Guideline Goal
The goal of the guideline is to provide recommendations for consideration of fecal microbiota transplant (FMT) as an alternative treatment modality in the management of severe medication-refractory and recurrent CDI.

Key Points
- *Clostridium difficile* infection (CDI) is the most common cause of healthcare-associated diarrhea occurring in 12 to 64% of patients.
- Active CDI is defined as diarrhea (> 3 unformed stools per day) and other symptoms of CDI with a positive stool PCR for *C. difficile* toxin. OSUWMC guideline *Prevention and Management of Clostridium difficile Infection*.
- CDI is usually managed with antibiotics; however, severe disease may be refractory to medication therapy necessitating colectomy.

Indications
- FMT could be considered for CDI patients meeting any of the following criteria:
  - Recurrent CDI after ≥ 2 episodes of mild-to-moderate CDI and failure to respond to appropriate antimicrobial treatment regimens.
  - ≥ 2 episodes of severe CDI resulting in hospitalization and significant morbidity within 1 year.
  - Severe first episode of active CDI requiring hospitalization and non-responsive to maximal medication therapy

See CDI Guideline, for definition of CDI and appropriate treatment regimens

- A second FMT may be considered by Infectious Diseases (ID) or Gastroenterology (GI) in patients who failed the first.
- In patients with multiple potential etiologies for diarrhea, a C. difficile cell cytotoxin assay could be obtained.

NOTE: FMT for the management of inflammatory bowel disease and other conditions is currently under investigation and requires an IND application.

Contraindications
- Patients with the following should NOT be considered for FMT:
  - Toxic megacolon.
  - Anatomic contraindication to NGT, enteroscopy and colonoscopy.
  - Pregnancy.
- Exercise caution when considering an FMT for patients with:
  - A suppressed immune system.
  - Other severe comorbid conditions.
- The need for broad spectrum antimicrobials immediately post-FMT is considered a relative contraindication to FMT. FMT may be pursued in such patients at the discretion of ID/GI.

Risks of FMT
- The most common side effects of FMT include:
  - Belching.
  - Nausea/vomiting.
  - Abdominal cramps.
  - Diarrhea.
  - Constipation.
- The risk of infection transmission, colonic perforation, aspiration pneumonia, and death cannot be excluded.
- Data are lacking regarding long term safety risk.

Consults
- Consult Infectious Disease or Gastroenterology for all FMT.
- Both Infectious Disease and Gastroenterology Consults are recommended for Inpatient FMT.
- Consider Nutrition consultation (may occur pre- or post-FMT)

Recipient Preparation
- Gastroenterology or Infectious Diseases will advise patients on the proper discontinuation of antimicrobial treatment (generally 2 days prior to the planned procedure).
  - For critically ill patients, GI and ID should discuss appropriate timing of C. difficile antimicrobial therapy discontinuation.
- Patients should follow colonoscopy preparations if that is the intended route of fecal microbiota instillation.
  - Patient education
  - Two Day Bowel Prep with Miralax and Dulcolax
- One dose of loperamide immediately before the procedure.
FMT Procurement

- Frozen fecal microbiota from pre-screened donors is now commercially available and is advantageous from a cost perspective as compared to using a known donor.
  - Please see Appendix A for donor selection and the required screening process if frozen fecal microbiota from a pre-screened donor is not used.
- 24-48 hours prior to a sample being needed for inpatient or outpatient use, the OSUWMC Pharmacy Department must be contacted to aid in delivering the product to the Endoscopy suite on the day of the procedure.
- In the event of an emergency case on a weekend, contact the pharmacy administrator on call.

Sample Handling

- In order to prepare the sample for use, the fecal microbiota must be thawed according to the instructions provided.
  - Thawing should be performed by the Endoscopy suite staff.
  - The thawing process should NOT begin until the date/time of the FMT has been confirmed.
  - Once thawed, the sample is only stable at room temperature up to 4 hours and refrigerated/ice up to 8 hours.

Instillation of Fecal Microbiota

- Administration of fecal microbiota is restricted to gastroenterology attending physicians/fellows.
- The sample volume required varies based on the mode of instillation:
  - 250 ml for colonoscopy instillation.
  - 30 ml for NG or push enteroscopy administration.
- At OSUWMC, the preferred route of FMT is colonoscopy due to risk for aspiration and long-term bacterial overgrowth in the small intestine following NG or enteroscopy administration.
  - Please see this article for information on risks associated with NG administration.

IHIS Documentation

- The following items must be documented in/scanned into the patient’s record:
  - Patient consent specific to FMT.
  - FMT date/time in the procedure note.
  - Document FMT on patient problem list.

Post-procedural Care

Immediate Post-FMT Period Care

- C. difficile antimicrobials should not be administered.
- Bed rest while lying on the right side in order to decrease chance of an early bowel movement.
  - Outpatients: 2-3 hours bed rest
  - Inpatients: 4-5 hours bed rest
- Drink water only (no sugary or caffeinated drinks) for 8 hours following the procedure.
- Resume normal diet 8 hours after the procedure.
- Contact GI to report symptoms.

Long-Term/Discharge Care

- Follow-up with GI by phone one week following the procedure and by office appointment one month following the procedure.
  - Given that FMT is not FDA approved, any adverse reaction must be documented and reported accordingly to the FDA through MedWatch.
  - For instructions on how to report adverse events to OpenBiome, please click here.
- Encourage a diet based on United States Department of Agriculture’s MyPlate recommendations, of consuming adequate fiber from whole grains, fruits and vegetables.
- Physical exercise 120-180 minutes / week if tolerated.
- Avoid NSAIDs if possible.
- No smoking.
- Avoid antibiotics after the procedure for as long as possible (ideally 12 months).
  - In particular, clindamycin, fluoroquinolones, and cephalosporins should be avoided and alternative therapies considered if possible.
  - For additional recommendations on antibiotic use post-FMT, please see this article.

Quality Measures

- Appropriateness of patient selection.
- Percent of patients with serious adverse reaction to FMT:
  - Colonic perforation.
  - Aspiration pneumonia.
  - Unplanned admission.
- Percent of patients who required second FMT within 6 months of initial procedure.
- Percent of patients who required repeated doses of oral vancomycin or fidaxomicin for treatment of C. difficile within 6 months of FMT completion.
- Percent of patients requiring colectomy for recurrent C. difficile infection.

Order Set

- OSU IP GE: FMT Procedure Orders [3838]

References

(SHEA) and the Infectious Diseases Society of America (IDSA). Infection Control and Hospital Epidemiology, 31(5): 431-55.


- ChooseMyPlate.com, U.S. Department of Agriculture, January 2018

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**Disclaimer:** Clinical practice guidelines and algorithms at The Ohio State University Wexner Medical Center (OSUWMC) are standards that are intended to provide general guidance to clinicians. Patient choice and clinician judgment must remain central to the selection of diagnostic tests and therapy. OSUWMC’s guidelines and algorithms are reviewed periodically for consistency with new evidence; however, new developments may not be represented.

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Appendix A. Donor Selection and Screening for Fecal Microbiota Transplant (FMT)

Prior to FMT, if frozen fecal microbiota from a pre-screened donor is not used, the fecal microbiota donor must be screened to mitigate the risk of infection transmission to the recipient. This screening process is costly in both time and money.

Donor Selection

- Donors must first complete a screening questionnaire with the Infectious Diseases or Gastroenterology.
- Donors should not have:
  - History of incarceration.
  - Received a tattoo or piercing in past 6 months.
  - Known exposure to communicable disease.
  - Use of immunosuppressants or antibiotics within past 6 months.
  - History of high-risk behaviors such as illicit drug use, unprotected sexual activity or sexual activity with multiple partners.

Donation Screening

Baseline screening should include the following:

- Blood tests:
  - HIV Antibody (EIA).
  - Syphilis antibody (EIA).
  - Hepatitis A IgM.
  - Hepatitis B surface antigen and core antibody.
  - Hepatitis C antibody.
  - Strongyloides antibody.

- Stool tests:
  - Stool culture including *E. coli*.
  - Comprehensive ova and parasite exam.
  - Cryptosporidium/Entamoeba/Giardia antigens (parasite antigen screen).
  - Microsporidia stain.
  - *C. difficile* PCR.
  - *H. Pylori* antigen (only if FMT is to be performed via NGT route).

- Psychiatric evaluation:
  - Psychiatric evaluation and screening at the clinical discretion of the provider based on history and/or presenting signs and symptoms.