HACKETTSTOWN REGIONAL MEDICAL CENTER
ADMINISTRATIVE POLICIES

FECAL MICROBIOTA TRANSPLANTATION

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SCOPE

All physicians and staff members caring for patients who present with Clostridium Difficile Infection (CDI) and are eligible for Fecal Microbiota Transplantation (FMT)

PURPOSE

To provide guidelines for the diagnosis, treatment and care of the patient who undergoes FMT

DEFINITIONS

I. Recurrent CDI is one of the most difficult and increasingly common challenges associated with CDI. About 20%-30% of initial cases relapse within 30 days, and the risk of recurrence doubles after two or more occurrences. Antibiotics and other factors disrupt the normal balance of colonic flora, allowing C. difficile strains to grow. This leads to clinical presentation of diarrhea and pseudomembranous colitis.

II. During FMT, normal flora is introduced via donor feces into the patient's gastrointestinal tract. The imbalance can be corrected, the cycle interrupted and normal bowel function reestablished. Data reports that FMT has been highly effective at eradicating CDI and restoring a healthy gut microbiota in over 90% of procedures.

III. Indications for FMT
   - A. Recurrent or relapsing CDI
     1. $\geq$ three episodes of mild to moderate CDI and failure of 6-8 week taper with Vancomycin with or without an alternative antibiotic
     2. $\geq$ two episodes of severe CDI resulting in hospitalization.
   - B. Moderate CDI not responding to standard therapy (Vancomycin) for at least one week
   - C. Severe (including fulminate C.difficile colitis) with no response to standard therapy after 48 hours

POLICY

HRMC physicians will assess and treat patients who present with CDI. Those patients diagnosed with CDI who meet the indications for FMT will be treated in accordance with this policy.

PROCEDURE

I. Preparation
   - A. Commercial Fecal Microbiota Preparation
     1. Commercial fecal microbiota preparations are available for both upper and lower delivery methods
        a) 250 ml for lower delivery (colonoscopy or enema)
        b) 30 ml for upper delivery (nasogastric or nasoduodenal tube)
     2. Follow storage and shipping controls per manufacturer's recommendations (attached).
     3. Thawing recommendations as per manufacturer's recommendations. Once thawed, the material may remain at room temperature for $\leq$ 4 hours (refrigerated

≤ 8 hours). Dispose of material thawed and not used ≤ 8 hours. Never refreeze the material.

B. FMT Recipient Preparation

1. Informed consent signed (see attached). The recipient will be tested for Hepatitis B and C, and HIV.
2. The recipient will be scheduled for a colonoscopy for the FMT procedure when s/he has been off antibiotics unrelated to the treatment of the CDI for one week.
3. Liquid diet two days before procedure, clear liquid the day before procedure
4. The evening before the FMT procedure, the recipient will prepare his or her colon with a standard preparation for a colonoscopy.

II. Procedure Steps

A. Standard colonoscopy preparation and set-up at MD discretion. Recommended: Loperamide 4mg PO prior to procedure

B. Thawed FMP material loaded in standard syringes compatible with endoscope channel

C. Completion of colonoscopy in keeping with standard guidelines

D. At most proximal level visualized, targeting the cecum, delivery of all pre-loaded FMT material through endoscope channel using FMT loaded syringe

E. May use a standard saline/sterile water flush to clear all material from endoscope channel

F. Withdrawal of endoscope and termination of procedure

G. Patient should attempt to retain FMT material for 1 hour post-procedure in recovery area

H. Administer a second dose of Loperamide 4 mg po 4 hours after the procedure.

III. Infection Prevention

A. While the patient is off the Nursing Unit for the procedure, have patient's room cycle cleaned to decrease C.diff environmental burden.

B. When patient returns from procedure, discontinue Contact/Enteric precautions.

C. Patient belongings should be returned home with education on washing and new, clean clothes returned for discharge. Outpatients should have clean change of clothes for after procedure.

References:

Cecil, J. A. (2012). Clostridium difficile: Changing epidemiology, treatment and infection prevention measures. *Current Infectious Disease Reports, 14*(6), 612-619. doi:http://dx.doi.org/10.1007/s11908-012-0298-9

Fitzpatrick, F.F. & Barbut F.F. (2012) Breaking the cycle of recurrent Clostridium difficile infections. Clinical Microbiology & Infection. 182-4. DOI:10.1111/1469-0691.12043.

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