

Patient Care Procedure – Endoscopy and Infectious Disease Clinic

FECAL MICROBIOTA TRANSPLANTATION (FMT)

Description

Endoscopically or orally introduced fecal stool from a known donor or purchased donor stool obtained from OpenBiome for the management of *Clostridium difficile* associated diarrhea and colitis that has not responded to standard therapies. Stool bacterial flora replacement to resolve recurrent episodes of *Clostridium difficile* associated colitis.

Indications

- ONLY in recurrent or relapsing *Clostridium difficile* infection:
 - At least 3 episodes of mild to moderate CDI and failure of a 6 to 8 week taper with vancomycin
 - At least 2 episodes of severe CDI resulting in hospitalization and associated with significant morbidity
- FMT **requires** an infectious disease consult or a GI consult
- Any other indications will **require** a separate IND application to the FDA by the ordering provider

I. Oral Administration

A. Contraindications

- i. Dysphagia or inability to swallow placebo test capsule
- ii. History of aspiration
- iii. History of intestinal obstruction or gastroparesis
- iv. Severe food allergy or allergy to components of capsule
 1. Donor diet cannot be guaranteed and stool may contain food allergen components such as tree nuts or seafood
 2. Capsule inactive ingredients include: sodium chloride, glycerol, Theobroma oil, hide bovine gelatin, sodium lauryl sulfate, colorants FD&C, and titanium dioxide
- v. Severely immunocompromised state
- vi. Pregnancy

B. Purchased Donor Stool (from OpenBiome)

- i. Verify that product is available prior to scheduling patient.
- ii. The product is available as 30 size 00 capsules with PET Alpha Packaging bottle (FMPCapG3). They are stored in the -20°C freezer located in Laboratory (A-200) or in the ID clinic.
- iii. No thawing is required. Patients may begin consuming capsules under direct supervision once they are removed from the freezer.
- iv. If capsules are removed from the freezer and not used, they must be returned to freezer within 10 minutes or be discarded.
- v. **Equipment needed:**
 1. Purchased donor stool capsules
 2. Gloves
 3. Biohazard bags
 4. Clean K-basin or equivalent sterile container

C. Administration:

- i. FMT capsules must be administered under direct observation by a care provider.
- ii. Empty capsules from bottle into a sterile container. A clean K-basin or equivalent container should be used.
- iii. Provide the patient with plenty of clear liquid to drink during administration.
- iv. All 30 capsules must be ingested within 90 minutes after freezer removal. If capsules are not consumed during the allotted 90 minutes, the remaining capsules should be discarded.

D. Patient Preparation for Stool Transplant

- i. Have patient ingest test placebo capsule under direct observation from physician prior to scheduling administration appointment.
- ii. Have patient sign informed consent for fecal microbiota transplantation as an experimental therapy to treat *Clostridium difficile* infection.
- iii. Discontinue *C. Difficile* antibiotic (vancomycin, fidaxomicin) 48 hours prior to FMT Capsule administration.
- iv. Administer oral proton pump inhibitor once daily for 48 hours prior to FMT Capsule administration.
- v. Prophylactic anti-emetic agents are not recommended for routine administration.
- vi. Have patient maintain a clear liquid diet the day of FMT Capsule G3 administration.
- vii. Patient should fast (nothing by mouth) for 2 hours prior to the FMT Capsule G3 administration.

E. Patient Teaching

- i. Fecal bacteriotherapy is investigational and has potential risks.
- ii. Patient may return to normal high fiber diet and exercise.
- iii. Advise patient to thoroughly clean their home to avoid reinfection after FMT.
- iv. No significant side effects: some patients may have mild diarrhea symptoms a few days after the procedure. Adverse effects have been transient and mild and consist mainly of abdominal gurgling, gas, noise, nausea, bloating, and mild cramping.

F. Potential Complications

- i. Adverse effects have been transient and mild and consist mainly of abdominal gurgling and gas, noise. Symptoms such as nausea, bloating, and mild cramping have been reported.
- ii. FMT carries the risk of known and unknown infectious disease transmission and potentially microbiome-mediated diseases.

G. Post-Procedure Assessment/Care

- i. Patients should fast (nothing by mouth) for 1 hour after the administration of FMT capsules.
- ii. Patients may return to a full diet following post-administration fasting.

II. Upper and Lower Administration

A. Contraindications

- i. Patient is too unstable to undergo procedure
- ii. Appropriate testing has not been completed on donor stool

B. Pre-Procedure Assessment/Care

- i. See [Colonoscopy](#) procedure
- ii. See [Gastrointestinal Intubation: Tube Insertion and Removal](#) procedure

C. Purchased Donor Stool (from OpenBiome)

- i. Verify that product is available prior to scheduling patient.
- ii. The product is available as 250 mL (FMP250) for administration via colonoscopy or 30 mL (FMP30) for nasogastric administration. They are stored in the -20°C freezer located in Laboratory (A-200).
- iii. Thaw product at room temperature 4 hours, in warm bath 30 degrees centigrade for 1 hour, or overnight in refrigerator (4°C).

iv. Equipment needed:

1. Purchased donor stool, thawed
2. 5-60 mL syringes
3. Blue pad
4. Biohazard bags

v. Preparation of Stool

1. Prepare thawed stool 20 minutes prior to administration.
2. Wear Personal Protective Equipment (PPE), protective waterproof gown, and face shield.
3. Cover working area with blue pads.
4. Using 50 mL syringes, draw up the total contents of the FMP250 product for colonoscopic administered treatment or total contents of the FMP30 product for nasogastric administration.

vi. Administration of Purchased Donor Stool per Colonoscopy or Nasogastric Tube

1. Draw up liquid stool in 50 mL syringe (5 syringes of 50 mL) and infuse mixture in several regions of the cecum, proximal ascending colon, transverse and descending colon. Have patient lie on right side while in recovery, give patient loperamide (Imodium®) 4 mg tablet after the procedure and instruct to repeat in 4 hours.
2. For NG administration, confirm placement of NG tube with x-ray and infuse 30 mL of stool preparation into the stomach, followed by 20 mL of water to clear tubing. Remove NG tube, when appropriate.

D. Patient Preparation for Stool Transplant

- i. Have patient sign informed consent for fecal microbiota transplantation as an experimental therapy to treat *Clostridium difficile* infection.
- ii. Patient will have prepped with a laxative ordered by physician unless physician determines the patient is too compromised to complete prep.
- iii. Patient will have taken oral antibiotic at home as ordered for this procedure. Patient will be off antibiotics for 3 days prior to the procedure.
- iv. Patients with active *Clostridium difficile* infection and diarrhea should be placed in [contact enteric precautions](#) during the procedure and recovery.
- v. Patients with resolved *Clostridium difficile* infection without diarrhea are admitted to the unit and prepared for colonoscopy in the usual fashion. Contact enteric precautions should be used during the procedure.
- vi. If the patient is currently an inpatient, follow hospital [infection control protocols](#).

E. Patient Teaching

- i. See Discharge Instructions either for colonoscopy or NG administration.
- ii. Fecal bacteriotherapy is investigational and has potential risks.
- iii. Patient may return to normal high fiber diet and exercise.
- iv. No significant side effects: some patients may have mild diarrhea symptoms a few days after the procedure. Adverse effects have been transient and mild and consist mainly of abdominal gurgling and gas, noise.
- v. Instruction regarding second dose of loperamide (Imodium®) if administered per colonoscopy.

F. Procedure Nurse Responsibilities during Procedure

- i. Same as colonoscopy; see [Colonoscopy](#) procedure.
- ii. Preparing donor stool for procedure.
- iii. Drawing up the transplant material into 50 mL syringes.
- iv. Assisting physician with distribution of donor stool throughout the colon.
- v. Administration of loperamide (Imodium®) after procedure.

G. Environmental Cleaning after Procedure

- i. Bleach wipes 1:10 bleach dilution should be used to clean all surfaces in the procedure room after the procedure.
- ii. It is imperative to allow wet contact time of 3 minutes and full dry time.
- iii. Once the patient has completed recovery, the stretcher should be cleaned thoroughly with bleach wipes.
- iv. Environmental Services should perform a terminal cleaning of the procedure room following the procedure.

H. Potential Complications

- i. See [Colonoscopy](#) procedure for possible complications of colonoscopy.

- ii. Adverse effects have been transient and mild and consist mainly of abdominal gurgling and gas, noise.

I. Post-Procedure Assessment/Care

- i. See [Colonoscopy](#) procedure for post-procedure assessment.
- ii. NG: Patient is permitted to resume a normal diet and all customary activities immediately after discharge from endoscopy.
- iii. Patient is encouraged to stay up right.

III. Physician Office/Endoscopy Patient Follow-up

- A. The patient should be evaluated 14-28 days after transplantation with a routine outpatient interim history, physical examination, no laboratory confirmation is required.
 - i. A follow up phone call or office visit should be performed to assess for clinical cure at 8 weeks post procedure.
- B. Follow OpenBiome SAFE protocol for quality and safety when using the OpenBiome product.
 - i. Adverse Events: Complete required form FDA MedWatch 3500 and submitted to FDA and OpenBiome. Adverse Event within 15 days. Fatal or Life-threatening within 7 days. Please contact OpenBiome as soon as possible, ideally within 24 hours.
 - 1. Serious Adverse Events
 - a. Death.
 - b. Life-threatening.
 - c. Hospitalization.
 - d. Disability or permanent damage.
 - e. Congenital anomaly, birth defect.
 - ii. Evaluation: Inventory Tracking Log will be submitted to OpenBiome with the next OpenBiome order. FMT Follow-up form must be completed and returned to OpenBiome after the 8 week follow up.

References:

1. Brandt, L. Aroniadis, O.C., Mellow, M & et. al. (2012). Long-term follow up of colonoscopic fecal microbiota transplant for recurrent *Clostridium difficile* infection. *American Journal of Gastroenterology*. 107 (7): 1079-87
2. Lofland, D., Josephat, F., Partin, S. (2013). Fecal transplant for recurrent *Clostridium difficile* infection. *Clinical Laboratory Science*. 26(3): 131-5
3. Pozzoni, P. et al. *Saccharomyces boulardii* for the prevention of antibiotic-associated diarrhea in adult hospitalized patients: a single-center, randomized, double –blind, placebo-controlled trial. *AM J Gastroenterology*., 107, 922-31 (2012)
4. Glidenberg, J. et al. Probiotics for the prevention of *Clostridium difficile*-associated diarrhea in adults and children. *Cochrane Database System Rev.*, 31, 5 (2013)
5. Koo, H et al. Antimotility agents for the treatment of *Clostridium difficile* diarrhea and colitis. *Clinical Infectious Disease*. 48, 598-605 (2009)
6. OpenBiome. "FMT Capsule G3 Clinical Primer." May 2017. Web. 08 Aug. 2017.