

Clinical Procedure for administering Faecal Microbiota Transplantation (FMT) at the Endoscopy Unit located at NNUH and Quadram Institute (QI)

Clinical Procedure recommended:

For use in:	Endoscopy Unit at NNUH and QI
By:	Endoscopy staff
For:	Patients needing Faecal Microbiota Transplantation
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Purpose: The purpose of this Guideline is to ensure patient safety and enable Healthcare professionals at NNUH to follow a procedure to administer FMT for the treatment of *Clostridioides difficile* infection (CDI)

Version and Document Control:

Version Number	Date of Update	Change Description	Author
3	22/06/2021	Minor changes with layout amended.	Ngozi Elumogo Carmen Walker

This is a Controlled Document

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1. Patient selection criteria :

- Multiple recurrences of CDI (two or more episodes).
- CDI non-responders (patients categorised as non-responders , having been treated with 2 or more courses of Anti- *Clostridioides difficile* (C. diff) Antimicrobials including Metronidazole, Vancomycin and sometimes Fidaxomicin and the patients remains symptomatic.

2. Patient inclusion / exclusion criteria:

* Patient Inclusion Criteria:

- Patient meets the patient selection criteria.
- Patient suitable for flexible sigmoidoscopy / colonoscopy procedure.
- Patient receiving anti C .diff antibiotic for at least 4 days prior to FMT.
- Signed Informed Consent – provide with Trust MCA and BIM ID document (case by case decision). [Trustdocs Id: 10373](#).

* Patient Exclusion Criteria:

- Decompensated liver cirrhosis.
- Active gastrointestinal bleeding.
- Life threatening food allergy such as peanuts, seafood etc.
- Intolerance to flexible sigmoidoscopy / colonoscopy procedure.

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- 3. Requesting FMT Treatment** – Please follow the Instructions for the FMT Pathway for Inpatients. A Referral Form should be completed and emailed at : FMTReferrals@nnuh.nhs.uk
- 4. For FMT Procedures performed at Quadram Institute (QI) and NNUH the following guidance should be followed:**

4.1 Instructions for the FMT Treatment due to be performed at QI

All the procedures for the FMT Treatment at Quadram Institute must follow the guidance mentioned in the *Standard Operating Procedure for the processes to maintain a COVID secure environment at QI for all the Endoscopy Procedures during COVID 19 Pandemic. (Version 1.0 – Dated April 2020).*

4.2 Instructions for the FMT Procedures to be performed at NNUH as inpatient procedure:

All inpatients should have a Covid Swab on admission to the Hospital and should follow the “*Standard Operating Procedure for the processes to maintain a COVID secure environment at QI for all the Endoscopy Procedures during COVID 19 Pandemic. (Version 1.0 – Dated April 2020).*”

5. Patient Information Leaflet:

The Patient Information Leaflet for Faecal Microbiota Transplantation Treatment (FMT) [Trustdocs Id: 17830](#) should be given to the patient before the procedure and time needs to be allocated for the patient to consider having the treatment done on the day. Any questions asked by the patient need to be answered before the procedure commences.

The risks and the benefits of having the treatment performed via the flexible sigmoidoscopy / colonoscopy must be discussed with the patient.

6. Informed Consent :

- Consent should be taken in line with the Human Tissue Authorities published Code of Practice and Consent <https://www.hta.gov.uk/policies/list-materials-considered-be-'relevant-material'-under-human-tissue-act-2004>.
- Appropriate Informed Consent Form [Trustdocs Id: 12062](#) must be signed and dated by the patient and the member of the team taking the consent. Faecal material- NE, Endoscopy- QI/DI. Discuss with SD / SMR re: Luminal gastroenterologist.

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- A copy of the Informed Consent must be given to the patient and one copy to be retained in the Patient's Medical Notes.

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7. Bowel Preparation:

The bowel preparation should be performed according to the 'Standard Operating Procedure for Supplying Bowel Preparation to patients for Lower GI Endoscopy Procedure' [Trustdocs Id: 17644](#).

The patient's bed must be placed near the toilet and the staff must be aware that this is a *C. diff* patient, and appropriate infection control enteric precautions must be taken. The local decontamination process must be followed in liaison with the Trust Infection Control Team.

- In the Endoscopy Room, the patient must be positioned in a comfortable position on the left Side and a choice of the sedation must be discussed with the patient prior the procedure.

Faecal Slurry Administration:

- Ensure patient is comfortable throughout the procedure. Ask if patient has any complaints.

For administration via Flexible Sigmoidoscopy , > 50g of faecal transplant material in a total of 300mL slurry will be introduced by infusing the slurry down the working channel of the endoscope at the most proximal feasible are of the colon. After completing the infusion, the channel of the scope should be flushed with 20 mL of normal saline. Faecal slurry will be supplied in capped 60mL oral syringes.

8. Following the procedure:

- We advise to keep the patient on their right side post procedure for 10 minutes.
- Monitor the patient for any side effects as per local procedure within the Endoscopy Unit and recovery from the procedure.
- We may expect bowel motion soon post procedure please make sure the patient does not need toilet facility before leaving the Unit.

Patients will be followed up by the FMT team by phone the following day. No further *C. difficile* toxin test is indicated and if patient develops new episode of diarrhoea within 28 days of FMT this should be clinically assessed on a case by case basis.