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 continues on page 2—ENFit.
ENFit—continued from page 1
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 under-
stand 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 con-
nectors, ENFit syringes are the opposite. They have
a female syringe tip that fits around a male con-
ector 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.

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 sy-
ringe 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). How-
ever, 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 re-
main in the syringe tip after administration—as
much as 0.2 mL.

This lost volume in the dead space could be prob-
lamatic for doses of 2 mL or less, which represents
at least a 10% underdose of the medication. Rep-
resentatives 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 ad-
minister 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
continued on page 3—ENFit>

According to BD, the loss of potency is also time dependent. At 24 hours, fenta
NYL remains between 90 to 100% potent, but by 48 hours, some deterioration may al-
ready be underway, as noted above. Pa-
tient safety could be compromised if sub-

potent 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.

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 inde-
pendent 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 stud-
ies have demonstrated (see our June 13,

Initial infusion pump settings for fluorouracil
are often programmed by an oncology
nurse or home care nurse, but involving
continued on page 3—SAFETYbriefs>
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
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.

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.

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.

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