Birmingham Children's Hospital
NHS Foundation Trust

ENFit & concerns about safe Medicines Administration

Joanna.Correa@bch.nhs.uk
Medicines Management Nurse
October 2016

ENFit™

Birmingham Children's Hospital NHS
NHS Foundation Trust

ENFit ISO 80369-3 Aims to reduce medical misconnections globally by preventing connection of enteral products to IVs

The ENFit connection will be added to ALL Enteral feeding system products including medicines syringes . Current (UK only) reverse LUER connections are to be discontinued

Luer to ENFit is not a straight product swap out ENFit introduces NEW risks & errors!

- ENFit medicines syringes CE marked ENTERAL (i.e. **not** Enteral/Oral like Luer)
- Oral syringes & filling devices are available for oral medicines administration
- During the Transition the 'mixed economy' will require use of Luer/ ENFit adapters
- ENFit syringe must be selected for it to prevent connection to an IV connection
- ENFit will increase other medicines errors as dose administration is more complex than previous systems and is wholly dependent upon perfect performance.
- Time scales tight

Hobson's choice ……

- ORAL & ENFit syringes V.S. only ENFit

- Timing of transition (In hospital / For home)

Assessment

Birmingham Children's Hospital NHS
NHS Foundation Trust

Current LUER	ENFit™	NEW Oral	RISK
ROUTE: Oral / Enteral	Enteral	Oral	**i**
Syringes: 1ml; 2.5ml(or 3ml); 5ml; 10ml; 20ml; 50ml	**ENFit Low Dose (LD) Syringes** 1ml; 2.5ml (or 3ml); 5ml **ENFit Standard Syringes** 1ml; 2.5ml; 5ml; 10ml; 20ml; 50ml syringes	**Syringes:** 1ml; 2.5ml(or 3ml); 5ml; 10ml; 20ml; 50ml	**ii**
Dose Accuracy: Medicines straws & bottle adapters available but NOT Required	Medicines straws or bottle adapters available and REQUIRED for Low Dose	Medicines straws or bottle adapters- available but NOT Required	**iii**
Design: Single moulded design Narrow tip Purple plunger	Low Dose syringes only Joined b/n tip-barrel (some) Tip - surrounded by a 'Moat' Non ISO features -'Wings' added for width - purple plunger	Single moulded design Narrow tip Purple plunger	**iv**
Connections: Incompatible – Adapters available to manage Luer/ ENFit combinations for transition period			

Risks

Birmingham Children's Hospital NHS
NHS Foundation Trust

i. Oral or Feeding tube route would need to be decided BEFORE preparation and administration

RISK: Complex assessment required for every enteral medicine because influenced by CYP choice and their unique care needs

ii. Syringes ENFit & Oral plus bottle adapters, straws, filter straws / needles etc

RISK: Visual similarity of Luer, Oral & ENFit (LD and normal) syringes & packaging, potential for miss supply, storage & selection. Whilst incompatible connections prevent Oral to ENFit feeding system administration, there are no controls in place to prevent a) ENFit Enteral syringe being used to administer a medicines orally b) if an oral syringe is unavailable a visually similar IV one might be used rather than an ENFit one risking accidental administration via IV route

iii. Accuracy of ENFit syringes is assured only when filled with ENFit medicines bottle adapter or straw

RISK: Direct fill – without a filling device the 'moat' around the tip Low dose syringes fills with medicine; the moats contents are displaced by the feeding tube connection during administration however caking of medicines could result in contamination / damage to feeding tube connection/ exposure to medicines being administered. Tapping out excess medicine from moat would increase exposure to medicines. Emptying moat is an extra step that could be missed, accidental use of ENFit syringe orally without clearing the moat could add up to approx. 0.2ml to dose volume..

Medicines Straws – not used for Luer & not necessary for oral syringes, a new extra step that could be confused or forgotten. Straws need to be readily available. Single use item Cost pressures

Bottle Adapters –ENFit adapters on medicines bottle would prevent use of oral syringes. Oral adapters are available but would require two medicines supplies to be available to connect with Oral or ENFit syringes. Bottles and adapters difficult to tell apart. – Storage & Cost pressure

iv. Safety of ENFit Syringe (Low Dose only) design

RISK: Syringe Tip & barrel breaking at join (Brand A / Brand B manufactured in two pieces then clipped and glued) During user testing at BCH when torque applied during connection the join fail on some syringes. The tip swivelled in the connection and or broke leaving the whole syringe tip attached to the connecting device or potentially in a CYP mouth

W Design (Width added by plastic 'Wings' behind the syringe tip) On single moulded design syringe (Brand C) During user testing at BCH, the wings edges were identified das too sharp for use orally.

Controls.

Birmingham Children's Hospital NHS
NHS Foundation Trust

i. Also use ENFit for ORAL medicines administration

Complex decision making unnecessary, reducing likelihood of rework, waste and error. ENFit syringes are more expensive

i. ENFit Syringes & filling devices only stocked in clinical areas

With procurement controls in place to prevent purchase of oral syringes & filling devices risk of confusion and miss selection and therefore accidental error is reduced. Single system for all enteral route simpler reducing risk of confusion & ready availability of appropriate syringes for route reduces likelihood of IV syringe being used for oral administration in preference to ENFit and accidentally administered IV.

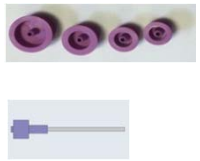
iii. Standardise practice on safe & accurate use of ENFit syringes with feeding systems & orally

Standardise practice - provide guidance on safe use (ban 'Direct Filling' of ENFit syringes). Educate staff on the vulnerability of system to error and risk of harm to CYP if their performance is not perfect. Ensure availability by managing purchasing, supply & storage Require reporting of non compliance as a medicine incident , include in two person medicines administration check. Add to safe & secure storage of medicines audit & engage Pharmacy staff in checking and reinforcing use of filling devices during transition. Consider preferential purchase of liquid medicines where possible & insertion of ENFit adapters at manufacturing stage for BCH specials.

Bottle Adapters - All liquid medicines bottles should have an ENFit adapter to be fitted at point of opening to prevent filling of low dose syringe moat.

Having a bottle adapter will reduce risk of an IV syringe being used to draw up

Medicines Straws - Use for ALL dispersed / dissolved medicines doses <2.5mls



iv. Remain with LUER syringes until NEW design ENFit (Low Dose) Syringe is available

Ensure transition adapters are available in all clinical areas to enable connection of LUER syringes with ENFit feeding tubes

Share design flaws with manufacturers & secure guarantees on LUER syringes supply until new design is available

Share decision making, concerns and controls with clinical staff the MHRA and wider stakeholders

Recommendations:

Birmingham Children's Hospital NHS
NHS Foundation Trust

- Delay transition to ENFit until safe low dose syringes are available
- Document the role of ENFit in any errors
- Engage community teams, children, young people and carers in decisions about ENFit v.s. Oral syringes for home administration
- Consider syringe management for Self–administration
- Engage with manufacturers
  - Continued supply of Luer enteral syringes whilst they address design flaws
  - Seek CE mark for oral & enteral use
  - Produce suitable ENFit information for staff, children, young people & carers
- Medicines Safety Forums to facilitate
  - Raising awareness with other paediatric centres
  - Sharing local solutions to reducing the risk of ENFit
  - Opportunities to standardise practice across organisations
  - An open debate on possible system wide solutions
  - Raising concerns with MHRA