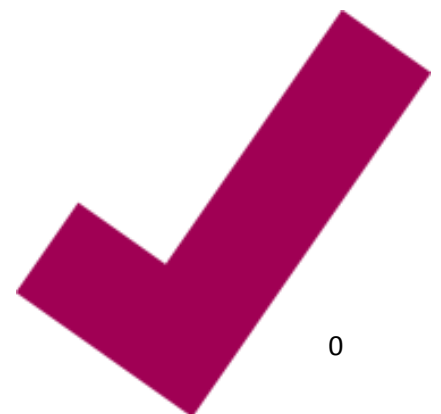


The NHS England Innovation and Technology Tariff 2017 to 2019 Technical notes



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Publications Gateway Reference: 06792

Document Purpose	Report
Document Name	The NHS England Innovation and Technology Tariff 2017 to 2019 Technical notes
Author	NHS England
Publication Date	09 May 2017
Target Audience	CCG Clinical Leaders, CCG Accountable Officers, CSU Managing Directors, Care Trust CEs, Foundation Trust CEs, Medical Directors, NHS Trust Board Chairs, NHS England Regional Directors, NHS England Directors of Commissioning Operations, Directors of Finance, NHS Trust CEs
Additional Circulation List	Directors of PH, Directors of Nursing, Local Authority CEs, Directors of Adult SSs, Allied Health Professionals
Description	This guidance is provided as a supporting document to section 3.4 of the 2017/18 and 2018/19 National Tariff Payment System. It sets out the innovation themes, specifications, reimbursement and reporting requirements.
Cross Reference	N/A
Superseded Docs (if applicable)	N/A
Action Required	Note the report findings and proposed next steps
Timing / Deadlines (if applicable)	N/A
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Document Status

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The NHS England Innovation and Technology Tariff 2017 to 2019 Technical notes

Version number: V 5.7

First published:

Updated: N/A

Prepared by: Paul Fenlon

Classification: Official

Equality and Health Inequalities Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

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1. Purpose and background

This guidance is provided as a supporting document to section 3.4 of the 2017/18 and 2018/19 *National Tariff Payment System*. It sets out the innovation themes, specifications, reimbursement and reporting requirements.

The Innovation and Technology Tariff (ITT) was introduced to incentivise the adoption and spread of transformational innovation in the NHS. The themes for the ITT were sought in conjunction with NHS Innovation Accelerator (NIA) programme (see section 2.1 for more information).

2. About the ITT

The ITT represents a new approach by using a number of mechanisms to fund innovations which meet the required theme specifications. The majority of the themes (2, 3, 4 and 5) are funded under a simple zero cost model. Providers order the innovations directly from the supplier at no cost and NHS England reimburses the supplier directly.

Themes 1 and 6 operate under different arrangements. For theme 1 “guided mediolateral episiotomy to minimise the risk of obstetric anal sphincter injury” providers will be reimbursed based on use. For theme 6 “Prostatic urethral lift systems to treat lower urinary tract symptoms of benign prostatic hyperplasia as a day case” providers are refunded under the National Tariff for this innovation. Further details on how each theme can be found in section 2.

Theme	Funding model	Page
Theme1 :- Guided mediolateral episiotomy to minimise the risk of obstetric anal sphincter injury	Incentive based on activity.	7
Theme 2:- Arterial connecting systems to reduce bacterial contamination and the accidental administration of medication	Provided under the zero cost model.	10
Theme 3:- Pneumonia prevention systems which are designed to stop ventilator-associated pneumonia	Provided under the zero cost model.	13
Theme 4:- Web based applications for the self-management of chronic obstructive pulmonary disease	Provided under the zero cost model.	18
Theme 5:- Frozen faecal microbiota transplantation for recurrent Clostridium difficile infection rates	Provided under the zero cost model.	22
Theme 6:- Prostatic urethral lift systems to treat lower urinary tract symptoms of benign prostatic hyperplasia as a day case	Funded under a new OPCS code in the National Tariff.	30

In parallel, but separately from the ITT, NHS England is centrally funding a 7th theme “Identification and measurement of atrial fibrillation through mobile ECG technology”. Further information on this programme of work is described in the separate note, which is also attached in appendix A.

The Academic Health Science Networks (AHSNs) have been closely involved in developing the ITT. Each AHSN can offer a range of support to help commissioners and providers to implement the ITT themes in local geographies. See <http://www.ahsnnetwork.com> for more information on AHSNs and Appendix B for a list of AHSN contacts.

NHS England is undertaking further work to develop its approach to the ITT with plans to expand it to new areas of innovation in 2018 /19. For further information on this or any other ITT related queries contact the Innovation and Research team at england.innovation@nhs.net

3. Nationally agreed pricing

NHS England will cover the costs of the innovations identified in this document as outlined in each theme specification. Additional costs associated with implementation are not covered by the ITT and should form the basis of local discussions.

This document identifies national prices which have been agreed between NHS England and the manufacturers/suppliers identified as being able to provide the innovations which meet the required specifications (except for prostatic urethral lift systems for benign hyperplasia, where National Tariff pricing applies). It is likely that local commissioners and providers will choose to use these on the basis that they consider them to be the best available price. However they are not precluded from engaging in additional negotiations, and commissioners and providers must still comply with the local pricing rules set out in the National Tariff.

4. ITT Suppliers

The themes for the ITT were sought in conjunction with the NHS Innovation Accelerator (NIA) programme. Submissions were tested against clinical criteria with input sought from leading medical experts.

Following due diligence on the innovation theme submissions the shortlist was evaluated by a Selection Panel on 13th October 2016. The Panel agreed 5 innovation themes for which providers would be funded through a centrally agreed pricing structure.

At the current time a number of suppliers have been identified in this document as meeting the clinical and service standards required to deliver the required outcomes. In the future other products or providers may be identified as being available. Current availability of approved suppliers can be found listed in each theme specification.

Any supplier of a product/innovation within the ITT who is not listed in this document but considers that they are or may be able to provide that innovation in accordance with the specifications in the ITT, may contact NHS England using the following

address to obtain information about review of the list and the process for future inclusion in the ITT: england.innovation@nhs.net

5. Data collection

To inform future work in promoting innovation, it is essential for NHS England to assess both the impact of the ITT in facilitating access to innovations and the impact of the innovations themselves (i.e. the extent to which the anticipated outcomes set out in section 2 are met through use of the innovations). For this purpose, providers are required to provide data on uptake and use. Details of the data reporting requirements are set out in the each theme specification.

As prostatic urethral lift systems to treat benign prostatic hyperplasia is covered by National Tariff coding and mandatory pricing, data about use of the procedure will be collected through National Tariff processes and specific data reporting requirements are not included for the ITT.

6. ITT and digital technology

The ITT aims to resolve some of the limitations in the types of innovations that can be incentivised through national prices. The COPD theme represents an initial step in testing methods which will work for digital health. This is a good example of where technology can be used to support patients with pulmonary rehabilitation who would otherwise struggle to attend a face to face appointment in secondary care. Currently the tariff is centred on funding activity primarily in secondary care where digital health can play an important role in improving patient care and improving system productivity. However NHS England recognises that significant gains can be made in primary care and the community. Different approaches to funding need to be considered for this to work.

Flexibility already exists in the National Tariff to allow commissioners to agree local prices which could be used to support innovations in digital health services. For example the National Payment System encourages providers and commissioners to agree local prices for non-consultant led and non-face-to-face activity and has with effect from 1st April removed the non-mandatory non face to face price. Reference costs should be considered as a starting point for a discussion on the development of services which could, where clinically appropriate, include digital products and services.

NHS England continues to support the adoption and roll out of digital health as set out in the “Next Steps on the NHS Five Year Forward View”. The plan references ways in which the NHS can harness new technology and innovation to meet new demands. In particular it references the use of digital technologies in mental health

and helping patients to manage their own long term conditions using NHS and NICE approved “Health Apps”, see <https://apps.beta.nhs.uk> for more information.

7. ITT themes and product specifications

The following section provides more information on each of the ITT themes. It sets out the specification met by the innovations which are covered by the ITT and explains the pricing and payment mechanisms applicable to each innovation.

Innovation and Technology Themes – Paid for centrally by NHS England

Theme 1: Guided mediolateral episiotomy to minimise the risk of obstetric anal sphincter injury

Theme 2: Arterial connecting systems to reduce bacterial contamination and the accidental administration of medication

Theme 3: Pneumonia prevention systems which are designed to stop ventilator-associated pneumonia

Theme 4: Web-based applications for the self-management of chronic obstructive pulmonary disease

Theme 5: Frozen faecal microbiota transplantation (FMT) for recurrent *Clostridium difficile* infection rates

Innovation and Technology Themes Paid through National Tariff

Theme 6: Management of Benign prostatic hyperplasia as a day case

8. Theme and Product Specification – Guided mediolateral episiotomy scissors

Expected outcome:

Approximately 15% of births in England require an episiotomy. Of these, around 25% experience OASIS. OASIS repair, litigation and elective caesarean sections cost the NHS £57 million annually. The angle of the cut is important and NICE Guidance recommends that cuts need to be between 45 and 60 degrees to reduce the incidence of poor patient outcomes, reconstructive surgery and litigation costs. The use of angled scissors in episiotomies therefore should improve patient experience and outcomes and reduce OASIS repair and litigation. Recent published evidence shows using angled scissors can lead to a reduction in OASIS between 18-50%.

Payment / price detail:

NHS England will pay £16 per patient to NHS providers who implement this innovation. This price, which is based on an estimate of 20 uses, should cover the costs of the purchase of an appropriate set of angled scissors within the first year. The £16 per patient use price will be reimbursed by NHS England on a quarterly basis based on recorded evidence of use. See section 5 in the specification below for reporting instructions.

Product availability:

The Department of Health have centrally procured a number of angled episiotomy scissors and once there is agreement between providers and commissioners on usage, providers may purchase the appropriate product via the NHS Supply chain website. For this theme NHS England will reimburse providers £16 per patient use. Order from NHS Supply Chain.

<http://my.supplychain.nhs.uk/Catalogue/product/fcc454>

Product Specification:

8.0. Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific details as to the basis on which this product is included in the Innovation and Technology Tariff (ITT) with respect to guided mediolateral episiotomy.

8.1. Population Needs

8.1.1. National context and evidence base

An episiotomy is a procedure performed during labour, in which a woman's vaginal wall and perineum (the area between the vagina and anus) are cut in order to allow the baby to pass through the vagina more easily.¹ In 2011/2012, 15.2% (101,678) of all births in England required an episiotomy.² Studies have demonstrated that where

¹ HESonline (2012) [NHS Maternity Statistics – England, 2011–2012](#). Published December 06, 2012 [Online accessed 12 March 2015]

² Ibid

clinically indicated, mediolateral episiotomy can protect against obstetric anal sphincter injuries (OASIS), which are the most common cause of faecal incontinence in otherwise healthy women. They occur in 2.9% of births in the UK overall, in 6.1% of first-time births and 1.7% of births to women who have given birth 2 or more times before.³ A meta-analysis found that 30% of women who had an OASI still had symptoms 1 year after childbirth.⁴ Symptoms can include faecal urgency, inability to control wind and uncontrolled bowel movements.⁵

Guidance from NICE and the Royal College of Obstetricians and Gynaecologists (RCOG) states that where indicated, a mediolateral approach to episiotomy is preferable. Evidence supports an angle of incision 60 degrees from the perineal midline to maximise the effectiveness of the procedure and minimise the risk of complications.^{6,7}

8.2. Scope

8.2.1. Aims and objectives of product

Products covered under this ITT theme must aim to:

Prevent avoidable harm by removing human error; specifically in reducing the incidence of obstetric anal sphincter injuries and of 3rd/4th degree tears.

8.2.2. Product description

Products covered under this ITT theme must:

- Be a surgical incision device
- Offer an alternative to the standard episiotomy scissors (for which the cutting angle must be estimated), to facilitate accurate mediolateral episiotomy during labour at 60 degrees to the perineal midline, as per the recommendations of NICE and the RCOG.
- Be designed for use by qualified midwives and obstetricians trained in mediolateral episiotomy
- Not need any special maintenance, servicing or training measures, and should require the same reprocessing as normal episiotomy scissors

³ Thiagamoorthy G, Johnson A, Thakar R et al. (2014) National survey of perineal trauma and its subsequent management in the United Kingdom. International Urogynecology Journal 25: 1621–7

⁴ Oberwalder M, Connor J, Wexner SD (2003) Meta-analysis to determine the incidence of obstetric anal sphincter damage. British Journal of Surgery 90: 1333–7

⁵ Dudding TC, Vaizey CJ, Kamm MA (2008) Obstetric anal sphincter injury: Incidence, Risk Factors, and Management. Annals of Surgery; 247: 224–37

⁶ Kalis V, Karbanova J, Horak M et al. (2008) The incision angle of mediolateral episiotomy before and after repair. International Journal of Gynaecology and Obstetrics 103: 5–8

⁷ Stedenfeldt M, Pirhonen J, Blix E et al. (2012) Episiotomy characteristics and risks for obstetric anal sphincter injuries: a case-control study. British Journal of Obstetrics and Gynaecology 119: 724–30

8.2.3. Population covered

Products covered under this for ITT theme must be appropriate for use in:

- Pregnant women during labour whom an episiotomy is indicated
- Secondary care midwifery and obstetric units, primary care midwifery units or birth centres and during home births

8.2.4. Clinical Standards

Products covered under this ITT theme must:

- Be CE-marked as a Class I medical device
- Be supported by a sufficient clinical evidence-base, i.e. governed by criteria similar to those used by NICE.
- As of 2017 NICE Medtech Briefing (MIB33) recommends, the EPISCISSORS-60 as the sole guided mediolateral episiotomy scissors on the market compliant with EU health and safety requirements

8.3. Applicable Service Standards

8.3.1. Applicable national standards (e.g. NICE)

Episcissors-60 for guided mediolateral episiotomy: Medtech innovation briefing [MIB33] (published July 2015)

8.3.2. Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

Royal College of Obstetricians and Gynaecologists: Third- and Fourth-degree Perineal Tears, Management (Green-top Guideline No. 29)

8.4. Applicable quality requirements and CQUIN goals

None

8.4.1. Reporting

For this theme reporting should be on a monthly basis where possible. Payments will be made directly to the provider at £16 per patient use based on recorded evidence of use. For each period of activity claimed providers must report back on the following minimal data set:-

- Number of mothers requiring surgical repair after obstetric anal sphincter injury for the previous quarter. This is only required for the first claim.

- Number of guided mediolateral episiotomies undertaken using the Episcissors or other approved device during this period of reporting. Providers will be paid based on this number.
- Number of mothers requiring additional surgical repair after undergoing guided mediolateral episiotomy during this period of reporting
- Average discharge time of mothers who have received a guided mediolateral episiotomy using the Episcissors or other approved device.

Reports should be returned to Arden GEM CSU using the following email address FinanceQueries@ardengemcsu.nhs.uk . CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address.

9. Theme and Product Specification – Arterial connecting systems to reduce bacterial contamination and the accidental administration of medication

Expected outcome:

Arterial cannulation is associated with complications including bacterial contamination, accidental intra-arterial injection and blood spillage. Needle-free connectors prevent blood spillage and through a one-way valve allow aspiration only thus preventing accidental administration of medication to the arterial line.

Arterial line placement is a common procedure in various critical care settings. Intra-arterial blood pressure (BP) measurement is more accurate than measurement of BP by non-invasive means, especially in the critically ill. Although rare, when wrong route drug administration occurs, it has the potential to cause serious damage to the vessel and surrounding tissue.

Payment / price detail:

The ITT agreed price for this innovation is £2 per unit. This is available to providers under the zero cost model. See section 5 in the specification below for reporting instructions.

Product availability:

From the 1st April the Needle-free arterial non-injectable connector (NIC) devices can be ordered direct from Amdel Medical www.amdelmedical.com under the zero cost model. NHS England is working to include this product and any others which may meet the specification on the NHS Supply Chain by the end of summer 2017.

Product Specification:

9.0. Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific details as to the basis on which this product is included in the Innovation and Technology Tariff (ITT) with respect to arterial connecting systems to reduce bacterial contamination and the accidental administration of medication.

9.1. Population Needs

9.1.1. National/local context and evidence base

Patients in intensive care often require arterial access lines to provide blood pressure monitoring, arterial blood gas readings and to facilitate the collection of numerous and repetitive blood samples⁸. The administration of medication via this line is not advised, and almost never procedurally carried out because of the potential to cause serious damage to the vessel and surrounding tissue. However, given the environment usually surrounding a patient with an arterial line (a busy clinical environment, many ports, many different lines, and a need for rapid interventionist care), accidental injection of IV medication into arterial lines has been reported, including cases where the resulting necrosis has led to major amputations.

Accidental injection into the arterial line currently occurs because the standard arterial connectors do not prevent the ability to administer medication into the line. The misadministration of medication via the wrong route is classified as a “never”-event.

A difficulty is that accidental injection into the arterial line is well-known to be underreported. In a national survey of ICUs in England, for example, 28.5% of responding ICUs reported that they had seen an accidental injection into the arterial line within the last 5 years.

9.2. Scope

9.2.1. Aims and objectives of product

Products covered under this ITT theme must aim to:

- Improve arterial line safety for patients
- Minimise the risk of transmission of blood borne infections from patients to staff
- Make arterial line sampling a simpler process for staff
- Prevent incorrect administration of medication

⁸ The non-injectable arterial connector (NIC): A cost effectiveness assessment to improve arterial line safety - Dr Maryanne Mariyaselvam, Dr Mark Blunt, Dr Peter Young (The Queen Elizabeth Hospital, Kings Lynn), The Eastern Academic Health Science Network, Patient Safety Study FC171013/11

9.2.2. Product description/care pathway

Products covered under this ITT theme must:

- Be needle-free connector for arterial cannulation using a one-way valve
- Allow aspiration only
- Be attached to the sampling port of the 3-way tap, via the luer connection

- Be compatible with other current NHS equipment linked with existing arterial line connectors; in other words, offer a like for like replacement for currently used arterial connectors or caps currently used in the NHS to cover the sampling port of the arterial line.
- Be appropriate for use in operating theatres and critical care units (i.e. intensive care units, high dependency units, major trauma units, etc.)
- Prevent the misadministration of medication into the arterial line
- Prevent the ingress of bacteria into the arterial line
- Prevent blood spillage during sampling
- Be suitable to remain on the arterial line for the duration of time the arterial line is used (according to individual hospital policy, between 3-7 days)
- Use the same method as with standard arterial connectors for taking a blood gas sample
- Require only minimal, once-off training for staff
- Not require any additional facilities or technologies to use the device

The needle-free arterial non-injectable connector (NIC; Amdel Medical) is the only such CE-marked device currently available, as per [NICE Medtech Briefing \[MIB85\]](#).

9.2.3. Population covered

Products covered under this ITT theme must be appropriate for use in:

- Adult patients with arterial lines in critical care facilities, operating theatres, and emergency departments.

9.2.4. Clinical standards /acceptance and exclusion criteria and thresholds

Acceptance Criteria:

- None

Exclusion Criteria:

- The current available NIC is not licensed for use in children

Products covered under this ITT theme must:

- Be CE-marked as a Class IIa medical device
- Be supported by a sufficient clinical evidence-base, i.e. governed by criteria similar to those used by NICE.

The needle-free arterial non-injectable connector (NIC; Amdel Medical) is the only such CE-marked device currently available, as per [NICE Medtech Briefing \[MIB85\]](#).

9.3. Applicable Service Standards

9.3.1. Applicable national standards / guidance (e.g. NICE)

[Needle-free arterial non-injectable connector. Medtech innovation briefing \[MIB85\]](#)
[Published date: October 2016](#)

9.4. Reporting

NHS England will undertake some follow up research with providers who take up this innovation. NHS England will contact a sample of trusts that have implemented the innovation seeking answers to the following questions:

- Number of patient incidents of bacterial contamination and accidental intra-arterial injection prior to the introduction of this innovation.
- Number of patient incidents of bacterial contamination and accidental intra-arterial injection after the implementation of this innovation.
- Number of Non Injectable Connectors or other approved devices directly used in patient care and a breakdown of usage levels against clinical intervention.

10. Theme and Product Specification – Pneumonia prevention systems which are designed to stop ventilator-associated pneumonia

Expected outcome:

Ventilator-associated pneumonia (VAP) is defined as pneumonia that occurs 48-72 hours or thereafter following endotracheal intubation, characterised by the presence of a new or progressive infiltrate, signs of systemic infection (fever, altered white blood cell count), changes in sputum characteristics, and detection of a causative agent.

Improved airway management in critically ill patients who are having mechanical ventilation can prevent ventilator-associated pneumonia by minimising the risk of pulmonary aspiration and micro-aspiration in patients having ventilation for 24 hours

or more. This could see a reduction in the length of time spent on ventilation and length of stay in ICU. There are available pneumonia prevention systems which are designed to stop ventilator-associated pneumonia through the use of a cuffed ventilation tube and an electronic cuff monitoring and inflating device which prevents leakage of bacterial laden oral and stomach.

Payment / price detail:

The ITT agreed price for this innovation is £150.00, based on the purchase price of the tubing . From the 1st April the PneuX device can be ordered direct from the manufacturer under the zero cost model.

Availability:

Qualitech Healthcare is currently the only supplier identified by NHS England as able to provide this innovation in accordance with the specification below. The ITT for this theme covers the cost of the tracheal tubes valued at £150 per unit. Qualitech will provide the PneuX tracheal seal monitor (TSM) required to use the PneuX tubing system on a loan basis to hospitals. Trusts requiring the monitor will be provided with one on a loan basis from Qualitech when a minimum order of 24 tubes is placed by the Trust. Contact Qualitech directly for more information

<https://www.qualitechhealthcare.co.uk/home.html>

NHS England is working to include this product and any others which may meet the specification on the NHS Supply Chain by the end of summer 2017.

Product Specification

10.0. Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific details as to the basis on which this product is covered under the Innovation and Technology Tariff (ITT) with respect to pneumonia prevention systems which are designed to stop ventilator-associated pneumonia.

10.1. Population Needs

Ventilator-associated pneumonia (VAP) is a hospital-acquired infection. It is often defined as pneumonia that occurs in patients at least 48 hours after they have been given an endotracheal or tracheostomy tube to help or control respiratory function continuously for at least 48 hours⁹. The presence of a tracheal tube interferes with the normal protective reflexes of the upper airway, such as coughing. This can result in impaired clearance of micro-organisms. This is the main cause of VAP [1].

VAP is a common complication of mechanical ventilation and the most common infection in the intensive care unit (ICU) [2]. Between 10% and 20% of patients who have mechanical ventilation for longer than 48 hours will develop VAP. Critically ill

⁹ <https://www.nice.org.uk/advice/mib45/chapter/introduction>

patients who develop VAP appear to be twice as likely to die compared with similar patients without VAP [3]. Prolonged mechanical ventilation is a risk factor for the development of VAP [4].

Approximately 100,000 patients are admitted for ventilation in critical care units in the UK each year. The risk for patients is highest during early ICU stay when it is estimated to be 3% per day during days 1–5 of ventilation, 2% per day during days 5–10 of ventilation and 1% per day thereafter (Masteron, 2008). On average 10 - 20% (10,000- 20,000) of patients will be diagnosed with Ventilator Associated-Pneumonia (VAP) resulting in an attributable mortality rate of about 30% or between 3,000 and 6,000 deaths. Each episode of VAP has an estimated cost to the NHS of between £10,000 and £20,000. Using products that prevent VAP could save the NHS over £100 million per annum. Various strategies have been developed to reduce the risk of ICU patients developing VAP, including specialised endotracheal tubes.

10.2. Scope

10.2.1. Aims and objectives of product

Products covered under this ITT theme must aim to:

Prevent ventilator-associated pneumonia by minimising the risk of pulmonary aspiration and micro-aspiration in patients having ventilation for 24 hours or more.

10.2.2. Product description

Products covered under this ITT theme must:

- Be an endotracheal/ tracheostomy tube system for airway management, consisting of an endotracheal or tracheostomy tube, tracheal seal monitor and an extension tube.
- Replace standard endotracheal and tracheostomy tubes that have no subglottic drainage access, subglottic drainage access but with a high-volume low pressure cuff, or no continuous cuff-pressure monitor.
- Meet the below standards:
 - A beneficial tube should have been shown in comparative bench studies to prevent pulmonary aspiration (leakage past the cuff) across the entire tracheal diameter range compared to standard tubes [5, 6, 7].
 - The endotracheal tube should maintain the seal despite either vertical or rotational movement of the tube within the trachea or tracheal model [7].
 - To achieve a fluid seal, lubrication should not be required to achieve this, as the protective effect of this has been shown to be transient [8].
 - Each of the above points should also have been confirmed in clinical studies in patients. [9, 10]
 - The cuff seal should be maintained for example by a continuous pressure mechanism for days or weeks at a time without the seal breaking [6, 7].

- The cuff should also be shown not to cause overpressure on the tracheal wall [11].
- There should be subglottic ports allowing both aspiration and irrigation to maintain the cleanliness of the subglottis, larynx, pharynx and oral cavity. This is important because should user error or poor clinical judgement occur, and the cuff is deflated then this area should be maintained clean [12].

10.2.3. Population covered

Products covered under this ITT theme must be appropriate for use in:

- Intensive or critical care patients having mechanical ventilation
- Cases where the duration of intubation is expected to be more than 24 hours (but not more than 30 days).
- Patients for whom tracheal intubation is required during routine anaesthesia.

10.2.4. Clinical Standards

Products covered under this ITT theme must:

- Be CE-marked as a class III device (endotracheal/tracheal tube) and a class IIb device (tracheal seal monitor)
- Be supported by an appropriate clinical evidence-base, i.e. governed by criteria similar to those used by NICE¹⁰, which ensures the inclusion of evidence indicating that key quality standards have been met. This means that products or services are:
 - Safe – avoiding harm to patients wherever possible
 - Effective – providing support based on clear benefit to patients
 - Efficient – avoiding waste
 - Person centred – accepting patient's needs and preferences
 - Timely – reduces waits and harmful delays
 - Equitable – care does not vary in quality due to patient characteristics

10.3. Applicable Service Standards

- The British Society for Antimicrobial Chemotherapy recommends that measures should be taken to prevent VAP by reducing aspiration via subglottic secretion drainage, correct positioning of the tube and sufficient cuff pressure to avoid aspiration and tracheal damage.

¹⁰ <https://www.nice.org.uk/advice/mib45/chapter/introduction>

- The Patient Safety First How to Guide for critical care (2008) provides advice on mechanical ventilation and the NHS ventilator care bundle. The NHS ventilator care bundle has 4 key components:
 - elevation of the head of the bed to between 30 and 45 degrees
 - daily sedative interruption and daily assessment of readiness to extubate
 - peptic ulcer disease prophylaxis and venous thromboembolism prophylaxis
 - appropriate humidification of inspired gas and appropriate tubing management

10.4. Reporting

For each period of activity providers must report back on the following minimal data set:

- Prevalence of Ventilator-associated pneumonia (VAP) for the previous financial year. This is only required for the first report.
- Prevalence of Ventilator-associated pneumonia (VAP) during this period of reporting
- Number of PneuX tubes or other approved VAP prevention devices used on patients ventilated for 24 hours or more

Reports should be returned to Arden GEM CSU using the following email address FinanceQueries@ardengemcsu.nhs.uk. CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address.

10.5. References

1. Hunter JD (2012) Ventilator associated pneumonia. *British Medical Journal* 344: e3325
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11. Theme and Product Specification – Web-based applications for the self-management of chronic obstructive pulmonary disease

Expected outcome:

Managing Chronic Obstructive Pulmonary Disease (COPD) costs the NHS more than £1bn each year. However, treatment is complex, with different inhalers needing to be used in different ways. Compliance with treatment is often extremely low, leading to poor outcomes and potentially wasted prescribing. For this reason, improving self-management for patients with COPD is a key priority for the NHS. There is no cure for COPD and good symptom management is essential to stabilise disease and prevent recurrent flare-ups or exacerbations.

Exacerbations often require intensive treatment and can be severe enough to require hospital admission. There is evidence from recent studies that disease-specific self-management improves health status and reduces hospital admissions in COPD patients. It is critical to implement health education programs in the continuum of care aimed at behaviour modification. Studies in COPD have shown that self-management increases knowledge and skills the patients require to treat their own illness. It gives patients the ability to manage their condition by more effective use of their inhalers, support self-care, and complements face to face pulmonary rehabilitation programmes. NHS England has identified MyCOPD as the only self-management software solution which currently meets the specification in this document, although a number of web-based and iOS applications that help patients manage their condition more effectively are also available.

Payment / price detail:

The ITT payment arrangement for this innovation is based on software licenses for the MyCOPD programme valued at £20 per patient. Before deciding to use this innovation under the arrangements in this document, providers and commissioners need to be aware of the following eligibility criteria. NHS England will fund MyCOPD licences for patients with a diagnosis of severe / very severe COPD up to a maximum of 20% of the total COPD patient population per CCG. It is the responsibility of the CCG to record the number of licences obtained and not to seek further licences through the zero cost arrangement where the 20% threshold has been reached: the cost of any such additional licences sought above the threshold would be liable to clawback by NHS England. The following patient groups are eligible:

1. New COPD patients referred to an acute pathway managed by community or secondary care
2. Existing COPD patients on the acute pathway managed by community or secondary care

Availability:

CCGs can order licences directly from the supplier at zero cost, up to the limit specified above. Forward enquiries to ian.thompson@mymhealth.com

Product Specification:

11.0. Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific details as to the type of web-based applications for the self-management of chronic obstructive pulmonary disease centrally purchased by NHS England.

11.1. Population Needs

11.1.1. National/local context and evidence base

COPD, or chronic obstructive pulmonary disease, refers to a group of lung conditions which includes bronchitis and emphysema. An estimated 3 million people have COPD in the UK. About 900,000 have diagnosed COPD and approximately 2 million people have COPD which remains undiagnosed.¹¹ The UK is among the top 20 countries for COPD mortality worldwide; in 2012, 29,766 people died (5.3 per cent of the total number of UK deaths and 26.1 per cent of deaths from lung disease).¹²

People living with a long-term condition are more likely to use health and care services. They account for 50% of all GP appointments, 64% of all hospital outpatients appointments, 70% of all hospital bed days and 70% of total health and social care spend.¹³

COPD is usually managed with a combination of inhaled and oral pharmacological therapy, pulmonary rehabilitation and lifestyle management e.g. smoking cessation.² Self-management education refers to formal education or training for people with long-term conditions that focuses on helping people to develop the knowledge, skills and confidence to manage their own health and care effectively.¹⁴ The NICE quality standards for COPD advocate that all patients receive a current individualised comprehensive self-management plan.¹⁵

¹¹ NICE Chronic obstructive pulmonary disease in over 16s: diagnosis and management Clinical guideline [CG101] Published date: June 2010

¹² British Lung Foundation (online): <https://statistics.blf.org.uk/copd>

¹³ The NHS Outcomes Framework 2013/14, Department of Health (November 2012)

¹⁴ Realising the value: Ten key actions to put people and communities at the heart of health and wellbeing. Nesta, 2016

¹⁵ Health Foundation Shine 2012 Final Report myCOPD Solution - Delivering self-management, reducing wasteful prescribing and improving compliance in patients with COPD March 2014

11.2. Scope

11.2.1. Aims and objectives of the product

Products covered under this ITT theme must aim to:

- Support people with severe or very severe COPD to self-manage through a web-based application by providing:

11.2.2. Product description

Products covered under this ITT theme must:

- Be a web-based application
- Be consistent with consensus definitions of what constitutes a COPD self-management intervention, which includes¹⁶:
 - goals of motivating, engaging and supporting the patients to positively adapt their health behaviour(s);
 - helping patients develop skills to better manage their disease;
 - iterative interactions between patients and competent, patient-centred healthcare professionals

11.2.3. Population covered

Products covered under this ITT theme must be appropriate for use in:

- Patients with severe or very severe disease managed by community or secondary care
- Patient with COPD on an acute care pathway managed by community or secondary care
- Patients discharged from hospital as part of the COPD discharge bundle (which can be linked to the Best Practice Tariff)

11.2.4. Clinical Standards

Products covered under this ITT theme must:

- Be CE-marked MHRA class I device

¹⁶ 'Definition of a COPD self-management intervention: International Expert Group consensus' Tanja W. Effing, Jan H. Vercoulen, Jean Bourbeau, Jaap Trappenburg, Anke Lenferink, Paul Cafarella, David Coultas, Paula Meek, Paul van der Valk, Erik W.M.A. Bischoff, Christine Bucknall, Naresh A. Dewan, Frances Early, Vincent Fan, Peter Frith, Daisy J.A. Janssen, Katy Mitchell, Mike Morgan, Linda Nici, Irem Patel, Haydn Walters, Kathryn L. Rice, Sally Singh, Richard Zuwallack, Roberto Benzo, Roger Goldstein, Martyn R. Partridge and Job van der Palen; *Eur Respir J* 2016; 48: 46–54

- Be supported by an appropriate clinical evidence-base, which ensures the inclusion of evidence indicating that key quality standards have been met. This means that products or services are:
 - Safe – avoiding harm to patients wherever possible
 - Effective – providing support based on clear benefit to patients
 - Efficient – avoiding waste
 - Person centred – accepting patient’s needs and preferences
 - Timely – reduces waits and harmful delays
 - Equitable – care does not vary in quality due to patient characteristics

11.2.5. Information Governance

Products covered under this ITT theme must:

- Be NHS IG toolkit compliant
- Use NHS IT servers for secure hosting of data,
- If the products are NHS IGT compliant then they are fine to be used in the NHS. Many providers will use other cloud services that provide the same level of security as being on NHS servers and pass IGT.
- Have a dedicated support team available to providers 8am-5pm.

11.3. Reporting

For each period of activity, providers must report back on the following minimal data set:

- Number of patients receiving face to face pulmonary rehab for the previous financial year. This is only required for the first report.
- Number of non-elective COPD admissions into secondary care during the previous financial year. This is only required for the first report.
- Number of non-elective COPD admissions into secondary care during this period of reporting.
- Number of patients receiving face to face pulmonary rehab during this period of reporting.
- Number of patients registered on MyCOPD or other approved web based service during this period of reporting.

Reports should be returned to Arden GEM CSU using the following email address FinanceQueries@ardengemcsu.nhs.uk. CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address.

12. Theme and Product Specification – Frozen Faecal Microbiota Transplantation (FMT)

Expected outcome:

Clostridium difficile infection (CDI) can be a serious, life threatening condition. It can occur in patients undergoing antibiotic treatment, in particular those on broad-spectrum antibiotics. Older people over 65, patients with weakened immune systems and those with bowel conditions are also at an increased risk of CDI.

CDI rates are climbing in frequency and severity, and the spectrum of susceptible patients is expanding beyond the traditional scope of hospitalized patients receiving antibiotics. Faecal microbiota transplantation is becoming increasingly accepted as an effective and safe intervention in patients with recurrent disease. Cure rates of > 90% are being consistently reported from multiple centres. FMT is the provision of a screened specially prepared stool administered via a nasal tube into the intestine to restore the balance of bacteria in the gut. FMT is a NICE recommended treatment for Chronic CDI. FMT is an effective alternative to antibiotic treatment for CDI at a comparable cost and has been shown to reduce length of stay. To date nine trusts have performed FMTs on their own site via the frozen service.

Payment / price detail:

The ITT payment arrangement for this innovation is £95 per FMT aliquot supplied. Providers can order FMT aliquots under the zero cost model.

Availability:

Orders for FMT can be placed with Portsmouth Hospitals NHS Trust, email orders to fmt@porthosp.nhs.uk quoting ITT FMT.

Product specification:

12.0. Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific details as to what is covered under the ITT with respect to FMT, in terms of the characteristics of FMT to be supplied and the way in which it should be used within care pathways by the purchasing Trusts. This specification has been developed with the help of Wessex CCGs and Portsmouth Hospital NHS Trust.

12.1. Population Needs

12.1.1. National context and evidence base

Clostridium difficile (C. diff) bacteria can live harmlessly in the gut of approximately 5% of healthy people. However, the decline of intestinal bacteria as people get older, together with a reduction in immune response, increases the risk of C. diff infection (CDI) in the elderly, with over 80% of cases reported occurring in people aged over

65.¹⁷ Prevalence can be as high as 20% among elderly patients in hospital¹ and as high as 50% in some long-term care facilities.¹⁸ The use of certain medications (such as proton pump inhibitors or H2 receptor antagonists) can also increase the risk of *C. diff* infection, as can – due to the way in which they change the balance of bacterial species in the gut – antibiotics or immunosuppressive agents. Symptoms can range from mild to severe, and can at times be life-threatening. The risk of death increases in patients with multiple comorbidities.^{19,20}

Initial treatment involves rehydration and antibiotic therapy. The majority of people recover successfully. Relapse (defined as a second episode occurring within 2–8 weeks) occurs in about 20% of patients treated initially with either metronidazole or vancomycin and in 50-60% of patients following a second episode of CDI.^{21,22,23} Recurrent or refractory CDI can be defined as two or more treatment failures within three months of the initial case. Typically, patients with recurrent CDI have significant co-morbidities, compromised immune systems and poor health outcomes overall. Samples donated as part of the FMT treatment are an underused, but very effective, product for tackling recurrent CDI.^{24,25}

12.2. Scope

12.2.1. Aims and objectives of product

FMT donor samples aim to offer an additional effective option for reducing the risk of repeated CDI relapse in patients with recurrent CDI, by rebalancing the patient's bowel flora. Use of the donor samples will reduce morbidity and mortality for patients with recurrent CDI. Donor samples will reduce the risk of avoidable harm and provide a positive experience and enhanced quality of life for patients.

12.2.2. Service description/care pathway

Providers should follow the NHS West Hampshire CCG Community Management of *Clostridium difficile* Infection Pathway (Adults). Patients who meet the acceptance criteria should:

- Be prescribed PO Vancomycin 125mg QDS for symptom control

¹⁷ National *Clostridium difficile* Standards Group. Report to the Department of Health, February 2003. http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1194947372533

¹⁸ Asymptomatic Carriers Are a Potential Source for Transmission of Epidemic and Non-epidemic *Clostridium difficile* Strains among Long-Term Care Facility Residents: Riggs et al, October 2007. <http://cid.oxfordjournals.org/content/45/8/992.full.pdf+html>

¹⁹ National Institute for Health and Care Excellence ESNM1 *Clostridium difficile* infection: fidaxomicin July 2012, <http://www.nice.org.uk/advice/esnm1/chapter/Relevance-to-NICE-guidance-programmes>

²⁰ National Institute for Health and Care Excellence IPG485 Faecal microbiota transplant for recurrent *Clostridium difficile* infection. March 2014

²¹ Kelly CP, LaMont JT. *Clostridium difficile*--more difficult than ever. *N Engl J Med*. 2008;359(18):1932-1940

²² Johnson S. Recurrent *Clostridium difficile* infection: causality and therapeutic approaches *International Journal of Antimicrobial Agents* 33 (2009) S33-S36

²³ Public Health England. Updated guidance on the management and treatment of *Clostridium difficile* infection, May 2013

²⁴ Sofi AA, Silverman AL. et al. Relationship of symptom duration and faecal bacteriotherapy in *Clostridium difficile* infection--pooled data analysis and a systematic review. *Scandinavian Journal of Gastroenterology* 2013; 48(3): 266-273.

²⁵ van Nood E, Vrieze A. et al. Duodenal infusion of donor faeces for recurrent *Clostridium difficile*. *New England Journal of Medicine*. 2013; 368 (5): 407- 415.

- Be discussed directly with the microbiology team performing the FMT procedure.
- In complex cases, the patient may be asked to attend a clinic appointment to confirm that they meet the acceptability criteria.
- If the patient is deemed eligible for FMT, they should be provided with a patient information leaflet, and informed consent should be obtained form
- Usually within 2-4 weeks of a referral, a date for the procedure should be arranged
- Most cases currently require one overnight stay. Some cases will be carried out as a day case; increasing use of day case procedures will be a priority for appropriate patients
- The procedure is carried out as per the FMT: Step-by-step guide to procedure

FMT procedures will be recorded using the following coding:

- ICD-10 A04.7 (Clostridium difficile enterocolitis (if applicable) or Not a case of Clostridium difficile enterocolitis
- G48.8 Other specified other operations on stomach
- Y37.8 Other specified introduction of other substance into organ
- FZ25A Therapeutic Endoscopic or Intermediate Stomach or Duodenum Procedures 19 years and over OR FZ25B Therapeutic Endoscopic or Intermediate Stomach or Duodenum Procedures 19 years and under.

12.2.3. Population covered

Patients who have had recurrent CDI which has not been successfully treated with Metronidazole and Vancomycin management and who meet the acceptance criteria.

12.2.4. Any acceptance and exclusion criteria and thresholds

Acceptance Criteria:

- Confirmed recurrent or refractory CDI, defined as two or more treatment failures within three months of the index case; with these recurrences following appropriate treatment (an initial toxin positive test required with clinical relapse, or repeat confirmed toxin-positive sample)
- Aged over 16 years
- Appropriate swallow reflex to reduce the risk of aspiration post-procedure.

Exclusion Criteria:

These are possible contra-indications – however, none are absolute contra-indications by themselves and all cases should be discussed

- Aged under 16 years
- Significant swallowing difficulty
- Severe peptic or duodenal ulcerative disease
- Neutropenia

- Long-term immunosuppression via steroids or other immunomodulators
- Current inflammatory bowel disease, colitis, perforated bowel or increased permeability of the bowel likely to lead to translocation of bacteria
- Two previous FMTs (from different donors already received)
- All patients will be assessed and considered on a case-by-case basis

Other considerations:

Food allergies must be recorded. A donor will be sourced who has not eaten the indicated foods for at least a week. Please note: sourcing a donor who has not eaten a particular food may increase the time between referral and the procedure.

Risks:

- Perforation of (making a hole in) the alimentary canal during naso-jejunal tube placement (<1 in 10,000)
- Infection – actual risk uncharacterised, but less than 1 in 100. Including possible peritonitis, enteritis, aspiration pneumonia.
- Transfer of microbiologically uncharacterised material
- Bleeding – reported in one case to date, and not clearly linked to FMT (1 in 350)
- Diarrhoea is common immediately following the procedure but resolves over the next 5-7 days (>1 in 10)
- Constipation (1 in 350)
- Irritable bowel like syndrome has been reported in 5 of 350 cases
- Failure to cure (19% after first FMT, 6% after two FMTs)

Benefits:

- Overall cure rate of 94% (81% after first FMT) in recurrent CDI compared with 31% with standard therapy
- Low recurrence rate of 6%, compared with 69% on standard therapy in recurrent CDI

12.2.5. Service Standards

All procedures must be carried out in accordance to the guidelines established by Portsmouth Hospitals NHS Trust and the Wessex Faecal Donor Bank.

Donor stools will be sourced via the Wessex Faecal Donor Bank and screened in accordance with current protocols. Donors will be healthy adults (aged between 18 and 60), with a BMI not greater than 25, non-smokers, with no family history of gastrointestinal disorders and no indication of / risk factors for an infection. At the time of donation, donors will be screened for:

- HIV 1+2
- HTLV I/II
- Hepatitis A total Ab and if positive, IgM
- Hepatitis B sAg, cAb, sAb

- Hepatitis C total Ab
- Hepatitis E IgM
- Syphilis EIA
- CMV IgM and IgG
- EBV IgM and IgG
- as well as stool screening for:
 - Verotoxin and enterohaemorrhagic E.coli, Salmonella spp., Shigella spp., Campylobacter coli/jejuni/lari, Yersinia enterocolitica, Entamoeba histolytica, Cryptosporidium spp. and Giardia lamblia by PCR
 - Vibrio spp. by culture
 - Ova, cysts and parasites by concentration
 - C. diff GDH EIA – if positive a toxin B PCR should be performed
 - Screen for carbapenemase producing Enterobacteriaceae
 - Screen for Vancomycin resistant enterococci
 - Screen for Extended spectrum beta-lactamase production
 - Helicobacter pylori antigen
 - Rotavirus, adenovirus, astrovirus, sapovirus and norovirus by PCR

Suitable services will be delivered to patients:

- Adequate facilities (including premises and equipment)
- Maintenance of infection control standards
- Information to patient on treatment or tests being proposed
- Maintenance of records for each episode of care

Patient experience

Hospitals are expected to provide the following standards of patient experience;

- All patients are to be treated with dignity & respect
- Care is delivered in a clean and pleasant environment that is safe and hygienic for patients, carers/relatives and staff
- Processes should be in place to ensure that all patients are able to communicate with relevant staff and understand their diagnosis & treatment. This includes access to translation services and support for people with particular needs e.g. deaf patients and patients with learning disabilities (as appropriate)
- Patients attending the service may be accompanied by carers and relatives and provision should be made to accommodate them whilst waiting

Infection Control

Appropriate infection control measures must be in place and must comply with The Health & Social Care Act 2012 and follow current guidance from the Department of Health and the National Institute for Health & Clinical Excellence.

Safeguarding Children & Vulnerable Adults

Hospitals should have appropriate policies and processes in place to ensure the safeguarding of children & vulnerable adults in compliance with National & local policies and statutory requirements.

Patient records and reporting of episode of care

- All clinical records will be clear concise, accurate and legible.
- Systems should be set up within the service so that patients should only need to repeat their registration and case history details for safety and clinical reasons and not because the information cannot be transferred
- Clinical discharge summaries should include:
 - The patient's demographic details and NHS number
 - The patient's presenting condition and diagnosis
 - Details of any diagnostics conducted and where possible, their results
 - Any treatments provided, management plans followed and any medications prescribed
 - Clinical outcomes
 - Details of any referrals to specialist services to address the patients immediate needs
 - Any recommendations made to the patient for services to which they might self-refer
 - Any recommendations about appropriate services (including social services) that the GP might wish to refer the patient for their ongoing needs.

12.3. Governance

Operational Governance

Hospitals will be expected to maintain appropriate operational governance arrangements and to undertake regular reviews of operational processes and resolve any problems or issues that arise.

Clinical Governance

Hospitals will be expected to demonstrate that robust clinical governance arrangements are in place. Hospitals are expected to maintain registration with the Care Quality Commission and comply with all appropriate national regulatory requirements.

Clinical Standards

Hospitals will be expected to comply with locally agreed clinical standards.

Information Governance

Hospitals will be expected to comply with all local & National Information Governance regulations.

Complaints procedures

Hospitals must operate a complaints procedure which is consistent with the principles of the NHS complaints procedure. Complaints addressed to Hospitals relating to patients using the FMT service should, subject to the patient's consent being obtained, be shared with the relevant CCG.

Serious Incidents Requiring Investigation (SIRI)

Hospitals must demonstrate robust arrangements for recording and investigating SIRIs. All SIRIs involving patients must be reported to the relevant Clinical Commissioning Group.

Legal Protection

The service provider must demonstrate that they are appropriately indemnified to meet the costs of any legal claim by having full indemnity and liability insurances in place.

12.4. Interdependence with other services/providers

The Wessex FMT donor bank is currently at Portsmouth Hospital; FMT services provided at Portsmouth Hospitals NHS Trust are supported by the Wessex Academic Health Science Network and the University of Portsmouth.

12.5. Applicable Service Standards

12.5.1. Applicable national standards (e.g. NICE)

- NICE FMT for Recurrent CDI March: [NICE IPG485 March 2014](#)
- Updated Guidance on C. Difficile: [Public Health England guidance on the management of CDI](#)

12.5.2. Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

Nil

12.5.3. Applicable local standards

- Community CDI Algorithm (See Appendix C)
- FMT GP referral form (See Appendix D)
- FMT document pack (See Appendix E)
- FMT Form 2 – Pt. information (See Appendix F)
- FMT Form 3 – Informed consent (See Appendix G)

12.6. Applicable quality requirements and CQUIN goals

12.6.1. Applicable Quality Requirements (See Schedule 4A-C)

- Patients accepted for FMT will receive samples within two to four weeks (average) three weeks of acceptance of the referral
- All patients will receive the a Patient Information Leaflet and be consented in accordance with national and local standards, including the risks and benefits of the procedure
- All patients will be offered the opportunity to complete:
- Pre-FMT Quality of Life Questionnaire
- 1 week post FMT survey
- 1 week post FMT Quality of Life Questionnaire
- 6 week post FMT survey
- 6 month post FMT survey
- Total procedure numbers, success, failure and complication rates for patients will be made available on request to the CCG or NHS England.

12.6.2. Applicable CQUIN goals (See Schedule 4D)

None.

12.7. Reporting

For each period of activity providers must report back on the following minimal data set:

- Hospital admission rates due to recurrent CDI for the previous financial year.
This is only required for the first report.
- Number of patients receiving fidaxomicin therapy for the previous quarter.
This is only required for the first report.
- Hospital admission rates due to recurrent CDI for this period of reporting
- Number of patients receiving fidaxomicin therapy for this period of reporting
- Number of patients treated using FMT for this period of reporting.

Reports should be returned to Arden GEM CSU using the following email address FinanceQueries@ardengemcsu.nhs.uk. CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address.

13. Theme and Product Specification – Prostatic urethral lift systems

Expected outcome:

Benign prostatic hyperplasia (BPH) is a common and chronic condition where the enlarged prostate can make it difficult for a man to pass urine, leading to urinary tract infections, urinary retention, and in some cases renal failure. Existing treatments TURP (transurethral resection of the prostate) involve cutting away or removing existing tissue, require an average hospital stay of 3 days and often catheterisation for many days post-surgery. A prostatic urethral lift system is a less complex and invasive procedure performed as a day case and, increasingly carried out under a local anaesthetic. There will be savings from reductions in inpatient stay and general anaesthesia costs. There are significantly fewer side effects (notably 0% risk of permanent sexual dysfunction) and post-operative complications. Healthcare teams may want to use a prostatic urethral lift system as an alternative to transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP).

Payment / price detail:

The cost of this innovation is covered under the National Tariff and should be reported via SUS charging per patient spell using HRG LB70C and LB70D), the cost to the commissioner is £2,538 and £2,107. The OPCS 4.7 code combination to identify Prostatic urethral lift systems under the previous National Tariff is M678 (Other specified other therapeutic endoscopic operations on prostate) + Y022 (Therapeutic endoscopic implantation of prosthesis into prostate) which will group to the LB70 Complex Endoscopic, Prostate or Bladder Neck Procedures (Male and Female) HRG Root. The new OPCS 4.8 code effective from 1st April 2017 identifies

this procedure as M683, Endoscopic insertion of prosthesis to compress lobe of prostate. This code will also map to LB70. This will be effective once the HRG4+ 2017/18 Local Payment Grouper is published.

Availability:

The Urolift innovation can be purchased direct from the manufacturer Neotract. Direct enquiries to ukinfo@neotract.com. NHS England is working to include this product on the NHS Supply Chain by the end of summer 2017.

Product specification:

13.0. Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific details as to the type of prostatic urethral lift system currently supported by NHS England and the basis on which this is identified as an innovation which merits particular support and promotion to enable it to be accessible to and implemented by providers of NHS services.

13.1. Population Needs

13.1.1. National/local context and evidence base

The prostatic urethral lift has been shown in several prospective studies, including a double blind randomised controlled FDA trial, to provide rapid and sustained improvement in symptoms and flow in men with LUTS due to BPH. Peer-reviewed outcomes from its pivotal study – LIFT – are now published up to 4 years, which demonstrate the durability of effect.

The UroLift® System is an example of a proven and durable, ambulatory treatment for urinary symptoms of enlarged prostate. Permanent implants pin back the prostate so it does not block the urethra. Compared with current surgical care (requiring 3 days in hospital). Urolift is a short, (<30-min procedure), performed under local anaesthetic or light sedation, with no overnight stay requirement. Unlike current surgical options, Urolift does not cause tissue injury and therefore avoids the side effects (notably 0% sexual dysfunction risk) and well-documented complications associated with current surgical options – TURP and laser.

Urolift has been reviewed by NICE under its Medical Technologies Evaluation Programme. Medical Technology Guidance (MTG26) was published in September 2015. The guidance states:

- The clinical and cost case for adopting the UroLift system for treating symptoms of benign prostatic hyperplasia is supported by the evidence if it is used in a day surgery unit.

- The UroLift system relieves lower urinary tract symptoms while avoiding the risk to sexual function associated with transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP). It also reduces the length of hospital stay and may be done in a day surgery unit.
- The UroLift system should be considered for use in men with lower urinary tract symptoms of benign prostatic hyperplasia who are aged 50 years and older and who have a prostate of less than 100 cm³ and without an obstructing middle lobe.

Recent guidelines from the European Association of Urology (EAU) gave prostatic urethral lift a positive recommendation (with Level 1 evidence) for the treatment of patients with LUTS from BPH.

13.2. Outcomes

13.2.1. NHS Outcomes Framework Domains & Indicators

Patient outcomes

- Rapid and sustained improvement in symptoms and flow
- Improved safety and side effect profile compared with current surgical treatments
- Preservation of sexual function
- Significantly reduced post-operative complications

NHS outcomes

- Improved bed capacity
- Improved theatre capacity
- Improved outpatient capacity
- Reduced incidence of post-operative complications and readmissions following surgery
- Reduce burden on waiting times
- Cost savings through reduction in post-operative complications and readmissions

13.3. Scope

13.3.1. Aims and objectives of service

The objectives of offering this service are:

- Improved patient experience - more rapid return to daily living compared with TURP and preservation of sexual function
- Improved safety – reduced risk of post-operative complications
- Reduce inpatient length of stay
- Improved theatre capacity

- Reduce outpatient visits
- Achieve compliance with
- To comply with NHS England's ambition is to achieve full adoption of the technologies awarded an Innovation & Technology Tariff (such as Urolift) during 2017/18 wherever clinically appropriate.

13.3.2. Service description/care pathway

The UroLift system is used to perform a prostatic urethral lift, an alternative to current standard surgical interventions (such as TURP and laser). The UroLift system uses adjustable, permanent implants to pull excess prostatic tissue away so that it does not narrow or block the urethra. In this way, the device is designed to relieve symptoms of urinary outflow obstruction without cutting or removing tissue.

The UroLift system comprises two single-use components: a delivery device and an implant. The delivery device consists of a hand-held pistol grip to which a needle-shaped probe is attached. Each UroLift implant consists of a super-elastic nitinol capsular tab, a polyethylene terephthalate monofilament, and a stainless steel urethral end-piece. The surgeon inserts the probe into the urethra until it reaches the prostatic urethra (the widest part of the urethral canal); a fine needle at the end of the probe deploys and secures an implant in a lobe of the prostate. One end of the implant is anchored in the urethra and the other is attached to the firm outer surface of the prostatic capsule, so pulling the prostatic lobe away from the urethra. This is repeated on the other lobe of the prostate. Typically about four implants are used. The procedure is done as a true day-case (patients generally return home after a few hours) and is performed under a local anaesthetic or light sedation, taking less than 30 minutes.

13.3.3. Population covered

Men are selected and identified for the Urolift procedure using the existing care pathway for BPH, although changes may be made to the pathway to better incorporate the Urolift system, such as assessing the size of the prostate and the presence of a middle lobe by cystoscopy (or in some cases ultrasound). Selection for Urolift usually involves a nurse specialist or a consultant urological surgeon assessing all men referred to secondary care. Patients are either selected from men attending outpatient clinics or from the waiting list for BPH surgery. (that is, where symptoms are severe and conservative management has failed or is inappropriate) for whom surgery is an option are given information about all appropriate surgical options, including the UroLift procedure. They are then seen by a consultant urological surgeon to discuss these options in more detail. Men who choose the UroLift procedure are generally those who wish to preserve their sexual function or do not want TURP.

After confirmation that the UroLift procedure is appropriate, the patient follows the same day-case pathway as all other urological day-case procedures. Patients typically return home after a few hours, typically without a catheter (following patient discharge, a nurse follows up by phone).

13.3.4. Any acceptance and exclusion criteria and thresholds

Acceptance Criteria:

Men are offered surgery for LUTS from BPH if symptoms are severe or if drug treatment and conservative management options have been unsuccessful or are not appropriate. Referrals will come from GPs or urologists/specialist nurses in secondary care urology clinics.

UroLift is indicated in men with LUTS from BPH who are aged 50 years and older and who have a prostate of less than 100 cm³ and without an obstructing middle lobe. Patients may also be selected from existing waiting lists of men waiting for BPH surgery.

Exclusion Criteria:

- Men aged <50
- Prostate >100cm³
- Obstructing middle lobe

Other considerations:

Geographical coverage for prostatic urethral lift systems should be determined locally. 120 NHS Trusts are currently offering surgery for BPH at a level of >50 procedures/year.

Urolift is easily and rapidly deployable and requires minimal training and no capital outlay or infrastructure change. It should be easily available to patients as an alternative to TURP or laser, ideally with minimal travel requirements.

Theatre lists are normally scheduled so a number of UroLift procedures can be done in a single session.

13.3.5. Service Standards

Patient experience

All patients should receive their treatment within the time-frame defined by National Waiting time guidelines. Patients are provided with an information sheet which explains their treatment, any post-operative self-care and what they should expect from the Urolift procedure.

Patients typically return home on the same day as the procedure and are followed up by telephone. Their care then continues in primary care. Patients are only referred back into secondary care if there are complications that require specialist care. Hospitals are also expected to provide the following standards of patient experience;

- All patients are to be treated with dignity & respect
- Care is delivered in a clean and pleasant environment that is safe and hygienic for patients, carers/relatives and staff
- Processes should be in place to ensure that all patients are able to communicate with relevant staff and understand their diagnosis & treatment. This includes access to translation services and support for people with particular needs e.g. deaf patients and patients with learning disabilities (as appropriate)
- Patients attending the service may be accompanied by carers and relatives and provision should be made to accommodate them whilst waiting.

Infection Control

Appropriate infection control measures must be in place and must comply with The Health & Social Care Act 2012 and follow current guidance from the Department of Health and the National Institute for Health & Clinical Excellence.

Safeguarding Children & Vulnerable Adults

Hospitals should have appropriate policies and processes in place to ensure the safeguarding of children & vulnerable adults in compliance with National & local policies and statutory requirements.

Patient records and reporting of episode of care

- All clinical records will be clear concise, accurate and legible.
- Systems should be set up within the service so that patients should only need to repeat their registration and case history details for safety and clinical reasons and not because the information cannot be transferred
- Clinical discharge summaries should include:
 - The patient's demographic details and NHS number
 - The patient's presenting condition and diagnosis
 - Details of any diagnostics conducted and where possible, their results
 - Any treatments provided, management plans followed and any medications prescribed
 - Clinical outcomes
 - Details of any referrals to specialist services to address the patients immediate needs
 - Any recommendations made to the patient for services to which they might self-refer
 - Any recommendations about appropriate services (including social services) that the GP might wish to refer the patient for their ongoing needs.

13.4. Governance

Operational Governance

Hospitals will be expected to maintain appropriate operational governance arrangements and to undertake regular reviews of operational processes and resolve any problems or issues that arise.

Clinical Governance

Hospitals will be expected to demonstrate that robust clinical governance arrangements are in place. The Trust are expected to maintain registration with the Care Quality Commission and comply with all appropriate national regulatory requirements.

Clinical Standards

Hospitals will be expected to comply with locally agreed clinical standards.

Information Governance

Hospitals will be expected to comply with all local & National Information Governance regulations.

Complaints procedures

Hospitals must operate a complaints procedure which is consistent with the principles of the NHS complaints procedure. Complaints addressed to Hospitals relating to WHCCG patients using the FMT service should, subject to the patient's consent being obtained, be shared with the relevant CCG.

Serious Incidents Requiring Investigation (SIRI)

Hospitals must demonstrate robust arrangements for recording and investigating SIRIs. All SIRIs involving patients must be reported to the relevant Clinical Commissioning Group.

Legal Protection

The service provider must demonstrate that they are appropriately indemnified to meet the costs of any legal claim by having full indemnity and liability insurances in place.

3.6 Interdependence with other services/providers

Urolift is easily and rapidly deployable. There are no required changes in staff numbers or grades. Surgeons (urologists) undergo a 90 minute training programme provided by the manufacturer. There is additional training for the theatre staff that is also provided by the manufacturer.

Clinical support for cases is provided until the surgeon is proficient (approximately 10 cases and ongoing as requested) free of charge by the manufacturer

Interdependencies include the following:

- Patients and carers
- CSU
- Day case surgery unit

13.5. Applicable Service Standards

13.5.1. Applicable national standards (e.g. NICE)

- NICE guidance (MTG26)
- Recommendations in the final report of the Accelerated Access Review regarding offering Urolift as an alternative to TURP or laser.

13.6. Applicable quality requirements and CQUIN goals

13.6.1. Applicable Quality Requirements (See Schedule 4A-C)

Performance Indicator	Indicator	Threshold	Method of Measurement	Consequence of breach
<u>Quality</u>				
<p>Relevant to the following domains:</p> <p>Domain 2: Enhancing quality of life for people with long-term conditions</p> <p>Domain 3: Helping people recover from episodes of ill health or following injury</p> <p>Domain 4: Ensuring that people have a positive experience of care</p>	<p>IPSS and Sexual function scores including: IIEF, ejaculatory function score, sexual health inventory for men (SHIM)</p>	<p>Sexual function: improved or unchanged</p> <p>Quality of life: improved or unchanged</p> <p>IPSS: significant improvement</p>	<p>Baseline audit and measurement at follow-up</p>	
<u>Performance & Productivity</u>				
Reduction in inpatient bed requirement	Length of stay	LOS = 0	Patient records	
Improving theatre efficiency	Number of procedures	Procedure time < 30 mins	Patient records	

Performance Indicator	Indicator	Threshold	Method of Measurement	Consequence of breach
	completed in a single list and procedure time			

13.7. Reporting

Providers should report via SUS charging per patient spell using HRG LB70C and LB70D). From April 2017 this will be combined into a new OPCS code for Urolift M68.3.

13.8. References

Meta-Analyses and Guidelines:

1. NICE MTG26. UroLift for treating LUTS of BPH. 2015. nice.org.uk/guidance/mtg26.
2. Shore N. A Review of the Prostatic Urethral Lift for Lower Urinary Tract Symptoms: Symptom Relief, Flow Improvement, and Preservation of Sexual Function in Men With Benign Prostatic Hyperplasia. *Curr Bladder Dysfunct Rep*. DOI 10.1007/s11884-015-0296-5.
3. Perera M, Roberts MJ, Suhail ARD, Bolton D. Prostatic urethral lift improves urinary symptoms and flow while preserving sexual function for men with benign prostatic hyperplasia: a systematic review and meta-analysis. *Eur Urol* 2015; 67; 704-713. Addendum *Eur Urol* 2015; 68; E53-E54.
4. Gravas S et al. Guidelines on the management of non-neurogenic male lower urinary tract symptoms (LUTS), incl. benign prostatic obstruction (BPO). *Eur Assoc Urol* 2015.

Clinical Studies:

1. Roehrborn CG. Prostatic urethral lift: a unique minimally invasive surgical treatment of male lower urinary tract symptoms secondary to benign prostatic hyperplasia. *Urology Clinics* 2016.
2. Sonksen J, Barber N, Speakman M, Berges R, Wetterauer U, Greene D, Sievert KD, Chapple C. Multi-National, prospective, randomized study of the prostatic urethral lift (PUL) vs. transurethral resection of the prostate (TURP): two year result. *J Urol* 2016; 195(4S): e456.
3. Roehrborn CG, Rukstalis DB, Barkin J, Gange SN, Shore ND, Giddens JL, Bolton DM, Cowan BE, Cantwell AL, McVary KT, Te AE, Gholami SS, Moseley WG, Chin PT, Dowling WT, Freedman SJ, Incze PF, Coffield KS, Borges FD,

- Rashid P. Three year results of the prostatic urethral L.I.F.T. study. *Can J Urol* 2015; 22(3); 7772-7782.
4. Sønksen J, Barber NJ, Speakman M et al. Prospective, Randomized, Multinational Study of Prostatic Urethral Lift Versus Transurethral Resection of the Prostate: 12-month Results from the BPH6 Study. *Eur Urol* 2015; 68; 643-652.
 5. Roehrborn CG, Gange SN, Shore ND, Giddens JL, Bolton DM, Cowan BE, Brown BT, McVary KT, Te AE, Gholami SS, Rashid P, Moseley WG, Chin PT, Dowling WT, Freedman SJ, Incze PF, Coffield KS, Borges FD, Rukstalis DB. Durability of the prostatic urethral lift: two year results of the L.I.F.T. Study. *Urology Practice* 2015 (2); 1-7.
 6. Shore N, Freedman S, Gange S, Moseley W, Heron S, Tutrone R, Brown T, Barkin J. Prospective multi-center study elucidating patient experience after prostatic urethral lift. *Can J Urology* 2014; 21(1): 7094-7101.
 7. Cantwell AL, Bogache WK, Richardson SF, Tutrone RF, Barkin J, Fagelson JE, Chin PT, Woo HH. Multi-Center prospective crossover study of the prostatic urethral lift for the treatment of LUTS secondary to BPH. *BJUI* 2013; 113: 615-622.
 8. McVary KT, Gange SN, Shore ND, Bolton DM, Cowan BE, Brown BT, Te AE, Chin PT, Rukstalis DB, Roehrborn CG. Treatment of LUTS secondary to BPH while preserving sexual function: randomized controlled study of the prostatic urethral lift. *J Sex Med* 2014; 11: 279-287.
 9. Roehrborn CG, Gange SN, Shore ND, Giddens JL, Bolton DM, Cowan BE, Brown BT, McVary KT, Te AE, Gholami SS, Rashid P, Moseley WG, Chin PT, Dowling WT, Freedman SJ, Incze PF, Coffield KS, Borges FD, Rukstalis DB. Multi-Center randomized
 10. Controlled blinded study of the prostatic urethral lift for the treatment of LUTS associated with prostate enlargement due to BPH: the L.I.F.T. study. *J Urol* 2013; 190: 2162-2167.
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15. Woo HH, Chin PT, McNicholas TA, Harscharan G, Plante MK, Bruskewitz RC, Roehrborn CG. Safety and feasibility of the prostatic urethral lift: a novel minimally invasive treatment for lower urinary tract symptoms (LUTS) secondary to benign prostatic hypertrophy (BPH). *BJU Int* 2011; 108: 82-88.
16. Roehrborn CG. Prostatic Urethral Lift. A Unique Minimally Invasive Surgical Treatment of Male Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. *Urol Clin N Am* 2016;43;357–369

Appendix A:- Identification and measurement of atrial fibrillation through mobile ECG technology

Expected outcome:

Atrial fibrillation (AF) is the most common heart rhythm disturbance, affecting about 2 million people in the UK and Ireland and is responsible for a third of all strokes. Many cases of AF go undetected, and the current process for diagnosis can be lengthy, particularly as waiting times for services are often long.

Mobile ECG devices provide a portable electrocardiogram (ECG) recorder. Monitors work with a compatible mobile device and use an app or equivalent platform to analyse the ECG recording and send it to a healthcare professional for analysis.

Current status:

This technology theme is not part of the Innovation and Technology Tariff. Instead NHS England is working with the 15 Academic Health Science Networks (AHSNs) across England to procure mobile ECG technologies based on local CCG needs. Further details on this will be released in due course, in the meantime please contact england.innovation@nhs.net for further information.

Further information:

NICE has produced the following guidance on the management of Atrial Fibrillation, see <https://www.nice.org.uk/guidance/CG180/chapter/introduction>

Appendix B:- The Academic Health Science Networks (AHSNs) contacts

Eastern

E: enquiries@eahsn.org

T: 01223 661 500

East Midlands

E: emahsn@nottingham.ac.uk

T: 0115 823 1300

Health Innovation Network

E: hin.southlondon@nhs.net

T: 0207 188 9805

Greater Manchester

E: info@gmahsn.org

T: 0161 667 1040

Imperial College Health Partners

E: ea@imperialcollegehealthpartners.com

T: 0207 960 6241

Innovation Agency

E: info@innovationagencynwc.nhs.uk

T: 0177 252 0250

Kent, Surrey and Sussex

E: enquiries@kssahsn.net

T: 0300 303 8660

North East and North Cumbria

E: enquiries@ahsn-nenc.org.uk

T: 0191 208 1326

Oxford

E: info@oxfordahsn.org

T: 0186 578 4994

South West

E: info@swahsn.com

T: 0139 224 7903

UCLPartners

E: contact@uclpartners.com

T: 0207 679 6633

Wessex

E: enquiries@wessexahsn.org.uk

T: 0238 202 0840

West Midlands

E: info@wmahsn.org

T: 0121 452 5636

West of England

E: contactus@weahsn.net

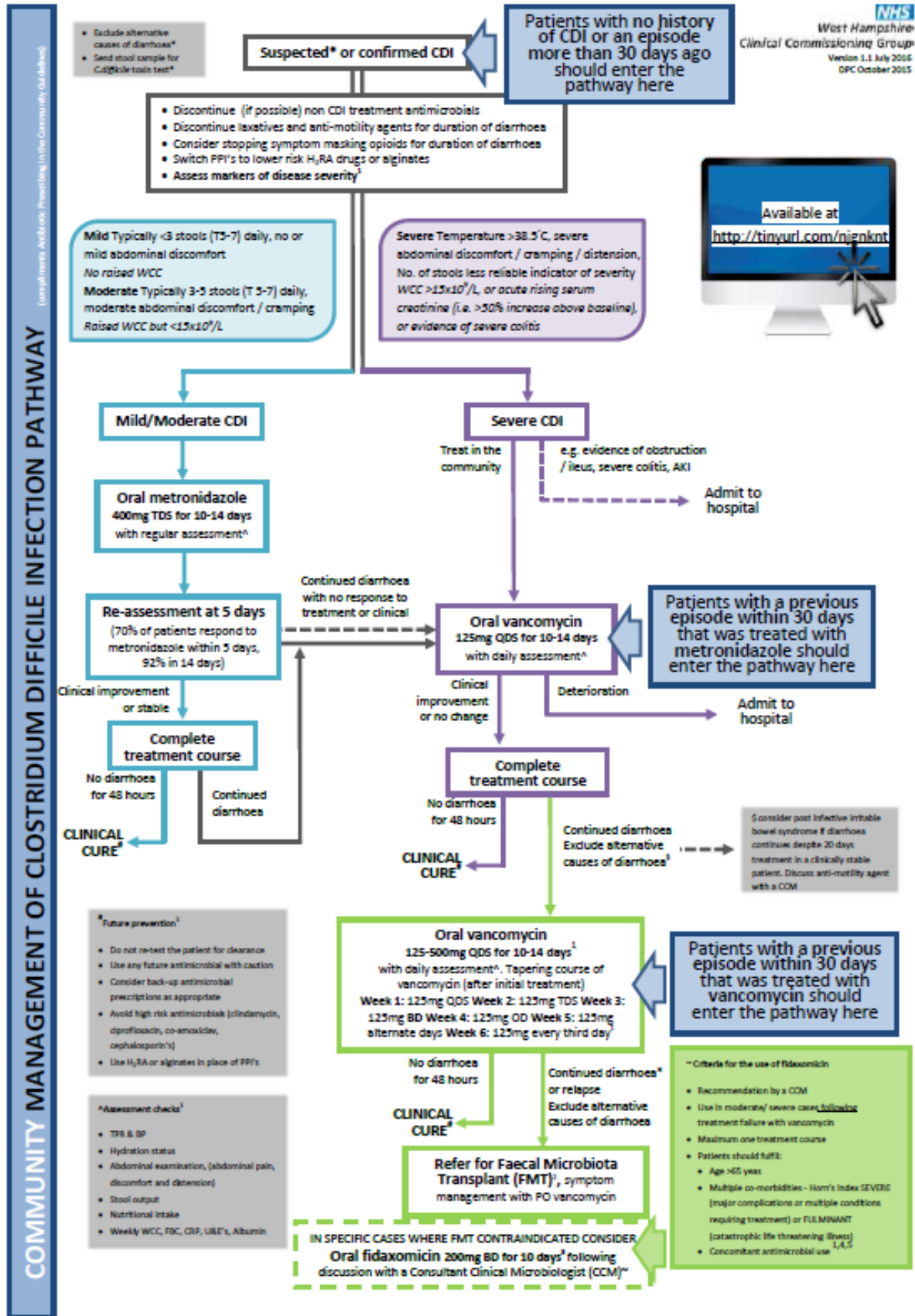
T: 0117 900 2604

Yorkshire and Humber

E: info@yhahsn.com

T: 0192 466 4506

Appendix C:- Community CDI Algorithm



Abbreviations

BD – Twice daily
BP – Blood Pressure
CDI – Clostridium difficile Infection
CCM – Consultant Medical Microbiologist
CRP – C-Reactive Protein
FBC – Full Blood Count
FMT – Faecal Microbiota Transplant
H2RA – H2 Receptor Antagonist
QD – Once daily
PPI – Proton Pump Inhibitor
QDS – Four times daily
TDS – Three times daily
TPR Temperature, Pulse, Respiration
U&E – Urea and Creatinine
WCC – White Cell Count (total)

References

1. Public Health England. Updated guidance on the management and treatment of Clostridium difficile infection, May 2013
2. National Institute for Health and Care Excellence IPG485 Faecal microbiota transplant for recurrent Clostridium difficile infection. March 2014
3. National Institute for Health and Care Excellence ESNM1 Clostridium difficile infection: fidaxomicin July 2012,
4. Hu MY, Katchar K, Kyne L, et al. Prospective derivation and validation of a clinical prediction rule for recurrent Clostridium difficile infection. Gastroenterology 2009; 136: 1206-14.
5. Arora V, Kachroo S, Ghantaji SS et al. High

Appendix D:- FMT GP referral form

Faecal Microbiota Transplant

GP Referral Form

Referral Criteria

- Confirmed recurrent Clostridium difficile Infection (CDI) defined as two or more treatment failures within three months following appropriate treatment

- Common contraindications to FMT include:
 - Age <16 years old
 - Significant swallowing difficulty
 - Severe peptic or duodenal ulcerative disease
 - Neutropenia
 - Long-term immunosuppression via steroids or other immunomodulators
 - Two previous FMTs (from different donors) already received

None of these are absolute and case-by-case assessment should be undertaken – call Portsmouth Microbiology Department on 02392 286 872

GP details

Referring GP:

GP Practice:

GP

Tel:

Patient details

Patient Name:

NHS number:

Date of birth

|_|_|/|_|_|/|_|_|_|_|

Gender

Male

Female

PMHx and allergies (including food allergies)

Any known swallowing difficulties?

yes

no

Please detail:

Any Hx of Gastric or duodenal ulcers?

yes

no

Any allergies (including food allergies)?

yes

no

Please detail:

Any other PMHx of note:

C. difficile history

Date of first diagnosis

|_|_|/|_|_|/|_|_|_|_|

No. of CDI episodes:

1 / 2 / 3 / >3

Previous/current C. difficile treatment

Metronidazole 10-14d

yes

no

Vancomycin 10-14d

yes

no

Vancomycin 6 weeks

yes

no

Other

yes

no If yes, please specify:

Additional information

Any mobility issues?

yes

no

If yes, please detail:

Does patient require an overnight admission or 2 x consecutive day case appointments? (Frailty, transport or severity of symptoms may indicate need for overnight admission)

Overnight admission

2 x day case appointments.

Please record anything else of note:

Date of referral

|_|_|/|_|_|/|_|_|_|_|

Appendix E:- FMT document pack



FMT Form 0

Pre-FMT Quality of life Questionnaire

English version for the UK

Once completed please return to:

Wessex FMT Bank,
Microbiology Department
Queen Alexandra Hospital,
Southwick Hill Road,
Cosham. PO6 3LY.

PT NHS NUMBER	
COMPLETED BY	
COMPLETED ON	

Under each heading, please tick the ONE box that best describes your health TODAY.

The best health you
can imagine

MOBILITY

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

SELF-CARE

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

PAIN / DISCOMFORT

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

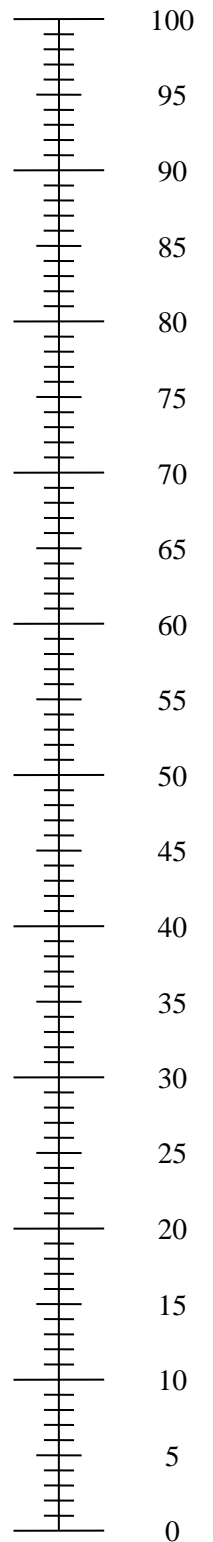
ANXIETY / DEPRESSION

- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed

•

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =



The worst health
you can imagine

FMT FORM 1 (PRE-TRANSPLANT DATA)

1. Site details

Hospital

Attending Consultant

2. Patient details

Patient initials

NHS number

Date of birth

|_|_| / |_|_| / |_|_|_|_|

Gender

Male

Female

3. Indication for FMT

Chronic recurrent C.diff

Acute fulminant C.diff

Other

Please describe:

4. C Difficile history

Diagnosis

Date of first diagnosis

|_|_| / |_|_| / |_|_|_|_|

GDH

positive

negative

Tox A/B

positive

negative

PCR toxB (if available)

positive

negative

Ribotype (if available):

Previous/current treatment

Metronidazole 10-14d	<input type="checkbox"/> yes	<input type="checkbox"/> no
Vancomycin 10-14d	<input type="checkbox"/> yes	<input type="checkbox"/> no
Vancomycin 6 weeks	<input type="checkbox"/> yes	<input type="checkbox"/> no
Other	<input type="checkbox"/> yes	<input type="checkbox"/> no

If yes, please specify:

Risk factors for CDI

Previous antibiotics	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown
Recent hospital admission	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown
Use of PPIs	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown
Recent pregnancy	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown

5. Pre-procedure details

Blood results	WCC x 10 ⁹ /L		
	Albumin g/L		
	eGFR ml/min/1.73m ²		
	CRP mg/ml		

<p>Charlson score (tick all that apply)</p> <ul style="list-style-type: none"> <input type="checkbox"/> History of myocardial infarction <input type="checkbox"/> Congestive cardiac failure <input type="checkbox"/> Peripheral vascular disease (including aortic aneurysm ≥ 6cm) <input type="checkbox"/> Cerebrovascular disease (including TIA) <input type="checkbox"/> Dementia <input type="checkbox"/> Chronic pulmonary disease <input type="checkbox"/> Connective tissue disease <input type="checkbox"/> Peptic ulcer disease <input type="checkbox"/> Mild liver disease (without portal hypertension, includes chronic hepatitis) <input type="checkbox"/> Diabetes without end organ damage (excludes diet controlled) <input type="checkbox"/> Hemiplegia <input type="checkbox"/> Moderate or severe renal disease <input type="checkbox"/> Diabetes with end organ damage (includes brittle diabetes) <input type="checkbox"/> Tumour without metastasis <input type="checkbox"/> Leukaemia <input type="checkbox"/> Lymphoma <input type="checkbox"/> Moderate or severe liver disease <input type="checkbox"/> Metastatic solid tumour <input type="checkbox"/> AIDS (not just HIV)
--

Has the patient completed the **quality of life** questionnaire?

yes

no

6. FMT details

Date

|_|_| / |_|_| / |_|_|_|_|

Batch Number (found on side of
FMT tube)

Route

NG

NJ

Colonoscopy

Procedure completed?

yes

no

If no, give reason:

Immediate complications?

yes

no

If yes, describe:

Please complete Form 1B if further FMT required

Once completed please return to:
Wessex FMT Bank,
Queen Alexandra Hospital,
Southwick Hill Road,
Cosham. PO6 3LY.

• Faecal Microbiota (stool) Transplantation

• FMT Form 2

Patient Information Leaflet

• Introduction

The human gut is normally full of bacteria and other micro-organisms. These bugs live with us, and play a role in digestion and our gut immune response. They form what is known as the gut microbiota.

When we take antibiotics the drugs have a profound effect on our microbiota and the numbers and types of organisms that we live with. There is a reduction in the overall diversity of bacteria, with under-representation of some species groups, and over-representation of other groups. This alteration seems to be important in making patients susceptible to *Clostridium difficile* (*C. diff*) infection.

C. diff is a bacteria, which may in some individuals form part of their normal microbiota. However, if that microbiota is altered (usually by antibiotics) *C. diff* can overgrow. Some types of *C. diff* produce toxins and when a toxin-producing organism overgrows it can lead to *C. diff* infection. Stool tests are used to look for the presence of *C. diff* (often using a test called GDH), and for the presence of, or ability to produce, toxins (toxin A/B immunoassay, PCR, or culture).

C. diff infection can range from very mild disease, to severe, life-threatening diarrhoea and gut inflammation. It often affects patients who are elderly and infirm, or individuals with cancer or long term serious medical conditions. These patients may already be frail, or poorly nourished, making the disease more serious.

Patients with mild disease may not need specific treatment. Often stopping any precipitating antibiotics is enough. However, if patients have more severe disease they will usually be prescribed special antibiotics to treat the *C. diff* infection. Common antibiotics used for this include metronidazole, vancomycin or fidaxomicin. Some patients with severe disease may need surgery to remove the infected gut.

Frustratingly *C. diff* infection can often return following apparently successful treatment. After one episode of *C. diff* infection the chance of a recurrence is around 1 in 4 or 1 in 5 (20-25%). Patients who have had more than one recurrence have an even higher risk. Treating these recurrences can be difficult, as the standard antibiotic therapy becomes less effective. Your doctors may try longer courses of antibiotics, or different types of antibiotics or other medications to try and get you better.

• Faecal transplant

You have been given this information sheet because your doctors believe you, or your loved one, may benefit from a different type of treatment; faecal microbiota

transplantation (FMT). It has been shown in trials that replacing the bacterial flora in an infected patient's gut, with those from a healthy individual can make them better.

Stool is collected from an individual who has been carefully screened to ensure they are not carrying any potentially infectious diseases (including HIV, hepatitis, and gut parasites). The donors are unpaid volunteer adults who are fit and well and of normal weight. This stool is then processed so that it can be passed down a fine tube into the un-well patient's small bowel.

Patients with food allergies, vegetarians or vegans, or individuals with specific religious dietary requirements should discuss these prior to the procedure. It is very likely that we will be able to accommodate your requirements for this treatment.

- **The procedure**

To help you prepare for this procedure you should expect the following to occur. We will collect some simple blood tests to check your haemoglobin and kidney function. The night before the procedure you will be asked to stop taking any treatment you might already be on for *C. diff* infection. You will also be asked to drink a laxative preparation. We ask that you take 3-4 litres of laxative, but many patients struggle to take this quantity, but the more you manage the better. This is designed to flush out any residual infected stool from your system. For some patients with kidney or heart problems we may decide it is safer not to take the laxative or to take a reduced amount. Diabetics should take their medication as normal and no special adjustment is required.

Either the day before, or on the morning of the procedure, you will have a Naso-Jejunal Tube (NJT or NJ tube) placed. This is a fine tube that is passed through the nose, down the oesophagus (food pipe), through the stomach, and down into the small bowel (jejunum). At the bottom of the stomach there is a strong muscle that will help prevent any of the faecal transplant from coming back up the wrong way. As a result, during and after the procedure, you will not be able to taste or smell the faecal transplant, and the procedure should not be offensive in any way.

The NJ tube can be placed using an endoscope (flexible camera) or by hand. You may experience a retching sensation during placement, but once in place the tube should not be uncomfortable. Depending upon how the NJ tube is placed you may also need an X-ray to confirm that it is in the right place.

It is possible to perform the transplant using a tube placed via the rectum. This is more invasive and may put your gut at higher risk of damage. We would only suggest this route if there is a problem using an NJ tube.

The transplant itself takes about 30 minutes, and during this time you can chat, and it is often nice to have a friend or loved one with you to keep you company. The transplant is syringed through the tube into the gut. As the tubing is transparent, note that the faecal material is visible through it. Note also that when the faecal container is opened there it gives a strong smell, but this is short-lived. The only thing you may feel during transplantation is a sensation of coldness at the back of your nose. Once the procedure is over the NJ tube can be removed (unless your team of doctors think you may need it for another reason). Removing the tube is not painful though may feel peculiar for just a few seconds.

At any point before the procedure you may eat and drink whatever takes your fancy. You do not need to be starved for this treatment. We recommend that you do not eat or drink for 1 hour following the procedure.

- **After the procedure**

Following the procedure you are very likely to have a loose motion – this is normal. If the procedure is effective the gut often takes a few days to begin to get better. You should notice that your stool frequency gradually reduces and that your motions are more formed. After a week you should be passing a nearly normal stool. During this time you may have some stomach cramps, or feel nauseous. You will not need any new medications or special diets after the transplant, and you will be asked to stop any treatment you may already be taking for *C. diff* infection. The faecal transplant should not adversely affect your ability to carry out your normal daily activities.

Patients who have come into the hospital especially for the procedure can go home again as soon as they wish (although it is often sensible to wait until after you have opened your bowels).

About 1 in 5 patients will have a relapse after their first faecal transplant; these patients benefit from having a second faecal transplant. Overall for all patients having one or two faecal transplants the cure rate is 94%. If a second transplant is needed we would usually use a different donor. It is not clear if this is important, but some evidence suggests it might improve your chance of cure.

The procedure itself does not carry any risk to your friends or family. However it is important to always maintain good hand hygiene (washing hands after using the toilet or before preparing food/eating). We are always happy to discuss any specific concerns you might have, and will ensure you know who to contact should the need arise.

• Faecal Microbiota Transplantation

• FMT Form 3: Informed Consent

• Indication

Faecal Microbiota Transplantation (FMT) is a treatment for *Clostridium difficile* infection (CDI).

It involves the transfer of gut micro-organisms from a healthy donor to a patient with CDI. It can be used as a treatment for any patient with CDI, but commonly in those who have multiple recurrences, or have failed standard therapy.

Healthy donors are extensively screened for infective pathogens, including HIV, hepatitis, gut parasites and other known transmissible organisms.

• Risks

- Perforation of (making a hole in) the alimentary canal during naso-jejunal tube placement (<1 in 10,000)
- Infection – actual risk uncharacterised, but less than 1 in 100. Including possible peritonitis, enteritis, aspiration pneumonia.
- Transfer of microbiologically uncharacterised material
- Bleeding – reported in one case to date, and not clearly linked to FMT (1 in 350)
- Diarrhoea is common immediately following the procedure but resolves over the next 5-7 days (>1 in 10)
- Constipation (1 in 350)
- Irritable bowel like syndrome has been reported in 5 of 350 cases
- Failure to cure (19% after first FMT, 6% after two FMTs)

• Benefits

- Overall cure rate of 94% (81% after first FMT) in recurrent CDI compared with 31% with standard therapy
- Low recurrence rate of 6%, compared with 69% on standard therapy in recurrent CDI

Date: _____

Patient's signature:

Consenting doctor's signature:

Patient's printed name:
name: _____

Consenting doctor's printed

- Faecal Microbiota Transplantation
- FMT Form 4: Step-by-step guide to procedure

Small bowel delivery

Pre-procedure

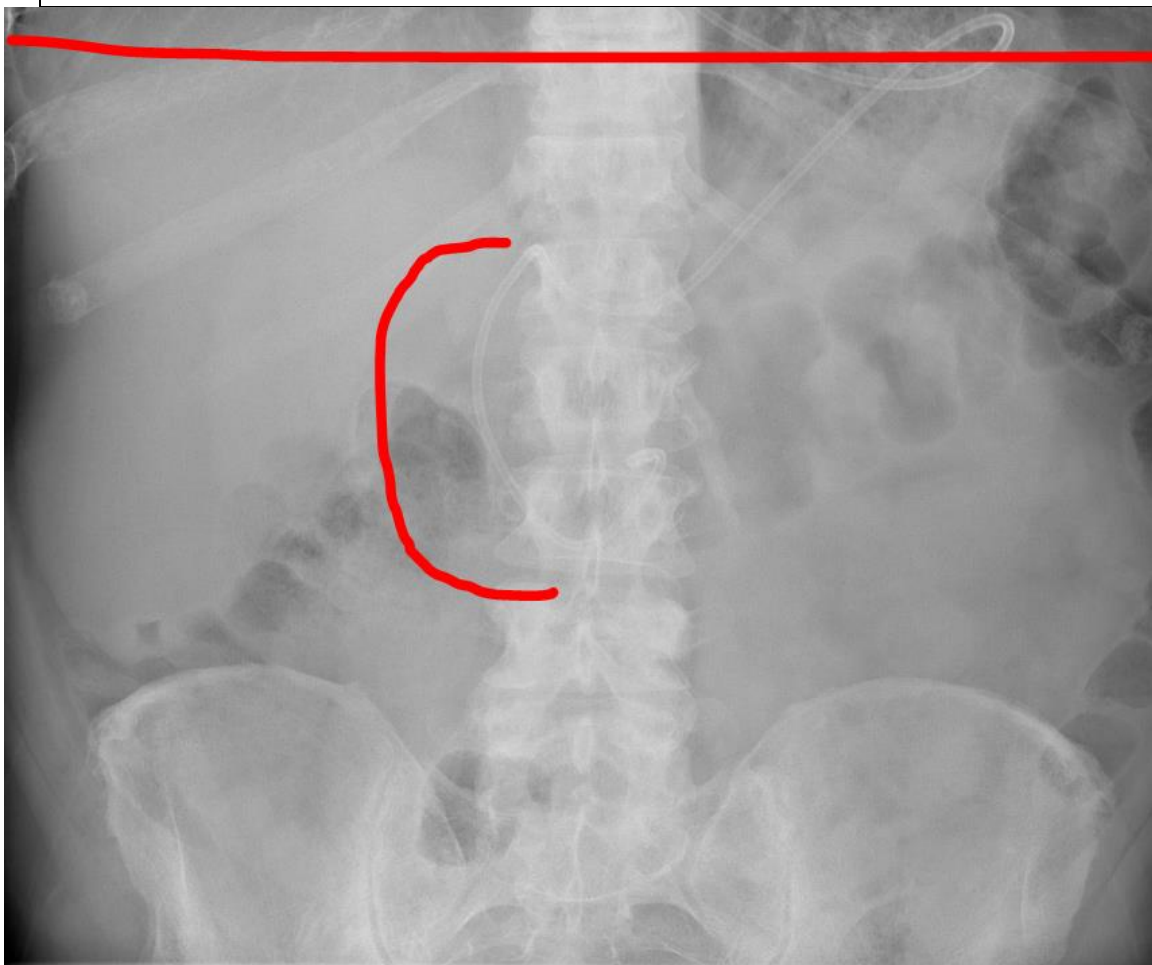
1. Arrange naso-jejunal tube (NOT naso-gastric) for patient (we preferentially use self-advancing nasally placed NJ such as Bengmark or Cortrak as patients have reported better tolerability over endoscopically placed tubes)
2. A heavy meal should be avoided for 30-45 mins prior to NJT insertion. Once the NJT has been inserted the patient can eat and drink as normal
3. Allow 12+ hours for tube to advance to jejunum and arrange extended CXR/AXR for the next morning to check placement of the tube – it should be seen to sit below the diaphragm and to pass through the C shaped duodenum (see guidance image below)
4. Arrange for C.diff specific therapy (e.g. vancomycin/metronidazole/ fidaxomicin) to stop the night before the planned FMT (i.e. no antibiotics on the day of procedure)
5. Prescribe macrogols as indicated on ward information sheet (this step is not essential and either reduced dosing or no laxative may be safer for patients who may be put at risk with large volume fluid shifts)

Day of procedure

1. FMT received via overnight DX as 40ml aliquot.
2. As soon as FMT received remove from packaging wearing suitable hand protection (FMT is frozen at -80°C) and keep at room temperature.
3. The FMT will take about 2 hours to defrost and once at room temperature should be used as soon as possible.
4. Review X-ray of patient and confirm NJT in position (see image on page 2).
5. Check connection ports on feeding tube (or extension tube if using) – Luer or catheter tip (Luer lock is preferred as the risk of disconnection is lower).
6. Obtain written informed consent.
7. Draw FMT into 60ml Luer lock enteric syringe (or catheter tip if required) using an “enteral milk straw”.
8. Ensure patient is sitting upright.
9. Place “inco” pad under NJT/connector set to protect patient if any leaks.
10. Warn patient that they will feel a cold sensation at the back of the nose.
11. Flush NJT with 20-50ml water, and ensure flowing smoothly. If high pressure required try withdrawing NJ by 5-10cm and re-flushing – caution if push fit connections, as high pressure can cause these to come apart!
12. Push FMT via NJT over approx. 30 seconds.
13. Flush with further 20-50ml water.
14. Leave tube in place for at least 30 mins.
15. Warn patient that they may feel the need to pass stool shortly after FMT (this is normal), and may experience mild abdominal discomfort or cramping.

16. Advise that if the FMT is successful the patient should experience steadily more formed stool and reduced frequency. This should be noticeable by day 2 and by day 5-7 they should be nearly back to normal.
17. 20% failure rate after first FMT.
18. If FMT fails they will experience on-going watery diarrhoea without sign of improvement – if this occurs we re-test the stool for C.diff and restart vancomycin at 500mg qds before arranging a further FMT.
19. Remove NJT if not required for other purposes.
20. Enter consent form and FMT coding sticker in notes and document procedure.

Image: Chest X-ray depicting NJT in correct position, below diaphragm and past beyond the stomach into the small bowel as demonstrated by the curvature marked.



•

• Faecal Microbiota (stool) Transplantation

• FMT Form 5: Ward Procedural Checklist

• Prior to admission

- Inform nutrition nurses (if at Portsmouth Hospital, ext. 5918) that a patient is being admitted for FMT and request nasally placed naso-jejunal tube (NJT) for day of admission (this is best placed nasally rather than endoscopically, as there is less risk and discomfort to the patient)
- Inform Microbiologist when the patient will be admitted.
- Admit patient the day before the procedure

• Admission Day 1

- Admit patient into side-room with barrier precautions and chlorine cleaning.
- Provide patient with an information sheet (if not already received one).
- Inform Microbiologist (if at Portsmouth Hospital, bleep 0217, ext. 1724) and nutrition nurse (if at Portsmouth Hospital, ext. 5918) that patient has arrived.
- Prescribe patient's regular medications.
- Prescribe oral vancomycin (125mg – 500mg qds) or oral metronidazole (400mg tds) at the patient's current dose. Stop the vancomycin or metronidazole on the day of the FMT (i.e. last dose the night before the procedure)
- Prescribe 4L of macrogols (either 4 sachets of Klean-Prep, or 4 pairs of sachets (A+B) of Moviprep). This should be taken over the evening prior to FMT – nb many patients only manage 2-3L.
- Book CXR for first thing on the morning of the procedure to check position of NJT.

With the exception of 1 hour before NJT is placed, the patient can eat and drink as they wish – the patient does NOT need to be nil by mouth.

No TTO discharge meds will be required.

• Admission Day 2

- Send patient for CXR first thing in the morning
- Inform Microbiologist when CXR complete
- FMT is usually performed around midday. The patient should be observed for 30 minutes – 1 hour and may wish to use the toilet following the procedure.
Patient should be nil by mouth for 1 hour following the procedure.
- Remove NJT
- The patient can be discharged

FMT FORM 7: 1-WEEK POST FMT PATIENT SATISFACTION SURVEY

PATIENT DETAILS	
NAME	
DOB	
NHS NUMBER	
FMT DATE	

INTERVIEWER DETAILS	
NAME	
INTERVIEW DATE	
INTERVIEW METHOD	FACE-TO-FACE / TELEPHONE

We welcome your feedback so that we can continue to improve this new service for future patients.

Please answer the following questions by circling a response. There is space at the end of the questionnaire to tell us about anything else you feel can be done to improve the service, or any other comments you have.

BEFORE THE PROCEDURE

1) How would you rate the usefulness of verbal information provided?

Very poor Poor Average Good Excellent

2) How would you rate the adequacy of written information provided?

Very poor Poor Average Good Excellent

3) How would you rate the overall quality of your admission/treatment?

Very poor Poor Average Good Excellent

4) How much laxative were you able to take before the procedure (Litres)?

None 0-0.5 0.5-1 1-2 2-3 3-4

5) How did you find the laxative to take?

Very easy Easy Average Difficult Very difficult

DURING THE PROCEDURE

6) How did you find the Naso-Jejunal (NJ) tube insertion?

Very uncomfortable Uncomfortable Slightly uncomfortable
Comfortable

7) How did you find the Naso-Jejunal (NJ) tube removal?

Very uncomfortable Uncomfortable Slightly uncomfortable
Comfortable

AFTER THE PROCEDURE

8) How would you rate the information you were given on discharge?

Very poor Poor Average Good Excellent

ABOUT THE STAFF

9) How would you rate staff awareness of procedure?

Very poor Poor Average Good Excellent

10) How would you rate what you saw of staff compliance with hygiene standards
i.e. gloves/gowns/hand-washing?

Very poor Poor Average Good Excellent

Please tell us anything else we should know about your experience of the FMT transplant service, including any suggestions for improving the service.

Once complete Please return to:
Wessex FMT Bank, Microbiology Department,
Queen Alexandra Hospital, Southwick Hill Road, Cosham. PO6 3LY.

THANK YOU for taking the time to complete this questionnaire.
The FMT team.



FMT Form 8

1-week Post FMT Quality of life Questionnaire

English version for the UK

Once completed please return to:

Wessex FMT Bank,
Microbiology Department
Queen Alexandra Hospital,
Southwick Hill Road,
Cosham. PO6 3LY.

PT NHS NUMBER	
DATE OF FMT	
COMPLETED BY	

COMPLETED ON	
---------------------	--

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

SELF-CARE

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

PAIN / DISCOMFORT

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

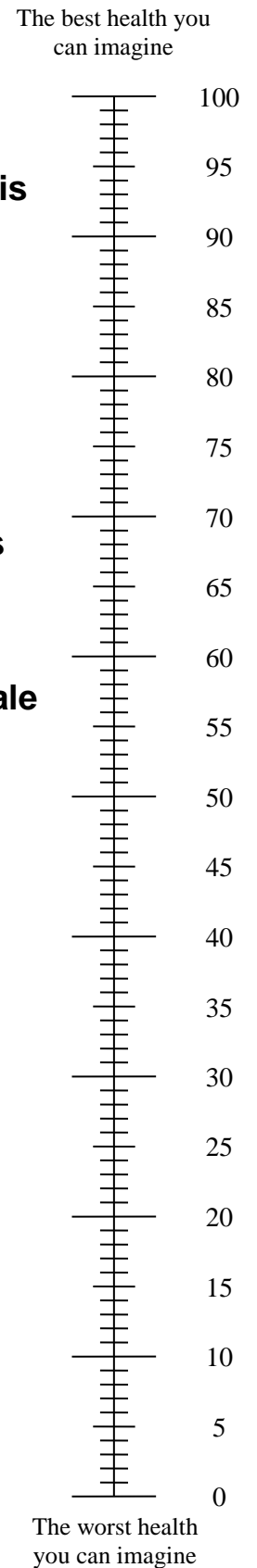
ANXIETY / DEPRESSION

- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =



FMT FORM 9: 6-WEEK POST FMT FOLLOW UP

1. Site Details

Hospital

2. Patient Details

Name

Hospital number

Number of FMTs received

Date of last FMT

3. CDI Symptoms

Did diarrhoea resolve post-FMT?

yes

no

If so, has the diarrhoea returned since the FMT?

yes

no

Does the patient currently have any of the following symptoms?

Diarrhoea

yes

no

Abdominal pain

yes

no

Distension

yes

no

If diarrhoea has recurred since FMT, please give details where possible of frequency of diarrhoea and date(s) when recurred:

4. Has the patient been readmitted to hospital since the FMT for diarrhoeal symptoms?

yes

no

5. Quality of life

Has the EQ5D questionnaire (FMT FORM 8) been

yes

no

completed?

If no, give reason:

6. Other comments

Please record any other issues of note following discussion with the patient:

7. Completed by:

Date: |_|_|/|_|_|/|_|_|_|_|

Once complete Please return to:

Wessex FMT Bank, Microbiology Department,
Queen Alexandra Hospital, Southwick Hill Road, Cosham. PO6 3LY.

FMT FORM 10: 6-MONTH POST FMT FOLLOW-UP

1. Site details

Hospital

Treating Clinician

2. Patient details

Name

Hospital number

Number of FMTs received

Date of last FMT

3. Vital status

Is the patient still alive?

Y/N

Date of death (if available):

4. Symptoms

Did diarrhoea resolve post-FMT?

yes

no

If so, has the diarrhoea returned since the FMT?

yes

no

Is patient currently having:

Diarrhoea

yes

no

Abdominal pain

yes

no

Abdominal bloating

yes

no

If diarrhoea has recurred since FMT, please give details where possible of frequency of diarrhoea and date(s) when recurred:

5. Has the patient been readmitted to hospital since the FMT for diarrhoeal symptoms?

yes

no

6. Other comments

Please record any other issues of note (e.g. cause of death, inc whether CDI or not):

6. Completed by:

Date: |_|_| / |_|_| / |_|_|_|_|

Once complete Please return to:

Wessex FMT Bank, Microbiology Department,
Queen Alexandra Hospital, Southwick Hill Road, Cosham. PO6 3LY.

Appendix F:- FMT Form 2 – Pt. information

Faecal Microbiota (stool) Transplantation

FMT Form 2

Patient Information Leaflet

Introduction

The human gut is normally full of bacteria and other micro-organisms. These bugs live with us, and play a role in digestion and our gut immune response. They form what is known as the gut microbiota.

When we take antibiotics the drugs have a profound effect on our microbiota and the numbers and types of organisms that we live with. There is a reduction in the overall diversity of bacteria, with under-representation of some species groups, and over-representation of other groups. This alteration seems to be important in making patients susceptible to *Clostridium difficile* (*C. diff*) infection.

C. diff is a bacteria, which may in some individuals form part of their normal microbiota. However, if that microbiota is altered (usually by antibiotics) *C. diff* can overgrow. Some types of *C. diff* produce toxins and when a toxin-producing organism overgrows it can lead to *C. diff* infection. Stool tests are used to look for the presence of *C. diff* (often using a test called GDH), and for the presence of, or ability to produce, toxins (toxin A/B immunoassay, PCR, or culture).

C. diff infection can range from very mild disease, to severe, life-threatening diarrhoea and gut inflammation. It often affects patients who are elderly and infirm, or individuals with cancer or long term serious medical conditions. These patients may already be frail, or poorly nourished, making the disease more serious.

Patients with mild disease may not need specific treatment. Often stopping any precipitating antibiotics is enough. However, if patients have more severe disease they will usually be prescribed special antibiotics to treat the *C. diff* infection. Common antibiotics used for this include metronidazole, vancomycin or fidaxomicin. Some patients with severe disease may need surgery to remove the infected gut.

Frustratingly *C. diff* infection can often return following apparently successful treatment. After one episode of *C. diff* infection the chance of a recurrence is around 1 in 4 or 1 in 5 (20-25%). Patients who have had more than one recurrence have an even higher risk. Treating these recurrences can be difficult, as the standard antibiotic therapy becomes less effective. Your doctors may try longer courses of antibiotics, or different types of antibiotics or other medications to try and get you better.

Faecal transplant

You have been given this information sheet because your doctors believe you, or your loved one, may benefit from a different type of treatment; faecal microbiota transplantation (FMT). It has been shown in trials that replacing the bacterial flora in an infected patient's gut, with those from a healthy individual can make them better.

Stool is collected from an individual who has been carefully screened to ensure they are not carrying any potentially infectious diseases (including HIV, hepatitis, and gut parasites). The donors are unpaid volunteer adults who are fit and well and of normal weight. This stool is then processed so that it can be passed down a fine tube into the un-well patient's small bowel.

Patients with food allergies, vegetarians or vegans, or individuals with specific religious dietary requirements should discuss these prior to the procedure. It is very likely that we will be able to accommodate your requirements for this treatment.

The procedure

To help you prepare for this procedure you should expect the following to occur. We will collect some simple blood tests to check your haemoglobin and kidney function. The night before the procedure you will be asked to stop taking any treatment you might already be on for *C. diff* infection. You will also be asked to drink a laxative preparation. We ask that you take 3-4 litres of laxative, but many patients struggle to take this quantity, but the more you manage the better. This is designed to flush out any residual infected stool from your system. For some patients with kidney or heart problems we may decide it is safer not to take the laxative or to take a reduced amount. Diabetics should take their medication as normal and no special adjustment is required.

Either the day before, or on the morning of the procedure, you will have a Naso-Jejunal Tube (NJT or NJ tube) placed. This is a fine tube that is passed through the nose, down the oesophagus (food pipe), through the stomach, and down into the small bowel (jejunum). At the bottom of the stomach there is a strong muscle that will help prevent any of the faecal transplant from coming back up the wrong way. As a result, during and after the procedure, you will not be able to taste or smell the faecal transplant, and the procedure should not be offensive in any way.

The NJ tube can be placed using an endoscope (flexible camera) or by hand. You may experience a retching sensation during placement, but once in place the tube should not be uncomfortable. Depending upon how the NJ tube is placed you may also need an X-ray to confirm that it is in the right place.

It is possible to perform the transplant using a tube placed via the rectum. This is more invasive and may put your gut at higher risk of damage. We would only suggest this route if there is a problem using an NJ tube.

The transplant itself takes about 30 minutes, and during this time you can chat, and it is often nice to have a friend or loved one with you to keep you company. The transplant is syringed through the tube into the gut. As the tubing is transparent, note that the faecal material is visible through it. Note also that when the faecal container is opened there it gives a strong smell, but this is short-lived. The only

thing you may feel during transplantation is a sensation of coldness at the back of your nose. Once the procedure is over the NJ tube can be removed (unless your team of doctors think you may need it for another reason). Removing the tube is not painful though may feel peculiar for just a few seconds.

At any point before the procedure you may eat and drink whatever takes your fancy. You do not need to be starved for this treatment. We recommend that you do not eat or drink for 1 hour following the procedure.

After the procedure

Following the procedure you are very likely to have a loose motion – this is normal. If the procedure is effective the gut often takes a few days to begin to get better. You should notice that your stool frequency gradually reduces and that your motions are more formed. After a week you should be passing a nearly normal stool. During this time you may have some stomach cramps, or feel nauseous. You will not need any new medications or special diets after the transplant, and you will be asked to stop any treatment you may already be taking for *C. diff* infection. The faecal transplant should not adversely affect your ability to carry out your normal daily activities.

Patients who have come into the hospital especially for the procedure can go home again as soon as they wish (although it is often sensible to wait until after you have opened your bowels).

About 1 in 5 patients will have a relapse after their first faecal transplant; these patients benefit from having a second faecal transplant. Overall for all patients having one or two faecal transplants the cure rate is 94%. If a second transplant is needed we would usually use a different donor. It is not clear if this is important, but some evidence suggests it might improve your chance of cure.

The procedure itself does not carry any risk to your friends or family. However it is important to always maintain good hand hygiene (washing hands after using the toilet or before preparing food/eating). We are always happy to discuss any specific concerns you might have, and will ensure you know who to contact should the need arise.

Appendix G:- FMT Form 3 – Informed consent

Faecal Microbiota Transplantation

FMT Form 3: Informed Consent

Indication

Faecal Microbiota Transplantation (FMT) is a treatment for *Clostridium difficile* infection (CDI).

It involves the transfer of gut micro-organisms from a healthy donor to a patient with CDI. It can be used as a treatment for any patient with CDI, but commonly in those who have multiple recurrences, or have failed standard therapy.

Healthy donors are extensively screened for infective pathogens, including HIV, hepatitis, gut parasites and other known transmissible organisms.

Risks

- Perforation of (making a hole in) the alimentary canal during naso-jejunal tube placement (<1 in 10,000)
- Infection – actual risk uncharacterised, but less than 1 in 100. Including possible peritonitis, enteritis, aspiration pneumonia.
- Transfer of microbiologically uncharacterised material
- Bleeding – reported in one case to date, and not clearly linked to FMT (1 in 350)
- Diarrhoea is common immediately following the procedure but resolves over the next 5-7 days (>1 in 10)
- Constipation (1 in 350)
- Irritable bowel like syndrome has been reported in 5 of 350 cases
- Failure to cure (19% after first FMT, 6% after two FMTs)

Benefits

- Overall cure rate of 94% (81% after first FMT) in recurrent CDI compared with 31% with standard therapy
- Low recurrence rate of 6%, compared with 69% on standard therapy in recurrent CDI

Date: _____

Patient's signature:

Consenting doctor's signature:

Patient's printed name:
name:

Consenting doctor's printed