein, or other nutrients due to higher metabolic demands. Consequently, unfortified human milk or standard ready-to-feed infant/pediatric formulas may not provide the level of nutrients required. Therefore, hospitals often add fortifiers (e.g., calories, protein, vitamins) to prepared feedings or human milk, or they use powders, concentrates, and/or modulars (i.e., formulas with modifiable nutrient amounts) to create facility-prepared formulas. Occasionally, adult patients require specialty-prepared formulas and/or the use of modular components as well. Similar to medication compounding, at any step of the process, practitioners may inadvertently use the wrong, expired, or recalled ingredients, putting the patient at risk. Even when pre-made EN formulas are available, there is still the risk of a practitioner administering a wrong, expired, or recalled formula.

One method for ensuring safety during EN feeding preparation and administration is using barcode scanning technology to verify each component that a provider ordered in the electronic health record (EHR) for a patient. However, in our June 4, 2015 article, *Results of survey on pediatric medication safety*, we shared that the lowest-scoring safety strategy of nearly 1,500 practitioners was the use of barcode scanning at the bedside to verify human milk before each feeding; less than half (46%) reported full compliance with this technology. While many hospitals now scan human milk to confirm the correct milk is administered to the correct patient, the practice of scanning all fortifiers, additives, and enteral formulas has yet to be universally adopted. Without such practices in place, the use of incorrect or expired items is likely common and underreported. Furthermore, frequent formula recalls in the past few years have added to the problem.

Background of Barcode Scanning

Healthcare organizations regularly use barcode scanning technology to properly identify items and reduce the risk of errors reaching patients. The patient's armband is scanned along with the product barcode to confirm the correct medication, blood product, or human milk is being administered.[1-8] Barcode scanning is preferred over a manual two-person visual verification as it is more efficient, has a lower chance of human error, and reduces the opportunity for confirmation bias.[4-5] The benefits of barcode scanning are well documented while there is little evidence that the use of two-person visual verification is associated with any significant reduction in errors.[9-12]

Barcode scanning of EN feedings can help hospitals prevent adverse events that may occur if patients receive the wrong formula, modular/fortifier, or human milk as well as an expired or recalled item. This technology also enables hospitals to monitor close calls (i.e., near misses, good catches). For example, scanning the wrong, expired, or recalled item and having the barcode scanning system alert the practitioner, preventing the error from reaching the patient, would be considered a close call. ISMP and the American Society for Parenteral and Enteral Nutrition (ASPEN) have worked collaboratively to educate practitioners about the benefits of reporting errors and close calls involving nutrition support therapy so that learning can occur, and you can make changes to prevent an error from reaching a patient. For more information, visit the ASPEN-ISMP project site at: www.ismp.org/ext/645.

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Micafungin carton contains incorrect reconstitution concentration. A pharmacist reported that a micafungin 100 mg injection (NDC 25021-191-11, lot number 523240302, expiration date 2/27) carton by Sagent contains incorrect information about the reconstituted vial's concentration. The carton indicates that once the 100 mg vial is reconstituted with 5 mL of diluent, each mL contains 10 mg of micafungin (**Figure 1**). However, according to the prescribing information, after reconstitution of the 100 mg vial, each mL contains 20 mg of micafungin (www.ismp.org/ext/1409). If a practitioner refers to the information stated on the carton, they may assume the reconstituted vial concentration is 10 mg/mL, rather than the actual 20 mg/mL, which could result in a two-fold overdose.

Figure 1. A micafungin for injection carton by Sagent incorrectly indicates that once the 100 mg vial is reconstituted with 5 mL of diluent, each mL contains 10 mg of micafungin (10 mg/mL), rather than the actual concentration (20 mg/mL).

We have notified the US Food and Drug Administration (FDA) and the manufacturer of this concern. Sagent confirmed the carton for impacted lot numbers (523220502, 523220503, 523230201, 523230601, 523240101, 534240301, 523240302, 534240302) was mislabeled and updated packaging is expected to be approved and implemented within one month. If your organization purchases this product, check your inventory for the mislabeled product. Verify that your pharmacy system (e.g., master formulation record, intravenous workflow management system [IVWMS]) reconstitution instructions have the correct

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Scanning Human Milk

Many professional organizations consider scanning human milk at the time of administration a practice standard.[1,2,8,13] Publications from ASPEN, the Academy of Nutrition and Dietetics, and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN), discuss the importance of scanning human milk to prevent errors.[1,2,8] In addition, the National Patient Safety Goals from The Joint Commission recognize that neonates are at higher risk of misidentification in the hospital setting. If a neonate receives the wrong mother's expressed human milk, there are significant risks of passing along potential pathogens to the infant.[13] The Joint Commission recommends a reliable identification system to prevent such errors.[13] Research studies have shown that scanning human milk before feeding preparation, feeding administration, and at hospital discharge reduces errors.[3-5] Some recently reported outcomes published from hospitals that scan human milk follow:

- Wrong patient errors
  - Scanning prevented the use of the wrong human milk 8.3 times per 1,000 bottles when nurses were preparing infant feedings, and 2 times per 1,000 bottles when dedicated human milk/formula technicians were responsible for feeding preparation.[3]
  - Scanning prevented the use of the wrong human milk 1,226 times in a 7-year time frame.[5]
- Administration of expired human milk
  - Scanning prevented the use of expired human milk 84 times per 1,000 bottles when nurses were responsible for infant feeding preparation, and 8.9 times per 1,000 bottles when dedicated human milk/formula technicians were preparing feedings.[3]
  - Scanning prevented the use of expired human milk 2,103 times in a 7-year time frame.[5]

Scanning EN Formulas and Products

Unfortunately, the routine practice of scanning all EN products at the time of preparation and administration varies widely among organizations, even though administering an incorrect formula or fortifier could cause significant metabolic or electrolyte disturbances, allergic reactions, or gastrointestinal intolerance.[5] Several organizations, including, ASPEN and the Academy of Nutrition and Dietetics, recommend scanning EN products.[1,8,14] For example, the *ASPEN Safe Practices for Enteral Nutrition Therapy* suggest that scanning barcodes on enteral nutrition containers "supports both the physical and cognitive efforts of nurses and other caregivers involved in maintaining safe practices around EN administration."[14]

Some recently published findings of EN error frequency and product scanning outcomes follow:

- A review of 1,045 adult EN feeding data points found 275 errors (a 26% error rate), with 140 being administration errors.[15]
- Attempts to use the wrong additives when fortifying human milk occurred 4.8 times per 1,000 bottles with nurses and 2.2 times per 1,000 bottles with dedicated human milk/formula technicians responsible for feeding preparation.[3]
- Use of barcode scanning to confirm all additives in human milk preparations prevented fortification errors from reaching the patient. Attempts to use the wrong fortifiers occurred 4% of the time with nurses and 0.5% of the time with dedicated human milk/formula technicians responsible for human milk feeding preparation.[16]
- Scanning all ingredients for human milk fortification and facility-prepared EN formula preparation prevented 480 errors in 2.5 years in a children's hospital.[5]
- A Veteran Affairs study found that documentation of EN feedings improved because of scanning and concluded that the "safety, documentation, and transparency for EN therapies" was enhanced.[17]

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concentration. Consider adding an auxiliary label to the carton when product is received, to alert users of the actual concentration (20 mg/mL) once the vial is reconstituted. Report errors to FDA, ISMP, and the manufacturer.

Do not rely on vial cap color for medication identification. Two hospitals reported events related to practitioners relying on the vial cap color to identify medications, further highlighting the need for barcode scanning throughout perioperative areas. In the first case, an anesthesiologist was removing medications from an open matrix drawer of an automated dispensing cabinet (ADC) and noticed that the heparin (10,000 units/10 mL) vials (Shenzhen Techdow), stored near the **BUP**ivacaine 0.25% (25 mg/10 mL) vials (Eugia), had similar blue caps (**Figure 1**). The anesthesiologist was concerned that the two products could be mixed up when viewing the vial caps only (**Figure 2**, page 3), especially since the hospital had not yet implemented barcode scanning prior to medication administration in the operating room (OR).

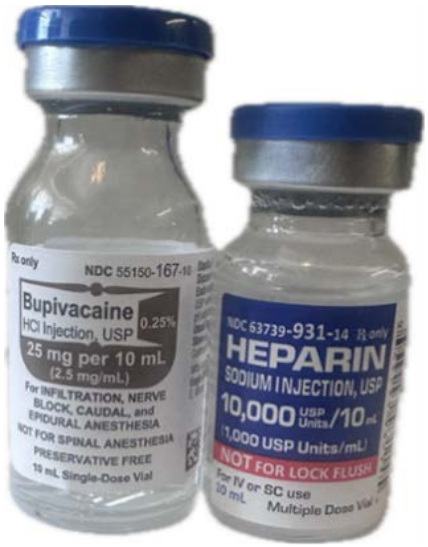

Figure 1. BUPivacaine 0.25% (25 mg/10 mL) vial (left) and heparin 10,000 units/10 mL vial (right) with blue caps.

While the color of medication vial caps should not be relied on alone, OR staff said that they did not expect heparin to have a blue cap because the pharmacy typically purchased it from other manufacturers with different color caps (e.g., orange, white). Pharmacy removed the heparin vials from all

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- Data from the National Center for Patient Safety (NCPS) Joint Patient Safety Reporting (JPSR) system revealed that of the 1,227 EN-related safety events reviewed, 691 were directly related to the medication-use process. Errors occurred most frequently during administration (31%), followed by monitoring (28%), dispensing (26%), prescribing (11%), and transcription (4%), with many events involving more than one step.[18]

EN Product Recalls

Recalls have occurred for infant, pediatric, and adult EN products in the past several years, adding to the risk of errors.[19-21] For example, in 2022, recalls impacted multiple brands of powdered infant formula and liquid ready-to-feed pediatric and adult products due to bacterial contamination from *Cronobacter sakazakii*.[19,21] These recalls were especially problematic for the infant population. The recalls led to severe shortages that left millions of parents and practitioners scrambling to find products, causing uncertainty about the safety of available alternative products.[20] Scarcity of all types of store-bought infant formula contributed to stockpiling and high out-of-stock rates. Practitioners encountered parents using unsafe feeding practices such as diluting formula with water, preparing homemade infant formula, introducing cow's milk before 1 year of age, and using human milk from informal sharing (the practice of using milk from a friend or family member rather than obtaining pasteurized donor milk from a licensed milk bank).[22] In short, practitioners were forced to base decisions on what products were available, rather than the most clinically appropriate product, resulting in some patients needing to be placed on parenteral nutrition.

Communication challenges compounded the problem. Many organizations did not receive timely notification of the recalls, thus patients continued receiving potentially contaminated formulas.[23] In addition, unless the hospital scans EN formulas and fortifiers at the time of preparation and feeding, product lot numbers are not typically documented. Thus, identifying which patients received recalled lot numbers is not possible. Furthermore, many organizations do not have an in-house inventory tracking system that alerts users as to where specific inventory is stored, thereby increasing the likelihood that all of the recalled formula products may not be removed. Practitioners also struggled to identify and contact patients and families in the community directly impacted by the recall.[23] Many clinics and physician offices give samples of infant and enteral formulas to patients and families; unless these dispensed samples are scanned or documented, practitioners will not know exactly which patients received the recalled lots.[23]

In response, the recalls led to updated federal legislation. The US Food and Drug Administration (FDA) created a new Office of Critical Foods (OCF) and enacted the Food and Drug Omnibus Reform Act of 2022, which has two requirements:[24]

1) FDA is responsible for the oversight, coordination, and activities related to critical foods (e.g., infant formula, medical foods, supplements)

2) Hospitals are responsible to identify and track recalled items, carry out the instructions of the recall, and maintain records

Furthermore, FDA has increased its oversight of formula manufacturers through increasing inspections.[24] If a sanitation code violation is found which necessitates a recall, the manufacturer must determine the root cause of contamination, perform cleaning activities, evaluate the sanitation practices and procedures, and provide a detailed corrective action plan to the FDA.[24]

Safe Practice Recommendations: Hospitalized patients of all ages represent a vulnerable population, making safe administration of EN feedings crucial. Organizations must ensure proper verification of EN products prior to preparation and administration, regardless of the feeding components (i.e., human milk, fortifiers, formulas, modulars). Consider the following strategies:

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ADCs and plans to purchase heparin from a manufacturer that does not use blue caps.

Figure 2. When stored upright, **BUP**ivacaine and heparin vials can be misidentified if only the caps are viewed.

In the second case, a cardiologist ordered a patient to undergo a transesophageal echocardiogram (TEE) to assess the structure and function of their heart under general anesthesia. A certified registered nurse anesthetist (CRNA) removed what she thought was a vial of lidocaine 1% (50 mg/5 mL) injection from an open matrix drawer of an ADC in the catheterization laboratory, prepared a 50 mg dose in a syringe, and administered it to the patient. Shortly after, the patient became apneic, so the cardiology team paused the procedure and provided bag-valve-mask (BVM) ventilation to the patient. The team discussed potential causes for the unexpected apnea and found that instead of lidocaine, the patient had inadvertently received rocuronium (50 mg/5 mL), a neuromuscular blocking agent. The CRNA administered **BRIDION** (sugammadex) for the reversal of neuromuscular blockade and the patient's apnea subsided so the TEE could be completed.

The lidocaine (Eugia, formerly AuroMedics) and rocuronium (Sanovel) injections were supplied in 50 mg/5 mL vials with blue caps (**Figure 3**, page 4). The CRNA relied on visual cues (cap color and storage location) to identify what they thought was lidocaine, but unknowingly administered rocuronium to the patient. Similar to the first case, the vials were stored next to each other in an ADC open matrix drawer in a perioperative area that had yet to implement barcode scanning.

Manufacturers' products (and cap colors) might change color, so that alone should not be used to identify any medication. To prevent misidentifying medications by

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Consider an FMEA. Create a plan to use barcode scanning during the preparation and administration of EN feedings. Start with conducting a failure mode and effects analysis (FMEA) to identify risk points before implementation.[4] This process will help evaluate safety concerns with the workflow and technology, and then develop strategies to prevent those errors.

Implement centralized preparation with dedicated human milk/formula technicians. Provide a dedicated space used solely for preparing fortified human milk and any EN formula that requires preparation before administration. A centralized EN preparation room with dedicated human milk/formula technicians reduces the risk of errors and feeding contamination.[3-5,25]

Build standard EN orders. Create EN feeding orders for providers to select from. When possible, provide standard ready-to-feed formulas. When manipulation is required (e.g., fortifiers, modulars), the orders should specify amounts based on patient needs (e.g., indication, age, weight, laboratory values). If possible, incorporate clinical decision support (e.g., drug-nutrient-herbal interactions, allergies, therapy duplicates) to alert the prescriber during the ordering process.

Implement barcode scanning. During preparation and prior to administration, use barcode scanning to confirm all EN products are correct and match the provider's order for the patient. Alert the user if an incorrect, expired, or recalled EN product is selected. Ensure the technology can document the product's lot number and expiration date. Barcode scanning improves the ability of the healthcare team to document what has been ordered and administered, along with what has not been administered and for what reason (e.g., rationale for holding an EN feeding). This information can also be used to track usage, waste, adherence to care protocols, and monitor for adverse reactions.

Develop an escalation process. Develop an escalation process for what to do when an EN product barcode will not scan; otherwise, practitioners may employ workarounds. The process should include when and how to report barcode-related issues, why it is dangerous to use a proxy scan (scanning the barcode not affixed to what is actually being used), and who is responsible for monitoring barcode issues. When a barcode will not scan, the EN product needs to be visually verified to ensure it matches what the prescriber ordered for the patient (e.g., right product for the right patient at the right time) and confirm it is not expired prior to administration.

Plan for recalls. Recalls are time sensitive; therefore, organizations must have effective communication with manufacturers and staff to ensure a timely response. Implement an automated process to quickly identify and remove products based on affected lot number(s). This process should include identifying products in stock, products used in preparation, products administered to patients, and samples provided to outpatients or inpatients to take home.

Notify patients about recalls. Create a policy and procedure to address the steps the organization will take to follow up with patients impacted by an EN product recall. Include required documentation (e.g., any potential patient harm) and retention of records.

Educate practitioners. During orientation and annual competency assessments, educate practitioners who may order, dispense, or administer EN products about the various formulations and fortifiers available within the organization. Also review and reinforce the organization's policy on barcode scanning.

Analyze data. Regularly review barcode scanning data (e.g., compliance, alerts) to identify EN products commonly administered and manually documented without scanning to help identify potential workflow or product issues. Educate end users to report workflow or barcode issues so that the organization can assess for contributing factors related to workarounds or equipment malfunctions.

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viewing only the vial caps, avoid storing medication vials in an upright position, especially when stored in a bin or drawer below eye level. Store them in a way that always keeps their labels visible. Store neuromuscular blocking agents in a rapid sequence intubation (RSI) kit or locked-lidded ADC pockets/drawers in perioperative areas. Place auxiliary labels on all storage bins and/or ADC pockets/drawers, as well as all final medication containers of neuromuscular blocking agents (e.g., syringes, intravenous [IV] bags) that state, "WARNING: CAUSES RESPIRATORY PARALYSIS – PATIENT MUST BE VENTILATED." For additional recommendations to prevent accidental administration of neuromuscular blocking agents to patients, review the ISMP ***Targeted Medication Safety Best Practices for Hospitals*** (www.ismp.org/node/160) *Best Practice 7*.

Figure 3. Lidocaine 1% (50 mg/5 mL) vials (left) and rocuronium 50 mg/5 mL vials (right) with blue caps.

In addition, when the pharmacy receives a new product (e.g., new product added to formulary, drug shortage), conduct a proactive review of product characteristics that might cause confusion and lead to medication errors (e.g., same cap colors). When problems are recognized, consider purchasing the product from a different manufacturer. Communicate with staff when a new product is available in ADCs and any medication trays, and review the packaging, storage location, and other pertinent information. Implement barcode scanning throughout perioperative areas and elsewhere. ISMP *Best Practice 18* calls for maximizing the use of barcode verification prior to medication administration by expanding use, including in perioperative areas.

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Report and learn from errors. Encourage staff to report close calls and errors involving nutrition support internally and through our error-reporting program (www.ismp.org/report-medication-error). Review internally reported errors as well as published external events. During safety huddles, share impactful stories and recognize staff for good catches, including those caught through the use of barcode scanning.

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