Study on ENFit Enteral Dosing Accuracy:
Incomplete Methods & Questionable Statistics
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The study on ENFit enteral dosing is deeply flawed due to shortcomings in methodology. In addition, the study’s findings are not supported in actual experience. ENFit and the ENFit Low Dose Tip have been implemented across the European Union and in many U.S. hospitals over the past three years with no known reports of dosing issues.

ENFit protects patients by following a rigorous global ISO standard that reduces the risks of tubing misconnections that can result in patient injury or death. Developed by international clinical, technical, and regulatory experts under the framework of ISO and in partnership with leading global manufacturers, suppliers and distributors, ENFit complies with guidance from the FDA, the Centers for Medicaid Services, and The Joint Commission.

Concerns with this study:

1. The authors equate ISO 7886-1:2017’s tolerance on graduated capacity (TOGC) to dose variance/accuracy and arbitrarily states a 5 percent value.
   a. They are not the same thing. TOGC is a component of dose accuracy but it doesn’t consider anything but the accuracy of the markings on the syringe barrel. Dose accuracy is about the actual delivery accuracy of the dose that was intended for the patient and this is more complex for enteral delivery (where the connections and disconnections between the syringe and feeding tube have to be considered).
   b. Per the ISO 7886-1:2017 standard, 5 percent is not the actual value for TOGC in many scenarios. For syringes that are less than 5mL in nominal capacity, TOGC of 5 percent is appropriate only for fill scenarios where the fill volume is ≥ ½ the nominal capacity of the syringe. For fill scenarios < ½ nominal capacity, it is necessary to follow a mathematical formula in the standard. For the 20 percent fill volume (0.20mL in a 1mL syringe) that was used in GEDSA’s work, the calculated TOGC value would actually be ±9.5 percent.

2. The study mischaracterizes GEDSA’s role. The study states that “The Global Enteral Device Supplier Association (GEDSA) was created to develop a syringe design compliant with ISO 80369-3. This is a mischaracterization. GEDSA has not created any product designs (syringes or otherwise).

3. The methodology of the study is devoid of procedure. This study methodology is incomplete and it points large parts of its methodology back to the original study. However, the original study is also lacking in its explanation of the methodology. Without more information around the protocol that was used and the raw data that was collected, it’s difficult to even speculate on why the results are as they are and what those results may actually mean.
4. The number of test samples utilized in each test scenario, and whether or not they were statistically significant, is unclear based on the results section and Table 1. The n value for each syringe size and type should be reported along with repetitions per syringe for oral versus enteral delivery. The reporting of ‘test conditions’ is very unclear and does not indicate how many syringes were evaluated of each size and type (LDT vs standard tip).

5. The dose variance percentages used in the results lack meaning because the methodology does not call out the actual dose volume that was used. Dosing accuracy (dose variance as the study refers to it) is relative to the nominal capacity of the syringe AND the dose volume that is intended for the patient (usually expressed as a percentage of the syringe’s nominal capacity). This crucial bit of information is omitted from the methodology. The previous study describes two dose volumes but in this more recent study it isn’t clear as to which was used or even if an entirely different value was perhaps used. Basically, as the dose volume decreases to a smaller and smaller percentage of the nominal capacity of the syringe, the dose accuracy deteriorates. Thus, meaning cannot be inferred from the results without knowing what the intended dose was, relative to the syringe capacity. For all the reader knows, the dose could have been 0.01mL from a 1mL syringe (1% of its capacity), and that dose accuracy would be expected to be poor from any syringe type (Luer IV, male oral, ENFit LDT, proprietary female, etc.).

6. The data for all syringe sizes should not be grouped together as they are in Figure 1. The dose accuracy would necessarily differ for different size syringes, especially since the author appears to be asserting that the dose accuracy is adversely impacted by the low dose tip, and this tip represents a different volume percent for different size syringes. Also, in order to group these syringe sizes together, statistics must show that they are not statistically different from one another with respect to dose accuracy values. This analysis is not presented, and most likely the dose accuracies are statistically different for different size syringes. Therefore, these data should be reported separately for each syringe size.

7. It appears that the standard tip 12mL ENFit syringe dose accuracy was compared to the Low Dose Tip (LDT) dose accuracy for all sizes (0.5, 1, and 6mL) grouped together. This comparison is not valid since the dose accuracy for a large volume syringe with the same percent fill would be expected to be higher than for a smaller volume syringe, and as discussed above, the data for different sizes should not be grouped together unless they are statistically the same.

8. The study states that peer reviewed literature is relatively absent for dose accuracy and LDT. However, the study fails to acknowledge that an extensive and comprehensive Master File for the LDT was reviewed by the FDA and that manufacturers have obtained clearances to market devices that reference that Master File.

9. The results in Table 2 are difficult to interpret without more explanation of the methodology. A LDT syringe and the 12mL standard tip ENFit syringe would be expected to have relatable dose accuracy but this study shows them to be considerably different.

10. The study’s point that is intended to be supported by citations 11 & 12 is unclear because those citations actually support that syringes are better than medication cups for administering accurate doses.
11. It is unclear what differed in the methods between oral and enteral delivery, and the author does not provide a rationale for why these dose accuracies would differ. This is a major shortcoming that should be addressed as it points to potential deficiencies in the methodology.

12. This study is supposed to be about enteral dosing accuracy but there is no methodology or explanation given on how this was tested to represent an enteral system. For this one would expect to find a description of the enteral feeding tube that was used. The study mentions a straw, but straws are meant for filling syringes, and are not used as feeding tubes. Therefore, the design of this study may be flawed in that it’s not reflecting reality; a better description of the methodology would help clarify that.

Additional Information:

In addition to the numerous internal studies done by leading European hospitals, U.S. hospitals have conducted their own independent evaluations and decided to use the LDT. These hospitals, after their own internal reviews, have determined the LDT performance meets their patient safety requirements.

“After 18 months using exclusively ENFit and ENFit low dose tip syringes for our inpatient population for both oral and enteral use, no reported issues related to dosing discrepancy or variance related to ENFit have been observed compared to standard slip tip oral syringes. Education focusing on minimizing air bubbles in the smallest low-dose syringes (cycling syringe before withdrawal from bulk bottles, capping technique, etc.) aided in our transition to the ENFit syringes. Furthermore, as more and more institutions in the health care community convert away from traditional slip tip oral syringes to prevent tubing misconnections, the supply for ENFit products will become more abundant as companies are able to streamline product”.

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