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

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, dietitians, 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

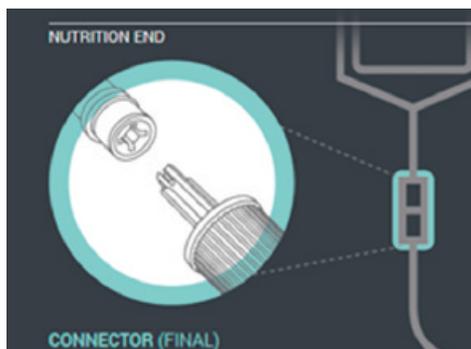


Figure 1. Enteral feeding administration sets already have an enteral-only connector that fits into the feeding container (nutrition end). (Picture provided by GEDSA.)

been named ENFit to 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
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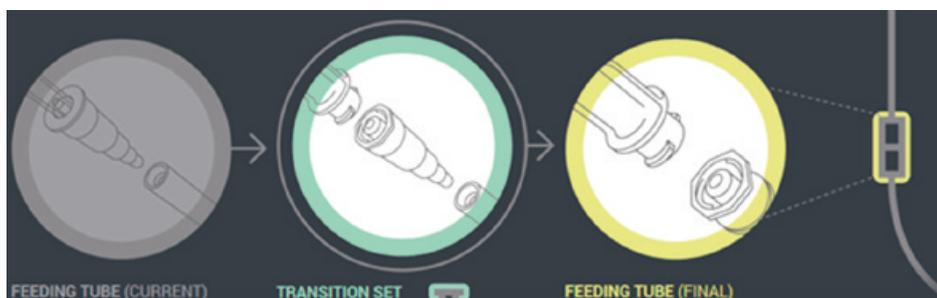


Figure 2. A new ENFit Transition Connector will be used to connect the feeding tube to the administration set until new feeding tubes with ENFit connectors are available (second quarter 2015). (Picture provided by GEDSA.)

check it out

Follow these recommendations to prepare for the new enteral device connectors.

- ✓ **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.
- ✓ **Establish a communication plan.** Have the implementation team 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).
- ✓ **Plan a dispensing process.** Have the implementation team 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 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.
- ✓ **Plan the transition.** Have the implementation team 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 the following stakeholders:

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> **Enteral**—continued from page 1

the transition adapter from the package. Early in 2015, a new enteral syringe with the ENFit connector will be available (**Figure 3**). Once new enteral feeding tubes are

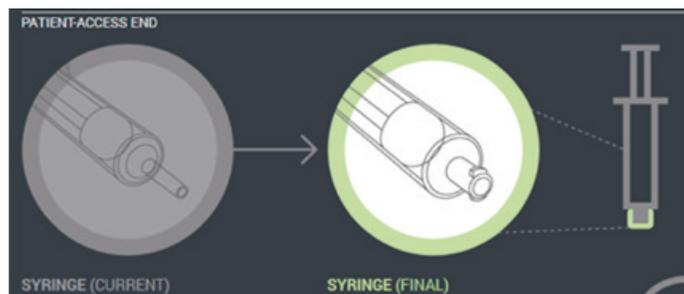


Figure 3. Enteral syringe (coming in 2015). (Picture provided by GEDSA.)

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.

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. Consider the recommendations in the **check it out** column to the right, starting on page 1, to prepare your organizations for the transition.

Vancomycin injection for oral use given IM

We recently received a report from a long-term care (LTC) pharmacy that discovered administration errors at two of its LTC facilities. The pharmacy had received orders for vancomycin 125 mg orally every 6 hours to treat *Clostridium difficile*-associated diarrhea for residents at these facilities. Vancomycin is available in capsule form for oral use. However, the powder in vials of vancomycin injection can also be reconstituted with sterile water to make an oral solution. Due to the high cost of **VANCOCIN** brand capsules and occasional problems obtaining specific vancomycin products, the pharmacy elected to send the LTC facilities vials of the injectable form of vancomycin powder along with diluent for the nurses to reconstitute the powder to make an oral solution. The vials and diluent were provided in two separate bags, along with directions for mixing and storing the oral solution, and the volume of solution to administer for each 125 mg dose. But soon after, a series of medication errors occurred.

The nurses at both facilities were unfamiliar with the practice of using injectable vancomycin for oral administration. Although nurses reconstituted the powdered drug

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> **check it out** continued from page 1

■ **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 the 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 healthcare practitioners and materials/inventory management staff about the impending changes and any associated revised policies, procedures, or processes. Visit the Stay Connected website often for opportunities to attend FREE webinars. Currently, the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) is offering a recorded 2014 webinar, **Raising Awareness: New Enteral Connectors** free during August (www.ismp.org/sc?id=398).

To The Point

If safety is making sure people are not harmed, and culture is how we do things around here, then the simplest definition of a safety culture is:

Making sure people are not harmed is how we do things around here.

---Institute of Nuclear Power Operations

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correctly, they administered each dose intramuscularly (IM). The error was discovered when the director of nursing at one LTC facility mentioned to a consultant pharmacist that she was concerned the medication had not been provided in capsule form and needed to be reconstituted by nurses at the facility. One patient received 5 doses of the drug IM before the error was detected. This resident experienced pain at the administration sites when the drug was injected (IM administration of the drug is not advised).

Unfortunately, vancomycin given by the parenteral route (IM or IV) does not treat a *C. difficile* infection in the bowel. This put the residents at risk for worsening infection, and the duration of oral therapy had to be extended to cover the missed treatment. It is also worth noting that parenteral vancomycin has been inappropriately prescribed to treat *C. difficile*, and oral vancomycin has been prescribed or otherwise used erroneously to treat a systemic infection in other patients.

For the treatment of *C. difficile* diarrhea, oral metronidazole may be a viable alternative if the patient is experiencing their first episode and it is not a resistant case (www.ismp.org/sc?id=355; www.ismp.org/sc?id=356). But if oral vancomycin is needed, and vancomycin injection will be reconstituted for oral use, pharmacists should prepare the solution in the pharmacy and provide each individual resident dose in an oral syringe, marked "FOR ORAL USE ONLY." Dispensing medications in the most ready-to-administer form should be the prevailing practice for all pharmacies that provide medications in hospitals and LTC facilities.

Topical anesthetics for teething infants

Lidocaine viscous is indicated for use as a topical anesthetic for irritated or inflamed mucous membranes of the mouth and pharynx and to reduce gagging when taking X-rays of the mouth or performing dental impressions. The US Food and Drug Administration (FDA) has not approved this product for use in children who are teething. Nevertheless, earlier this year we learned about a tragic event involving twin 1-year-old infants who were prescribed lidocaine viscous for that reason.

The first infant suffered a seizure at home, followed by cardiac arrest. She was successfully resuscitated by emergency medical personnel and transferred to a hospital. Since she had been playing with toy beads, the initial impression was asphyxiation. Just two days later the second twin also had a seizure and arrested. Tragically, this twin could not be resuscitated. Upon hearing about the second twin, concern for toxic exposure or ingestion was raised. Toxicology results for the first twin indicated toxic levels of lidocaine. It was learned the infant's physician had prescribed lidocaine viscous 2% for teething/irritability. Toxic levels of lidocaine were also noted in the second infant. It's unclear how the infants received an overdose of the medication.

Although many parents like to rub topical anesthetics on their baby's gums to treat the pain, the directions for use and potential for toxicity with these products are often not clear to parents and, sometimes, not even to their healthcare providers. One issue is that the anesthetic effects may be short-lived, resulting in well-meaning parents using the product more often than recommended. Parents have also been known to put the topical anesthetic into the infant's formula, or to soak a pacifier in the solution. This is a dangerous practice since it is difficult to determine the amount of medication the infant receives. Also, a portion of the medicine often ends up being swallowed. When that happens, the mucous membranes of the throat may become anesthetized (www.ismp.org/sc?id=392), which can affect the gag reflex and make it difficult to sense liquids during swallowing, increasing the risk of choking or aspiration.

As for anesthetic products like **ANBESOL** and **ORAJEL** that contain benzocaine, the same can occur, in addition to developing methemoglobinemia (www.ismp.org/ continued on page 4—Teething >

SAFETY wires



CMS: Follow up on infection control breaches. The Centers for Medicare & Medicaid Services (CMS) is telling state health department surveyors to notify appropriate state public health authorities when an infection control breach occurs, including several specific to medication administration practices that pose a risk of bloodborne pathogen transmission. The state authorities would need to perform a risk assessment and, as necessary, notify patients involved (www.ismp.org/sc?id=377). The breaches mentioned in the May 30, 2014, CMS memo include: using the same needle for more than one patient; using the same syringe, pen, or injection device for more than one patient; reusing a needle or syringe used for another patient to enter a medication container (e.g., vial, bag), and then using contents from that medication container for another patient; and using the same lancet/fingerstick device for multiple patients, even if the lancet is changed.



Updated High-Alert Medications List. ISMP extends our thanks to more than 200 pharmacists and nurses who completed our survey on high-alert medications between May and June 2014. We have analyzed the results (www.ismp.org/newsletters/acutecare/s/howarticle.aspx?id=83) and used the information to update the **ISMP List of High-Alert Medications in Acute Care Settings**. The updated list is now posted on our website at: www.ismp.org/sc?id=387. The updated list includes two additions: subcutaneous **EPINEPHRine** (IV **EPINEPHRine** is already on the list), and insulin U-500 (special emphasis). All subcutaneous and IV insulin are high-alert medications. However, insulin U-500 has been singled out for special emphasis to bring attention to the need for distinct strategies to prevent errors with this concentrated form of insulin.

Incidentally, a new study out of Denmark (Saedder EV, Brock B, Nielsen LP, Bonnerup DK, Lisby M. Identifying high-risk medication: a systematic literature review. *Eur J Clin Pharmacol.* 2014;70(6): 637-45) provides additional evidence re- continued on page 4—Safety Wires >

> **Teething**—continued from page 3

[sc?id=393](#)). Methemoglobinemia can occur within minutes after exposure, even the first time the product is used. It isn't very common, but children under 2 years of age appear to be at particular risk. In 2011, FDA issued an alert ([www.ismp.org/sc?id=394](#)) about the risks of over-the-counter benzocaine gels and stated that these products should not be used except under the advice and supervision of a healthcare professional. The American Academy of Pediatrics discourages topical anesthetic use ([www.ismp.org/sc?id=395](#)) and instead suggests using a rubber teething ring that's been chilled in the refrigerator (not the freezer). Pain medications like acetaminophen and ibuprofen can also be useful when given in conjunction with advice from a healthcare professional. The bottom line is, lidocaine viscous is not approved by FDA as a treatment for teething. For safety reasons, lidocaine viscous and benzocaine gels or liquids should not be used.

Issues with Medtronic MiniMed Revel insulin pump

Office staff at an endocrinology practice were asked to see a patient who was experiencing mysteriously low blood glucose levels while receiving insulin via a Medtronic MiniMed Revel portable infusion pump. The pump's data showed that the patient was getting boluses up to 10 units each during the night. The patient denied administering any doses, so it's suspected that he leaned over onto the pump while sleeping, putting enough pressure on the activation system to release a dose. We asked Medtronic about this, and the company has received rare reports of people accidentally rolling over onto the pump at night and activating a bolus dose. A patient would have to activate 2 buttons for the pump to actually deliver a dose, which is why this is a rare occurrence. There is a feature to lock out the keypad so that this doesn't happen. The patient was shown how to use this, which solved the problem.

A second patient also had mysteriously low blood glucose levels while using the Revel pump. In this case, it had nothing to do with accidentally activating the bolus system. Instead, this involved the patient entering erroneous information into the pump's software. The pump has a bolus dosing "wizard" that allows patients to enter their blood glucose and the amount of carbohydrate grams they've eaten. By mistake, the patient was accidentally entering the measured blood glucose into the carbohydrate field instead of the number of carbohydrates eaten. For example, a blood glucose level of "220" was entered in the carbohydrate field instead of 60 grams.

The safest way to administer a bolus dose is to use the glucose meter that goes with the pump. This automatically communicates the glucose level to the pump so the user does not need to manually enter the results. In this case, the patient's insurance did not cover the test strips for this pump, so the patient was using his own glucose meter and entering the results manually. Also, the pump will warn you when an entry is outside the usual range, but the warning can be overridden. In the latter case, the patient could not see the pump screens clearly because the backlighting is quite dim. Medtronic told us the light could not be made brighter. The company agreed to pass on the information from this report internally to consider whether any enhancements were needed to improve the device. In the meantime, if you have patients using this pump make sure you and your patients are familiar with all the features.

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garding the classification of certain drugs as "high-alert" (called "high-risk" in the study). The study's purpose was to define drugs that cause serious errors. After a meta-analysis of more than 70 studies of harmful events, 10 drugs or drug classes were identified as causing two-thirds of all fatal events, and 7 of those drugs or drug classes caused half of all serious errors. These "high-risk" medications included many on the ISMP list, including methotrexate, warfarin, opioids, and beta-blockers. The drug causing the most fatalities and serious harm was methotrexate. While insulin was included in the top 20 drugs causing serious harm, it ranked nineteenth of twenty. In the US, insulin was ranked at the very top of drugs causing serious illness or side effects. A few drugs are not on the ISMP list, including: nonsteroidal anti-inflammatory drugs, aspirin, and theophylline.

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. During the webinar, participants will learn how to identify medication safety risks using various approaches for collecting proactive, concurrent, and retrospective data. For details, 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**. For details, please visit: [www.ismp.org/educational/MSI](#).

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