Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Faecal Microbiota Transplantation Policy – Use of FMT in the management of Clostridioides Difficile Infection

This procedural document supersedes: Faecal Microbiota Transplantation Policy – PAT/IC 34 V 1

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Executive Sponsor(s):	Director of Nursing, Midwifery and Allied Health Professionals
Author/reviewer: (this version)	Dr Ken Agwuh (Consultant Microbiologist) Dr Anurag Agrawal
Date written/revised:	October 2022
Approved by:	Patient Safety Review Group Infection Prevention and Control Committee
Date of approval:	October 2022
Date issued:	April 2024
Next review date:	October 2025
Target audience:	All Trust Clinical Staff and Staff Employed or Working on Behalf of the Trust

Amendment Form

Version	Date Issued	Brief Summary of Changes	Author
Version 2	April 2023	• Minor on page 7 (section 4.4 on the current cost of FMT) • Changes of the nomenclature from *Clostridium difficile* to *Clostridioides difficile*	Dr Ken Agwuh & Dr Anurag Agrawal
Version 1	November 2015	• This policy was approved at the Trust Patient Safety Review Group September 2019, (PAT/T68), However, it has now moved to the Infection Prevention and Control Category PAT/IC • Changes to the procurement centre for FMT, updated guidelines, hyperlinks and adverse reaction details	Dr Ken Agwuh & Dr Anurag Agrawal

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1 INTRODUCTION

The vast majority of patients with *Clostridoides difficile* infection (CDI) can be treated effectively using antibiotics such as Metronidazole, Vancomycin and Fidaxomicin that have activity against the organism.

Symptoms of C. difficile infection range from mild diarrhoea which may resolve completely by as little as discontinuation of the offending antibiotic and supportive measures, to severe disease associated with pyrexia, elevated C-reactive protein (CRP), white cell count (WBC), toxicity and intractable loose stool.

Treatment of C difficile infection with current antimicrobial therapy achieves clinical response in more than 90% of patients. A small percentage of patients have been reported been to recurrence of loose stool with C difficile first, and the frequency of subsequent relapses rises after this up to 60% after two or more recurrences.

Fatality rates as high as 24% have been reported in case series of critically ill patients with Clostridium difficile colitis.

The aim of faecal microbiota transplant (FMT) is to restore a healthy balance of bacteria in the gut of patients who have had multiple recurrent Clostridium difficile infection by introducing enteric bacteria from screened and safe faeces of healthy donors. Successful resolutions of symptoms or cure rates have been reported in the range of greater than 90% in most publications.

2 PURPOSE

The purpose of this guideline is to ensure patient safety and enable Healthcare professionals at Doncaster and Bassetlaw Hospitals Foundation NHS Trust to follow a procedure to administer Faecal Microbiota Transplant for the treatment of Clostridioides difficile Infection (CDI).

3 DUTIES AND RESPONSIBILITIES

This policy covers selection of patients to under FMT, and the infection prevention and control management issues:

Trust Board: The Board, via the Chief Executive, is ultimately responsible for ensuring that systems are in place that effectively manages the risks associated with Infection Control and management. Their role is to support the implementation of a Board to Ward culture to support a Zero Tolerance approach to Health Care Associated Infections and their appropriate management.
The Director of Infection Prevention and Control will provide assurance to the board that effective systems are in place.

Director of Infection Prevention and Control: Is responsible for providing expert advice together with a named gastroenterologist in accordance with this policy, for supporting staff in its implementation, and assisting with risk assessment where complex decisions are required.

The Infection Prevention and Control Team: is responsible for supporting the director of infection prevention and control with implementation of this policy, for supporting staff in its implementation, and assisting with risk assessment where required.

Divisions: are responsible for ensuring the policy is adhered to and for ensuring action is taken if staff fails to comply with the policy.

Matrons: are responsible for ensuring implementation within their area.

Ward and Department Group Managers: are responsible for ensuring implementation within their area and for ensuring all staff that works within the area adheres to the principles at all times.

Clinical Team responsible for the patient: are responsible for ensuring their junior staff read and understand this policy, and adhere to the principles contained in it at all times. Also that they work closely with the medical microbiologist and Infection Prevention and Control Team in the administration and management of the transplant procedure.

Clinical Site Managers/On-call Managers: are responsible for ensuring patients are placed in accordance with this policy, and for escalating any situations where safe placement cannot be achieved.

PATIENTS LACKING CAPACITY

Sometimes it will be necessary to provide care and treatment to patients who lack the capacity to make decisions related to the content of this policy. In these instances staff must treat the patient in accordance with the Mental Capacity Act 2005 (MCA 2005).

- A person lacking capacity should not be treated in a manner which can be seen as discriminatory.
- Any act done for, or any decision made on behalf of a patient who lacks capacity must be done, or made, in the persons Best Interest* see definitions.
- Further information can be found in the MCA policy, and the Code of Practice, both available on the intranet.

4 PROCEDURE

In March 2014, NICE published guidance stating the evidence on the efficacy and safety of faecal microbiota transplant for recurrent Clostridioides difficile is adequate to

support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

4.1 Patient Selection

The following criteria for selection of patients, after consultation with the DIPC/named gastroenterologist for treatment with faecal microbiota transplant include the following:

a) Multiple recurrence of CDI (patients who have suffered from ≥ 3episode of confirmed CDI).
b) CDI non-responders (patients categorized as non-responders, having been treated with 3 or more courses of anti-C. difficile antimicrobials including Vancomycin and Fidaxomicin, and who remain symptomatic).

4.2 Patient Inclusion and Exclusion

The following inclusion and exclusion criteria must be met for patient treatment:

a) Inclusion

i. Patents meets the criteria in 4.1 (multiple recurrence or non-responder) category.
ii. Patient suitable for Nasogastric tube (NGT) insertion.
iii. Patient receiving anti-C. difficile antibiotic for at least 4 days prior to FMT.
iv. Informed consent.

b) Exclusion

i. Decompensated liver cirrhosis.
ii. Ulcerative/bleeding of the upper gastrointestinal tract.
iii. Life threatening food allergy e.g. peanuts.
iv. Intolerance to NGT placement.

4.3 Patient Consent

The Trust Consent to Examination or Treatment Policy (PAT/PA 2 v.7) must be followed with full documentation, with use of specific Consent form for FMT (see appendix 1). When consent is taken it should be in line with the Human Tissue Authorities published Code of Practice and Consent (https://www.hta.gov.uk/sites/default/files/files/HTA%20Code%20A.pdf).

When consent is obtained, this should be done by an individual who has the ability to explain the nature of the procedure, its risks and benefits. The information leaflet dedicated for patient undergoing FMT should be provided (See appendix 2).

The risk of FMT can include:

a) Low risk of perforation from NGT insertion

b) Risk of aspiration while NGT in place
c) Low risk of transmission of an unknown infectious agent

4.4 Requesting FMT

Consultation request to the DIPC or microbiologist and or the named gastroenterologist with interest in FMT should be made if patient meets the inclusion criteria.

The provision of FMT service in the Trust is reliant on obtaining already pre-screened faecal samples from healthy donors supplied by the University of Birmingham Microbiome Treatment centre (UoBMTC).

The request for patient treatment should be made by a named clinician (the DIPC) by email, using the FMT request form(see appendix 3), to the microbiology FMT email bhs-tr.FMT@nhs.net The request should be made at least 4 days before the planned transplant date. A financial contract with UoBMTC has been completed, giving details of authorised financial representatives and contract length and value. The current cost is £1300 (VAT exempt) for 50ml aliquot supplied by UoBMTC is charged to the NHSE innovation tariff.

FMT supply is available from Monday to Friday and between 9 am and 5 pm. No weekend service available.

One FMT is supplied as a 50 ml aliquot in a screw capped plastic tub. The aliquot is stored at - 80^{o}C until the day of delivery and thawed on the day of delivery by the PHE laboratory at Birmingham.

All FMT supplied with a validated certificate which will be retained in the patient's note for traceability purposes.

The FMT will be transported at room temperature to microbiology department for attention of the DIPC via the Blood Bikes service, a charity transporting urgent medical products between NHS Trusts. This service is currently free. There must be a constant address and cannot change with each FMT request and complies with packaging instructions 620 and 650 and identified with the UN3373 label.

4.5 Logistics of FMT Treatment

FMT samples take about three hours to defrost. As the FMT leaves UoBMTC at Birmingham from the freezer, it is expected to be still thawing or almost ready for transfer into the enteral feeding syringe in the ward on arrival to Microbiology laboratory at Doncaster Royal Infirmary via the Blood Bike Service delivery.

FMT can be administered by a doctor or a staff nurse competent to administer enteral feeding via NGT.

4.6 Patient Pre-Treatment

Ensure patient understands and have read through the FMT leaflets and consent form singed for the FMT and insertion of NGT.

a) Clotted blood sample (red top) is collected from patient and formed to microbiology for indefinite storage (for clinical governance and potential look back exercises)
b) Collect another blood sample for patient's baseline blood investigation
c) Patient must have received at least 4 days C. difficile antibiotic prior to FMT.
d) Stop the C difficile antibiotic the evening before the FMT treatment.
e) Patient should be nil by mouth at least 6 hours prior to FMT, but can take their regular medications for other medical conditions.
f) Insert the NGT and confirm positioning with check X-ray following Trust guidelines. See Nasogastric Tube Management and Care Policy (PAT/T 17 v4).
g) Give a STAT dose of oral omeprazole 20 mg 2 hours prior to FMT administration.
h) Give a STAT dose of oral domperidone 10 mg 2 hours prior to FMT administration.

4.7 FMT Adminisration

a) FMT should be stored at room temperature until administration.
b) Administration should be completed as soon as possible after delivery.
c) Before administration cross check the FMT batch and lot number against the validation certificate, and retain certificate in the patient's notes.
d) Confirm positioning of the NGT as per Trust guidelines before its use
e) Connect FMT enteral syringe to the NGT and administer 50 ml of the FMT into the stomach over 30 minutes.
f) Flush the NGT with 30 ml of saline
g) Remove NGT one hour after the procedure
h) The patient can eat 1 hour following the procedure and removal of the NGT
i) Patient can be discharge home same day or following day.

4.8 Disposal in the Event FMT is not used

The FMT aliquots supplied are for use on the same day of delivery. If the FMT is not used on the day of delivery, the aliquot will be dispose of in clinical waste stream as per Trust policy (yellow bag). Audit trail kept, the FMT validation certificate will be destroyed into the confidential waste.

4.9 Serious Adverse Events (SAE) and Serious Adverse Reactions (SAR)

Any serious adverse events and reaction associated with administration of should be notified to the DIPC on 01302 644224, or duty microbiologist via 01302 642831, who in turn will email within 24 hours of the event occurring to the UoBMTC, Birmingham contacts:

Professor Peter Hawkey Professor
Mobile Number: 07764285879
Landline number: 01452 814666

Tariq Iqbal
Mobile Number: 07713575156

Dr Mohammed Nabil Quraishi
Mobile Number: 07561101015

Dr Naveen Sharma
Mobile Number: 07801924818

Please follow up all calls with an e-mail to bhs-tr.FMT@nhs.net within 24 hours

Following notification of the SAE/SAR, a root Cause Analysis (RCA) is expected to be performed, within 5 days as documented in Appendix 4.

a) A SAE is defined by the Human Tissue Authority as 'any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of tissues or cells intended for human application and which, in relation to a donor of tissues or cells intended for human application or a recipient of tissues or cells:

   i. Might lead to the transmission of a communicable disease, to death or life- threatening, disabling or incapacitating conditions or

   ii. Might result in, or prolong, hospitalisation or morbidity'

b) A SAR is defined by the Human Tissue Authority as 'any unintended response, including communicable disease, in a donor of tissues or cells intended for human application or a recipient of tissues or cells, which may be associated with the procurement or human application of tissue or cells and which is fatal, life threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.

4.10 Post FMT Monitoring

FMT is a new technique and therefore patients will be followed up within the routine clinical service and by the FMT team post discharge, to audit outcome of the treatment. Patient will be reviewed at the out-patient gastroenterology clinic 2 weeks and via telephone by the FMT team three months. The telephone interview will help gather information on the effectiveness of the procedure and to improve the procedure in the future.

5 TRAINING/SUPPORT

The training requirements of all staff will be identified through a training needs analysis. Role specific education will be delivered by the service lead or nominated person.

Training and development in relation to the safe and secure handling of the FMT can be achieved using standard Infection Prevention and Control policy and effective disposal of body waste.

5.1 As Stated in Nasogastric Tube Management and Care

All nurses and midwives have a responsibility to ensure that they have sufficient knowledge, skills and competence to perform any procedure as outlined by the Nursing and Midwifery Council (NMC 2008) It is expected that student nurses/midwives will gain the knowledge and skills necessary to perform wide bore (Ryles tube) nasogastric insertion during their education.

Upon registration they will gain competence under guidance of a preceptor until they can complete the procedure independently. For fine bore nasogastric insertion, registered nurses/midwives must extend their scope of practice and undertake additional education and training using the Trust Clinical Skills Training Package.

All nurses, midwives and medical staff have a responsibility to ensure that they have received training and been assessed as competent on the use of pH indicator strips and the NPSA Guidelines for confirming the correct placement of nasogastric feeding tubes.

6 MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

This policy will be reviewed routinely every three years unless, when new national or international guidance are received and when newly published evidence demonstrates need for change to current practices or any action required from Root Cause Analysis Serious Incident Investigation Report. The policy will be approved and by the Infection Prevention and Control Committee.

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Compliance with policy to negate unnecessary request out the policy for FMT	DIPC / Microbiologist	Annually	Reviewed through annual contract set up with PHE Birmingham
Audit of outcome of FMT	DIPC/Microbiologist and Gastroenterologist	Annually	Feedback questioner and clinics follow up

7 DEFINITIONS

Antibiotics/antimicrobials: Agents used to treatment or prevention of infections.

Colitis: Inflammation of the large bowel.

Diarrhoea: A loose stool enough to take the shape of a container used to sample it or as Bristol Stool Chart Types 5-7.

Infection: The presence of an organism on the surface of any part in the human body or in any tissue accompanied by an inflammatory response.

Lansoprazole: Is a medicine that is one of the proton pump inhibitors.

Microbiota: Refers to the organisms of a particular site or habitat.

Relapsing/Recurrence Infection: An infection that recurs despite initial treatment.

Transplantation: The process of removing from one place or content and settling or introduction elsewhere.

8 EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment For All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (See Appendix 4)

9 ASSOCIATED TRUST PROCEDURAL DOCUMENTS

- Clostridioides difficile Infection (CDI) Policy – PAT/IC 26
- Consent Examination or Treatment Policy –PAT/PA 2
- Glove Use Policy - CORP/HSFS 13
- Hand Hygiene - PAT/IC 5
- Health and Safety at Work - Medical Surveillance - CORP/HSFS 2
- Isolation Policy - PAT/IC 16
- Medical Devices Management Policy - CORP/PROC 4
- Medical Equipment Training Policy - CORP/RISK 2
- Mental Capacity Act 2005 - Policy and Guidance including Deprivation of Liberty Safeguards (DOLS) - PAT/PA 19
- Nasogastric Tube Management and Care – PAT/T 17
- Nasogastric Tube Management and Care – PAT/T 17
- Nasogastric Tube Management and Care – PAT/T 17
- Selection and Procurement of Medical Devices Policy - CORP/PROC 3
- Spillage of Blood and other Body Fluids PAT/IC 18
- Standard Infection Prevention and Control Precautions Policy - PAT/IC 19
- Waste Management Policy - CORP/HSFS 17 (A)
- Waste Management Manual – CORP/HSFS 17 (B)
- Mobile Communications Policy – CORP/HSFS 16
- Fair Treatment For All Policy - CORP/EMP 4
- Equality Analysis Policy - CORP/EMP 27.

10 DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the UK General Data Protection Regulation (GDPR) 2021.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website: https://www.dbth.nhs.uk/about-us/our-publications/information-governance/

11 REFERENCES

NICE guidance: Faecal microbiota transplant for recurrent Clostridium difficile infection. NICE interventional procedure guidance [IPG485], March 2014. https://www.nice.org.uk/guidance/ipg485/resources/faecal-microbiota-transplant-for- recurrent-clostridium-difficile-infection-1899869993554885

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

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

Hamilton, M. J., Weingarden, A. R. et al. (2012) Standardized frozen preparation for transplantation of fecal microbiota for recurrent Clostridium difficile infection. American Journal of Gastroenterology 107 (5): 761-767.

Rubin, T. A., Gessert, C. E. et al. (2013) faecal microbiome transplantation for recurrent Clostridium difficile infection: report on a case series. Anaerobe 19: 22-26.

Brandt, L. J., Aroniadis, O. C. et al (2012) Long-term follow up of colonoscopy faecal microbiota transplant for recurrent Clostridium difficile infection. American Journal of Gastroenterology 107 (7): 1079-1087.

William M et al. Faecal Microbiota Transplant Protocol for Clostridium Difficile Infection. www.medscape.com. 2015. Pages 1-3.

FMT-DON-012 FMT Clinical Protocol v2 issued 17 April 2019

APPENDIX 1 – CONSENT FORM FOR FMT

Doncaster and Bassetlaw Hospitals NHS
NHS Foundation Trust

Specific Consent Form for Faecal Microbiota Transplantation (FMT)

PATIENT NAME:……

DIAGNOSIS/CONDITION:……

DATE OF PROCEDURE:……...

I hereby authorize _____
To perform the following procedure: Faecal Microbiota Transplantation (FMT).

1. I understand that FMT may be performed through a nasoduodenal tube inserted via the nose into the first part of the small intestine. FMT is administered to treat chronic (recurrent) or severe *Clostridium difficile* infection (CDI), an inflammatory condition of the large intestine (colon). FMT consists of introducing normal bacterial flora contained in stool collected from a healthy donor into the diseased colon where the flora is missing.

2. The nature, purpose, risks and benefits of this procedure has been discussed with me. I understand that the donor will be screened for a possible history of exposure to a communicable infectious agents through a detailed health questionnaire, and also undergo blood and faeces testing for occult infectious pathogens as some infectious diseases may be silent or clinically undetectable.
   I have discussed all alternative treatments for recurrent CDI with my physician, including various antibiotic options, surgery, or no treatment at all, and understand the risk and benefits of the alternative treatments. I understand that my condition could improve, worsen or stay the same with each of the alternative treatment options, including FMT.
   I understand that individuals who are severely ill with FMT have a high risk of dying from their illness, regardless of what treatment is used. I understand that at the current time the cumulative experience with FMT is limited and that FMT is therefore considered investigational.
   In choosing to proceed with FMT I understand that a solution of donor stool will be infused into the beginning of my small intestinal tract via a hollow tube inserted through the nose OR into my colon through a tube with an inflatable balloon at the tip.

3. The risks of FMT procedure has been discussed in detail with me. I understand that complications may arise as a result of FMT. Complications may include but are not limited to:
   ·Transmission of infectious organisms contained in stool (bacteria, viruses, fungi, parasites)
   ·Allergic reactions to constituents (antigens) contained in the donor stool
   ·Mechanical complication related to the insertion and presence of the tube, such as potential perforation of the lining of the oesophagus, stomach, or duodenum, or aspiration of stool into the lungs (for the Nasogastric tube), or trauma to the rectum and perforation of the colon (for the enema).
   I understand that the outline above is not a complete list of potential complications, and that unforeseen risks that have not been discussed with me may exist.

4. I understand that the above risks, as well as other complications, may require additional procedures or operations and that these issues have been discussed with me. I give my consent to undergo additional procedures which my physician deems necessary.

5. Recuperation from FMT is generally complete within a few hours following the procedure if done on an outpatient basis. Most individuals can return to typical activities and diet at that time. Increasing abdominal pain, bleeding, fever or other signs of illness could be signs of complications and should be reported promptly to your physician.

6. I am aware that the practice of medicine is not an exact science. I acknowledge that no guarantee or promise can be made by my physician as to the outcome of my treatment.

7. I acknowledge that the entire content of this form has been explained to me, and that I understand the contents. I have had the opportunity to ask questions, and all of my questions have been answered to my satisfaction.

Signature:_____ Date_____ Time _____ (Patient or legal guardian)

Signature:_____ Date_____ Time _____ (Stool donor)

Provider's Acknowledgement:
I confirm that I have fully explained to the above patient or legal representative the nature and purpose of Faecal Microbiota Transplantation and the possible risks and benefits of FMT and treatment alternatives.

Printed name:_____ Signature: _____ (Provider)
(Provider)

Date:_____ Time: _____

Interpreter's Acknowledgement (when applicable):
I confirm that consent to proceed with FMT, as explained above, has been given by this patient or legal guardian.

Printed name:_____ Signature: _____ (Interpreter)
(Interpreter)

Date:_____ Time: _____

APPENDIX 2 – PATIENT INFORMATION LEAFLET

Doncaster and Bassetlaw Hospitals NHS
NHS Foundation Trust

Patient Information Leaflet – Recipient

What is *Clostridioides difficile*?

Clostridioides difficile (C. diff) are bacteria that can live in the intestine (also known as the gut). These bacteria can live amongst normal bacteria in the intestine and cause no harm in healthy individuals.

Diarrhoea related to *Clostridioides difficile*

However, if the normal bacteria in the gut are reduced, e.g. by the use of antibiotics to treat other infections, then the numbers of *Clostridioides difficile* can increase. This can lead to diarrhoea caused by toxins which are released from some strains of *C. difficile* bacteria.

What are the symptoms of *Clostridioides difficile* infection?

Clostridioides difficile causes diarrhoea symptoms which range from mild to severe, other symptoms include fever, loss of appetite, nausea and abdominal pain, and weight loss. It can also cause a rare complication which is life-threatening inflammation of the intestines.

How does *Clostridioides difficile* spread to other people?

Clostridioides difficile forms spores which are able to live in the environment for a long time and are resistant to standard cleaning methods. If the spores are ingested by another person then C. diff may colonise that person's intestine for a period, but will not generally cause diarrhoea unless the person is on antibiotics and is weakened by illness. It is also less likely to cause harm if the patient has a healthy level of normal bacteria. It affects the over 65 year olds to a much greater degree than younger patients.

Treatment of *Clostridioides difficile* infection (CDI) using antibiotics

Antibiotics such as Metronidazole, Vancomycin and Fidaxomicin kill the *Clostridioides difficile* bacteria, allowing the normal bacteria in the intestine to return. However, in some people diarrhoea returns a few days after stopping the antibiotics, this is called a recurrence or relapse.

Why does the disease relapse?

Recurrence/relapse can occur when the normal intestine bacteria do not return, thus allowing any remaining *C. difficile* in the intestine to increase in numbers and cause symptoms again.
People with reduced immunity or other chronic conditions are more likely to suffer recurrence/relapses. Also, people who have one recurrence/relapse are at increased risk of suffering from further recurrence/relapse of infection.

Treatment of *Clostridioides difficile* Infection using Faecal Microbiota Transplant (FMT)

A Faecal Microbiota Transplant (FMT) is a filtered suspension of stool prepared from a healthy donor stool which is given to a patient. The normal bacteria in the donor stool replace the bacteria which are missing in the intestine of CDI patients, competing with the *Clostridioides difficile* and preventing it from growing. As the *Clostridioides difficile* is unable to grow it cannot cause the symptoms of CDI and the diarrhoea stops. This is a novel treatment for CDI. The symptoms of CDI are resolved by FMT in around 91% of patients. With antibiotic treatment, only 30–40% of patients have resolution of their diarrhoea. Patients usually see improvement in their diarrhoea within 24–72 hours after the FMT. Flatulence, belching and/or constipation may be experienced in the days following FMT.

What's involved in FMT treatment?

Donors are anonymous and have agreed to act as a donor through the FMT team. They are healthy, between the age of 18 and 50, have not taken antibiotics in the last 3 months and have had no recent change in bowel habit. They will be screened for gut infections and for infections that can be transmitted by bodily fluids (usually blood), including Hepatitis A, B, C, E, HIV and syphilis. Only those negative for these infections will be allowed to be donors.

The patient will be treated with oral Vancomycin antibiotic for 4 days prior to the FMT, but will stop the night before. They will receive a dose of omeprazole, a proton pump inhibitor, on the morning of the infusion to reduce the amount of stomach acid which could kill the bacteria being given in the FMT. Domperidone will also be given to stimulate stomach emptying into the small intestine.

On the day of the FMT, the patient will have a nasogastric tube inserted on the ward, which is a narrow tube inserted through the nose, down the throat and into the stomach (normally used as feeding tubes). A syringe containing the FMT is connected to the nasogastric tube and the FMT is administered down the tube. The patient should not smell or taste the FMT. The nasogastric tube is then flushed with saline and removed

Is FMT likely to be successful?

Many transplants using this method have been performed in the USA and other countries with a more limited experience in the UK. Most groups report that over 4 out of every 5 patients receiving faecal transplant are cured of their *Clostridioides difficile.* The procedure has been approved for use in the UK by NICE in 2014.

What are the risks of FMT treatment?

There is a theoretical risk of transmission of a pathogen from the donor to the recipient. Donors are screened for common bloodborne and enteric pathogens and restricted from donating if any pathogens are detected. Donors undergo clinical, social and travel risk assessment and are only allowed to donate if there are no risks for infection found. However, there may be unrecognised pathogens in the FMT material, which could cause infection in the recipient. Of the approximately 500 patients who have been treated with FMT, there has been one death which was possibly attributable to FMT treatment

Follow up

FMT is a new technique and therefore patients will be followed up within the routine clinical service and by the FMT team after discharge, to audit outcome of the treatment. A member of the FMT team will contact the patient or the patient's carers three months after discharge, via telephone. This telephone interview will be used to ask about the patient's health since discharge and the information will be used to assess the effectiveness of the procedure and to improve the procedure in the future. Finally the patient will be asked about their experience of the FMT treatment.

APPENDIX 3 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/Strategy	Division	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Faecal Microbiota Transplantation Policy – PAT/IC 34 v 2	Nursing, Midwifery and Quality (IP&C and Gastroententerology)	Dr Ken Agwuh – Consultant Microbiologist & DIPC	Previous Policy Number PAT/T 68. Now PAT/IC 34	20/10/2022

1) Who is responsible for this policy? Name of CSU/Directorate: Infection Prevention and Control & Gastroenterology

2) Describe the purpose of the service / function / policy / project/ strategy? Who is it intended to benefit? What are the intended outcomes? The purpose of this guideline is to ensure patient safety in the administration of Faecal Microbiota Transplant for the treatment of Clostridium difficile Infection (CDI).

3) Are there any associated objectives? Legislation, targets national expectation, standards: NICE Interventional Procedure guidance [IPG485], March 2014

4) What factors contribute or detract from achieving intended outcomes? – None

5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? Details: [see Equality Impact Assessment Guidance] - No

- **If yes, please describe current or planned activities to address the impact** [e.g. Monitoring, consultation] –

6) Is there any scope for new measures which would promote equality? [any actions to be taken] No

7) Are any of the following groups adversely affected by the policy?

Protected Characteristics	Affected?	Impact
a) Age	No	Neutral
b) Disability	No	Neutral
c) Gender	No	Neutral
d) Gender Reassignment	No	Neutral
e) Marriage/Civil Partnership	No	Neutral
f) Maternity/Pregnancy	No	Neutral
g) Race	No	Neutral
h) Religion/Belief	No	Neutral
i) Sexual Orientation	No	Neutral

8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box

Outcome 1 ✓	Outcome 2	Outcome 3	Outcome 4

If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form – see CORP/EMP 27.

Date for next review: **October 2025**

Checked by: **Carol Scholey** **Date:** **10/11/2022**