Implementation Support for Phase 2 of Transition to ENFit Devices

Contents:

I. Suggested timelines and actions for the introduction of ENFit devices from the 4th July 2016

- Agree local implementation plan based on manufacturer and local procurement guidance on product availability to your area.

- Consider patient discharge planning and admissions to and from out of area locations.

- Agree a communication plan with your enteral feed company provider and tube or syringe manufacturer.

II. Potential risks (for adaptation and use in local risk assessments)

Potential Risk	What could go wrong?	Causes / Hazard	Consequences	Current controls	Risk ranking			Recommendations	Risk Ranking		
					C	L	R		C	L	R
1	Communication and training.	Patients, carers and staff are not given adequate support and guidance regarding the introduction of ENFit.	• Connection confusion may delay administration of enteral tube feed. • Confusion and lack of understanding as to how to attach the enteral adaptors during the transition phase. • Potential for a mixture of original and transition sets to be in circulation both in the acute and community setting.	• Refer to available sources of information: GEDSA UK, NNNG, PENG, BAPEN, feed companies and tube/syringe manufacturers.				• Identify an implementation lead within your NHS organisation. • Introduce an MDT steering group to guide the implementation process across primary and secondary care. Consider procurement/ pharmacy/endoscopy/ A&E /radiology/ DNs/gastroenterology/acute nursing/feed company/tube or syringe manufacturers. • Identify potential training issues relevant to individual enterally fed patients within your clinical caseload. • Request support from your local enteral feed contract or tube/syringe provider and agree a collaborative implementation plan. • Access training resources to be used as visual aids to train patients, carers and NHS staff. • Update local nutrition policies and procedures. • Review trust procedure to ensure stock utilisation.			

Potential Risk	What could go wrong?	Causes / Hazard	Consequences	Current controls	Risk ranking			Recommendations	Risk Ranking		
					C	L	R		C	L	R
2	Adaptor Specific Issues.	• Await confirmation of CE mark allocated and manufactures information for use regarding usage frequency and cleaning. • Potential choking risk due to size and being untethered in some cases. • Potential to lose adaptors, which would have a financial implication as increased giving set requirement, or additional purchase of adaptor packs. • Potential to throw away adaptors when connecting single use syringes. • Infection control issue. • Access to adaptors for ENFit syringe connection for bolus fed patients where ENFit enteral feed tube is not in placed initially in July 2016.	• Harm to patient from choking • Financial burden to Trust • Infection risk to patients • Patients unable to connect syringe or giving set to tube or extension set.	• Fully connected giving set for use within a 24hr period. • Adaptors are expected to follow 24hr use of the giving set once attached. • Adaptors should now be manufactured individually wrapped • If single patient use can be used for multiple applications and within the lifetime of the giving set.				• Follow manufactures guidance and information for use documentation. • Risk assess choking risk if relevant to individual patient or care setting. • Ensure supply of spare adaptors to out of hours services and individual patient settings. • Highlight potential cost impact on your individual service if need to purchase additional packs of adaptors or as a result of throwing away unused non-ENFit stock. • If infection risk perceived as high for a specific population, e.g. immunocompromised consider frequency of use of adaptors and individual infection risk. • Syringe manufacturers will produce adaptors compatible with their product and estimate stock levels required which will vary dependent on product license/ IFU. • Complete local risk assessment relating to the Trusts transition to ENFit implementation plan. • Agree local strategy for transition to ENFit			

Potential Risk	What could go wrong?	Causes / Hazard	Consequences	Current controls	Risk ranking			Recommendations	Risk Ranking		
					C	L	R		C	L	R
3	Transition Issues.	• Inadequate supply of ENFit devices to meet demand. • Transition giving set will be available until the end of December 2016. ENFit only giving sets will be available thereafter. • Additional training and support may be required.	• Connectivity issues, such as inability to connect giving set of enteral feeds to the enteral tube. • Increased burden on dietetic services providing training or delivering syringes, extension sets or adapters to patients.	• Provision of adaptors. • Transition giving sets to be supplied by the companies together with the adaptor packs until end of December 2016. • Adaptor packs may be required after this date. • Feed company ordering systems should have dispatched order history.				• Ensure adequate stock has arrived within the Trust before implementation date. • Liaise with local procurement to ensure orders are placed in timely fashion to replenish usage. Refer to information from supply chain. • Enteral companies to ensure they have adequate stock before implementation dates of the Trusts they cover. Any shortfalls to be relayed to the Trusts in a timely manner. • Clarify with feed provider how delivery information will be recorded and available to view on enteral feed contractor's delivery system. Initial information suggests this may not be clear or identifiable. • Future planning of tube replacement of your trusts enterally fed population from July 2016. • Which patients will be changed in primary or secondary care settings. • Identify which patients have been transferred over to ENFit giving set and feeding end and which are outstanding. Or Consider setting up database of patients on HEF to monitor Phase 2 transition onto ENFit			

III. Frequently asked questions for Healthcare Professionals and Healthcare Providers

1. Why is a new enteral connector being introduced?

To reduce the risk of misconnections, the International Organization for Standardisation (ISO) has developed a series of new International Standards for small bore connectors in a range of medical devices (ISO 80369). Currently included are breathing systems and driving gases, enteral feeding, limb cuff inflation devices, neuraxial devices, and intravascular/ hypodermic applications. The standards define the design of the connectors for these applications so that the risk of misconnections with other connectors in the series is reduced.

2. What are the changes?

The new enteral connector, known as ENFit

- addresses “patient side” connections between feeding tubes, administration sets, enteral syringes, and other enteral devices
- passes a rigorous validation process including computer aided design (CAD), human factors, and usability testing as part of the pathway to ISO standards
- Additional testing on dose accuracy of medication syringes has ensured this risk is minimised.

3. When will Healthcare providers have to change?

The introduction of Phase 2 is from the 4th of July 2016 when ENFit devices will be available to order from supply chain.

- www.supplychain.nhs.uk/product-news/customer-notices/2016/june/105-enfit-connector-update--npc/

4. What will each Healthcare provider consider doing?

- Identify implementation lead for Trust
- Introduce MDT steering group to manage transition, including representatives from both primary & secondary care
- Who needs to know? Consider Pharmacy, Procurement, Endoscopy, Radiology, gastroenterology, acute nursing, community nursing, health and social care agencies, nursing homes.
- Risk assess the process and equipment
- Update Nutrition policies and local information
- Share information and create awareness
- Agree an implementation plan between acute and community services. Ensure communication of ENFit device placement/ tube end replacement/ and associated ancillary items from point of placement and ordering of associated equipment on discharge
- Confirm a local implementation plan including
    - Seek agreement for roles and responsibilities with feed company providers and tube/syringe manufacturers
    - Training, information and equipment for patients and staff (samples and training materials).

5. Transition Sets

Transition feeding/administration sets will allow connection to both current feeding tubes as well as new tubes. Transition feeding/administration sets will allow manufacturers and NHS to work through current stock of feeding tubes and feeding/administration sets. Manufacturers have agreed to keep these in circulation until December 2016 at the earliest this may extend dependant on stock utilisation.

6. What will the enteral devices look like?

Your device manufacturer representatives will have samples available for training purposes and each company will have their specific product information that you may want to include in your local policies. Enteral plastic providers are producing training literature for patients and staff.

7. Will patients have to change the way they feed?

No. Patients will continue to use their tube in the same way. They will not have to change their feed or how or when they feed, but they may have to use an adaptor in the interim period to connect their giving set to their feeding tube, or to administer medication or flushes of water via the medicines port.

There will be an increased use of adaptors during transition. These will need to be provided separately for bolus fed patients. It is advised that you discuss and agree a process direct with your own provider.

8. Will we have to use different syringes?

Syringes will be available to order at the same time as the feeding tubes (from 4th July 2016). The transition sets with adaptors will be available until December 2016. It makes sense to use up non ENFit stock.

9. What if the company that supplies the Trust feed, administration sets or syringes change?

That won't matter as giving sets from all companies will be changing to ENFit.

10. Where will we get the new ENFit devices from?

You will continue to get your supplies in your usual way. Supply chain will dual list ENFit and Non ENFit items available to order from the 4th July 2016. The changes will be introduced automatically. You should liaise with procurement to ensure all ancillary codes and EOS codes are updated. The following communication has been sent to all supply chain procurement managers nationally.

- www.supplychain.nhs.uk/product-news/customer-notices/2016/june/105-enfit-connector-update--npc/

Ensure each ordering point has updated ordering information including theatres, endoscopy and radiology. Agree a method of communication to identify the placement of an ENFit device. Ensure all wards have a supply of adaptors to ensure connectivity between stocks of syringes and extension sets.

11. When will the current giving sets and tubes run out?

That will differ depending on the stock your organisation holds. Your feed company or ancillary items manufacturer will be able to provide timelines for products entering or exiting the market.

Homecare providers are clarifying a method of identifying ENFit or NON ENFit delivery. You should direct this query to your local provider. You may wish to consider adding the potential for your patients receiving mixed items on enteral equipment deliveries to your trust risk register. This has the potential to impact on admission prevention figures.

12. How will button devices be affected by this change?

The button devices will not change. ENFit extension sets, will have an ENFit connector. It is advisable to liaise with your enteral tube provider and request samples to establish and individual manufacturer changes to production.

13. Will adaptors be available separately?

It has been recommended that adaptors will be supplied with each device and transition set. You should confirm with manufacturer whether their products will include an adapter. Some homecare providers have agreed to automatically send bolus fed patients a supply of adaptors in the event they receive ENFit syringes, or have their device changed to ENFit, to allow utilisation of syringe stock.

14. How much will these cost?

There will be no additional cost to the Trust for the transition sets. There may be a small charge for adaptor packs and a pricing change for tubes. For further details contact your local provider.

15. Where can I get more information?

- For more information about the introduction of new ENFit connectors in the NHS: www.england.nhs.uk/ourwork/patientsafety/medical-device-incidents/small-bore-connectors
- www.supplychain.nhs.uk/product-news/customer-notices/2016/june/105-enfit-connector-update--npc/

Links to other useful websites

- Global Enteral Device Supplier Association (GEDSA): www.gedsa.org
- Communication programme developed by GEDSA: www.stayconnected.org
- National Nurse Nutrition Group (NNNG): www.nnng.org.uk
- Parenteral and Enteral Nutrition Group – A Specialist Group of the British Dietetic Association: www.peng.org.uk and www.bda.uk.com

See also the websites of your local industry providers.

IV. Frequently asked questions for Patients and Carers

1. Why is a new enteral connector being introduced?

Different types of medical devices/equipment can easily be connected using Luer connectors. For example, an inflation tube of a blood pressure monitor can be connected to an intravenous catheter; an enteral feed administration set can be connected to a tracheostomy tube, any of which may result in serious harm. To reduce the risk of misconnections, the International Organization for Standardisation (ISO) has developed a series of new International Standards in a range of medical devices. Essentially this is being introduced across the world to improve your (patient) safety.

2. What are the changes?

The new ENFit connector provides a simple way to reduce the risk of enteral tube feeding misconnections and improve safety. Your tube will not change in its function but you will notice the connector you attach the feeding set and syringes to will be slightly different as will the feeding sets and syringes.

3. When will I have to change to the new connectors?

The introduction of ENFit will be in two phases. This is to have a simple and seamless transition from your current system. In September 2015 'transitions sets' will be introduced, they will have adaptors that will fit all current tubes and syringes. The new tubes and syringes will be introduced from the 4th of July 2016.

4. What is a 'transition set'?

Transition feeding/administration sets will allow connection to both current feeding tubes as well as new tubes. Transition feeding/administration sets allow manufacturers and NHS to work through current stock of feeding tubes, syringes, feeding/administration sets and ancillaries.

5. What will the ENFit devices look like?

Your Healthcare Professional will be able to provide you with information before the introduction of Transition sets from September 2015 and Tubes and syringes in March 2016.

6. Will they fit the tubes I currently use, even if from a different company?

The transition sets will fit all tubes that are currently used and every company that provides feeding sets and tubes will be changing to ENFit connectors, so every set, tube and syringe will have a the universal (ENFit) connector.

7. Will I have to change the way I feed?

You will continue to use your tube in the same way. You will not have to change your feed or how and when you feed.

8. Will we have to different syringes?

The syringes will change at the same time as the tubes (July 4th 2016). The transition sets with adaptors will be available for many months. If you have a non ENFit tube you will be able to continue to use it with adaptors until the tube needs to be replaced – when your feeding tube is replaced it will be with an ENFit tube.

9. What if the company that supplies the feed and sets change?

That won't matter as all companies will be changing to the new ENFit connector and will have sets that fit every feeding tube.

10. Will we have to change the way we get our tubes and supplies?

You will continue to get your supplies in your usual way and the changes will be introduced automatically. Each company will automatically substitute with ENFit if an obsolete code is used during the introductory period. Your Healthcare provider and professional are working with the companies that deliver your supplies to ensure you are able to continue to use your tube to feed.

11. What will my Healthcare provider be doing now to make sure I have the right equipment?

Each Healthcare provider is working closely with the feed company to make sure training and information is available for you.

12. When will the current sets and tubes run out?

That will differ depending on the stock each Healthcare Provider or feed company has to use up, but adaptors will be available for some time to ensure you are always able to use your tube.

13. How will button tubes be affected by this change?

The button tubes will continue to be used in the same way. The new extension sets will have the new ENFit connector. Adapters will be made available if needed to allow connection with a non-ENFit syringe – the connector that attaches the extension/feeding set to the button will not change only.

14. Will adaptors be available separately?

Adaptors will be supplied by your homecare delivery company. Please contact your Health care professional for further information.

15. Where can I get more information?

Please contact your local Health Care Provider that you would normally contact about your tube or feed.