Neonatal Survey on the potential impact of ENFit™ connector on syringe accuracy.

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Summary

Background

The recent Draft International Standard (ISO DIS 80369-3) defines a unique design for the enteral feeding connectors, with the aim of preventing misconnection with other applications (I.V., respiratory, neuraxial anesthesia …). This specific connector, called ENFit™, is currently proposed for all patients, from premature babies to adults.

Objective

The objective of this study was to gather the clinical expectations and requirements for enteral medication deliver in Neonatology and to evaluate the acceptability and suitability of the ENFit™ connector for use in neonatal populations.

Methods

One-hundred-nineteen clinicians (30%) and nurses (69%) working in Neonatal Intensive Care Units (NICU) were interviewed in 11 countries: Belgium, Denmark, France, Germany, Italy, Netherlands, Norway, Spain, Switzerland, Sweden, and United Kingdom. The interviews were done face-to-face individually or in small groups (> 6 people) in 81 hospitals (including 29 university hospitals), which used various feeding systems. The questionnaire focused on their daily practices of drug administration, their need of accuracy and their opinions on ENFit™ connectors. For this last point, ENFit™ prototypes were shown and technical data on the accuracy variation was provided.

Results

A total of 104 of 119 neonatal specialists delivered drugs enterally, in low volumes (< 0.2 ml) to their neonatal patients. The frequency of administration depends on the patient, it can be between 1 and 12 times per child per day. The lowest volume delivered enterally is between 0.05ml and 0.1ml for 80% of the interviewees; it is ≤ 0.05ml for 23%. When delivering these low volumes of drugs, the majority of the neonatal specialists expected from their administration system to provide the highest accuracy (close to 100%). 112 interviewees considered that a 0.12ml variation in drug administration could be detrimental for neonatal patient's health. They cited many critical enteral drugs, including digoxin, morphine, methadone, amiodarone, iron, levothyroxine, caffeine… With this potential variation of 0.12ml*, the ENFit™ connectors were judged unacceptable for use in NICU.

Conclusion

Very low volumes of drugs (0.05ml – 0.1ml) are administrated daily to neonatal patients in NICU. Mis-dosing of many enteral medicines can be detrimental for patient health, so a high level of accuracy in drug administration is requested. The design of ENFit™ connector is judged by neonatal specialists to provide inadequate dose accuracy for universal use in neonatology.

* 0.12ml used in this survey, but laboratory testing published in ISO 80369-3:2016 has shown 0.148ml mean average volume displacement.