### **SOFT Movement Survey of FMT Programs**

### Part 1: General Information about your Fecal Microbiota Transplant (FMT) Program

1) Please fill out the information below:

First Name:

Last Name: \_\_\_\_\_

Title: \_\_\_\_\_

Please enter an email address we can use to communicate with you.:

Please fill out the start date of this survey below.:

2) Please enter the name of the institution and city where your FMT program is based:

Institution name: \_\_\_\_\_

City: \_\_\_\_\_

3) Have you begun performing FMTs at your location?

() Yes

( ) No

4) Approximately what year did you start performing FMT? If you have not, what year do you anticipate you will be starting to perform FMTs?

() Please enter year:

() Not applicable

5) If applicable, please enter the number of FMTs performed since the program started? If not applicable, please enter 0 (zero).

#### 6) Have you performed FMT in the context of a research study, for clinical care or both?

- () Research only
- () Clinical care only
- () Both

### 7) Which approvals or endorsements did you require before starting your FMT program (check all that apply):

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[] Hospital Senior Administrators

- [] Research Ethics Board
- [] Other (please specify): \_\_\_\_\_

### 8) Approximately how long does it take for a patient to get a FMT from initial clinical assessment to first administration?

- () < 1 week
- () 1-4 weeks
- () 4-12 weeks
- ()>12 weeks

9) Aside from the persons who manufacture and administer FMT, who else supports the program and in what capacity (select all that apply and please list duties below)?

[ ] Coordinator:	
[] Clinical nurse:	_
[] Research nurse:	
[ ] Trainee MD:	
[] Students:	
[ ] Volunteers:	
[] Other (please specify):	
[] Not applicable	

#### Part 2: Donor Selection and Screening

### 10) Please attach your Standard Operating Procedures for FMT donor screening (if available) below.

Please attach on web survey

#### 11) Do you use universal FMT donors?

() Yes

( ) No

#### 12) If you use universal FMT donors, how often do you screen them?

- () Every month
- () Every 2 months
- () Every 3 months
- () Every 4 months
- () Every 5 months
- () Every 6 months
- () I do not use universal donors
- () Other (please specify): \_

#### 13) If you do not use universal FMT donors, when do you perform donor screening?

- () Within 2 weeks of donation for FMT
- () Within 4 weeks of donation for FMT
- () Within 3 months of donation for FMT
- () Within 6 months of donation for FMT
- () Other (please specify): \_\_\_\_\_

#### 14) Do you perform microbiota analysis of donor feces?

- () Yes
- ( ) No

**15)** If you perform microbiota analysis of donor feces, do you use this as part of your selection criteria for choosing donors?

() Yes

( ) No

() Not applicable

### 16) Which of the following agents suggested by Health Canada do you use as exclusion criteria when screening donors for FMT?

[] Systemic immunosuppressive or biological agents

[] Systemic antineoplastic agents

[] Exogenous glucocorticoids

[] Anti-diarrheal drugs

[] Mineral oil

[] Bismuth

[] Magnesium

[] Kaolin

[] Recent use of antibiotics (if yes, please specify your definition of recent use):

[] All of the above

#### 17) Do you screen for additional agents not included in Health Canada's suggestions?

() Yes (please specify):

() No

### 18) Which of the following microorganisms or diseases suggested by Health Canada do you use as exclusion criteria routinely in FMT donors? (Enter all that apply)

- [] Cancer
- [] Salmonella species
- [] Shigella
- [] Campylobacter
- [] Sorbitol-negative Escherichia coli 0157-H7
- [] Shiga toxin
- [] Yersinia
- [] Plesiomonas
- [] Aeromonas
- [] Vibrio
- [] Listeria
- [] Helicobacter pylori
- [] Clostridium difficile
- [] Vancomycin-resistant enterococci (VRE)
- [] Methicillin-resistant Staphylococcus aureus (MRSA)
- [] Syphilis
- [] Neisseria gonorrhea
- [] Chlamydia trachomatis
- [] Norovirus
- [] Rotavirus
- [] Adenovirus
- [] HIV 1/2
- [] HTLV-I/II
- [] Hepatitis B/C
- [] Ova and parasites
- [] Malaria
- [] Chagas disease
- [] Babesiosis
- [] Creuztfeldt-Jakob disease
- [] Prion-related diseases from dural mater grafts
- [] All of the above

#### Risk Medical Laboratory test factors assessment Test type (please Test enter Test Test performed below if Risk Medical performed performed at site applicable) at your factors assessment at PHL other than site PHL Salmonella [] [] species Shigella [] [] \_\_\_\_ [] *Campylobacter* [] Sorbitol-[] [] negative Escherichia *coli* 0157-H7 Shiga toxin [] [] [] [] Yersinia Plesiomonas [] [] [] [] Aeromonas Vibrio [] [] \_\_\_\_ \_\_\_\_\_ Listeria [] [] [] [] Helicobacter pylori Clostridium [] [] difficile Vancomycin-[] [] resistant enterococci (VRE) Methicillin-[] [] resistant Staphylococcus

#### 19) What screening modality do you use to screen for the above microorganisms/diseases?

Appendix to: Hota SS, Surangiwala S, Paterson AS, et al. Regional variability in fecal microbiota transplantation practices: a survey of the Southern Ontario Fecal Microbiota Transplantation Movement. *CMAJ Open* 2018. DOI:10.9778/cmajo.20170109. Copyright © 2018 Joule Inc. or its licensors

	-			I
aureus (MRSA)				
Syphilis	[]	[]	 	 
Neisseria gonorrhea	[]	[]	 	 
Chlamydia trachomatis	[]	[]	 	 
Norovirus	[]	[]	 	 
Rotavirus	[]	[]	 	
Adenovirus	[]	[]	 	 
HIV 1/2	[]	[]	 	 
HTLV-I/II	[]	[]	 	
Hepatitis B/C	[]	[]	 	 
Ova and parasites	[]	[]	 	 
Malaria	[]	[]	 	 
Chagas disease	[]	[]	 	 
Babesiosis	[]	[]	 	 
Creuztfeldt- Jakob disease	[]	[]	 	 
Prion-related diseases from dural mater grafts	[]	[]	 	 
Cancer	[]	[]	 	 

# 20) Do you screen for any additional microorganisms or diseases not included by Health Canada suggestions?

() Yes (please specify): \_\_\_\_\_

( ) No

**21)** Do you collect a dietary history of FMT donors in the event recipients have food allergies?

() Yes

( ) No

#### Part 3: FMT Manufacturing

22) Please attach your Standard Operating Procedures for FMT manufacturing (if available) below.

Please attach on web survey

23) Where is FMT manufactured in your centre (select more than one if applies)?

[] Clinical microbiology laboratory

[] Research laboratory

[] Pharmacy

[] Clinic

[] Other (please specify)

#### 24) Who manufactures FMT (select all that apply)?

[] MD

[] Trainee MD

[] Clinical nurse

[] Research nurse

[] Laboratory technologist

- [] Clinical microbiology technologist/technician
- [] Research technologist/technician
- [] Other (please specify): \_\_\_\_\_

25) Approximately what mass of donor stool do you use for each FMT (please select all that apply)?

	10g	20g	30g	40g	50g	100g	150g	Other amount (please enter below)
Enema	[]	[]	[]	[]	[]	[]	[]	
Colonoscopy	[]	[]	[]	[]	[]	[]	[]	
Nasogastric/nasojejunal	[]	[]	[]	[]	[]	[]	[]	

26) Approximately what volume of diluent do you use for each FMT (check all that apply if more than one route of administration at your center)?

	25mL	50mL	100mL	150mL	200mL	300mL	400mL	500mL	Other amount (please enter below)
Enema	[]	[]	[]	[]	[]	[]	[]	[]	
Colonoscopy	[]	[]	[]	[]	[]	[]	[]	[]	
Nasogastric/nasojejunal	[]	[]	[]	[]	[]	[]	[]	[]	

#### 27) What type of diluent do you use for FMT?

- [] Tap water
- [] Sterile water
- [] Sterile normal saline
- [] Other (please specify): \_\_\_\_\_

#### 28) What form of FMT do you manufacture (select all that apply)?

[] Fresh

[] Frozen

[] Capsules

[] Lyophilized (freeze-dried)

[] Other (please specify):

### **29)** What are your recommended storage conditions for donor feces prior to FMT manufacturing?

() Household freezer

() Household fridge

() Room temperature

() Other (please specify): \_\_\_\_\_

**30)** How long do you allow donor feces to be stored prior to delivery to your unit for FMT manufacturing?

() Up to 24 hour

() Up to 48 hour

() Up to 72 hour

() Other (please specify):

### **31**) What storage conditions for donor feces do you use after receiving donor feces for FMT manufacturing?

() Room temperature

() 4-5C

() -20C

()-80C

() Other (please specify):

### **32)** How long do you allow donor feces to be stored in your unit before manufacturing for FMT?

- () A few hours
- () A few hours to 24 hours
- () 24-48 hours
- () 48-72 hours
- () Other (please specify):

#### 33) If you use frozen FMT, which cryoprotectant do you use?

() Glycerol (please enter concentration in final FMT):

() Other (please specify): \_\_\_\_\_

() No cryoprotectant

() Not applicable

#### 34) If you use frozen FMT, at what temperature is the sample frozen?

- () -20C
- ()-80C
- () Other (please specify):
- () Not applicable

### **35**) What is the maximum acceptable time from FMT donation to patient administration in your institution?

- () 3 hours
- () 6 hours
- () 12 hours
- () 24 hours
- () 48 hours
- () 96 hours
- () >96 hours
- () Not applicable

**36)** Did you undertake any manufacturing validation studies prior to starting your FMT program?

() Yes

( ) No

## **37**) What are your rejection criteria for donor stools at the time of donation (select all that apply)?

[] Clinical criteria only (donor has active fever, diarrhea etc.)

[] Unformed stool provided for donation

[] Urine mixed in donated stools

[] Mucous in donated stools

[] Insufficient quantity of donated stools

[] Blood in donated stools (if so, do you do Fecal Occult Blood Testing?):

[] Other (please specify): \_\_\_\_\_

#### Part 4: Good Manufacturing/Biosafety Procedures

#### 38) Do you manufacture FMT in a biosafety cabinet?

() Yes

( ) No

#### 39) How do you disinfect your manufacturing equipment (select all that apply)?

[] Disinfect with sporicidal agent pre- and post-FMT

[] Disinfect with non-sporicidal disinfectant pre- and post-FMT

[] Use only disposable equipment for all manufacturing steps

[] Other (please specify)

## 40) What personal protective equipment is used by the FMT manufacturer (select all that apply)?

[] Single pair of gloves

[] Double gloves

[] Fluid-resistant gown

[] Non-fluid-resistant gown

[] Procedure mask

[] Face shield

[] Hair coverings

[] Shoe protection

[] Other (please specify): \_\_\_\_\_

#### Part 5: Patients

#### 41) For which of the follow conditions do you administer FMT?

[] Clostridium difficile infection

[] Inflammatory bowel disease

[] Irritable bowel syndrome

[] Other (please specify): \_\_\_\_\_

### 42) To which of the following subgroups of *Clostridium difficile* infection (CDI) do you administer FMT (select all that apply)?

[] Initial episode of CDI as part of treatment for acute disease or immediately thereafter (ie. within 2 weeks of symptom-onset)

[] First recurrent CDI episode as part of treatment for acute disease or immediately thereafter (ie. within 2 weeks of symptom-onset)

[] Second or greater recurrent CDI episode(s) as part of treatment for acute disease or immediately thereafter (ie. within 2 weeks of symptom-onset)

[] Patients with a history of recurrent CDI after they have been treated and are asymptomatic off therapy (i.e. beyond 2 weeks of symptom onset)

[] Patients with a history of recurrent CDI on chronic suppressive oral vancomycin

[] Patients with CDI who are unresponsive to antimicrobial treatment

[] Critically-ill patients with CDI

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I I minunocompromised putients with OD	ſ	1	Immunocom	promised	patients	with	CDI
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- [] Those with concurrent underlying GI disease with CDI
- [] Other (please specify): \_\_\_\_\_

[] Not applicable

#### 43) What are your major exclusion criteria for FMT receipt (select all that apply)?

- [] Age over 90 years
- [] Immunocompromised status
- [] Bleeding disorder (i.e. irreversible)
- [] Severe, uncontrollable diarrhea
- [] Bloody diarrhea
- [] Other (please specify): \_\_\_\_\_

#### Part 6: Clinical Procedures for FMT Administration

### 44) Please attach your Standard Operating Procedures for FMT administration (if available) below.

Please attach on web survey

#### 45) Where do you perform FMT (select all that apply)?

- [] Clinic room
- [] Day unit
- [] Inpatient room
- [] Outside of hospital
- [] Other (please specify):

#### 46) Who administers FMT to patients (select all that apply)?

[] MD

[] Trainee MD

[] Nurse

[] Other (please specify): \_\_\_\_\_

### 47) How long before FMT do you stop oral vancomycin (or other antibiotic) if a patient is on treatment/suppression?

- () <24 hours
- () 24-48 hours
- () 48-96 hours
- () >96 hours
- () Not applicable

#### 48) What route(s) of administration do you use for FMT?

- [] Enema
- [] Colonoscopy
- [] Nasogastric/nasojejunal tube
- [] Other (please specify): \_\_\_\_\_

#### 49) On average, how long does the FMT procedure take?

	<10minutes	10-30 minutes	30-60 minutes	>60 minutes	Not applicable
Enema	[]	[]	[]	[]	[]
Colonoscopy	[]	[]	[]	[]	[]
Nasogastric/nasojejunal	[]	[]	[]	[]	[]

#### 50) How many FMTs do you perform per patient?

	Only 1	Up to 3	Up to 5	>5 if necessary	Not applicable
Enema	[]	[]	[]	[]	[]
Colonoscopy	[]	[]	[]	[]	[]

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Nasogastric/nasojejunal	[]	[]	[]	[]	[]
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#### 51) If you administer multiple FMTs per patient, what is the frequency of FMT?

	Daily	Every 2-4 days	Every 4-7 days	Weekly	Every 10-14 days	Other (please enter a value below)	Not applicable
Enema	[]	[]	[]	[]	[]		()
Colonoscopy	[]	[]	[]	[]	[]		()
Nasogastric/nasojejunal	[]	[]	[]	[]	[]		()

### 52) What are your criteria for failure of FMT?

- () Return of CDI symptoms
- () Return of CDI symptoms and laboratory confirmation
- () Other (please specify): \_\_\_\_

### 53) What is your routine follow-up post-FMT?

- () I only see post-FMT patient's as needed, if they have concerns
- () I see post-FMT patients regularly, at the following time points (other please specify)::

### 54) Do you perform microbiota analysis of FMT recipient feces prior to FMT administration?

() Yes

( ) No

### 55) Do you perform microbiota analysis of FMT recipient feces following FMT administration?

() Yes (please specify frequency): \_\_\_\_\_

( ) No

#### **Part 7: Infection Control Procedures**

### **56)** What personal protective equipment is worn by the individual administering FMT (select all that apply)?

[] Single pair of gloves

- [] Double gloves
- [] Fluid-resistant gown
- [] Non-fluid-resistant gown
- [] Procedure mask
- [] Face shield
- [] Hair coverings
- [] Shoe protection
- [] Other (please specify): \_\_\_\_\_

### 57) How is the FMT procedure room/area disinfected between FMTs, if multiple FMTs are scheduled back to back?

- () I never have more than one FMT in a day
- () Wipe down with non-sporicidal hospital disinfectant by FMT team
- () Wipe down with sporicidal disinfectant by FMT team
- () Cleaning by housekeeping staff using non-sporicidal hospital disinfectant
- () Cleaning by housekeeping staff using sporicidal disinfectant
- () Other (please specify): \_\_\_\_\_

### 58) How is the FMT procedure room/area disinfected after FMT procedures are done for the day?

- () Wipe down with non-sporicidal disinfectant by FMT team
- () Wipe down with sporicidal disinfectant by FMT team
- () Cleaning by housekeeping staff using non-sporicidal disinfectant
- () Cleaning by housekeeping staff using sporicidal disinfectant

() Other (please specify):

Remarks

59) Do you have any other questions/comments/concerns to share?

Thank You!