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ISMP An ECRI Affiliate

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

Take action to prevent tubing misconnections—Part II

Problem: Tubing misconnections, or inappropriate connections between devices with different intended uses, have resulted in serious harm or death.[1,2] In Part I, published in our October 31, 2024 newsletter, we shared results from a recent survey by a group of clinical advisors working in coordination with the Global Engineered Device Supplier Association (GEDSA). The survey revealed that misconnections are common and likely underreported externally. The best solution to prevent misconnections is to eliminate the potential for interconnectivity between various types of medical tubing. Currently, a series of standards developed by the International Organization for Standardization (ISO), known as the ISO 80369 series (**Figure 1**), address misconnections among the different systems. These standards create unique connectors for each system, making them mechanically incompatible with one another. This reduces the risk of harmful and even fatal misconnections between these systems, in which medical tubing, syringes, or other medical devices have inadvertently connected to one another. The recognized standards have been evaluated by the US Food and Drug Administration (FDA), and manufacturers are encouraged to apply these standards to medical devices, as appropriate.

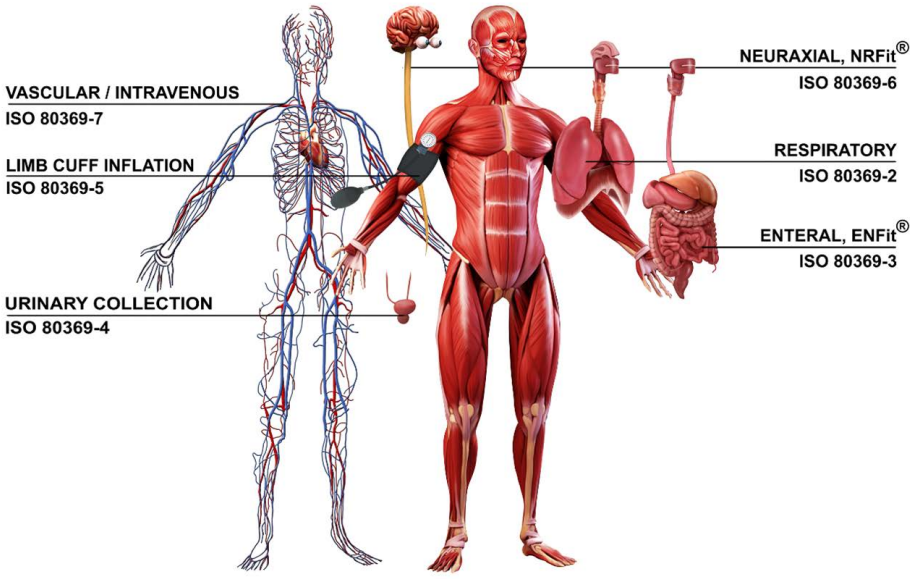

Figure 1. The ISO 80369 series has unique tubing connectors for each system that are incompatible with one another. Photo courtesy of GEDSA (www.stayconnected.org).

Safe Practice Recommendations: The survey data showed that tubing misconnections are not uncommon and continue to present a risk to patient safety, so assume this may be a risk within your organization and do not wait until an event occurs to take action. Consider the following recommendations:

Promote a culture of safety and learning. Promote and implement a fair and Just Culture (www.justculture.com), where safety is a primary value in the organization and staff continually

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Fatal route of administration mistakenly recommended in journal article. Have you ever caught yourself or anyone else inadvertently stating "intrathecal vin**CRIS**tine" instead of "intravenous vin**CRIS**tine" as the proper route of administration? We all know that it would result in a fatal error if carried out. Maybe it is the fact that we are so used to warning about "intrathecal vin**CRIS**tine" that mentally mixing up the words "intrathecal" and "intravenous" has become a serious risk. In a recent article (Pathiraja H, de Abrew G, de Silva L, Fernando S, Randeny S, Mettananda S. Methotrexate-induced leukoencephalopathy presenting as acute-onset limb weakness in a child: a case report. *J Med Case Rep*. 2024;18[1]:475), the authors did that twice! The mistake then got through the peer review process and was published, thus accidentally indicating that a child diagnosed with acute lymphoblastic leukemia was on daily dex**AMETH**asone, mercaptopurine, weekly oral methotrexate, and "intrathecal vin**CRIS**tine" once every two weeks.

Mistakes can be made even in respected peer-reviewed publications, so do not immediately accept everything you read, especially when the statement seems questionable. We appreciate receiving information about this publication error from our colleague Andrew Seger, PharmD, a pharmacist from Boston's Brigham and Women's Hospital who tracks vin**CRIS**tine errors from around the world. ***Safety* briefs** in our February 9, 2017, and January 16, 2020, newsletters mention other cases where journal publications mistakenly associated vin**CRIS**tine with the intrathecal route.

Since we have heard people accidentally say, "intrathecal vin**CRIS**tine" when they mean intravenous, this is a concern that must be addressed, especially as more organizations move toward the use of neuraxial connectors (NRFit devices). Educate practitioners that if "intrathecal vin**CRIS**tine" is inadvertently

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look for risks that pose a threat to patient safety. Incorporate policies about error reporting that align with a Just Culture. Routinely meet with practitioners to discuss concerns related to tubing misconnections and foster increased communication and feedback. Regularly ask staff about safety issues and exhibit appreciative listening. Maintain confidentiality of those involved in misconnection events while sharing event details and lessons learned. For additional information, see our July 11, 2024, newsletter article, *Cultivate discussions in a psychologically safe workplace—Part I*.

Plan for device conversion. The ISMP ***Targeted Medication Safety Best Practices for Hospitals***, *Best Practice #4*, calls for organizations to ensure that all oral liquid medications that are not commercially available in unit dose packaging are dispensed by the pharmacy in an oral/enteral syringe that meets the ISO 80369 standard. If not already done, leaders should make it an organizational priority to convert to ENFit devices as soon as practical. In addition, as we expect NRFit devices to become more readily available in the near future, leaders should begin evaluating the feasibility of converting to NRFit devices. As mentioned in **Part I**, GEDSA will be hosting an NRFit webinar with practitioners from Gillette Children's on November 20, 2024 (*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.

Identify key stakeholders. Organizations should understand the scope of transitioning to new devices (e.g., ENFit, NRFit). This is not just a single department (e.g., pharmacy, nursing, anesthesia) initiative but requires stakeholders from across the organization. Gather a multidisciplinary transition team composed of prescribers and specialists (e.g., surgery, anesthesiology, emergency department, gastrointestinal, oncology), pharmacists and pharmacy technicians (inpatient and outpatient), nurses, dietitians, respiratory therapists, risk management, educators, case management, materials management, and outpatient clinic staff.

Complete an FMEA. Prior to transitioning to ENFit and NRFit devices within your organization, the team should complete a failure mode and effects analysis (FMEA) to identify and address potential failure modes. Assess the potential for tubing misconnections with medical devices, connectors, and tubing used in your facility, including those reported in the literature, and determine mitigation strategies.

Partner with device vendors. It is important to partner with device vendors to understand what products your organization will need based on your patient population. Create a list of current products (i.e., legacy products) and complete a crosswalk to understand what new products (e.g., ENFit, NRFit) will be needed. Organizations should plan for one device system (e.g., ENFit) conversion prior to transitioning to the next (e.g., NRFit).

Evaluate products. Once you have a list of the needed products, bring in samples including all syringe sizes and product variations such as ENFit bottle adaptors in different diameters. Have practitioners test the products so any issues and concerns can be addressed prior to going live. GEDSA has tool kits for ENFit and NRFit devices which are available for a nominal fee. Also work directly with device vendors to understand potential problems that other organizations have reported to prevent them within your organization.

Use simulation. Before implementing ENFit and NRFit devices, use simulation to evaluate the system. Simulate the workflow to test what does and does not work, gain crucial feedback from frontline staff, and identify any potential safety gaps. Consider holding "a day in the life" with a diverse group of end users to run real-life simulations to see how the devices work in your clinical settings. Evaluate all devices practitioners may use and ask end users to identify vulnerabilities. Discuss concerns with the team so they can correct any issues before implementation.

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communicated, a less experienced pharmacist or technician might place vin**CRIS**tine in a NRFit syringe, which would lead to the inadvertent intrathecal administration of the drug, resulting in severe harm and most likely imminent death. Continually reinforce with staff the need to always confirm that the word "intravenous" is associated with vin**CRIS**tine when indicating the route of administration. If not already done, take steps to ensure vin**CRIS**tine can ONLY be ordered by the intravenous route and administered after dilution in a minibag (ISMP ***Targeted Medication Safety Best Practices for Hospitals***, *Best Practice #1*). Prominently label vin**CRIS**tine with the statement, "**FOR INTRAVENOUS USE ONLY— FATAL IF GIVEN BY OTHER ROUTES**."

Error when scanning Fluzone barcode. There is a potential safety issue when scanning the 2-dimensional (2-D) barcode on **FLUZONE** (influenza vaccine) 0.5 mL single-dose prefilled syringes (**Figure 1**). In September 2024, Sanofi released an important correction of drug information for this product, which included 33 impacted lot numbers. Per Sanofi, the order of the product's lot number and expiration date embedded within the 2-D barcode were reversed, causing the data to not transfer appropriately into electronic medical record systems. The human readable information on the syringe label, including the national drug code (NDC), expiration date, and lot numbers are correct. While the letter includes copies of the corrected 2-D matrix barcode for practitioners to scan as a proxy, this is a workaround that can lead to errors.

Figure 1. A Fluzone vaccine syringe label that contains a 2-D data barcode with incorrect embedded data.

We previously warned against the use of proxy scanning, because scanning a barcode that is not attached to the actual product may lead to a false positive barcode scan, and the wrong vaccine may be administered.

We reached out to Sanofi to notify them of this concern. They informed us that the 2-D barcode issue has been resolved for future

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Designate resources. Leaders should provide support for staff before, during, and after the conversion. Routinely meet with end users to discuss the rollout, enhance communication, and gather feedback. Have the device vendors available for question and answer sessions.

Maintain an adequate supply of devices. Purchase, store, and maintain an adequate supply of devices (e.g., ENFit syringes) in all patient care areas where oral/enteral medications may be prepared or administered. Pharmacy should verify the syringes are in stock and readily available during monthly unit inspections. In our experience, even in hospitals that are committed to stocking ENFit syringes, they are not consistently used because they are not always available.

Educate practitioners. During orientation and annual competency assessments, educate staff to verify the access point and trace the line toward the insertion site/cuff before any connection is made. Review tubing connections during bedside handoff, at the change of shift, and during patient rounds. Take every opportunity (e.g., huddles, newsletters) to communicate the rationale behind using ENFit and NRFit devices as a forcing function to prevent wrong-route misconnections. During orientation stress that parenteral syringes should never be used to prepare or administer oral liquid medications and reinforce this practice on a regular basis. This information is not routinely included as part of the academic curricula for healthcare practitioners, nor does this safety issue appear in fundamental textbooks used by many academic settings. Hospital orientation may be the first time a new practitioner hears about this risk.

Plan for discharge and outpatient care. Assess all steps in the continuum of care to determine patient supply needs. If your organization is sending prescriptions to outpatient pharmacies for dispensing, learn what products the pharmacies will supply so that you know how to support patients. If your organization's outpatient pharmacy carries both legacy oral syringes and ENFit syringes, and pharmacists can access the electronic health record (EHR), use the EHR to confirm the route of administration and the device that should be used.

Educate patients. Educate patients about the type of devices they will need so they understand how to safely administer their medications. Prior to hospital discharge, and when patients are picking up medications at outpatient pharmacies, staff should confirm the route of administration (e.g., oral, enteral) to ensure patients have access to the correct products. If planning for ENFit device transition, notify patients (e.g., through the patient portal) well in advance of conversion.

Report and learn from errors. Encourage staff to report close calls and errors involving tubing misconnections internally. Share reports with device manufacturers, ISMP, and the FDA. Educate staff that the goal is to increase reporting, so actions can be taken to improve system reliability. Review internally reported errors as well as published external events. During safety huddles, share impactful stories and recognize staff for good catches, including those prevented through use of ENFit or NRFit devices. Communicate the meaningful impact of implemented changes that resulted from error reporting.

Additional Resources

- Global Engineered Device Supplier Association's (GEDSA's) website and ENFit Pharmacy Resource Guide
- Call to Action: Experience in Adopting the ENFit System to Guard Against Accidental Tubing Misconnections
- FDA "Examples of Medical Device Misconnections"
- Ethington S. Five tips for smooth adoption of safer enteral connectors. Nebraska Medicine's ENFit conversion designed to improve patient safety. PSQH website. Published April 26, 2021. Accessed August 30, 2024.

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products. If your organization purchases this product, check your inventory for impacted lot numbers. For products that have been affected, scan the linear barcode found on each syringe to confirm the correct product and NDC. Educate practitioners that they will need to manually enter the lot number and expiration date.

Child received an entire multiple-dose vial of COVID-19 vaccine. There is a risk of accidentally giving the entire undiluted vial of Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine for children aged 6 months to less than 5 years. The vaccine is available in cartons of 10 multiple-dose vials that have yellow caps and labels with yellow borders (**Figure 1**). The vials must first be diluted with 1.1 mL of 0.9% sodium chloride injection. This provides 3 doses of 3 mcg (0.3 mL) each. However, there is also a single-dose vial for children who are 5 years old to under 12 that does not require dilution. Both products may arrive frozen and must be thawed prior to use. Refer to the prescribing information for additional instructions about vial storage prior to and during use.

Figure 1. Each multiple-dose vial of the Pfizer-BioNTech COVID-19 vaccine for ages 6 months to less than 5 years must be diluted prior to use and contains 3 doses of 0.3 mL each.

There is a risk that some users may confuse the two formulations and think that neither needs to be diluted. In a recent vaccine error report sent to ISMP, a prescriber ordered a COVID-19 vaccine 0.3 mL (3 mcg) intramuscularly for an 18-month-old child. In this case, a medical assistant entered the proper vaccine in the child's electronic health record but prepared and administered the entire undiluted contents of the vial. The carton and vial state, "DILUTE PRIOR TO USE," and the vial states, "after dilution—3 doses of 0.3 mL," but this may be overlooked by practitioners.

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- Larimer C, Reddick C. Making connections: practical transition techniques from legacy to ENFit enteral feeding tubes [White paper]. Salt Lake City, UT: Moog Medical. 2023. Accessed August 30, 2024.
- Institute for Safe Medication Practices (ISMP). NRFit: A global "fit" for neuraxial medication safety. *ISMP Medication Safety Alert! Acute Care*. 2020;25(14):1-4.

References

1) Simmons D, Symes L, Guenter P, Graves K. Tubing misconnections: normalization of deviance. *Nutr Clin Pract*. 2011;26(3):286-93.
2) Ethington S, Volpe A, Guenter P, Simmons D. The lingering safety menace: a 10-year review of enteral misconnection adverse events and narrative review. *Nutr Clin Pract*. 2024;39(5):1251-58.

Your *Reports* at *Work*

Nymalize oral solution now available in prefilled ENFit syringe. **NYMALIZE** (ni**MOD**ipine) 6 mg/mL oral solution is indicated for the improvement of neurological outcomes by reducing the incidence and severity of ischemic deficits in adult patients with subarachnoid hemorrhage. ISMP has been a proponent of the commercially available oral solution since it was first marketed. Prior to Nymalize, only liquid-filled gel capsules of ni**MOD**ipine were available. Errors sometimes occurred when the drug was extracted from the liquid-filled gel capsules with a parenteral syringe and needle to facilitate administration of the liquid orally or through a feeding tube. Unfortunately, the drug extracted from the gel capsules was sometimes accidentally administered intravenously (IV). Intravenous injection can cause profound hypotension, sometimes leading to fatalities.

In our May 21, 2020 newsletter, we shared that the manufacturer of Nymalize was discontinuing their unit dose cups and 473 mL bottles and transitioning to a prefilled legacy oral syringe. This led to concerns from hospitals that had converted to ENFit connectors, which are not compatible with legacy oral syringes. The company was considering ISMP's concern, with an aim to establish a resolution to the ENFit incompatibility issue. Since then, in addition to the prefilled oral syringes, the manufacturer, Azurity Pharmaceuticals, not only has a Nymalize 237 mL oral solution bottle available, but on September 3, 2024, they announced that the US Food and Drug Administration (FDA) approved their new formulation of Nymalize 30 mg/5 mL prefilled ENFit syringe. Providing the medication in ENFit syringes, which are only compatible with ENFit connectors, can prevent misconnections and further reduce the risk of oral liquids being administered intravenously (IV). Organizations should assess based on their patient populations (e.g., adult versus pediatric) which formulation(s) (e.g., oral syringe, ENFit syringe, bottle) should be available on their formulary.

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Report medication and vaccine errors to ISMP: Please call 1-800-FAIL-SAF(E), or visit www.ismp.org/report-medication-error. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

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The Pfizer-BioNTech COVID-19 vaccine intramuscular injection 2024-2025 formula for ages 5 years to less than 12 years has blue vial caps and labels (**Figure 2**). These are available as single-dose vials that should NOT be diluted. They each contain 1 dose of 0.3 mL (10 mcg).

If your organization purchases Pfizer-BioNTech COVID-19 vaccines, build order sentences with guidelines in the EHR that will help practitioners select the correct product and dose based on age; include preparation instructions that specify if the product is a single-dose vial that should not be diluted or a multiple-dose vial that must be diluted. Store vaccines in separate bins or containers based on name and formulation. Consider the use of signage in storage locations and/or auxiliary labels on the cartons and vials that specify if dilution is or is not required.

Figure 2. Pfizer-BioNTech COVID-19 vaccine for ages 5 years to less than 12 years is supplied as a 0.3 mL single-dose vial that should not be diluted.

When possible, the pharmacy should prepare and label vaccine syringes. If prepared outside of the pharmacy, provide practitioners with preprinted labels to affix to the prepared syringe specifying the vaccine name, indicated age range, and dose. Use barcode scanning before vaccine administration. Educate staff that the vaccine for patients 6 months to less than 5 years, must be diluted and once diluted, the vial will contain 3 doses. They should administer a 0.3 mL (3 mcg) dose. The vaccine for patients 5 years to less than 12 years, should not be diluted and they should administer a 0.3 mL (10 mcg) dose. Consider sharing immunization resources such as the tables provided by the Centers for Disease Control and Prevention (CDC).

Tuesday, December 10, 2024

Civic Theatre – New Orleans 6:00 pm

2024 Michael R. Cohen Lifetime Achievement Award Winner

David W. Bates, MD, MSc

David W. Bates, MD, MSc, Medical Director of Clinical and Quality Analysis, Mass General Brigham; Senior Physician and Director, Center for Patient Safety Research and Practice, Brigham and Women's Hospital; Professor, Harvard Medical School and Harvard T.H. Chan School of Public Health

Join us in December for our annual Cheers Awards celebration, where we will celebrate the amazing abilities of individuals and organizations that have advanced medication safety in the past year.

You can help share their **"magic"** with the healthcare community by attending the awards dinner and/or supporting the event! Your participation brings attention to advances in medication safety and enables ISMP to continue its lifesaving work.

For support opportunities and/or to register for the dinner, visit: www.ismp.org/cheers

Educational Sessions with ISMP Speakers at the 2024 ASHP Midyear Clinical Meeting

Please stop by and see us in booth #1813!

Tuesday, December 10, 2024

ISMP Medication Safety Update 2024
8:00 am – 9:30 am CT
Room 272 Level 2

Get in Top Form with the 2024 Health Technology and Patient Safety Hazards
2:00 pm – 3:00 pm CT
Room 272 Level 2

The (Not So) Big Easy of Safety: Measuring Meaningfully
3:30 pm – 4:45 pm CT
Room TBD

Wednesday, December 11, 2024

Executive View: Leaders Discuss Drug Shortage Policy and IV Fluid Updates
7:45 am – 9:45 am CT
Room TBD

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To show your support, visit:
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