Federal Officials Weigh in on Infant Tubing Saga

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The Alliance for Patient Access (allianceforpatientaccess.org), founded in 2006, is a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care. AfPA accomplishes this mission by recruiting, training and mobilizing policy-minded physicians to be effective advocates for patient access. AfPA is organized as a non-profit 501(c)(4) corporation and headed by an independent board of directors. Its physician leadership is supported by policy advocacy management and public affairs consultants. In 2012, AfPA established the Institute for Patient Access (IfPA), a related 501(c)(3) non-profit corporation. In keeping with its mission to promote a better understanding of the benefits of the physician-patient relationship in the provision of quality healthcare, IfPA sponsors policy research and educational programming.

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The Potential for Overdose

The "ENFit" tubing connector was developed to minimize dangerous tubing misconnections. But in the years since the device was released, it has become clear ENFit connectors introduce a different danger.

The ENFit design features a moat around the tip. If the moat area is not cleared before medication is administered, there is a potential for tiny babies to get an incorrect amount of medication. ENFit adaptors "significantly increase" the possibility of inaccurate dosing, according to one study. (3)

Recommendations for Safe Use

The FDA provided recommendations for optimizing dose accuracy with the ENFit device in its safety message. Among its guidance, the FDA suggests users should:

- Tap the tip of the syringe to ensure it is free of air bubbles and that the moat is free from fluids
- Use a filling adapter to prevent fluid and medications from entering the moat area of the syringe tip
- Flush the medication or fluid after administration to prevent overdose.

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Alerting Providers

Health care providers need this information to use ENFit tubing devices safely. Moreover, individual hospitals should have the autonomy to decide what is in the best interest of their tiniest patients – whether that is using ENFit or another safe, FDA-approved tubing option.

There is no margin of error when dosing medication for babies. Safety and precision must be a priority – even federal officials agree.

References:

1. https://www.youtube.com/watch?v=pu8H-5nCkwo
2. https://www.fda.gov/medical-devices/safety-communications/potential-medication-overdose-enfit-low-dose-tip-syringe-fda-safety-communication
3. https://onlinelibrary.wiley.com/doi/full/10.1111/jcpt.12810
4. *O'Mara K, Gattoline SJ, Campbell CT. Female low dose tip syringes-increased complexity of use may compromise dosing accuracy in paediatric patients. Journal of Clinical Pharmacy and Therapeutics. 2019;44(3):463-70. doi: https://doi.org/10.1111/jcpt.12810.*

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