Midwest Gastrointestinal Associates PC

# Fecal Donation Instructions

Date / Time of Procedure: _____

Physician: _____

Collection of the specimen needs to take place within 6 hours of procedure time. This specimen must be prepared and brought with the patient to the procedure.

**Please keep in mind that contaminated surfaces and hands can serve as reservoirs to pathogens and can potentially contribute to transmission of infections. Proper hand washing and disinfection or disposal of equipment used in stool preparation is imperative.**

DONOR INSTRUCTIONS

- Avoid antibiotics for thirty days prior to transplantation. Notify the physician if symptoms of an infection develop between the screening and time of donation.
- Obtain supply kit from Midwest Gastrointestinal at the 8901 Indian Hills, Suite 200 location. Kit will include: (1) Stool Collection Receptacle, (2) White Paper Strainers, (2) Graduates, (3) 120cc containers, and (3) biohazard bags.
- Purchase a gallon of distilled water. You will use about one 8 oz. cup.
- Dedicate an inexpensive blender to the preparation of the stool and throw it away after the stool preparation.

FECAL MATTER PREPARATION

1. Place the supplied stool collection receptacle between to toilet lid and toilet bowl towards the back of the toilet. Obtain a fecal (stool) sample as close to the time of the procedure, ideally six or less hours prior to procedure.
2. Working in a bathroom, transfer 1/3 cup of stool specimen into a clean, disposable blender. Add a small amount of distilled water and blend on low speed – Do NOT use tap water.
   - Initially, use a low setting until the sample breaks up. Then advance the speed gradually to the highest setting.
   - Add small amounts of distilled water and blend until the sample is thin liquid consistency. This may require up to a cup of distilled water. The goal is to end up with 1 ¼ - 1 ½ cups of thin liquid suspension.
   - Continue blending for 2-4 minutes until the sample is smooth.
3. Place one white paper strainer into the clear graduate. Filter the suspension using the strainer. Allow adequate time for slow filtration to come to an end.
4. Using a second graduate and strainer, re-filter the suspension. Allow for adequate time for slow filtration.
5. Pour the suspension into the supplied containers. Fill two containers each with 100cc of suspension. If there is any additional suspension, fill the third container and please discard the remaining in the toilet. Wipe the exterior of each container with wet paper towel or disinfecting wipe.
6. Wash your hands.
7. Seal the containers very tight. Place each container in an individual biohazard bag. Refrigerate the samples until time of transplant. Use care to assure the sample bag will not contaminate any potential food surfaces.
8. Throw away contaminated equipment, clean surfaces with a disinfecting wipe and thoroughly wash your hands.

For questions regarding donation collection, please call 402-397-7057 and ask to speak with scheduled physician's nurse.

**SUBJECT 0.5:** BACTERIOTHERAPY: FECAL TRANSPLANT

DESCRIPTION
In fecal transplantation, donor fecal matter is delivered from below through a colonoscope or retention enema, or from above through a nasogastric or nasoduodenal tube, for the purpose of replacing colonic flora wiped out by antibiotics in an effort to reestablish the patient's resistance to colonization by C. difficile.

INDICATIONS
Indicated for patients with recurrent C. Difficile infection who relapse after antibiotic therapy. The patient's medical record should include clinical documentation of:

(1) Laboratory-confirmed diagnosis of C. difficile colitis

(2) Two laboratory-confirmed relapses of C. difficile colitis after receipt of initial specific antimicrobial treatment

PRE-PROCEDURE ASSESSMENT/CARE
The donor should preferably be a family member with intimate contact with the recipient such as a spouse. The donor patient must be screened to ensure that they are in good health and any risk factors for diseases transmissible by fecal material can be identified. Recommend pre-procedure donor testing includes:

Donor stool screening:

- Ova and parasites
- Stool culture and sensitivity test (generally includes: Salmonella, Shigella, Escherichia coli, 0157:H7, Yersinia enterocolitica, and Campylobacter)
- Clostridium difficile toxins A and B
- Some practitioners additionally screen for: Cryptosporidium antigen and Giardia antigen

Donor serum screening:

- HIV-1 and HIV-2 (order Anti-HIV antibodies by EIA)
- Hepatitis A, B, and C (order Anti-HAV antibodies by EIA, HBV surface antigen, Anti-HCV antibodies by EIA)
- Syphilis (order rapid plasma regain)
- Some practitioners additionally screen for syphilis using fluorescent treponemal antibody-absorbed Treponema pallidum

The fecal transplant recipient should be treated with a course of Vancomycin (250mg po every 8 hours) starting 4 days before the transplantation procedure to reduce the burden

of vegetative C. difficile colonies. The last dose should be given 24-48 hours before the transplantation. A large volume bowel prep may be considered in an effort to reduce the recipient's colonic flora. If the fecal transplant will be done via NG tube, the recipient should also be treated with Omeprazole (20 mg po) evening before and the morning of the procedure to cut stomach acid and create a receptive environment for instilled bacteria.

PATIENT TEACHING

1. Determine the recipient and donor's readiness to learn and level of knowledge.
2. Explain the purpose of the procedure, the methods to be used for obtaining and preparation of the donor fecal matter.
3. Instruction to the donor to avoid antibiotics for thirty days prior to transplantation and to notify the physician if symptoms of an infection develop between the screening and time of donation.
4. Instruct the donor and recipient to handle the specimen container as a contaminated object. Remind them that contaminated surfaces and hands can serve as reservoirs to pathogens and can potentially contribute to transmission of infections. Proper hand washing should be performed. Disinfection or disposal of equipment used in stool preparation is imperative. The specimen should be prepared in a bathroom and all surfaces should be disinfected thoroughly.
5. Instruction to the recipient on the transplantation procedure and preparation for procedure to include large volume bowel prep if prescribed.
6. Document teaching and patient understanding.

FECAL MATTER PREPARATION

1. Obtain a fecal matter sample as close to the time of instillation, ideally six or less hours prior to procedure.
2. Add a small amount of distilled water (not tap water) and blend in a household blender. Initially, use a low setting until the sample breaks up. Then advance the speed gradually to the highest setting. Add small amounts of distilled water as needed. Continue blending for 2-4 min until the sample is smooth.
3. Filter the suspension using a paper strainer. Allow adequate time for slow filtration to come to an end.
4. Refilter the suspension, again using a paper strainer allowing for adequate time for slow filtration.
5. Place in a sealed container, Refrigerate the sample until time of transplant

PROCEDURE

1. The donor fecal matter may be delivered into the colon through a colonoscope or retention enema, or from above through a nasogastric or nasoduodenal tube.
2. If a nasogastric or nasoduodenal tube is used proper placement should be confirmed by x-ray. 25 ml of the fecal suspension is aspirated into a syringe and instilled into the gastric antrum via the NG tube or the proximal duodenum by nasoduodenal tube. After the fecal instillation the tube should be flushed with saline and then withdrawn.
3. If a retention enema is used, 180ml should be instilled into the sigmoid colon.

4. For colonoscopy transplantation, the patient should receive an adequate prep to allow colonoscopy visualization to the cecum. Using a 60cc syringe with flushing needle, 180ml of the fecal suspension should be instilled into the right colon or cecum through the biopsy port of the colonoscope. After instillation of fecal suspension the channel should be flushed with saline.

POST-PROCEDURE

1. The patient is permitted to resume a normal diet.
2. The patient may resume all physical activities unless restricted post colonoscopy.
3. The patient should be evaluated 14-28 days after the transplantation with a routine outpatient interim history, physical examination and stool examination for the presence of Clostridium difficle toxin.

REFERENCE:

Otto, M. Alexander. Gastroenterology: Fecal transplantation works for recurrent c. difficile infections when antibiotics fail. Internal Medicine News Digital Media 11/22/2010

Aas, Johannes. Gessert, Charles. Bakken, Johan. Recurrent clostridium difficile colitis: Case series involving 18 patients treated with donor fecal matter administered via a nasogastric tube.

Mattila, Eero. Uusitelo-Seppala, Raija. Wuorela, Maarit. March 2012. Fecal transplantation, through colonoscopy is effective therapy for recurrent clostridium difficile infection. Gastroenterology Volume 142, Issue 3, Pages 490-496

Bakken, Johan. Borody, Thomas. Brandt, Lawrence, Brill, Joel. Treating Clostridium difficile infection with fecal microbiota transplantation. Clinical gastroenterology and hepatology 2011 Volume 9, Number 12, Pages 1044-1049

Rohlke, Faith. Stollman, Neil. Fecal microbiota transplantation in relapsing Clostridiom difficile infection. Therap Adv Gastroenterol; November 2012. 5(6): 403–420. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3491681/

Midwest Gastrointestinal Associates PC

Patient Label

# DISCLOSURE AND CONSENT FOR BACTERIOTHERAPY

Bacteriotherapy, also known as fecal transplantation, is the process by which donor fecal matter is delivered into the digestive tract via an endoscopic procedure, nasogastric tube, &/or rectal enema retention. This procedure is performed to replace colonic flora destroyed by antibiotics in an effort to reestablish the patient's resistance to colonization by C. difficile. This procedure is indicated for patients with recurrent C. difficile infection who relapse after antibiotic therapy.

The procedure has proven effective, but is not guaranteed, as a treatment for patients that are refractory to standard treatments.

I acknowledge Bacteriotherapy has the potential risk for transmission of an infectious disease.

I recognize that Bacteriotherapy is well documented but remains experimental.

I accept full responsibility for the donor material I have provided and attest it will be prepared in accordance to the policy and procedure provided by the physician's office.

I acknowledge I have been given an opportunity to ask questions about my condition, alternative forms of treatment, and the risks involved. I voluntarily request Bacteriotherapy.

_____ _____

Patient and/or Legal Guardian Signature Witness

_____ _____

Date Time

Midwest Gastrointestinal Associates PC

## Release from Responsibility for Bacteriotherapy

Bacteriotherapy, also known as fecal transplantation, is the process by which donor fecal matter is delivered into the patient's colon through a colonoscope. The procedure is performed to replace colonic flora destroyed by antibiotics in an effort to re-establish the patient's resistance to colonization by C. difficile. This procedure is indicated for patients with recurrent C. difficile infection who relapse after antibiotic therapy. The procedure has proven effective, but is not guaranteed, as a treatment for patients that are refractory to standard treatments.

Midwest Gastrointestinal Associates, PC (MGI), requests the donor preferably be a family member with intimate contact with the recipient, such as a spouse or significant other. Additionally, MGI recommends the donor patient be screened to ensure that they are in good health and any risk factors for diseases transmissible by fecal material can be identified. The recommended pre-procedure donor testing includes:

| | | |
|---|---|---|
| Blood: | HBV | HBV surface antigen |
| | HCV | Anti-HCV antibodies by EIA |
| | HIV-1, HIV-2 | Anti-HIV antibodies by EIA |
| | Treponema palidum | Plasma regain test |
| | EIA, enzyme immunoassay | HIV, Human immunodeficiency virus |

Testing for Cytomegalovirus, Hepatitis A, Epstein-Barr Virus, human T lymphotropic virus, and syphilis may also be considered.

| | | |
|---|---|---|
| Stool: | Clostridium difficile | Culture and Toxin A/B test |
| | Enteric pathogens | Selective media culture |
| | Ova and Parasites | Light microscopy |

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**This is to certify that I, _____, a patient at Midwest Gastrointestinal Associates, PC, a recipient of Bacteriotherapy, acknowledge the following (please initial the following):**

**_____I acknowledge the potential risk for transmission of an infectious disease.**

**_____I understand that Bacteriotherapy is well documented, but remains experimental; thus acknowledge my insurance company may not cover the expenses of this procedure.**

**_____ I agree that I have been informed of the risks involved, as well as alternative treatments, and hereby release my physician and Midwest Gastrointestinal Associates, PC, from any and all responsibility for any ill effects which may result from this treatment.**

**_____I acknowledge that all my questions have been answered and I understand Bacteriotherapy.**

**_____I acknowledge that I have chosen to complete the recommended pre-procedure donor testing and accept the financial responsibility that this may not be covered by my insurance company.**

_____ _____

**Patient Signature** **Witness**

_____ _____

**DOB** **Date**

Midwest Gastrointestinal Associates PC

# Release from Responsibility for Bacteriotherapy and the REFUSAL OF PRE-PROCEDURE ASSESSMENT/CARE OF DONOR PRIOR TO BACTERIOTHERAPY

Bacteriotherapy, also known as fecal transplantation, is the process by which donor fecal matter is delivered into the patient's colon through a colonoscope. The procedure is performed to replace colonic flora destroyed by antibiotics in an effort to re-establish the patient's resistance to colonization by C. difficile. This procedure is indicated for patients with recurrent C. difficile infection who relapse after antibiotic therapy. The procedure has proven effective, but is not guaranteed, as a treatment for patients that are refractory to standard treatments.

Midwest Gastrointestinal Associates, PC (MGI), requests the donor preferably be a family member with intimate contact with the recipient, such as a spouse or significant other. Additionally, MGI recommends the donor patient be screened to ensure that they are in good health and any risk factors for diseases transmissible by fecal material can be identified. The recommended pre-procedure donor testing includes:

| | | |
|---|---|---|
| Blood: | HBV | HBV surface antigen |
| | HCV | Anti-HCV antibodies by EIA |
| | HIV-1, HIV-2 | Anti-HIV antibodies by EIA |
| | Treponema palidum | Plasma regain test |
| | EIA, enzyme immunoassay | HIV, Human immunodeficiency virus |

Testing for Cytomegalovirus, Hepatitis A, Epstein-Barr Virus, human T lymphotropic virus, and syphilis may also be considered.

| | | |
|---|---|---|
| Stool: | Clostridium difficile | Culture and Toxin A/B test |
| | Enteric pathogens | Selective media culture |
| | Ova and Parasites | Light microscopy |

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**This is to certify that I, _____, a patient at Midwest Gastrointestinal Associates, PC, a recipient of Bacteriotherapy, acknowledge the following (please initial the following):**

**_____I acknowledge the potential risk for transmission of an infectious disease.**

**_____I understand that Bacteriotherapy is well documented, but remains experimental; thus acknowledge my insurance company may not cover the expenses of this procedure.**

**_____ I agree that I have been informed of the risks involved, as well as alternative treatments, and hereby release my physician and Midwest Gastrointestinal Associates, PC, from any and all responsibility for any ill effects which may result from this treatment.**

**_____I acknowledge that all my questions have been answered and I understand Bacteriotherapy.**

**_____ I acknowledge that I have chosen <u>not</u> to complete the recommended pre-procedure donor testing, which is against the advice of my physician.**

_____ _____

**Patient Signature** **Witness**

_____ _____

**DOB** **Date**