

Nurse AdviseERR®

Educating the Healthcare Community About Safe Medication Practices

Update on implementation of the new ENFit enteral connectors

In 1996, during the first year of publishing our acute care newsletter, *ISMP Medication Safety Alert!*, we described cases of inadvertent intravenous (IV) administration of liquid substances intended for administration via feeding tubes (www.ismp.org/sc?id=567). Of course, incidents had been occurring long before that time, putting patients who simultaneously have IV lines and small bore nasogastric (NG) feeding tubes or percutaneously inserted gastric tubes at risk.

By now, most hospitals are aware of and in support of the global conversion to new enteral feeding device connectors that will take place during 2016 to eliminate, or at least significantly reduce, the risk of inadvertent parenteral connections. The new enteral device connectors, known as ENFit, will not be compatible with a Luer connection or any other small bore medical connector, thus preventing misadministration of enteral feedings or medications by the wrong route. However, the ENFit design changes have created potential drug administration dilemmas for hospitals, as mentioned in our April 9, 2015 acute care newsletter (www.ismp.org/sc?id=568).

To achieve a smooth transition, the Institute for Safe Medication Practices (ISMP), The Children's Hospital of Philadelphia (CHOP), and the American Society of Health-System Pharmacists (ASHP), organized an interdisciplinary meeting that was held at CHOP on July 16, 2015. More than



Figure 1. New ENFit female tip connects over male tip of filling device (left). Current oral syringe male tip fits within female filling device (right).

80 individuals from across the US attended, representing physicians, nurses, pharmacists, and pharmacy technicians from the pediatric and adult practice community, member companies from the Global Enteral Device Supplier Association (GEDSA), and patients. The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.), the National Association of Neonatal Nurses (NANN), and the Pediatric Pharmacy Advocacy Group (PPAG) cosponsored the meeting. A representative from the US Food and Drug Administration, Center for Devices and Radiological Health (FDA CDRH) also participated. The purpose of the meeting was to communicate several ongoing safety concerns from the field about the new enteral connector system so that industry and practitioners can best work together to address them.

During the meeting, GEDSA representatives reviewed circumstances in which misconnections can occur and presented a video about actual cases (www.ismp.org/sc?id=569). They then provided a timeline outlining the development of the new connectors, which began in 2006 after a Joint Commission *Sentinel Event Alert* (www.ismp.org/sc?id=570) called attention to the issue of catheter misconnections (2014 update: www.ismp.org/sc?id=571). This led to the creation of new global standards by the International Organization for Standardization, ISO

continued on page 2—ENFit >

Guidelines for adult IV push medications

ISMP recently released *Safe Practice Guidelines for Adult IV Push Medications*, which can be found at: www.ismp.org/sc?id=563. The guidelines are a compilation of safe practices that were developed as a result of a 2-day facilitated summit held in September 2014. The summit was funded through the generous support of BD. Fifty-six participants, representing a range of frontline providers, professional organizations, regulatory bodies, and product vendors from across the US attended the summit. Draft guidelines were developed and reviewed by participants, and shared on our website for comment. Each comment was considered when finalizing the safe practices. The guidance statements in the document represent a consensus for safe practices associated with IV push medication preparation and administration to adults. We thank those who submitted comments and our summit participants for their dedication to this project. Please take a moment to review the guidelines and share them with your colleagues.

10th ANNUAL ISMP CHEERS AWARDS



Each year, ISMP celebrates individuals and organizations that have set a standard of excellence in the prevention of medication errors during the previous 12 months. **Nominations for this year's CHEERS Awards will be accepted through September 11.** Join us for a gala at **The Chicory** in New Orleans on **December 8** as we celebrate this year's winners! Please visit www.ismp.org/Cheers/ to submit a nomination, register for the gala (click on Support), or make a donation to support ISMP medication safety efforts.

> **ENFit**—continued from page 1

80369-3. While the transition to new enteral connectors will happen first, other types of connectors for medical tubing, including respiratory, neuraxial, and urogenital, will be redesigned in the future. The introduction of ENFit syringes and feeding tubes has been delayed in the US, Canada, and Puerto Rico until the first quarter of 2016, with full implementation anticipated by July 2016.

Although healthcare practitioners and others understand the benefits of ENFit and want to see it succeed, potential problems with the new design that have been identified were discussed at the meeting. First, unlike current parenteral and oral syringes with male tips that fit into female connectors, ENFit syringes are the opposite. They have a female syringe tip that fits around a male connector on the feeding tube as well as new bottle adapters for filling syringes (**Figure 1**, on page 1). This presents challenges because the ENFit syringe now holds more volume in its dead space.

Because the male tip on the ENFit bottle adapter that is utilized by pharmacy will connect within the female tip of the syringe, displacement allows little or no liquid to remain in the dead space when the syringe is detached, capped (the cap is also male), and dispensed. During drug administration, if the syringe is filled using an ENFit adapter and then connected to the ENFit feeding tube, all of the medicine will reach the patient (**Figure 2**). However, if the ENFit syringe is filled with an ENFit adapter and the contents are given orally without an ENFit adapter (**Figure 3**), some liquid will remain in the syringe tip after administration—as much as 0.2 mL.

This lost volume in the dead space could be problematic for doses of 2 mL or less, which represents at least a 10% underdose of the medication. Representatives from CHOP shared data showing that more than 80 medications they use have liquid doses in volumes less than 2 mL, and they prepare as many as 1,250 such doses each day. Although less frequent, small volume enteral doses are also prepared for adults. Thus, using an ENFit syringe (filled with an ENFit adapter) for oral administration (without an ENFit adapter) could lead to clinically significant underdosing.

Ostensibly, ENFit syringes would be used to measure and administer liquids via connection to feeding tubes, and oral syringes would be used to measure and administer oral liquid medications. However, pharmacists wouldn't always know which syringe to use when preparing liquid medications since the delivery method (oral or enteral) may not be clearly communicated in a medication order. It would be helpful if physicians would order doses as "via NG or gastric tube" or "via mouth." However, a practitioner panel at the interdisciplinary meeting noted that prescribers are not always aware that a tube is being used to administer medications, and it may not be clearly noted in the medical record. Also, nurses may need to change the method of medication delivery during the course of therapy based on patient needs. When monitoring a patient's response to therapy, erroneous conclusions could be reached if the care team is unaware that a potentially significant percentage

continued on page 3—**ENFit** >

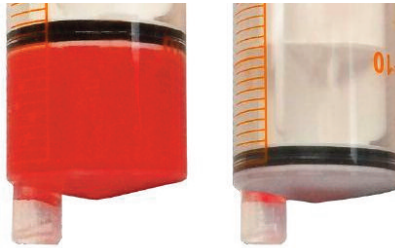


Figure 2. Medication drawn into an ENFit syringe in the pharmacy using an ENFit adapter, and then given via an ENFit device. The volume of medication in the syringe tip is the same before and after administration, so dosing is accurate.

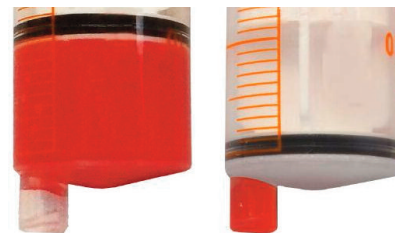


Figure 3. Medication drawn into a syringe using an ENFit adapter but given by mouth leads to under-delivery of medication. The volume of medication in the tip of the syringe differs before and after administration. The dose minus the drug leftover in the dead space was administered.

SAFETY wires



"TXA" mistaken as tenecteplase! A trauma patient in the emergency department (ED) required tranexamic acid (an antifibrinolytic) to control bleeding. The physician told the nurse to get "TXA." The nurse thought he said "TNK" (tenecteplase), a thrombolytic agent. She had the syringe in her hand and gave it to the physician to administer. Referring to tranexamic acid, the physician replied, "You can't push TXA; it has to be an infusion." At that point, the nurse said she thought TNK was requested, and the potentially fatal error was recognized and avoided. Both medications may be stored in automated dispensing cabinets (ADCs) in EDs and may be available via override since tranexamic acid is sometimes used to treat trauma patients who are bleeding, and tenecteplase is used to treat emergent cardiac cases. If tenecteplase had been administered, the patient may have bled further, leading to a fatal event.

After the close call, electronic references for TNK and TXA were removed from information technology systems, and warnings were placed in the computerized prescriber order entry system and ADC databases. The alerts, which state the indications for each drug, must be acknowledged before medication removal. Staff education about the use of these error-prone abbreviations in written, electronic, or spoken communications was also provided. This is another example of why ISMP's list of error-prone abbreviations (www.ismp.org/sc?id=558) includes avoiding the abbreviation of any drug name. Also note that the abbreviation "TPA" (alteplase) could possibly be confused with "TXA" and "TNK" as well, which could lead to a serious error. It is always best to use the complete drug name.



Seasonale or seasonal? Inaccurate or inappropriate allergies may be documented in health records when patients report "seasonal allergies." **SEASONALE**, the brand name of an oral contraceptive containing levonorgestrel and ethinyl estradiol, has been accidentally selected in the allergy field when the intention was

continued on page 3—**SAFETY wires** >

> **ENFit**—continued from page 2

of the dose was lost in the dead space. In addition, some patients may have their feeding tubes removed without pharmacy staff awareness, while others may be able to swallow medication, even with a tube in place. Such fluctuating conditions would likely lead to inefficiencies and rework for nurses and pharmacists. Furthermore, pharmacists and nurses would need two different filling systems (ENFit and oral), with separate filling devices and medication bottles. Pharmacy technicians may find it difficult to know which to use to prepare a medication. Because hospitals often prepare syringes of liquid medications ahead of time, many meeting attendees expressed a desire to maintain a single oral or enteral system, as is current practice, for preparing and dispensing liquid medications.

Additionally, there may be doses that nurses must prepare from pre-labeled unit dose cups of liquid medications, especially in hospitals without 24-hour pharmacy services. If an ENFit syringe without an ENFit filling device is used to draw up medications from a cup, the air in the dead space will form a bubble that must be removed for accurate dose measurement. If this is connected to an ENFit feeding tube, any remaining liquid in the ENFit syringe tip might be injected into the feeding tube, causing a small overdose (**Figure 4**). Ideally, it would be better to have either oral syringes that are compatible with the new system, or ENFit syringes that could be used with feeding tubes and for oral administration, to fully eliminate concerns about underdosing or overdosing.



Figure 4. Medication drawn from a cup but administered into an ENFit device can lead to over-delivery of medication. The volume of medication in the tip of the syringe differs before and after administration. The full dose plus the extra in the dead space was administered.

Complex human factors and patient care needs clearly dictate that the safe use of ENFit devices must not be wholly dependent on the perfect performance of nurses and pharmacists to always use the correct device in every unique situation, but rather on solutions based on system improvements. To that end, meeting participants discussed some existing industry initiatives and additional ideas that allowed most attendees to feel hopeful about the success of this massive undertaking. The importance of assuring that proprietary systems are compatible with one another was stressed, particularly given that patients may transfer from one institution to another, and home-bound patients will need to access supplies. A patient advocate caring for two special needs children at home raised this point.

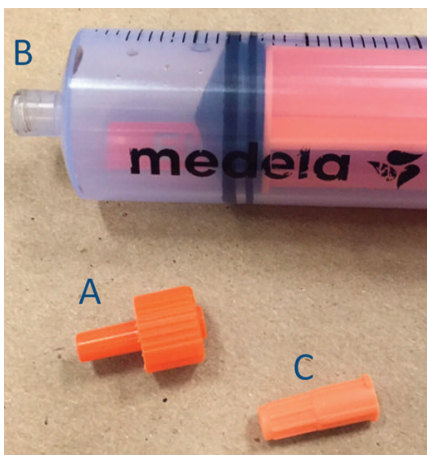


Figure 5. Syringe add-on device (A) attaches to ENFit syringe tip (B) to convert an ENFit syringe to an oral syringe. Part labeled "C" covers the add-on device tip.

ications might be excessively metabolized (during first pass through the liver). However, this would be a rare event and may not be a barrier to this option. Also, an oral syringe port already exists on some current (non-ENFit) feeding tubes. One

continued on page 4—**ENFit** >

> **SAFETY wires** continued from page 2

to document seasonal allergies. A hospital reported a persistent problem with healthcare providers selecting this choice. Their system accepts and records only actual substances (e.g., pollen, birch) to which a patient has as a specific seasonal allergen. So, "Seasonal" is not a choice, but staff see Seasonale listed and select it, believing they've found the right term. Thus, inaccurate allergy information is recorded, and the patient might be misdiagnosed with a birth control pill allergy in their medical record.

That's exactly what happened when we first reported this error in our May 2012 issue. A patient reported that she had seasonal allergies. The nurse typed 'seasonal' into the allergy database without realizing that the system converted it to Seasonale. Later, a medication reconciliation technician asked the patient about her allergy to Seasonale and learned that the patient did not have a uterus and had no need for the contraceptive, but she did experience seasonal allergies. In this case, no harm occurred, but one can imagine a scenario where a patient's oral contraceptive or hormone replacement therapy is never prescribed, or is discontinued inappropriately, based on the incorrect information.

If you list Seasonale in your allergy database, remind staff about potential mix-ups with seasonal allergies, and to never select this drug unless the patient is truly allergic to the medication.

⚡ Patches and suicide risk. A report describing improper disposal of a fentaNYL patch in the trash shed light on another issue with transdermal patches. Patients on suicide precautions may remove medication patches or obtain them from disposal bins and ingest large doses of the medication by chewing the patch. It is important for healthcare practitioners to be sure suicide precautions include an assessment to determine if the patient is wearing a transdermal patch upon admission. Also, it is important to avoid the use of patches in this population without carefully weighing the risks and benefits.

continued on page 4—**SAFETY wires** >

> **ENFit**—continued from page 3

style of feeding tubes, available from Corpak, is said to prevent Luer connections (www.ismp.org/sc?id=574). Hopefully, other companies will gain interest in pursuing this option.

Another suggestion was the use of a transition connector. This is an attachment that could be connected to an ENFit syringe when necessary for oral administration or be connected with an ENFit feeding tube. Several companies stated they have been working on such connectors; Medela showed one such device at the meeting (**Figure 5**, on page 3). This transition connector allows for medications to be drawn into an ENFit syringe with oral syringe bottle caps, requiring no change in practice. Then, at the bedside, if the medication is to be given orally, the transition connector should remain on the syringe for medication administration. However, if the medication is to be given through an ENFit feeding tube, the transition connector must be removed, and the ENFit syringe should be connected to the feeding tube ENFit connector. Both delivery methods are accurate. The only chance of an inaccurate dose is if the transition connector is removed and the medication is given orally.

Finally, NeoMed presented a new ENFit syringe tip concept which mimics traditional male-tipped oral syringes (**Figure 6**). This approach is intended to minimize low dose accuracy concerns while maintaining ISO 80369-3 compliance. It is intended for small doses when using small volume syringes. This tip configuration works with ENFit connections and minimizes dead space, which should also support direct oral administration. While still in development, initial results are said to be positive.



Figure 6. The new NeoMed small volume ENFit syringe design extends the fluid lumen to form a male-oriented tip within the female ENFit connector (colored white for visualization purposes only). The white portion inserts inside the internal lumen of an ENFit feeding tube connector, allowing the ENFit syringe to function similarly to oral syringes.

This interdisciplinary meeting exemplified how industry, regulatory agencies, national health organizations, practitioners, and patient advocates collaborated to find common ground, and all agree that change is necessary to keep our patients safe. While it is clear that work is still needed to assure that the ENFit system, designed to prevent one type of error, does not promote other types of errors, most meeting attendees walked away satisfied that industry has heard the concerns practitioners have raised and are acting in a positive manner to develop the best solutions. ISMP will continue to follow and report on progress.

The PowerPoint slides from ISMP and GEDSA used during presentations at the interdisciplinary meeting, and a LEAN A3 problem solving tool are available on the ISMP website at: www.ismp.org/docs/GEDSA. ISMP thanks NeoMed for providing Figures 2, 3, 4, and 6.

> **SAFETY wires** continued from page 3

And always make sure the patch is properly disposed of in a secure location, away from the patient.

Special Announcements

ISMP webinar

Join us on **August 27** for *Managing Human Error, At-Risk Behavior, and Reckless Behavior in a Just Culture*. As humans, we will make mistakes and drift into unsafe behaviors. However, a punitive response will not support safety, nor will the failure to address unsafe behavioral choices. Join us as we discuss how to address these complex issues in a manner that maximizes safety, is fair to the workforce, and supports an organization's mission and values. For details, visit: www.ismp.org/sc?id=349.

Unique 2-day program

Attend one of the ISMP Medication Safety **INTENSIVE** workshops being held in 2015: Bellevue, WA (near **Seattle**) on September 17-18; and **New Orleans** on December 4-5. This workshop provides hands-on experiences with event investigation, error analysis, error-reduction strategies, and more! For details, please visit: www.ismp.org/educational/MSI.

Annual Fund

Medication safety would be very different today without ISMP's advocacy efforts, which have led to hundreds of positive product and practice changes. ISMP has launched its **2015 Annual Fund** drive; please consider contributing to support the Institute in its fight against preventable medication errors. For more information or to make a charitable donation, go to: www.ismp.org/support.

If you would like to subscribe to this newsletter, visit: www.ismp.org/sc?id=384



ISMP Nurse AdviseERR (ISSN 1550-6304) © 2015 Institute for Safe Medication Practices (ISMP). Subscribers are granted permission to redistribute the newsletter or reproduce its contents within their practice site or facility only. Other reproduction, including posting on a public-access website, is prohibited without written permission from ISMP. This is a peer reviewed publication.

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

Editors: Ann Shastay, MSN, RN, AOCN; Judy Smetzer, BSN, RN, FISMP; Michael Cohen, RPh, MS, ScD (hon), DPS (hon); Russell Jenkins, MD; Ronald S. Litman, DO. ISMP, 200 Lakeside Drive, Suite 200, Horsham, PA 19044. Email: ismpinfo@ismp.org; Tel: 215-947-7797; Fax: 215-914-1492.