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ISMP An ECRI Affiliate

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Educating the Healthcare Community About Safe Medication Practices

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

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

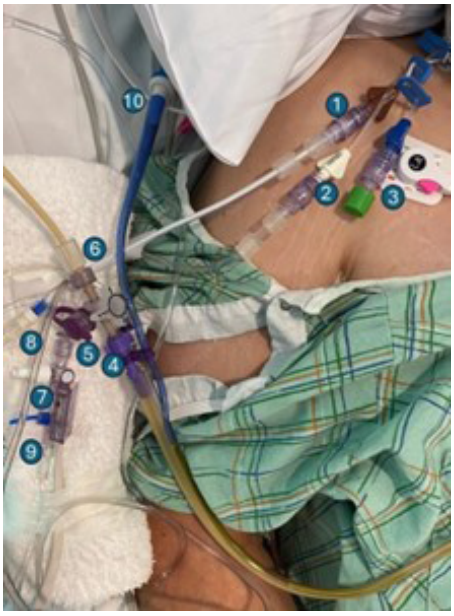

Figure 1. A patient with multiple devices is at risk for a tubing misconnection.

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 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

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B. Braun potassium chloride for injection concentrate almost infused into patient. A hospital reported a close call with two high-alert medications when potassium chloride for injection concentrate (500 mEq/ 250 mL) was found in the heparin injection (25,000 units/250 mL) bin of an automated dispensing cabinet (ADC) on a nursing unit. Both products, made by B. Braun, look similar and come in a 250 mL EXCEL plastic bag with blue and red labeling (**Figure 1**). Fortunately, a nurse caught the error after removing the bag's overwrap and scanning the barcode prior to administration.

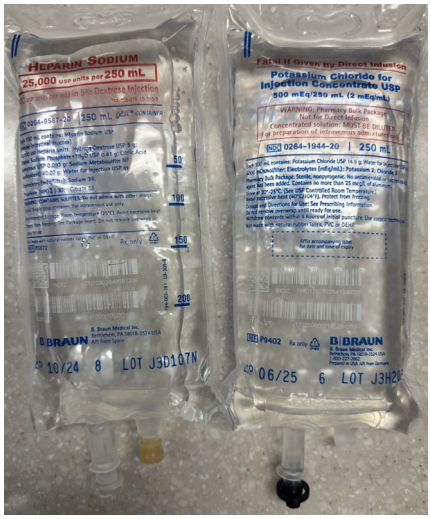

Figure 1. A nurse found B. Braun's heparin (left) and potassium chloride concentrate (right) in 250 mL EXCEL bags in the same ADC bin.

The organization purchased B. Braun's heparin due to a supply shortage from their typical manufacturer. Similar to concerns that we have previously published in the ***Worth* repeating** article in our September 2023 newsletter, the organization noted that a seam on the overwrap of B. Braun premixed bags obscures the already difficult-to-scan white barcode on the clear bag, resulting in the inability to scan the product in the pharmacy prior to dispensing and when filling the ADC. Since this event, the reporting organization has implemented a process in which, in addition to the

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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 (related to the central nervous system) 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 March 2019 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, 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 been reported since the previous literature review.[2] In 4% of the

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manufacturer-supplied auxiliary label, the pharmacy applies a pharmacy-generated barcode to the potassium overwrap bags to facilitate scanning. The organization is also storing the potassium in the controlled substance storage vault in the pharmacy. They are planning to purchase heparin from a different manufacturer once the shortage is resolved, which we would also recommend if using these products.

In May 2022, we issued a ***National Alert Network (NAN)*** alert, with recommendations to prevent an error with the new presentation of B. Braun potassium chloride for injection concentrate pharmacy bulk package. The product was formerly available in glass containers, which looked different than other premixed products, but the company decommissioned its glass manufacturing line in the first quarter of 2022. Organizations that use this product should review the NAN Alert and take immediate steps to prevent a potentially fatal medication error. This includes ensuring that only pharmacy can purchase, store, and use this product; segregating this product from other similar-looking infusion bags in pharmacy storage; affixing auxiliary labels on the case of the product and both sides of the overwrap on bags; and scanning the barcode on the bag (as well as the barcodes on all intravenous [IV] infusion bags to ensure none are potassium chloride for injection concentrate).

Both heparin and concentrated potassium chloride injections are high-alert medications that can lead to serious harm when involved in medication errors. The US Food and Drug Administration (FDA) and the manufacturer need to urgently address these long-standing look-alike issues and scanning difficulties before any deaths are reported.

We reached out to B. Braun and they told us they have added a white two-dimensional (2D) barcode to the left of the linear barcode on some bags, which is not obstructed by the overwrap seam and can be easier to scan. We recommended they use dark ink on white backgrounds for all barcodes and consider moving the 2D barcode away from the linear barcode to allow

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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 January 2022 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. Unfortunately, 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 more 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%), 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

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for proper scanning per FDA guidance—*Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors*.

Use of 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**) 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.

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

Irrigation syringes are typically used for dental cleanings or to irrigate wounds and should never be used to prepare or administer medications. During event investigation, a nurse drew up water to the marking that was on the irrigation syringe and transferred it into an oral syringe to determine what the actual volume/dose of medication the parents were administering to their baby. This confirmed that the parents had been

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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 convert. 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 hosted a webinar featuring practitioners from Gillette Children's on November 20, 2024 (*NRFit - Improving Patient Safety - presented with the first US clinicians to adopt NRFit*: click here to listen to the recording). 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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administering 20 mg (5 mL) twice daily instead of the prescribed dose of 8 mg (2 mL) twice daily.

Devices that do not have markings (i.e., mL) including irrigation syringes should never be used to prepare or administer medications to patients. Oral/ENFit syringes should be dispensed from pharmacy with all oral liquid medications and should be an appropriate size based on the dose of medication needed. The teach-back method should be used to make sure the patient or parent knows how to measure the proper dose.

References

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