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ISMP

Acute Care
ISMP Medication Safety Alert!®
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 the *ISMP Medication Safety Alert!*, we described cases of inadvertent intravenous (IV) administration of liquid substances meant for administration via feeding tubes (www.ismp.org/sc?id=567). Of course, incidents had been happening 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 pleased that a global conversion to new enteral feeding device connectors 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 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 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, and 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 provided 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 80369-3. While the transition

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).

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Special ALERT

Loss of drug potency

Some hospital pharmacists have been in touch with us recently to report potency issues with certain medications prepared in advance in 3 mL or 5 mL BD syringes. One of the medications is fenta**NYL** citrate injection diluted to 10 mcg per mL for pediatric use, which was prepared in a hospital pharmacy. One hospital sent 3 syringes of diluted fenta**NYL** 10 mcg/mL to an outside laboratory for testing. At 48 hours, the potency had declined to 67% on average, and by day 6, the potency was at 55%. Another hospital tested syringes of fenta**NYL** 5 mcg/mL in 3 mL syringes and found a range of potencies between 10% and 70%. Retesting at two other laboratories showed similar results. A third hospital reported inadequate patient analgesia, also with diluted fenta**NYL**.

We spoke with a BD representative, who confirmed that an issue exists. The issue may be related to black plunger rod stoppers from a secondary supplier that affect "pH sensitive" medications such as fen-

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18TH 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.

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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**, page 1). This presents challenges because the ENFit syringe now holds more volume in its dead space.

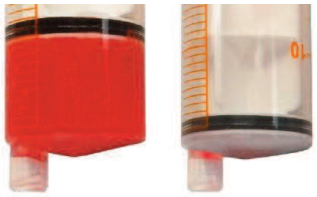

Figure 2. Medication drawn into an ENFit syringe in the pharmacy using an ENFit adapter, and then given via an ENFit device. The volume of medication in the syringe tip is the same before and after administration, so dosing is accurate.

Because the male tip on the ENFit bottle adapter that pharmacy will use connects *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.

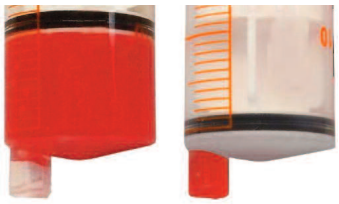

Figure 3. Medication drawn into a syringe using an ENFit adapter but given by mouth leads to under-delivery of medication. The volume of medication in the tip of the syringe differs before and after administration. The dose minus the drug leftover in the dead space was administered.

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.

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 tube" or "via mouth." However, during a practitioner panel at the interdisciplinary meeting, it was noted that prescribers are

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taNYL citrate, methadone hydrochloride, and possibly a few others. BD continues to investigate the matter and is planning to send a letter shortly to pharmacy directors to provide more details. Potency problems have **not** been identified with BD 1 mL, 10 mL, and larger syringe sizes, and no problems have been reported with other manufacturers' syringes.

According to BD, the loss of potency is also time dependent. At 24 hours, fentaNYL remains between 90 to100% potent, but by 48 hours, some deterioration may already be underway, as noted above. Patient safety could be compromised if subpotent opioid doses cause a dose elevation that is followed by administration of a fully potent opioid at the higher dose via a syringe that does not have this issue.

Until further information is available from BD and the problem is resolved, hospitals using BD 3 mL and 5 mL syringes should prepare medication syringes as close to the time of administration as possible. One of the hospitals that identified the problem is providing a 1 mL dose of fentaNYL 10 mcg per mL in a 2 mL vial for now.

SAFETY briefs

HIGH-ALERT

Fluorouracil infusions and independent double checks. We've previously reported accidental over-infusion of fluorouracil many times in this newsletter. As in the case published in our June 18, 2015 issue (www.ismp.org/sc?id=572), programming the infusion rate incorrectly is a common root cause of this type of error. An independent double check of chemotherapy infusions by a second practitioner should be required. Selective and proper use of independent double checks can play an important role in medication safety, as studies have demonstrated (see our June 13, 2013 newsletter: www.ismp.org/sc?id=573).

Initial infusion pump settings for fluorouracil are often programmed by an oncology nurse or home care nurse, but involving

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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 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 batch 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.

There also may be doses that nurses must prepare from prelabeled 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**, page 2). 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, without concerns about underdosing or overdosing.

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 industry initiatives already underway to address concerns, and other concepts 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.

Three options were presented. First was a suggestion to add an oral syringe port to feeding tubes and/or extension sets. This would allow pharmacists to continue dispensing all liquid medications in a conventional oral syringe. This would also resolve any issues with the ENFIT syringe dead space. Depending on its design, one downside could be that the oral syringe receptacle might somehow allow a parenteral syringe to be connected. If an inadvertent connection did occur, some parenteral medications 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 style, available from Corpak, is said to prevent Luer connections (www.ismp.org/sc?id=574). Hopefully, some other companies are interested 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 and connection with an ENFit feeding tube. Several companies stated they have

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pharmacy can help create an independent double check. When pharmacy prepares chemotherapy, two people independently double check the medication and diluents, their volumes, and so on. For added safety, shouldn't two people also independently double check pump programming? Pharmacy might set up the pump and program the initial settings, and later, the nurse can independently check that the proper device, drug, and concentration has been selected for the proper patient, and the proper rate of infusion has been programmed.

This is similar to what has been done with some patient-controlled analgesia (PCA) pumps where a pharmacist checks dose preparation completed by the pharmacy technician and also sets the basal rate (if there is one), bolus doses of the opioid, lock out periods, maximum amount of drug allowed per hour, and any other settings required to program the pump. The pump and medication are handed off to the nurse, who then independently verifies the patient's identification and compares what has been ordered against the pump settings entered by the pharmacist. In the same way, an independent double check for fluorouracil infusions can improve patient safety.

Unexpected painful breath. When teaching patients about the proper use of an inhaler, be sure to emphasize the importance of recapping the device after use. We were reminded of this recently when reading the April 9, 2015 *BMJ Case Reports*. A woman accidentally inhaled a small earring while using her asthma inhaler which was uncapped and stored in her purse (www.ismp.org/sc?id=575). As she inhaled the medicine, she felt a painful scratch in her throat and started coughing blood. She was taken to the emergency department, where the earring was removed from her lung. If the inhaler's cap had been in place, the loose earring in her purse would not have gotten into the inhaler.

Another event was reported in April 2015, in England (www.ismp.org/sc?id=576). A

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been working on such connectors; Medela showed one such device at the meeting (**Figure 5**). 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.

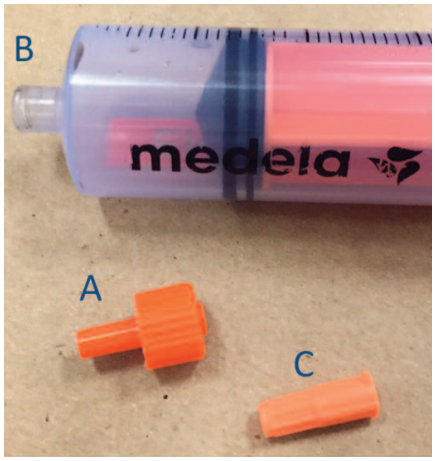

Figure 5. Syringe add-on device (A) attaches to ENFit syringe tip (B) to convert an ENFit syringe to an oral syringe. Part labeled "C" covers the add-on device tip.

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, should support direct oral administration, and minimizes dead space. 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.

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woman used her inhaler and suddenly felt something shoot to the back of her throat. She began gasping for air and spitting up blood. She ran outside, and a neighbor came to her rescue and called emergency medical services. The woman eventually coughed out a fake nail that had been part of a set she had worn weeks ago. In this case, the inhaler's cover had been in place before use, so the nail had probably lodged in the inhaler while using it when wearing the nails.

Tell patients to always inspect the inhaler thoroughly before use to ensure that there are no unwanted objects within the inhaler. Also be sure to have them replace the inhaler cap after every use. Some of the newer inhalers have an attached cap. If a foreign object enters the inhaler, it places the person at risk of breathing in the object and causing choking or severe respiratory difficulties.

Special Announcement

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.

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

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