Q & A for
Research Findings Concerning Dose Accuracy with ENFit™ Syringes

1. *Who funded the study presented and done at Shands?*
    a. No commercial or outside funding was used to support the Study.
    b. No Conflicts of Interest declared on either paper.

2. *I did a lit search and google search on Patient Harm caused by ENFit syringes and medication administration. Nothing came up. Do you have actual patient data/reports of patient harm caused by use of the low dose ENFit syringes for medication administration?*
    a. The first step to attributing an adverse outcome to the ENFit syringe is building the awareness in the healthcare community that the syringe could contribute dosing errors.
    b. The second step is to appreciate that over- or under- dosing medications administered with an ENFit syringe may have an insidious development making it difficult to immediately see cause and effect. Low detectability increases the risk of harm.

3. *Have the hospitals who have transitioned to ENFit missed sub-theraputic dosing in their NICUs?*
    a. As stated above, identifying sub-therapeutic or super-therapeutic dosing requires an awareness of the dose accuracy of ENFit syringes. Potentially 1 of 5 doses is outside of the =/- 10% range.

4. *What syringes (ENFit vs. non-ENFit) is Shands currently using for patient care?*
    a. Shands is using legacy enteral syringes. UF Health Jacksonville converted to ENFit but returned to the legacy system due complexity and risk.

5. *What is CHOPS doing?*
    a. Per the Director of Pharmacy Services - CHOP has not converted to ENFit due to numerous logistical and safety concerns.

6. *I just read an article from PT 2018, Grissinger highlighting use of oral meds given IV using legacy syringes. What is your answer to address this patient safety concern?*
    a. Assume you are referring to this article listed below. Both of the wrong route errors did include legacy parenteral syringes, but neither case would have been prevented by using ENFit. In the first case, the nurse misread C-IV to mean IV administration. When the enteral syringe would not connect to the IV port, the drug was transferred to a parenteral syringe. In the second instance, an oral product was prepared at the bedside in a parenteral syringe. Re-engineering the enteral system cannot eliminate the human aspect of medication errors. The author makes several recommendations that are appropriate whether using a legacy enteral system or the ENFit system.

    Grissinger M. A Successful ENFit Launch Still Won't Stop All Incidents of Oral Medications Given Intravenously. P&T. 2018;43(7):379–380.

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7. *If in December 2020 old enteral tubes will cease to be manufactured, won't all organizations be forced to use ENFit, and thus ENFit low dose syringes? What do you do at that point with the inaccuracy reported by Shands study?*
    a. Great question. The member manufacturers of GEDSA announced that they will phase out legacy feeding devices and transition adaptors by January 2021. There are several well-known manufacturers that will continue to make legacy devices available.
    b. Please note that **neither the FDA nor CMS require the use of the ENFit system**. The recommendation states "…hospitals and clinicians use enteral devices with connectors that meet the International Organization for Standardization (ISO) 80369-1 or ISO 80369-3 standard, or that are otherwise designed to reduce the risk of misconnections."
    c. https://www.appliedmedical.net/enteral/enfit/

8. *Will you send a handout? And will recording be available? Thank you!*

    You can access the slides and recording at the link below.

    https://www.visanteinc.com/new-webinar-research-findings-concerning-dose-accuracy-with-enfit-syringes/

9. *Suggestions why greater variance for enteral use of enfit syringes vs oral administration?*
    O'Mara K, Campbell C. Dosing inaccuracy with enteral use of ENFit ® low-dose tip syringes: The risk beyond oral adapters. J Clin Pharm Ther. 2019;00:1–5. https ://doi.org/10.1111/jcpt.13079
    "*Enteral application of ENFit LDT syringes resulted in significantly more tests with DV >10% compared to oral use (26.9% vs 12.9%, P = .01). The standard ENFit did not show a difference between enteral and oral applications (0% vs 2.8%, P = .4).*"

    Standard ENFit and ENFit with LDT were tested under the same conditions. Since the standard ENFit did not show a difference in DV between oral and enteral applications, one could surmise that the LDT feature may be a contributing factor.

10. *I do not agree this will be a silent problem. In our NICU, when this change was made, our PharmDs were hypervigilant in looking for differing patient responses to low dose meds. They were not necessarily proponents of these low dose syringes but we did NOT see patient medication response variances.*
    a. Thank you for your comment. It appears that your organization was aware that there is a concern for dose accuracy and ENFit syringes, and we agree that if you choose to convert, close observation following conversion is a well-informed safety strategy. As previously stated, the low detectability of errors and general awareness of syringe

limitations may have prevented identification of adverse events related to ENFit syringes.

11. *Are there European studies to compare your research to? What has the LDT experience been in Europe? It is reported that they have successfully converted to ENFit connections so it would be wise to study their experience as well.*
    a. Great question. There are no published studies at this time. We are aware of a researcher in the UK that is interested in this topic.
    b. French Society of Neonatology, and the Canadian Standards Agency Working Group are two international agencies that are voicing similar concerns about dose accuracy and ENFit syringes.

    http://www.safe-enteral.com/wp-content/uploads/2017/01/newsletter-sfn-march-2016-summary-en.pdf

12. What is the dead space volume in the legacy oral tip syringe to account for the 7 - 14% inaccuracy shown in your slide? Dead space volume in the legacy oral tip syringe is unknown but not at issue since the amount contained in the male syringe tip is part of the total dose volume.

13. Because difficult to assess morbidity/mortality for dose inaccuracies the fix may be worse from a patient care stand point particularly in pediatric and neonatal populations.
    a. Thank you for your comment. This is an important consideration when evaluating whether to stay with legacy design for now or convert to ENFit.