Implementation Support for Enfit Connector

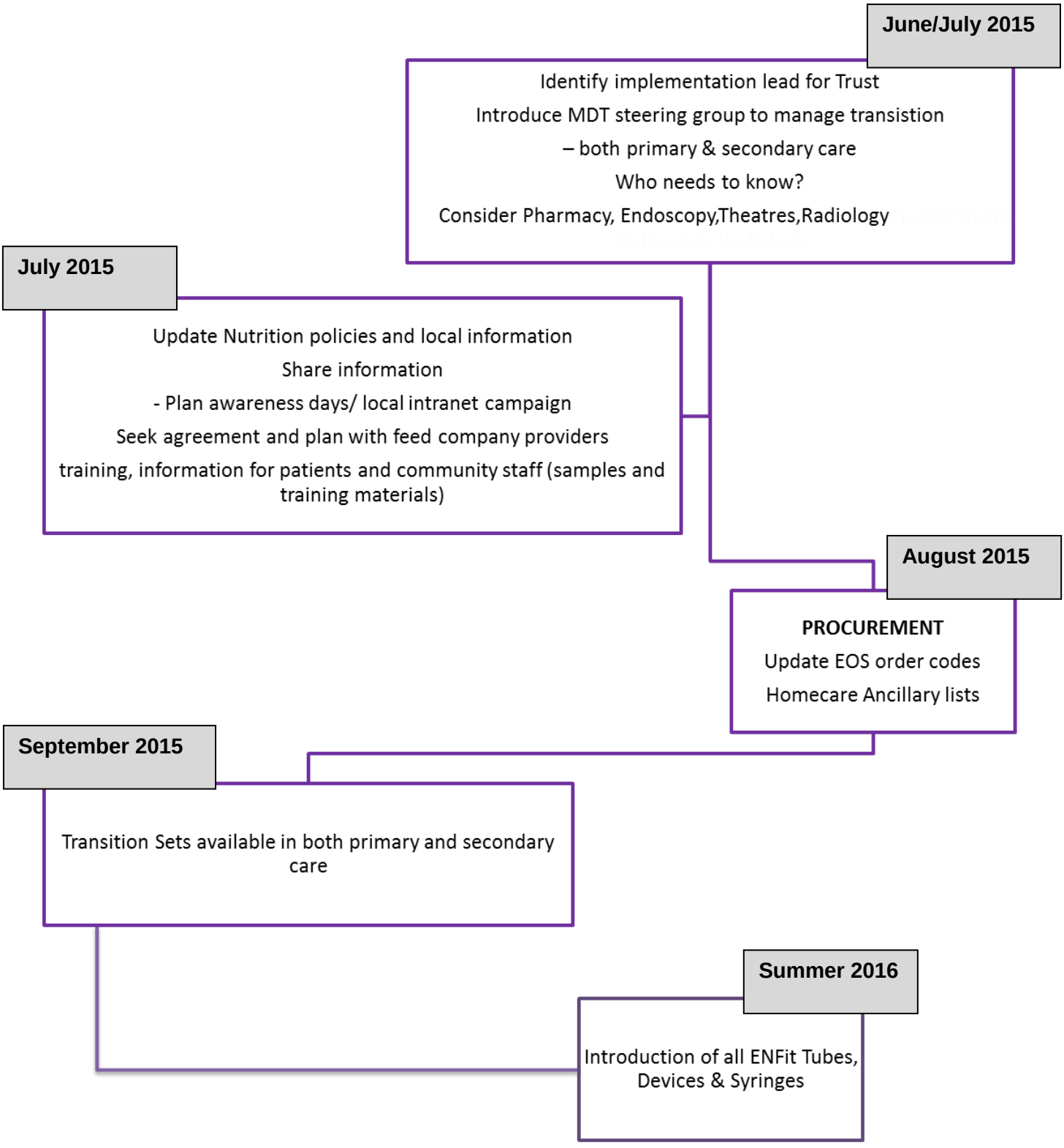
I. **Suggested timelines and actions** for introduction of ENFit connectors Transition Sets from September 2015.

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

III. Frequently Asked Questions for **Healthcare Professionals and Healthcare Providers**

IV. Frequently Asked Questions for **patients and carers**

I. Suggested timelines and actions for introduction of ENFit connectors Transition Sets September 2015



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 of mixture of original and transition sets in circulation in both acute and community setting.	• Refer available resources: GEDSA UK, NNNG, PENG, BAPEN and manufacturer.				• 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/ DN's. • Identify potential training issues relevant to individual enterally fed patients within your clinical caseload • Request support from your local enteral feed contract provider and agree a collaborative implementation plan. • Access training resources to be used as a visual aids in training of patients, carers and NHS staff, to demonstrate the minimal impact of the first phase of implementation. • Update local nutrition policies and procedures. • Review trust procedure to ensure stock rotation.			

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. • Infection Control issue, if spare adaptors are produced in large pack size this will increase the risk of cross contamination. • Access to adaptors for Enfit syringe connection for bolus fed patients where Enfit enteral feed tube is not in placed initially in summer 2016.	• If single patient use can be used for multiple applications and within the lifetime of the giving set.	• Fully connected giving set for use within a 24hr period.				• Follow manufactures guidance and Information for use documentation. Information which should be available prior to introducing into the market. • Risk assess choking risk if relevant to individual patient or care setting. • Ensure out of hours supply of spare connectors to out of hours services and individual patients. • Highlight potential cost impact on your individual service if need to purchase additional packs. • If risk perceived as high for a specific population, e.g. immunocompromised consider frequency of use of adaptors an individual infection risk. • Syringe manufacturers to consider adaptor supply compatible with their product and estimate stock levels required which will vary dependent on product license/ IFU.			

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.	• Lack of enough supply of the transition sets to meet demand. • Identify which patients have been transferred over to Enfit G.S and which are outstanding.	• Inability to connect giving set of enteral feeds to the enteral tube. • Additional training and support may be required.	• Transition giving sets to be supplied by the companies together with the adaptor packs. • 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. • Enteral companies to ensure they have adequate stock before implementation dates of the Trusts they cover. Any shortfalls to be related 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. • Future planning of tube replacement of your trusts enterally fed population in preparation for summer 2016 when transition sets will be phased out.			

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, which will be known as ENFiT:

- addresses “patient side” connections between feeding tubes, administration sets, medication, flush, and bolus feeding 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

3. When will Healthcare providers have to change?

The introduction will be in two phases. From September 2015 ‘transition feeding sets’ will be introduced, these will have adapters to fit current tubes and syringes. New feeding tubes, syringes and other ancillaries will be introduced in summer 2016.

4. What will each Healthcare provider may consider doing?

- Identify implementation lead for Trust
- Introduce MDT steering group to manage transition – both primary & secondary care
- Who needs to know? Consider Pharmacy, Procurement, Endoscopy, Radiology
- Risk assess the process and equipment
- Update Nutrition policies and local information
- Share information and create awareness
- Plan awareness days/ local intranet campaign
- Confirm a local implementation plan including
    - Seek agreement for roles and responsibilities with feed company providers
    - Training, information/equipment for patients and staff (samples and training materials)

5. 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 will allow manufacturers and NHS to work through current stock of feeding tubes and feeding/administration sets.

6. What will they look like?

Your Homecare feed company 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.

7. Will they fit the devices we currently use, even if from a different company?

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

8. 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.

9. Will we have to have different syringes?

The syringes will change at the same time as the feeding tubes (from summer 2016). The transition sets with adaptors will be available for many months. It makes sense to use up non ENFit stock between now and summer 2016.

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

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

11. Where will we get these from?

You will continue to get your supplies in your usual way the changes will be introduced automatically – you should liaise with procurement to ensure all ancillary codes and EOS codes are updated. NHSSC will automatically change their codes in summer 2016 for devices. Each company will automatically substitute with ENFit if an obsolete code is used during the introductory period. Ensure each ordering point has updated ordering information including theatres, endoscopy and radiology.

12. When will the current 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.

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

The button devices will continue to be used in the same way – the connector that is part of the button will not change only the extension sets.

14. 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.

15. How much will these cost?

There will be no additional cost to the Trust for the new transition sets. There may be a small charge for adaptor packs. and tubes.

16. Where can I get more information?

For more information about the introduction of new connectors in the NHS http://www.england.nhs.uk/ourwork/patientsafety/medical-device-incidents/small-bore-connectors/

Links to other useful websites:

- Global Enteral Device Supplier Association (GEDSA) http://www.gedsa.org/
- Communication programme developed by GEDSA http://www.stayconnected.org/
- British Association for Parenteral and Enteral Nutrition http://www.bapen.org.uk/
- National Nurse Nutrition Group (NNNG) http://www.nnng.org.uk/
- Parenteral and Enteral Nutrition Group – A Specialist Group of the British Dietetic Association http://www.peng.org.uk/ and https://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 in summer 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 they 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 summer 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 (EBFit) 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 or when you feed.

8. Will we have to have different syringes?

The syringes will change at the same time as the tubes (in summer 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 a ENFit tube. It makes sense to use up non ENFit stock between now and summer 2016.

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 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 is working with the companies that make the tubes and homecare companies to make sure order codes and supplies are in place already for both September 2015 and summer 2016

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

Each Healthcare provider is working closely with feed company and community healthcare professionals to make sure training and information is available for you and are in place before September 2015

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 connector that attaches the extension/feeding set to the button will not change only the extension sets connector to the feeding set.

14. Will adaptors be available separately?

Adaptors will be supplied with each device and transition set. Please contact your healthcare professional for further information.

15. Where can I get more information?

Please contact your local Healthcare provider that you would normally contact about your tube or feed.