

Acute Care ISMP Medication *Safety Alert!*[®]

Educating the Healthcare Community About Safe Medication Practices

URGENT! Health systems need to plan **NOW** for upcoming changes in enteral feeding device connectors



PROBLEM: Are you ready for the design changes coming soon for enteral feeding device connectors? While ISMP and other organizations and agencies have repeatedly publicized the upcoming global changes with all enteral device connectors, we are not confident that healthcare organizations are adequately preparing for such a significant change. The new ISO enteral connector design will no longer be Luer-compatible and will require major changes in enteral nutrition practices, policies, procedures, and processes that need planning. These new connectors will impact nurses, pharmacists, physicians, dieticians, caregivers, and patients across the continuum of care. We are concerned that healthcare organizations will be ill-prepared when the new enteral connectors begin to be systematically introduced later this year and into 2015. Our concern is heightened by several unresolved process dilemmas that the change will undoubtedly trigger, particularly related to preparation, dispensing, and administration of enteral medications.

Enteral device connector changes

In the first phase of changes, which have been in place since 2012, enteral feeding administration sets with the new enteral-only fitting at the proximal end have been introduced. This connector fits into the feeding substance container (**Figure 1**). In the next phase, which will begin by the fall of 2014, manufacturers will distribute administration sets with the new enteral-only connector at the other end that connects to the feeding tube (PEG-tube, G-tube, etc.). The new enteral-only connector has been named ENFit to

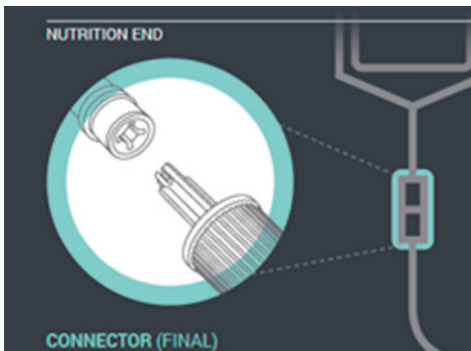


Figure 1. Enteral feeding administration sets already have an enteral-only connector that fits into the feeding container (nutrition end). (Picture provided by GEDSA.)

differentiate it from a Luer connector. Because new feeding tubes with the ENFit connector will not be available until the second quarter of 2015, a temporary transition adapter will be attached to the administration set (**Figure 2**). The transition adapter will be available for a specified time to assure that patients with older feeding tubes will not need an immediate replacement with a newer feeding tube. But eventually, the manufacturers of feeding administration sets will remove the transition

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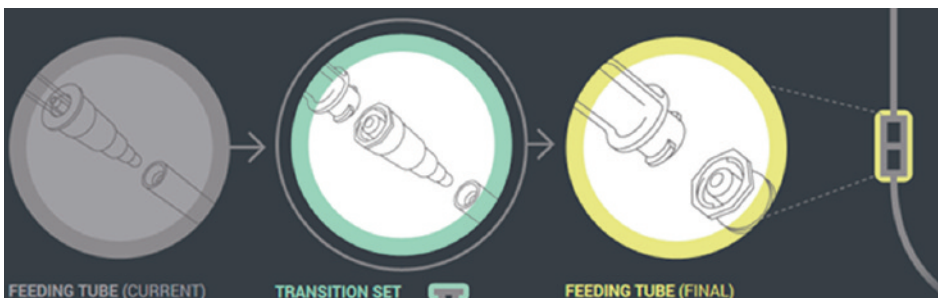


Figure 2. A new ENFit Transition Connector will be used to connect the feeding tube to the administration set until new feeding tubes with ENFit connectors are available (second quarter 2015). (Picture provided by GEDSA.)

Worth repeating...



Another dangerous Ofirmev-Naropin mix-up

An elderly surgical patient in a post-anesthesia care unit was prescribed a dose of IV acetaminophen (**OFIRMEV**). The patient's nurse picked up what she thought was an infusion bottle of acetaminophen from a nearby table and began to infuse it. After just 10 minutes, the patient experienced tonic-clonic seizures. It turned out that someone had placed an infusion bottle of ropivacaine (**NAROPIN**) near the acetaminophen,



Figure 1. Ofirmev and Naropin mixed up yet again.

and the nurse picked up the wrong container. Emergency steps were immediately carried out, including lipid infusion, and the patient recovered. The local anesthetic ropivacaine is used for epidural infusion when a prolonged anesthetic block is needed. It is also used for peripheral nerve blocks but never given IV, which can lead to cardiac arrhythmia or arrest.

This is the fourth report we have received about this potentially fatal mix-up in which a glass bottle of Naropin was mistaken for Ofirmev (**Figure 1**). In certain areas of the hospital, like the perioperative area, these drugs may be the only two in glass ready-to-use infusion bottles. If they are available concurrently, take steps to reduce the chance of a mix-up.

First, make sure staff are aware of the reports of mix-ups that ISMP has received. Consider adding auxiliary labels (for nerve block and epidural use only) to the Naropin containers before dispensing the product from the pharmacy. If possible, limit storage

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sition adapter from the package. Early in 2015, a new enteral syringe with the ENFit connector will be available

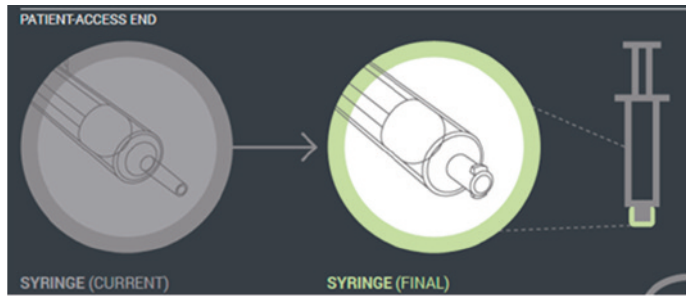


Figure 3. Enteral syringe (coming in 2015). (Picture provided by GEDSA.)

Unresolved process dilemmas

Once enteral syringes can only be used to administer liquid medications via a feeding tube, unit doses of liquid medications can no longer be prepared or administered using an oral syringe. While ISMP strongly recommends dispensing all medications in patient-specific doses, use of the new enteral syringes for this purpose raises two concerns:

- 1) **No bottle adapters.** Currently, there are no bottle adapters compatible with the ENFit connector that can be used with enteral syringes to easily draw up unit doses of liquid medications from bulk containers of the medicine. Screw on, snap in, and Christmas Tree-type adapters are available for use with oral syringes, but not for the new ENFit syringes. Industry has been made aware of the critical need for adapters. Although we have not heard back about plans to produce them, we are hopeful that details will soon be provided.
- 2) **No caps.** There is no cap currently designed for use with the new enteral syringes, making transport of pharmacy-filled syringes to patient care units problematic. Again, industry has been made aware of the need for syringe caps. Clearly, both caps and bottle adapters are needed to dispense liquid medicines in ENFit syringes.

Attend a **FREE Premier webinar (non-members invited) on August 20, Advisor Live: New Standards for Medical Tubing Connectors—Are You Ready?** For details, visit: <https://events.premierinc.com/ei/getdemo.ei?id=509&s=07C1586JR>.

SAFE PRACTICE RECOMMENDATIONS: Healthcare organizations need to plan ahead to ease the challenge of transitioning to the new enteral feeding device connectors and associated drug delivery. Awareness alone will not be enough to prepare organizations for the transition. Consider the following recommendations.

Form an implementation team. Form an interdisciplinary team that reports to the pharmacy and therapeutics and/or clinical safety committees to assess the existing systems, processes, and protocols that may need to be changed during and after transition to the new enteral connectors. The implementation team should specifically target:

- **Communication.** Reassess/improve/create a plan for communication between patient care units and the pharmacy when liquid medications are required for patients and how they will be administered (e.g., oral or enteral).
- **Dispensing.** Reassess how enteral liquid medications will be dispensed from the pharmacy. ISMP strongly recommends dispensing patient-specific unit doses in enteral syringes and has been in contact with manufacturers about the need for enteral syringe caps and bottle adapters for this purpose. While we are reasonably

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in automated dispensing cabinets (ADCs) to only one of the drugs, and store the products in locked, lidded compartments. For safety, some ADCs may allow “issue confirmation,” where you scan the product’s barcode to assure it’s placed in the correct ADC location, and “removal confirmation,” where you scan the barcode to assure the correct product has been removed from the ADC. New label technologies with barcode scanning may also be helpful in confirming that the correct product has been selected.

SAFETY briefs



Time-waster, error-maker. We get why people like to coin abbreviations for personal use. They are time-savers, may help avoid misspellings of product names, and are convenient for labeling when space is limited. The problem is, they’re not necessarily understood by others.

Check out the label on the syringe in **Figure 1**, which we assume holds **NAROPIN** (ropivacaine) 0.5%, 20 mL, combined with 10 mL of bupivacaine 0.25% and **EPINEPHRINE** injection 1:200,000. Evidently the syringe was not used immediately because the person who sent us the photo said it “serves as an example of how not to label a syringe with a coined abbreviation as well as improper preparation in advance of use.” It should also be noted that both vials are single-dose vials, so the syringe of medication should have been used immediately, and the vials should have been discarded.

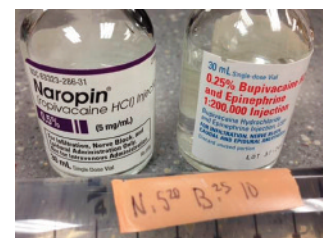


Figure 1. What’s in the syringe as im—that’s labeled using abbreviations? proper preparation in advance of use.” It should also be noted that both vials are single-dose vials, so the syringe of medication should have been used immediately, and the vials should have been discarded.

Personally coined abbreviations may be convenient for the user but they turn out to be time-wasters and error-makers for others. This unsafe practice should not be tolerated in hospitals.

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optimistic about the availability of these devices once enteral syringes are on the market, organizations should determine an alternative process for safely dispensing patient-specific doses in labeled, bar-coded, unit-dose cups or vials.

- **Transitioning.** Establish a transition plan in cooperation with hospital purchasers and enteral device suppliers.

Stay updated. Assign an individual or subgroup of the implementation team to stay updated and share transition updates with the full team. Maintain regular contact with:

- **Stay Connected.** The Global Enteral Device Supplier Association (GEDSA), the coalition formed to help introduce new medical device connectors, maintains a *Stay Connected* website (www.stayconnected2014.org/) to keep healthcare providers up-to-date. Email notifications are available when new information has been posted.
- **ISMP.** We will provide regular updates impacting enteral connector transition (e.g., availability of caps, bottle adapters, educational programs) (www.ismp.org/).
- **Purchasers/suppliers.** Stay in the loop to receive notifications and other information provided by purchasers and suppliers as the transition moves forward.

Reinforce purpose of change. Continue to make staff aware of the transition to new enteral connectors. Remind them that the initiative will enhance patient safety by reducing the risk of harmful tubing/catheter misconnections (e.g., enteral feeding injected IV).

Train staff. Train clinicians and materials/inventory management staff about the impending changes and any associated revised policies, procedures, or processes. Consider attending various webinars offered for **FREE**, including:

- **Advisor Live: New Standards for Medical Tubing Connectors—Are You Ready?**—hosted by Premier (non-members invited) on **August 20** (<https://events.premierinc.com/ei/getdemo.ei?id=509&s=07C1586JR>)
- **Raising Awareness: New Enteral Connectors**—a recorded 2014 webinar offered free by A.S.P.E.N. during August (www.ismp.org/sc?id=398)

Leg laceration following EpiPen use



Figure 1. First and second laceration visible on child's leg.

EPINEPHrine auto-injectors provide life-saving treatment of anaphylaxis. Prompt treatment in the home and community is associated with decreased morbidity and mortality. Many hospitals stock auto-injectors to enable rapid access to the medication in emergencies. Most often, auto-injectors are used successfully without complications. However, the ISMP National Medication Errors Reporting Program just received two reports of leg lacerations following **EPIPEN JR (EPINEPHrine)** auto-injector use.

A 4-year-old boy at daycare had an allergic reaction. The staff administered EpiPen Jr by holding the injector against the child's exposed lateral thigh. The child was standing with a daycare staff member behind him for support. Another staff member held the child's leg and administered the injection. The child kicked during administration, resulting in a

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Yearning for e-Rx everywhere! An order for **DESYREL (traZODone)** 50 mg was mistaken for **SEROQUEL (QUEtiapine)** 50 mg (**Figure 1**). Both medications may be

Desyrel 50 mg

Figure 1. An order for Desyrel (now only generic available) was mistaken for **SERO**quel.

used for patients with a psychiatric diagnosis. The error was only noticed by the patient right before he paid for the medication at the pharmacy because the cost of the **SERO**quel was much higher than what he was used to paying for the Desyrel.



New "Imaging Bulk Package" for use with power injectors. An **ISOVUE (iopamidol) Imaging Bulk Package (IBP)** from Bracco was just approved by the US Food and Drug Administration (FDA) and should be available later this year. This is a new dosage form designation, designed and labeled for multi-patient use in the CT suite in conjunction with an automated contrast injection system or a contrast management system approved or cleared for use with this new presentation. It can also be used with a syringe-based CT injection system and transfer set designed for multi-patient use.

Additionally, the **ISOVUE MULTIPACK PBP (Pharmacy Bulk Package)** has been renamed **ISOVUE PBP**. The PBP product should never be used in radiology for any purpose and should be limited to preparation of syringes in an ISO Class 5 environment in the pharmacy. The PBP product is **NOT** approved for use in automated contrast injection systems.

The introduction of the IBP product was apparently in response to the sterility issues we discussed in our newsletter (www.ismp.org/sc?id=400) with using PBPs of contrast for multiple patients in radiology. With the IBP product, FDA required testing for sterility and chemical continued on page 4—**Safety Briefs** >

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leg laceration. Believing the device had not been held in place long enough to deliver the drug (instructions call for the needle to remain in place for 10 seconds), the staff member attempted to re-inject the child using the same needle, which remained exposed. This resulted in a second laceration (**Figure 1**, page 3). The child's symptoms improved without additional **EPINEPH**rine. The two 8 cm lacerations were repaired with a combination of non-absorbable sutures, tissue adhesive, and Steri-Strips. Radiographic imaging and inspection of the needle showed it was bent, which likely prevented the needle cover from locking back in place when the needle was initially kicked free of the patient (**Figure 2**).



Figure 2. Radiographic image of EpiPen Jr showed that needle was bent.

In a very similar case, a 3-year-old boy with an allergic reaction during daycare was given a dose of EpiPen Jr in his exposed left lateral thigh. The child jerked his leg and sustained a 4 cm laceration. The daycare worker then subdued the child with her body weight and attempted to re-inject the same EpiPen Jr into his leg a second time to complete the 10-second administration period and ensure the drug had been fully delivered. The child was transported to the emergency department, where his symptoms improved without additional **EPINEPH**rine. He was sedated with intranasal midazolam, and the laceration was repaired with eight non-absorbable sutures.

These cases highlight features of the EpiPen and EpiPen Jr design and instructions for use that may have contributed to injuries. The instructions direct the user to hold the EpiPen and push firmly against the outer thigh, holding it in place for approximately 10 seconds (www.ismp.org/sc?id=399). The needle stays under the skin until the EpiPen is removed (<http://youtu.be/0SzkO4-a3NM>). Because of this, people may believe it takes 10 seconds for the medicine to be injected. However, the median time to inject the **EPINEPH**rine is much shorter, less than 3 seconds in most cases (Lieberman P. The 10-second rule and other myths about epinephrine and auto-injectors. *Ann Allergy Asthma Immunol.* 2011;107:189-90). The instructions don't say, "Never reinsert the same needle," or, "Don't worry if the needle comes out in less than 10 seconds. The drug is still likely delivered." The instructions for EpiPen use also do not mention patient restraint or the risk of injury with movement.

A newer device, the **AUVI-Q (EPINEPH**rine) auto-injector, has a needle that self-retracts in less than 1 second (<http://youtu.be/H6J2CU8lck8>). There is no risk of needle-associated injury once the needle is retracted. Providers using or prescribing **EPINEPH**rine auto-injectors for children should pay close attention to patient restraint prior to injection, as the child may move once aware of the injector or the initial discomfort during injection. This is particularly true for EpiPen Jr and other similar **EPINEPH**rine auto-injectors where the needle remains in the thigh for 10 seconds. If the needle is dislodged, reinsertion should never be attempted. If it was in place for at least 3 seconds, it is likely that **EPINEPH**rine was delivered. Repeat dosing should be determined based on clinical necessity.

ISMP thanks **Julie Brown, MDCM, MPH**, of Seattle Children's Hospital for providing the contents of this article based on errors that happened outside the facility in which she works.

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compatibility in simulated in-use studies with transfer sets, transfer syringes, and contrast injectors. But keep in mind, sterility is still a concern in radiology if the IBP products are not used exactly as described in the package insert. Other manufacturers besides Bracco may have similar IBP products available in the future.

Special Announcements

ISMP webinar

Join us on **September 18, 2014**, for our webinar, ***Beyond Medication Error Reporting: A New Approach for Understanding Medication Safety Risk***. Voluntary error reporting is just the tip of the iceberg when it comes to understanding medication safety. Identifying and measuring the level of risk within a system and understanding the reliability of processes is fundamental to safety improvement. During the webinar, participants will learn how to identify medication safety risks using methods beyond error reporting. Various approaches for collecting proactive, concurrent, and retrospective data will be discussed. For details, please visit: www.ismp.org/educational/webinars.asp.

Unique 2-day program

Attend the **ISMP Medication Safety INTENSIVE** workshop in **Nashville, TN**, on **October 2-3, 2014**. This workshop provides hands-on experiences with risk assessment, event investigation, error analysis, error-reduction strategies, measuring effectiveness, Just Culture, and more! For details, please visit: www.ismp.org/educational/MSI.

If you would like to subscribe to this newsletter, visit: www.ismp.org/sc?id=382



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Editors: Judy Smetzer, RN, BSN, FISMP; Michael R. Cohen, RPh, MS, ScD; Russell Jenkins, MD. ISMP, 200 Lakeside Drive, Suite 200, Horsham, PA 19044. Email: ismpinfo@ismp.org; Tel: 215-947-7797; Fax: 215-914-1492. This is a peer reviewed publication.