Reducing the Risk of Medical Device Tubing Misconnections

ENFit® Low Dose Tip Syringe Review

Q2 2016

ENFit and Dose Accuracy Background

- "Reducing the risk of (tubing) misconnection requires a complete design change with correlating standards established and adopted worldwide across the industry" (GEDSA website)
  - This is achieved through ISO 80369-3 for enteral connections
- Dose delivery accuracy *(which includes the entire system)* ensures that the correct dose is prepared and administered to the patient
- <u>There is no standard to reference for dose delivery accuracy applicable to enteral syringes and/or administration systems</u>
- Non-enteral reference points, such as hypodermic syringe performance standards (ISO 7886), provide information on container measurement accuracy, but not delivery accuracy

Dose Accuracy Concerns Raised

- Clinicians:
  - Raised concerns on the dosing accuracy of small volume ENFit® syringes, due to their reverse gender orientation
  - Indicated a dosing accuracy expectation of ± 10% for a target volume of 0.2mL when delivered from a 1mL syringe
- Industry:
  - There is no global standardized test (ISO, AAMI, ASTM, EN, etc.) for manufacturers to use to evaluate dosing accuracy for syringes
  - In absence of a standardized test, no baseline data existed for comparison

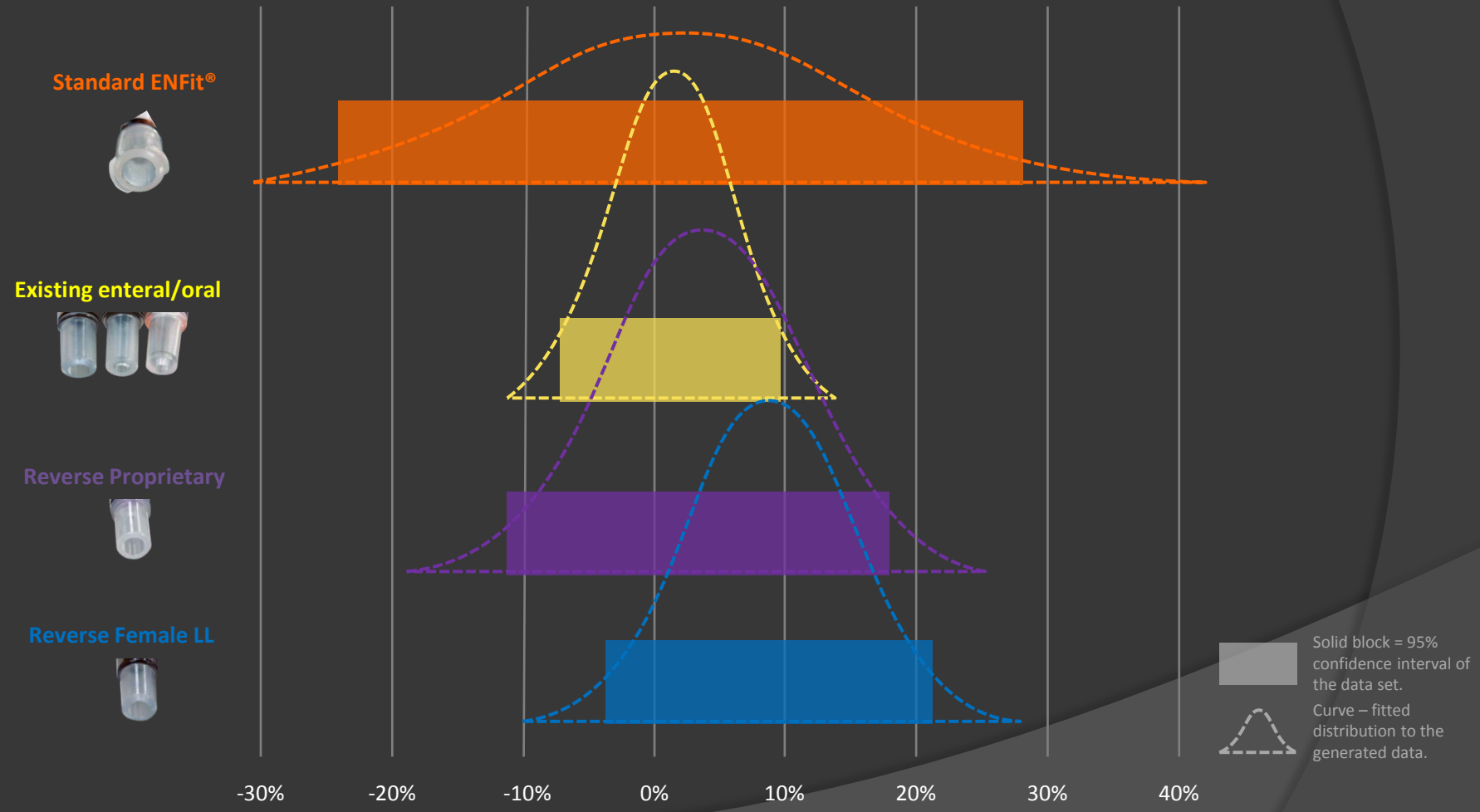
Performance Testing

- GEDSA members assessed the ability of the standard ENFit® syringe to meet a +/-10% delivery accuracy and determined that syringe sizes of 5 mL or smaller may require a “low dose tip” ENFit® connector design to meet this target
- Performance testing was then conducted by a third-party, accredited test lab. The following enteral syringe types were evaluated to determine the performance of the low dose design and to establish a baseline for the performance of existing syringes:
  - Leading brands of existing enteral/oral syringes *(all male tip)*
  - Female Luer lock *(reverse system used in the UK)*
  - Proprietary reverse system syringes currently marketed
  - Standard ENFit® syringe tip
  - Proposed ENFit® low dose tip syringe

OBJECTIVE: Address delivery accuracy concerns raised by clinicians and determine the baseline performance of existing enteral syringes/systems

Results were submitted to the FDA to support 510(k) submissions for the low dose tip design

Small Volume Dose Accuracy of Common Enteral/Oral Tip Syringes *(Delivering 0.2 mL in a 1 mL syringe)*



Note: Target is ±10% of a 0.2mL dose delivered in a 1mL syringe. Each box represents the 95% confidence interval of the data set.

ENFit® Dose Accuracy Solution

- The ENFit® Low Dose Tip *(LDT)* syringe was designed to specifically address the dose accuracy concerns
  - Design is proposed for inclusion into ISO 20695 standard and is under review by the committee

- LDT adds an internal male lumen to the standard ENFit® female syringe
  - This mimics the functionality of traditional male oral/enteral syringe designs

*Initial designs and samples used for testing and photography provided by NeoMed

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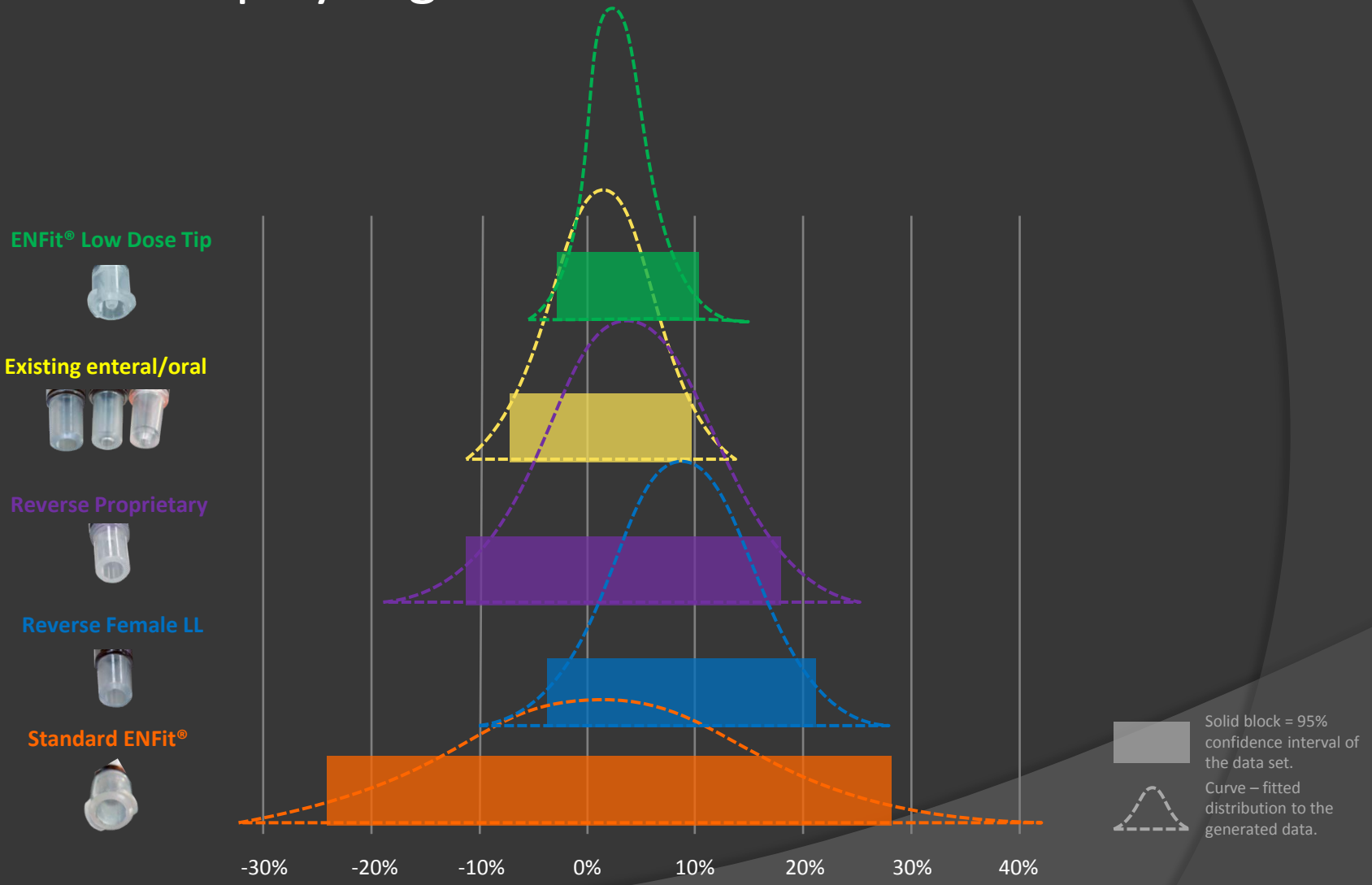


Note: Target is ±10% of a 0.2mL dose delivered in a 1mL syringe. Each box represents the 95% confidence interval of the data set.

Misconnection Risk Assessment

- The ENFit® Low Dose Tip provides a solution for accurate enteral dosing while maintaining a high level of mitigation to the risk of inadvertent tubing misconnections
- The addition of the internal male feature to the standard female ENFit® connector was evaluated for tubing misconnections across the other small bore connector designs of the ISO 80369 series
- The conclusion of this analysis was that the ENFit® LDT provides a solution for accurate enteral dosing while maintaining a high level of mitigation to the risk of inadvertent tubing misconnections

Usability Testing Top Level Summary

- 148 respondents worldwide representing pharmacy, nursing and caregivers evaluated the ENFit® LDT using current practices and methods for filling and administering enteral doses
- The respondents were able to complete the filling or administering of water or thick liquids (Pepto Bismol®/Children's Tylenol®/Paracare®) with the LDT successfully
- Responses about the LDT performance were consistent across all user groups, regardless of the tasks evaluated

"Lumen felt like it connected well with bottle."

"Well designed."

"I like the secure fit of the syringe on the bottle and the tip cap on the syringe after."

"Like how the syringe locks into patient side."

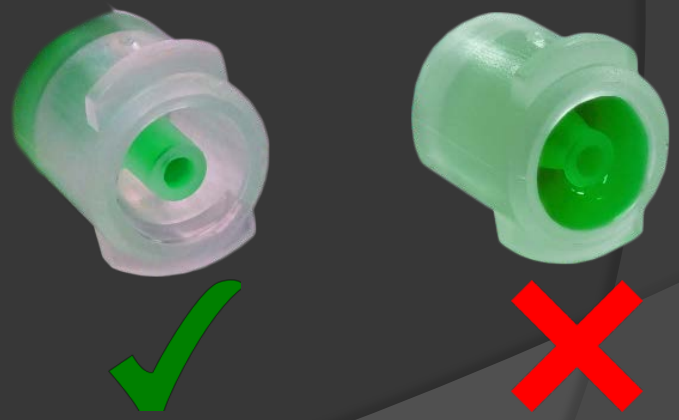
"No problems. Easy to use."

"Easy to attach and administer."

Overall, users found the ENFit® LDT design feature acceptable for filling and administering enteral doses

Recommended Syringe Use

- Method of filling the syringe *(cup fill vs straw/adapter fill)*
  - Using a straw or adapter to fill the syringe will deliver higher accuracy for each dose, similar to how other reverse orientation syringes are filled currently
  - The straw or adapter reduces the potential for excess residual fluid to be outside the fluid pathway
- Removal of Residual Fluid
  - The LDT internal feature behaves similarly to the male tip of existing oral/enteral syringes
  - LDT syringes, like standard syringes, should be tapped/flicked/wiped in order to move fluid that may be outside the fluid pathway



Low Dose ENFit® Syringe Conclusion

Performance Test Results *(when used as instructed)*:

- Substantially equivalent to standard orientation (male) enteral/oral syringes
- Performs better than Reverse Orientation (female tip) syringes
- Use of an adaptor (such as a straw) provides better performance than a cup fill

Misconnection Risk Assessment:

ENFit®, including the Low Dose Tip, mitigates the risk of inadvertent tubing misconnections and provides a clinical benefit

Usability:

No significant difference between use of ENFit® LDT syringe and current practice when filling or administering different viscosity fluids or between respondents (Pharmacist, Nurses, or Caregivers)