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

Survey results reveal tubing misconnections are common and underreported—Part I

Problem: Tubing misconnections refer to what happens when a tube, syringe, or medical device from one delivery system is inappropriately connected to a system that serves a completely different function. Unfortunately, ISMP has received numerous reports of tubing misconnections over the years. Universally used (cross-application) connectors, particularly luer connectors, have contributed to the risks of tubing misconnections. The most common misconnection reported has involved enteral feedings/medications connected to an intravenous (IV) line via luer-lock connection. The more device connections a patient has (**Figure 1**), the greater the risk could be that a tubing misconnection or wrong route error may occur, especially if the same type of connector (e.g., luer) is used for each device.

The connection points marked in **Figure 1** are as follows:

- **1 and 2:** Triple lumen central venous catheter with luer connector to IV tubing
- **3:** Triple lumen central venous catheter with luer connector to antiseptic barrier cap
- **4:** Salem Sump (nasogastric [NG]) connected to Lopez valve via ENFit connection
- **5:** Lopez valve with capped port to ENFit connection
- **6:** Lopez valve with ENFit connector to enteral feeding tubing
- **7:** Arterial line with capped port to luer connection
- **8:** IV tubing extension with luer connector to IV tubing
- **9:** Arterial line with luer connector to arterial tubing
- **10:** Salem sump vent lumen connected to antireflux valve

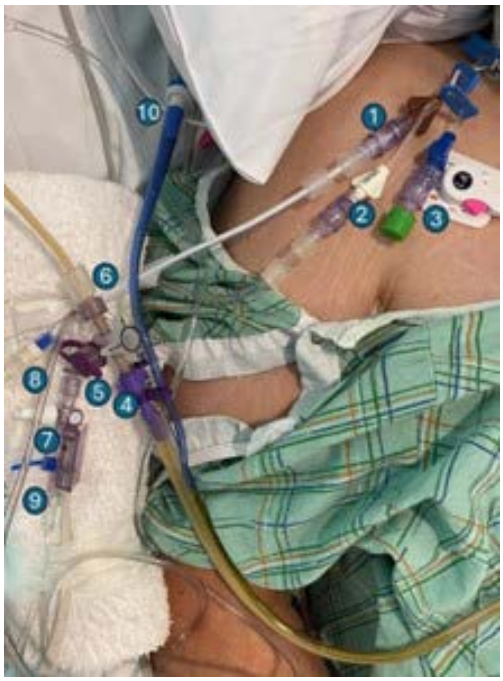

Figure 1. A patient with multiple devices is at risk for a tubing misconnection.

IV and Enteral Misconnections

Incorrectly using parenteral syringes or tubing with luer connectors for the administration of nutritional products and oral/enteral liquid medications puts practitioners at risk of inadvertently administering these fluids via the IV route. The unintended administration of nutritional products and oral/enteral liquid medications via the IV route can result in serious patient harm, including infection and/or pulmonary emboli, and even death.[1,2] ENFit is the name given to the International Organization for Standardization (ISO) 80369-3 connector that most manufacturers of enteral

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SAFETY briefs

Fluid shortage update—Safeguard imported products. Baxter announced it plans to restart manufacturing intravenous (IV) solutions at its North Cove, North Carolina facility this week. In the interim, as most readers are aware, the US Food and Drug Administration (FDA) has approved the importation of some fluid products due to shortages related to the Hurricane Helene aftermath. Prior to procuring imported products, organizations should ensure the product is included on the FDA-approved list. It is worth noting that some of these products may have different concentrations, packaging, and labeling than US products. For example, Baxter's Dear Healthcare Professional letter, *Temporary importation of 0.9% Sodium Chloride Injection from Shanghai, China, labeled in Chinese, to address drug shortages* (Hurricane Helene Clinical

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IMPORTANT! Read and utilize the Acute Care Action Agenda

One of the most important ways to prevent medication errors is to learn about problems that have occurred in other organizations and to use that information to prevent similar problems at your practice site. To promote such a process, selected items from the **July – September 2024** issues of the ***ISMP Medication Safety Alert! Acute Care*** newsletter have been prepared for use by an interdisciplinary committee or with frontline staff to stimulate discussion and action to reduce the risk of medication errors. Each item includes a brief description of the medication safety problem, a few recommendations to reduce the risk of errors, and the issue number to locate additional information.

The **Action Agenda** is available for download as an Excel file. **Continuing education** credit is available for nurses at: www.ismp.org/nursing-ce.

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devices use when manufacturing enteral feeding bags, tubes, and syringes. Practitioners can reduce or eliminate the risk of a misconnection through consistent use of ENFit (oral/enteral) syringes for preparation and administration of oral/enteral liquids. ENFit syringes have specially engineered connectors that practitioners cannot attach to standard luer connectors. Unfortunately, inexperienced practitioners may not be aware of the differences between oral slip tip, ENFit, and parenteral (luer) syringes and the associated risks. Sadly, we continue to receive reports in which patients were inadvertently given oral/enteral liquid medications and nutritional products IV.

IV and Neuraxial Misconnections

Clinicians are less familiar with NRFit, the system designed to prevent a neuraxial misconnection. NRFit connectors are 20% smaller in diameter than luer connectors and prevent medications in medical devices meant for neuraxial administration from connecting to devices used for IV, enteral, and other applications. The use of NRFit devices can help prevent another commonly reported misconnection, involving IV and neuraxial misconnections, such as epidural medications prepared in IV syringes erroneously connected to an IV access or vice versa. For example, in our October 4, 2018 newsletter article, *Mix-ups between epidural analgesia and IV antibiotics in labor and delivery units continue to cause harm*, we shared two events. In the first case, a fenta**NYL** with **BUP**ivacaine epidural solution was administered IV to a woman in labor. The patient later experienced seizures and respiratory arrest. A responding anesthesiologist noticed the error after reading the label on the infusion and immediately administered naloxone and lipid emulsion rescue to reverse the effects of the epidural medications given IV. The physician delivered the baby via emergency cesarean section, and the infant had a low Apgar score that improved over time. Fortunately, both mother and baby did not have long-term adverse effects. In the second case, an anesthesia practitioner administered IV gentamicin instead of epidural **BUP**ivacaine to a woman in labor. The patient complained of significant pain over the next 2 hours until her baby was delivered. The error was discovered when a nurse discontinued the epidural solution, which was actually the antibiotic, post-delivery. The anesthesia practitioner administered normal saline via the epidural route for 10 hours to dilute the gentamicin in the epidural space, and the patient recovered.

Other Types of Misconnections

Besides IV/enteral and IV/neuraxial misconnections, practitioners have reported errors with several other devices that have compatible connection types. This includes those shared on the US Food and Drug Administration (FDA) *Examples of Medical Device Misconnections* webpage:

- IV tubing erroneously connected to tracheostomy cuff
- IV tubing erroneously connected to nebulizer
- Oxygen tubing erroneously connected to a needleless IV port
- Blood pressure tubing erroneously connected to IV catheter
- IV tubing erroneously connected to nasal cannula tubing
- Syringe erroneously connected to tracheostomy cuff
- Enteral feeding tube erroneously connected to ventilator in-line suction catheter
- Foley catheter erroneously connected to an NG tube
- Air inflation line from a noninvasive vascular diagnostic system erroneously connected to an IV catheter

Events Reported in the Literature

A 2010 literature review found 116 cases of *enteral* tubing misconnections, resulting in 21 patient deaths (18%).[1] Frequent causes of death were sepsis and embolus. Hypersensitivity reactions,

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Resources for US Healthcare Professionals, scroll to Baxter Resources for Products Authorized for Temporary Importation) states that this imported product has labels written in Mandarin and contains the active pharmaceutical ingredient, concentration, volume, and product code in English. However, the label does not include a barcode, and the letter does not state if the label contains the US national drug code (NDC), lot number, and expiration date in English.

The FDA temporary importation list also includes several glucose and dextrose injections from different countries. It is important to note that glucose injections are not directly interchangeable with FDA-approved dextrose injection USP. Dextrose USP is a hydrated form of glucose. The imported glucose injection product is labeled based on the anhydrous form of glucose. For example, the caloric content of imported 70% glucose injection is 2,800 kcal/L whereas the caloric content of 70% dextrose injection, USP is 2,380 kcal/L. Organizations must consider any differences between glucose and dextrose products (e.g., caloric content, pH, osmolarity) and update protocols and systems (e.g., electronic health records, compounding systems).

Organizations must carefully review the information in the letter accompanying imported products, which can be found on the Baxter Medical Education page. Baxter US Medical Information may have additional product information that can be accessed here. Practitioners are required to register via valid email verification in order to search and access product information.

ISMP has created an ***Imported Fluid Product Checklist*** for organizations to use when evaluating imported products' safety during the current fluid shortage. Consider gathering an interdisciplinary team (e.g., pharmacy, nursing, prescribers, dietitians, central supply/materials management) and use the *Checklist* as a tool for completing a gap analysis to determine potential failure points and mitigation strategies. The checklist includes factors that should be considered when conducting a review to identify

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hypercoagulopathy, renal failure, multiorgan failure, severe and permanent neurological damage, and respiratory arrest were also reported. An article published this year describes 96 new cases of enteral misconnections that have occurred since the previous literature review.[2] In 4% of the reports, enteral misconnections resulted in patient death, with an additional 69% of the patients experiencing harm.

During a 20-year review period (between 1999 and 2019), the literature reported 133 cases of *neuraxial* misconnections.[3] Almost one-third of the events involved practitioners administering epidural medications into IV lines (29%), or IV medications into epidural lines (28%). Unfortunately, 26 of the events resulted in patient death, further highlighting the seriousness of this issue.

Underreporting

Although cases reported in the literature are enough to call for action, ISMP believes the true number of misconnections is much higher than reported. In our August 26, 2021 newsletter article, *Pump up the volume: Tips for increasing error reporting and decreasing patient harm*, we addressed reasons why errors are underreported as well as tips for increasing the frequency and the value of reporting. Staff reactions after making an error vary; however, it is known that candid confessions of a mistake are not comfortable. In fact, people have a natural desire to forget that the incident ever happened. Even if practitioners are willing to speak up about errors, they may still believe that the extra work to report it is not worth their time if they perceive no benefit will come, especially if they experience error fatigue due to inevitable and recurring errors that seem to never be addressed. They may be even less likely to report if the reporting process is time consuming, confusing, or complex.

In addition, the likelihood of reporting is highly dependent on the degree of psychological safety felt by practitioners. The workforce is understandably reluctant to report errors if they are worried that the information will get them or their colleagues in trouble, legally or socially, impact their job or working relationships with others, or lead to the perception of being careless, incompetent, or an informant. Remember, the easiest way to improve your error rate is to stop reporting—BUT that is certainly not the way for organizations and practitioners to learn and improve. Understanding that practitioners may not report misconnections, and to gather additional data, surveys were conducted in 2006 and 2023/2024, that specifically asked practitioners about their experiences with tubing misconnections.

Survey

In the 2006 enteral misconnection survey by the American Society for Parenteral and Enteral Nutrition (ASPEN) and FDA, 16% of the 182 responding clinicians shared that their organization had experienced an enteral misconnection incident.[4] More recently, in 2023/2024, clinical advisors working in coordination with the Global Engineered Device Supplier Association (GEDSA) (a non-profit trade association whose mission is the advancement of patient safety worldwide through the implementation of safer tubing connectors [www.stayconnected.org]), conducted an anonymous survey to understand clinicians' experiences with tubing misconnections or close calls (i.e., near misses). Survey results follow.

Respondent Profile

From October 2023 through May 2024, 261 clinicians shared their experiences with tubing misconnections. Most (83%) clinicians were from the United States, representing 38 states. Clinicians also responded from Canada (5%), France (5%), Australia (3%), and other (4%) countries (Brazil, Germany, Italy, Nigeria, Portugal, Scotland, and the United Kingdom). A variety of clinician types responded, including nurses (45%), dietitians (23%), pharmacists (7%), doctors (6%),

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potential risks with the imported product. For example, not having a scannable barcode on any medication or fluid is not an ideal situation, and the potential risks with implementing different strategy options to address the lack of a barcode must be evaluated to determine the safest option for your facility. For imported products that do not have a barcode, consider whether a scannable barcode should be created and how to safeguard the workflow when adding the barcode to the product. Educate practitioners about product differences and emphasize that practitioners must confirm the product's identity prior to dispensing and administration. Gather staff feedback about safety concerns related to imported products during huddles. Consider including a field in your error reporting program to designate if the event was related to a shortage so you can track such issues. Report errors and close calls internally and to ISMP to share lessons learned.

In addition, Baxter is now authorized by FDA to extend the use dates of some products to provide a 24-month expiration from the date of manufacture (Hurricane Helene Clinical Resources for US Healthcare Professionals, scroll to Expiration Dating Extension to 24 Months). Review this information to determine if a product has an extended expiration date, and if so, 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.

Lastly, the American Society for Parenteral and Enteral Nutrition (ASPEN) recently released shortage recommendations for intravenous dextrose and sterile water for injection.

HIGH-ALERT

Consider PN compatibility and stability data when applying USP <797> which accounts for sterility only. Parenteral nutrition (PN) is a complex life-sustaining therapy for patients who cannot intake adequate oral or enteral nutrition. It can contain more than 40 ingredients and is considered a high-alert medication.[1] PN can be compounded, including neonatal starter PN bags, or delivered using a commercially available multi-chamber bag. PN can also be administered with an intravenous lipid

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medication safety officers (6%), certified registered nurse anesthetists (5%), risk management/patient safety staff (4%), supply chain/procurement staff (2%), and others (2%).

Tubing Misconnections

Almost half (47%) of the responding clinicians reported having a tubing misconnection reach the patient or a close call occur within their organization. Of those, 17% reported more than one misconnection. The most common misconnections included IV/enteral (39%) and IV/neuraxial (22%). Clinicians also shared misconnections involving enteral/respiratory (7%), IV/limb cuff (6%), IV/unsure (6%), IV/respiratory (4%), enteral/unsure (3%), unsure (3%), enteral/neuraxial (2%), enteral/urinary (2%), respiratory/unsure (2%), and others (4%).

Adverse Patient Outcomes

Almost half (46%) of the events were close calls, followed by errors that reached the patient and did not cause harm (23%). Unfortunately, 16% of the errors reached the patient and caused harm, and 12% resulted in death. The remainder (3%) involved a patient death, but the cause was uncertain, or clinicians were unsure about the patient outcome.

External Event Reporting

Seventy-nine percent of the cases were either not reported externally or respondents were unsure if they were reported outside of their organization. Practitioners most often reported misconnections to a patient safety organization (PSO) (6%), ECRI/ISMP (5%), FDA (3%), the National Agency for the Safety of Medicines and Health Products (ANSM) (France) (2%), the device manufacturer (2%), the National Health Service (NHS) (England) (1%), or another organization (2%).

ENFit and NRFit Conversion

When asked if their organization has converted to ENFit, nearly half (48%) have already converted, with an additional 16% in the process of converting, and 11% planning to convert. Eighteen percent of clinicians did not know what ENFit was, and 7% did not have plans to convert. Reported barriers included cost and time.

When asked if their organization is planning to convert to NRFit, 9% have already converted, with an additional 9% in the process of converting, and 16% planning to convert. More than half (53%) of clinicians did not know what NRFit was, and an additional 13% did not have plans to covert. The most commonly reported barrier was the lack of product availability.

Conclusion

Transitioning to ENFit devices is a global patient safety initiative. GEDSA estimates that the United States is greater than 60% converted, Europe is at nearly 100%, and Australia/New Zealand is at approximately 80%. While some countries have widespread NRFit adoption (e.g., GEDSA estimates Japan is 100% converted, and the United Kingdom is greater than 65% converted), healthcare organizations in the United States have not commenced converting to this system until just recently. On July 24, 2024, B. Braun announced that Gillette Children's Hospital in St. Paul, Minnesota became the first US hospital to convert to NRFit connectors for epidural medication infusions. Gillette Children's told us they first heard about NRFit devices from our ISMP ***Guidelines for Safe Medication Use in Perioperative and Procedural Settings***, which calls for organizations to use an interdisciplinary team (e.g., pharmacy, nursing, anesthesia) to transition to the ISO 80369-6 design standards for neuraxial (NRFit) connectors to reduce the risk of misconnections. GEDSA will be hosting an NRFit webinar with practitioners from Gillette Children's on November 20, 2024

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emulsion (ILE) added to the PN bag (total nutrient admixture) or have the ILE co-infuse with the PN (dextrose-amino acid admixture with Y-sited ILE).

The most recent revision of USP General Chapter <797> *Pharmaceutical Compounding–Sterile Preparations* became official on November 1, 2023.[2] The goal of the standard is to reduce the risk of contamination and patient infections from compounded sterile preparations (CSPs). Categories of risk are now assigned as category 1, 2, or 3, and the interpretation of the standards has led PN to be viewed as a category 2 CSP.[2] Now, beyond-use dates (BUDs) (i.e., from the time of compounding to administration) for category 2 CSPs are 4 days at room temperature and 10 days if refrigerated.[2]

The American Society for Parenteral and Enteral Nutrition (ASPEN) has received feedback from practitioners who reported confusion with interpreting the standards, inquiring if PN should now have an extended expiration date (i.e., 4 days or 10 days). In fact, on October 16, 2024, ASPEN released a letter, sharing this concern as it relates to Appendix A, in the US Food and Drug Administration (FDA) temporary guidance during the current fluid shortage, *Temporary policies for compounding certain parenteral drug products*. It is important to understand that the BUD assigned by USP <797> is based on sterility. USP <797> states a shorter BUD must be assigned when the physical and chemical stability of the CSP is less than the BUD limit. Therefore, practitioners must also consider *compatibility* and *stability* data that is specific to each PN's components (amino acid solution, ILE, dextrose, and micronutrients) when determining the PN expiration date (i.e., the date/time the PN should no longer be administered).

Based on the literature on PN compatibility and stability,[3,4] ASPEN recommends PN generally have an expiration date of 30 hours at room temperature and 9 days refrigerated,[5,6] unless there is specific extended stability data for the components used in the PN formulation. Additionally, the hang time for PN should not exceed 24

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(*NRFit - Improving Patient Safety - presented with the first US clinicians to adopt NRFit*: register here). We encourage practitioners to attend the webinar and learn from Gillette Children's about how to overcome challenges when planning the transition to NRFit devices within your organization.

Thank you to all who responded to the survey. Your insights are invaluable in making healthcare safer for all. In the next issue of this newsletter, we plan to publish a follow-up article (**Part II**) describing how organizations can learn from these survey results and take action to prevent tubing misconnections.

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Worth repeating...

Do not push vancomycin

In our October 17, 2024 newsletter, we discussed concerns about the recent fluid shortages and a lack of understanding of how to administer medications via intravenous (IV) push that were previously administered by infusion. We recently heard of an organization considering administering vancomycin via "IV push," although if infused too quickly, this medication is known to cause a vancomycin infusion reaction called vancomycin flushing syndrome (formerly "red man syndrome"). According to the prescribing information (i.e., generic vancomycin prescribing information from Baxter), vancomycin should be infused over 60 minutes or greater to reduce the risk of an infusion reaction. Hypotension, shock, and cardiac arrest have been reported with too rapid of a vancomycin infusion.

When organizations are considering switching any medication from an infusion to IV push, ensure any change in drug concentration and/or rate of administration is appropriate based on the patient's clinical status and drug properties (e.g., pH, osmolarity). Refer to prescribing information, literature, and resources such as *Adult and pediatric IV push medication reference*: Vizient, Inc. 2023. For all IV medications, include a rate of administration in the medication administration record (MAR). For additional information, refer to the recommendations listed in the ISMP ***Safe Practice Guidelines for Adult IV Push Medications***.

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hours, and the hang time for a separate ILE infusion should not exceed 12 hours.[7] The ASPEN PN Committee recently authored an article about this important topic.[8] Ensure your organization's policy and procedures related to PN follow these updated standards and include an appropriate BUD (sterility), expiration date (stability), and hang time for PN to avoid patient harm.

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