NCfIH National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

October 5, 2017

Dr. Mark Chassin
President and Chief Executive Officer
The Joint Commission
One Renaissance Boulevard
Oakbrook Terrace, IL 60181

Dr. Ana Pujols-McKee
Executive Vice President and Chief Medical Officer
The Joint Commission
One Renaissance Boulevard
Oakbrook Terrace, IL 60181

Dear Dr. Chassin and Dr. Pujols-McKee:

On behalf of the National Coalition for Infant Health (NCfIH), we are writing to share concerns regarding the ENFit tubing connector design and the safety risks this design poses to neonatal intensive care unit (NICU) patients. For these tiny, vulnerable infants, concerns about inaccurate dosing of medications at small volumes must be taken very seriously.

The National Coalition for Infant Health is a collaborative of more than 150 professional, clinical, community health, and family support organizations focused on improving the lives of premature infants through age two and their families. NCfIH's mission is to promote lifelong clinical, health, education, and supportive services needed by premature infants and their families. NCfIH prioritizes safety of this vulnerable population and access to approved therapies.

While the ENFit design was meant to decrease risk of tubing misconnections through the new ISO 80369-3 standards, for the neonatal and pediatric populations, it has instead introduced new challenges. Pediatric health care providers must deliver medicine in small volumes to these tiny patients, and it must be done with the highest levels of accuracy. For NICU patients, there is no room for error. The new ENFit connector design makes this difficult.

The moat, or area around the syringe barrel, is difficult to clear. Medication can “hide” there, inadvertently increasing the dosage delivered when the syringe is inserted into the feeding tube. If the moat is not cleared, a premature infant may inadvertently receive up to 30 percent more medication per dose. This places the baby at risk for an overdose and adverse drug reactions. This moat design also increases the risk for infection if residual breast milk or formula remains in the moat and is then connected to the feeding tube. The potential for bacterial colonization of the moat (given that feeding tubes in NICU patients are in place for up to 10 days at a time) increases exponentially with the ENFit design.

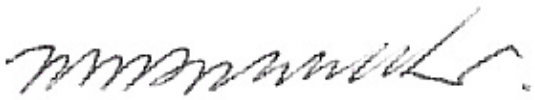
The specific ENFit design has left NICU’s in a state of limbo. Medication safety experts and the pharmacy community are urging caution before hospitals adopt the ENFit design. While some hospitals

hold off on adopting a product line, they must meanwhile ensure that *all* oral tubes and syringes are compatible both within their hospital and with any facility from which they receive or transfer patients. This design also poses workflow issues. Nursing staff face the added steps of regularly clearing syringe moats and feeding tubes and using multiple connectors and adapters for oral or enteral administration of medication. Pharmacy staff face the new burden of increased workflow drawing up medications in oral or enteral syringes, making sure the medication is not displaced when the syringe is capped and the moat is clear of additional medication.

The National Coalition for Infant Health has serious concerns about the current ENFit design, yet we support the concept behind the ISO 80369-3 standard to create an oral/enteral connector design to prevent misconnections and enhance patient safety. These improved standards are an important step toward protecting vulnerable patients from the dangers of tubing misconnection. However, this design solution creates new risks by increasing the delivered drug variance and adding extra steps to both nursing and pharmacy workflow. We believe this is neither in alignment with the National Coordinating Council for Medication Error Reporting and Prevention guidelines for prevention of medication errors nor the Joint Commission's mission to increase patient safety in healthcare organizations. We would encourage the Joint Commission to look at other alternative manufacturer designs for the ISO 80369-3 standard before considering any "mandatory" utilization or adoption regulation.

Thank you for the opportunity to voice our concerns on this important issue as we continue to support products and policies that enhance the safety and benefits for premature infants.

Sincerely,



Mitchell Goldstein, M.D.
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