NPPG
Neonatal & Paediatric Pharmacists Group

NEWS

Update on ENFit Syringes September 2016

ENFIT Syringes and Medicines Administration- Risk of Overdose

Background

Many patients, particularly those with complex medical needs, have enteral feeding tubes sited. If the need for the feeding tube is short-term, the tube is usually passed through the nose and then progressed down into the stomach or jejunum: known as Nasogastric (NG) or Nasojejunal (NJ) tubes respectively. Where a longer-term solution is required, the tube is surgically inserted into the stomach or jejunum through the abdominal wall: known as percutaneous endoscopic gastrostomy (PEG) and percutaneous endoscopic jejunostomy tubes respectively.

In some situations, patients also receive medicines via enteral feeding tubes. When patients with feeding tubes are hospital inpatients, they frequently also have intravenous (IV) access in place. Both nationally and internationally, there are numerous examples of incidents where a medicine intended for administration via an enteral tube has inadvertently been given intravenously instead. A review of data from the UK National Reporting and Learning System (NRLS) showed 33 patient safety incidents involving intravenous administration of oral liquid medicines between 1 January 2005 and 31 May 2006[1]. Between 2001 and 2004, 3 fatalities were reported as a result of intravenous administration of medicines intended for enteral use[1].

In March 2007, the National Patient Safety Agency (NPSA) issued a patient safety alert, which highlighted the risk of such wrong route errors and required all UK healthcare providers to undertake a number of actions. One of the key requirements was that enteral feeding tubes and enteral syringes were of such a design, they could not physically be connected to IV syringes and catheters respectively[1]. The result was that the UK changed to using reverse luer lock devices to prevent misconnection, and enteral syringes (and associated equipment) became purple in colour to make them visibly different to IV syringes.

Wrong route administration including IV administration of an enteral medicine is designated by NHS England as a Never Event. A Never Event is a serious incident which is wholly preventable as guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers[2].

International Standardisation

Background

More recently, at an international level, there have been efforts to further reduce the risk of inadvertent intravenous administration of a medicine intended for administration via a feeding tube. This change has been driven by the International Organisation for Standardisation (ISO), who have developed a new global standard for connectors used in enteral feeding devices[3].

A new standard design of syringe-to-feeding-tube connector, known as ENFit has been adopted by all manufacturers of enteral feeding tubes and syringes internationally. These products have been available on the UK market since July 2016. NHS Trusts throughout the UK are now charged with implementing the new products. A wide range of ENFit compatible equipment is now available, including:

- Feeding Tubes
- Syringes
- Feed "giving sets"
- Bottle adaptors, or "bungs" to aid the drawing up of liquid medicines into ENFit syringes

- Quills, or filter straws to aid the drawing up of liquid medicines into ENFit syringes
- Adaptors, allowing the connection of ENFit syringes and giving sets to existing gastrostomy tubes. These are necessary, as surgically-inserted feeding tubes will not be changed without a clinical need to do so, so old designs of feeding tubes will be still be in use for a number of years to come.

Can medicines be safely administered using the new ENFit syringes?

ENFit syringes can be used to administer medicines via enteral feeding tubes.

Standard Syringes

Most syringes (5ml and above) have a large hub at the end due to the way they connect to ENFit giving sets. This hub holds a volume of about 0.2mL.

- If the hub is left full before oral administration and is still full after administration then the correct dose will have been given.
- If the hub is left full before oral administration and the syringe is sucked, so the hub is empty after administration then the patient will have received an over dose of about 0.2mL.
- If the hub is cleared (drawn up from a bottle adaptor (bung) or using a medicine straw) before administration and full after administration then an under dose of 0.2ml will have been given.
- If the hub is clear before administration and the syringe is sucked at administration, leaving the hub empty after administration then the correct dose will have been given.

An under or overdose of 0.2mL for any dose above 2.5mL is unlikely to be of any clinical significance, but consistency of use should nonetheless be advised.

Low Dose Syringes

Due to the large hub at the end of the syringes most syringe sizes are not appropriate for the delivery of small doses (particularly less than 1mL). For this reason special "Low-dose" (LD) syringes are available, primarily 1mL and 2.5mL and 3mL syringes. Whilst each company has a slightly different design, they are all similar to that shown in Figure 1 below:

Figure 1

There is the risk of significant drug overdose if used incorrectly. This is due to the presence of an outer moat, or deadspace on the tip of the syringe. The volume of the outer moat varies according to manufacturer and syringe size, but may be as much as 0.15mL.

Any solution in the outer moat is not of concern if the dose is being given via an enteral feeding tube. The dose delivered will be accurate.

These syringes will deliver accurate low doses orally, providing the outside hub has been cleared of fluid before administration. For clinical accuracy it is important that the outside hub is empty prior to any oral use of the syringes. This can be achieved by either drawing the dose up via a bottle adaptor or a medicine straw, or by flicking the syringe to expel the excess fluid from the moat.

Figure 2 shows the agreed artwork to accompany the syringes from the manufacturers. The pictures show what is necessary before use of the syringes.

Figure 2

The advantages and disadvantages of these methods are summarised in Table 1.

The other consideration when using LD ENFit syringes to give medicines orally is that the syringe necks and "wings" (see Figure 1) are larger than those on other syringes, which may be an issue in particular patient groups e.g. cleft lip and palate patients, neonates etc.

How to ensure safe administration of medicines using ENFit syringes?

ENFit syringes are specifically designed for enteral NOT oral administration. Alternative purple syringes, bottle adapters and quills or filter straws will be available for oral administration of medicines. However, in the acute setting storing and using two incompatible but visually similar types of products has the potential to add risk. Many healthcare institutions are considering also using ENFit syringes to give medicines orally (although they do not have a CE marking for this). For individual patients at home it is probably best practice to give them oral syringes for oral use and enteral (ENFit) syringes for enteral use.

There are several methods of ensuring that medicine doses are administered accurately with LD ENFit syringes, each with attendant advantages and disadvantages. The most appropriate method may vary between different patient groups. These methods are summarised in Table 1 on Page 4. An options appraisal is included on page 5.

Whichever method is used, it is critical that the outer "moat" on the syringe (see Figure 1) is empty prior to administration. Medicine in this section of the syringe is not part of the measured dose, and if administered will result in overdose. The magnitude of the overdose will be increased if the overall dose volume is low.

Summary

ENFit syringes can be used to administer medicines, both orally and via an enteral feeding tube. However, there is the risk of significant overdose when drawing up medicine volumes using low dose syringes. The risk of overdose is greatest with volumes of less than 1mL being administered via the oral route.

In order to mitigate this risk, it is necessary to ensure that the "outer moat" of the syringe tip is empty prior to administration. This can be achieved in several ways, but the safest method when drawing up dose volumes less than 1mL is as follows:

*When drawing up a dose volume of under 1mL into an enteral syringe for medicine **administration via an enteral feeding** **tube**, it is best to draw up using a bottle bung or using a straw to avoid the risk of overdosing through any drug solution remaining in the moat being displaced into the enteral feeding tube.*

*When drawing up a dose volume of under 1mL into an enteral syringe for **oral administration**, it is essential that a bottle bung or straw are used to draw up the dose from the bottle in order to avoid overdosing through administration of the reservoir content to the child.*

Steve Tomlin and Andrew Wignell on behalf of the NPPG Committee

References

1. National Patient Safety Agency (2007): *Promoting safer measurement and administration of liquid medicines via oral and other enteral routes*; http://www.nrls.npsa.nhs.uk/resources/?entryid45=59808
2. NHS England (2015): *Never Events 2015-2016: https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2016/01/never-evnts-list-15-16-v2.pdf*
3. International Standardisation Organisation (2016), Standard 80369-3, *Connectors for enteral applications*; https://www.iso.org/obp/ui/#iso:std:iso:80369:-3:ed-1:v1:en

Table 1: Summary of Methods of Ensuring Safe Dosing with ENFit Syringes

Method	Advantages	Disadvantages
Draw up medicine via a bottle adaptor / bung.	• Moat will be empty after medicine has been drawn up, removing the risk of overdose. • Syringe does not come into contact with the liquid in the bottle, reducing the risk of cross contamination if an individual syringe is used for multiple doses. • If used routinely, bottle adaptors may further prevent the risk of a wrong-route never event by preventing the drawing up of a medicine into an IV syringe. Although it depends on the manufacturer, many bottle adaptors can be left in situ until the bottle is empty, or at least for multiple doses.	• It may not be possible to obtain a bottle adaptor to fit all medicine bottles. If using crushed tablets the liquid will be in an open container not a bottle • Some adaptors do not allow the original Child Proof bottle cap to be replaced over the top. This can lead to leaking of medicine, particularly during transit and risks a child gaining access to a medicine. • ENFit Bottle adaptors are NOT compatible with oral syringes, meaning that drawing up doses from the same bottle using an oral syringe is not possible. • Cost of adaptors, in addition to syringe costs.
Draw up medicine using a filter straw or quill.	• Moat will be empty after medicine has been drawn up, removing the risk of overdose. • Syringe does not come into contact with the liquid in the bottle, reducing the risk of cross contamination if an individual syringe is used for multiple doses. • Filter straws could also be used for oral administration, once attached to the syringe, and may be preferable to the LD tip in some situations. Due to the high negative pressure in a filter straw attached to an empty syringe, it is unlikely that a patient will be able to suck out the contents of the tube, so the risk of inadvertent overdose by this method is low.	• Routine use of filter straws or quills is likely to increase medicines wastage due to drug adherence to the tubing. This may be most problematic with controlled drugs. • Cost of medicines straws, in addition to syringe costs, particularly given they are only appropriate for single use. • Potentially a less robust physical barrier to the use of an IV syringe to draw up an oral dose than a bottle adaptor: IV filter straws are also available plus individual drawing needs to remember to use the medicine straw
Draw up medicine directly from a plastic medicine cup. "Flick" the syringe to remove the liquid from the moat prior to administration.	• Syringe does not come into contact with the liquid in the bottle, reducing the risk of cross contamination if an individual syringe is used for multiple doses. • Reduced costs for equipment needed. • Removes the need for duplicate supply of each stock medicine (one with an ORAL medicines bottle adapter and one with an ENFit medicines bottle adapter)	• Person administering medicine may forget to flick the syringe and administer a wrong dose. • Potential for occupational exposure to medicines through flicking of syringe. This may be especially significant with more toxic drugs. • Potential for increased wastage of medicine. • Does not prevent the use of an IV syringe to draw up an oral dose.

Optional Appraisal for Use

If separate syringes for Oral & Enteral routes are implemented

1. Route of administration must be decided BEFORE preparation .

RISK: Adds additional decisions re: syringe selection, preparation & administration technique adding opportunity for error.

2. Syringes ENFit & Oral would need to be stocked

RISK: Visually similar Luer, Oral & ENFit (LD and normal) syringe & packaging, potential for error during transition and following implementation during supply / storage / syringe selection. Incompatible connections prevent Oral to Enteral system administration however no controls in place to prevent ENFit Enteral syringe being used to administer a medicine orally

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

RISK: Medicines Straws –Extra step, risk of confusion as oral syringes don't require a straw. Cost Pressure - single use item required for all enteral doses (all doses if standardise practice and use for ENFit & Oral syringe filling)

Bottle Adapters – Double liquid medicines stock required to accommodate Oral & ENFit adapters – Cost pressure from increased medicines stock & bottle adapters, unable to distinguish between bottles with Oral or ENFit adapter

Direct fill - Low dose syringe 'moat' is filled with medicine; moat contents are displaced by the feeding tube connection during administration however caking of medicines could result in bacterial growth / damage to feeding tube connection/ exposure to medicines being administered. Oral administration of moat could add up to 0.2ml volume to dose. Tapping out excess medicine from moat would similarly increase occupational exposure to medicines.

4. Incompatibility of Luer & ENFit enteral feeding systems / medicines syringes

RISK: Adapters are necessary during transition

If ENFit syringes are used for Enteral and Oral route for In-patients

1. Decision on route of administration will NOT be required BEFORE preparation for dose volumes >2.5mL OR for dose volumes <2.5mL if always prepared with a medicines straw.

RISK: An additional 'rule' & new practice required due to risk of error with low doses due to design of syringes.

2. ENFit Syringes only stocked in clinical areas

RISK: Mis-ordering/ supply and selection could be limited with procurement controls

3. Accuracy of ENFit syringes- ENFit Bottle adapters & straws (for Low Dose syringes) used as standard

RISK: Medicines Straws –Necessary for medicines dose volumes <2.5mL (Standardise practice to enable dose accuracy for either Oral or Enteral administration). Cost Pressure per dose <2.5mL

Bottle Adapters Cost pressure of ENFit adapters

Direct fill – Reliant upon culture of this being unacceptable with Low dose syringes and provision of bottle adapters / straws to avoid risk of the 'moat' being filled with medicine.

4. Design of ENFit Syringe (Low Dose only)

RISK: Initial batches of syringes have tip & barrel joined together – sucking/biting can break join with potential risk of choking on swallowing the tip. New batches are moulded

W Design (Width added by plastic 'Wings' behind the syringe tip to prevent accidental passage down a Trache tube) potential to cause accidental injury to the mouth during oral administration due to size & sharp edges. Dose preparation and administration with a medicines straw use would remove this risk, but risk of overdose if straw content sucked out.

5. Incompatibility of Luer & ENFit enteral feeding systems / medicines syringes

RISK: Adapters are necessary during transition