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Educating the Healthcare Community About Safe Medication Practices

Take action to prevent tubing misconnections and patient harm—Part II

Tubing misconnections, or inappropriate connections between devices with different intended uses, have resulted in serious harm or death.[1,2] In Part I, 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.

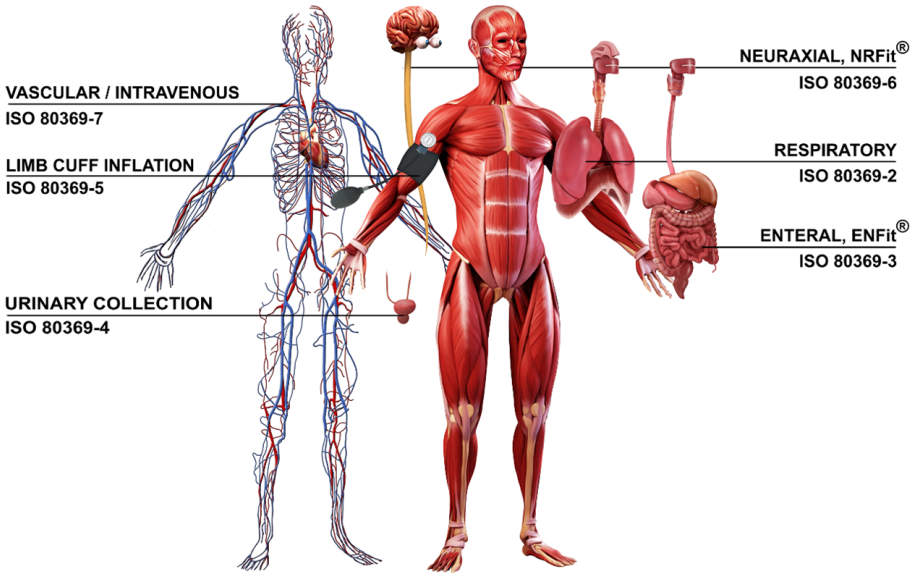

Figure 1. The ISO 80369 series has unique tubing connectors for each system that are incompatible with one another. Photo courtesy of GEDSA (www.stayconnected.org).

Recommendations

The survey data showed that tubing misconnections are common 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, where safety is a primary value in the organization and staff continually 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

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Worth repeating...

SUMAtriptan wrong route errors continue

ISMP has previously warned about wrong route errors with **SUMA**triptan, most recently in our June 2023 newsletter. **SUMA**triptan injection for migraine and cluster headaches should be administered as a subcutaneous injection, but we have received reports of it being given intravenously (IV). Most of these errors have occurred while practitioners were simultaneously administering several IV medications to patients and did not notice that **SUMA**triptan should only be administered subcutaneously.

The recent errors were attributed to the drug being described as an injection and practitioners assuming that meant it should be given IV. In one report, the subcutaneous route was displayed on the medication administration record (MAR), but the nurse saw "INJ" in the drug description and administered it IV. In a second report, a nurse saw the word "injection" after the medication name in the MAR, and also thought this meant it should be administered IV.

Figure 1. SUMAtriptan kit contains materials for a subcutaneous injection, including a subcutaneous needle and a warning on the kit label, "Subcutaneous Use Only."

To help prevent these types of errors, we thought it was ***Worth* repeating** some of the strategies presented in our previous articles. If pharmacy does not prepare and dispense syringes of **SUMA**triptan as needed, create a kit that contains the drug vial with an appropriate size syringe and subcutaneous needle (**Figure 1**). Add an auxiliary label to the kit to specify for "subcutaneous use only."

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appreciative listening. Maintain the confidentiality of those involved in misconnection events while sharing event details and lessons learned.

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 (enteral/oral) devices as soon as practical. In addition, as we expect NRFit (neuraxial [spinal and epidural]) devices to become more readily available in the near future, leaders should begin evaluating the feasibility of converting to NRFit devices.

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, radiology), 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.

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.

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>*Worth* repeating

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As an alternative, consider using the nasal formulation of **SUMA**triptan, which has a similar onset of action. While there are also autoinjectors and pens available, these are meant for self-injection by patients. To prevent these types of errors from occurring, manufacturers should provide subcutaneous medications in prefilled syringes with attached subcutaneous needles (and safety guards) to facilitate the correct route of administration.

Also, since this error continues to happen, we wonder why some practitioners interpret "injection" or "INJ" with the drug's name and drug description as meaning the medication is for IV administration. Many injectable medications will include the words "injection" or "for injection" with their drug names but are intended for only subcutaneous or intramuscular administration. We have not received repeated reports of wrong-route errors with most of those products. So, why for **SUMA**triptan? We would be interested in learning why this interpretation happens with **SUMA**triptan. Please share your thoughts with us at: ismpinfo@ismp.org. If this is identified as a problem for this drug and others, it may be time to explore whether drug descriptions should contain wording like "INJ" or provide a specific route only.

SAFETY wires

A dexmedeTOMIDine infusion almost administered instead of clindamycin. A nurse in a pediatric medical-surgical unit obtained a bag of what she thought was clindamycin (300 mg/50 mL) from an automated dispensing cabinet (ADC). The nurse scanned the barcode prior to administration and identified it was actually a bag of dexmede**TOMID**ine injection (200 mcg/50 mL). A pharmacy technician had mistakenly stocked the dexmede**TOMID**ine bag in the clindamycin bin in the ADC during the stocking process. Both products, made by Baxter, come in 50 mL bags and have nearly identical labels with similar colors, fonts, and designs (**Figure 1**, page 3).

Upon investigation, the hospital found that during the ADC stocking process, a pharmacy

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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, especially when staff are working with students, 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 post-acute facilities or outpatient pharmacies for dispensing, learn what products the facility and pharmacy will provide to the patient 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 and how they should and should not be used 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

- 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.
- 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! Nurse AdviseERR.* 2020;18(8):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.

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technician scanned the barcode on only one of the clindamycin bags to access and refill the clindamycin bin (following their process to only scan one product) and then placed a dexmede**TOMID**ine bag in the clindamycin bin in error. The pharmacy had previously purchased these medications from different manufacturers and had not identified the look-alike packaging when the new products were brought into the organization. The pharmacy is now purchasing dexmede**TOMID**ine from a different manufacturer to avoid future mix-ups.

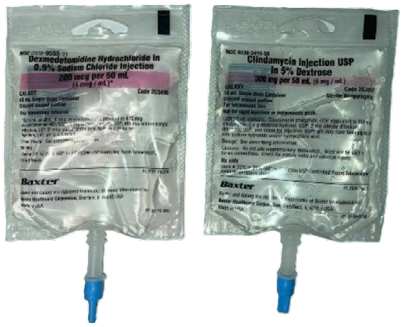

Figure 1. Dexmede**TOMID**ine injection (200 mcg/50 mL) (left) and clindamycin (300 mg/50 mL) (right) injection bags by Baxter look nearly identical.

Barcode scanning technology should be used in the pharmacy to confirm that medications chosen for distribution to the ADC match the medications listed on the ADC fill report, and ensure each individual product (e.g., each bag) is checked. Those loading the ADC should use barcode scanning to confirm the accurate placement of medications in the correct drawer or pocket. Finally, prior to administering the medication, employ bedside barcode scanning technology to confirm that the selected medication matches what is included on the patient's medication administration record.

MethylPREDNISolone injectable suspension was almost administered instead of triamcinolone. A prescriber ordered an intra-articular dose of triamcinolone 40 mg/mL injectable suspension for a patient being treated for joint inflammation in the radiology department. A nurse inadvertently removed a nearly identical-looking carton of methyl**PREDNIS**olone 40 mg/mL injectable suspension from a shelf where triamcinolone was stored nearby. The radiology department did not have an automated dispensing cabinet (ADC) and had not implemented barcode medication adminis-

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what's in a Name?

The "-grastim" drug stem name

Medications that end with the suffix "-grastim" belong to a class of medications known as granulocyte colony-stimulating factors (G-CSF). This class of medications belongs to a larger drug class of CSFs with the stem suffix "-stim." This article focuses only on "-grastim" stem name drugs.

G-CSFs are drugs that are used to stimulate hematopoietic cells in the bone marrow to produce more neutrophils (white blood cells). G-CSFs bind to specific cell surface receptors to trigger signaling pathways that stimulate proliferation, differentiation, commitment, and end-cell function activation. This leads to increased production and activity of neutrophils within the bone marrow.

Currently, there are four single-agent G-CSFs approved for use in the United States (**Table 1**). G-CSFs mainstay of treatment is prevention of severe neutropenia. They are typically given following a neutropenic event or the administration of cytotoxic chemotherapy. These agents are used to shorten the period of severe neutropenia and reduce the risk of bacterial and fungal infections. Filgrastim was the first approved medication in this drug class in 1991. In addition, it is also approved for recovery following hematopoietic stem cell transplant and severe chronic neutropenia (congenital, idiopathic, or cyclic). Pegfilgrastim has also been shown to increase survival in patients who experience Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS), which denotes stem cell injury following radiation exposure.

Table 1. List of G-CSFs available in the United States.

Generic name(s)	Brand name(s)
filgrastim	**GRANIX**, **NEUPOGEN**, **NIVESTYM**, **NYPOZI**, **RELEUKO**, **ZARXIO**
pegfilgrastim	**FULPHILA**, **FYLNETRA**, **NEULASTA**, **NEULASTA ONPRO**, **NYVEPRIA**, **STIMUFEND**, **UDENYCA**, **UDENYCA ONBODY**, **ZIEXTENZO**
eflapegrastim	**ROLVEDON**
efbemalenograstim alfa	**RYZNEUTA**

All four drugs are available in prefilled syringes for subcutaneous administration. Some brands of pegfilgrastim (Neulasta Onpro, Udenyca Onbody) are available as an on-body injector, which is a pod filled with the drug that is applied to the patient's skin by a healthcare provider to administer the dose over a specific duration (5 minutes for Udenyca or 45 minutes for Neulasta). Udenyca is the only agent available as an autoinjector pen. Filgrastim is also available in a formulation that may be given as a short infusion over 15 to 30 minutes or a continuous infusion with a maximum duration of 24 hours to allow the body time to metabolize the cytotoxic drugs before stimulating new neutrophil production.

Filgrastim is typically dosed once daily, and dose adjustments vary depending upon duration and severity of neutropenia with a goal to obtain a specific absolute neutrophil count (ANC). Pegfilgrastim, eflapegrastim, and efbemalenograstim alfa are given once per chemotherapy cycle. When used to treat H-ARS, pegfilgrastim is given once a week for two doses. Due to potential cell sensitivity, G-CSFs should not be given earlier than 24 hours following cytotoxic chemotherapy.

Common side effects include fatigue; gastrointestinal upset; and bone, back, or limb pain. Serious adverse reactions may include splenic rupture, acute respiratory distress syndrome, sickle cell crisis, glomerulonephritis, capillary leak syndrome, leukocytosis, thrombocytopenia, myelodysplastic syndrome, acute myeloid leukemia, and aortitis. Filgrastim also has a risk of cutaneous vasculitis (purple spots or redness on the skin). Patients should inform their healthcare provider of any signs or symptoms of a serious adverse reaction. G-CSFs are contraindicated in patients with a history of serious allergic reactions to filgrastim products. Patients should be given appropriate instructions for use and counseled on injection technique depending upon the prescribed dosage form.

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tration (BCMA) scanning. Fortunately, when preparing the dose, the nurse identified that it was the incorrect medication. Both products, made by Amneal, are the same concentration and came in the same size cartons with similar colors, fonts, and designs (**Figure 1**).

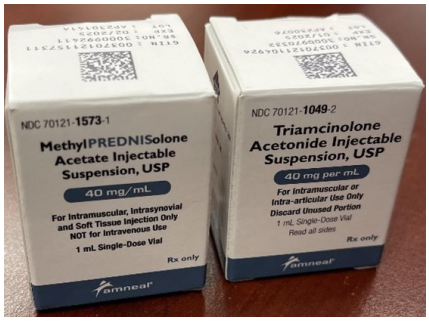

Figure 1. Methyl**PREDNIS**olone 40 mg/mL suspension (left) and triamcinolone 40 mg/mL suspension (right) by Amneal, came in nearly identical cartons.

When possible, hospitals should have ADCs in clinical areas such as the radiology department to support safe and secure medication distribution and require pharmacist review and approval prior to allowing access to medications. In addition, the ISMP ***Targeted Medication Safety Best Practices for Hospitals***, *Best Practice #18* calls for maximizing the use of barcode verification prior to medication and vaccine administration by expanding use beyond inpatient care areas. Organizations should specifically target clinical areas with an increased likelihood of short or limited patient stays, including radiology. Use barcode scanning when receiving, dispensing, filling the ADC, and prior to medication administration.

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