The use of faecal microbiota transplant as treatment for recurrent or refractory Clostridium difficile infection and other potential indications:

Mullish, Benjamin H.; Quraishi, Mohammed Nabil; Segal, Jonathan P.; McCune, Victoria L.; Baxter, Melissa; Marsden, Gemma L; Moore, David; Colville, Alaric; Bhala, Neeraj; Iqbal, Tariq H.; Settle, Christopher; Kontkowski, Graziella; Hart, Ailsa L.; Hawkey, Peter M.; Williams, Horace R. T.; Goldenberg, Simon D.

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The use of faecal microbiota transplant as treatment for recurrent or refractory *Clostridium difficile* infection and other potential indications: joint British Society of Gastroenterology (BSG) and Healthcare Infection Society (HIS) guidelines.

Additional Appendices

Appendix A. Scope

1. Guideline title

The use of faecal microbiota transplant as treatment for recurrent or refractory *Clostridium difficile* infection and other potential indications: joint British Society of Gastroenterology (BSG) and Healthcare Infection Society (HIS) guidelines.

1.1. Short title

The use of faecal microbiota transplant

2. The remit

i. To review the evidence (include randomised trial evidence) for the efficacy of faecal microbiota transplant (FMT) in the treatment of adults (≥18 years), both in CDI and in other clinical conditions, and use this to make recommendations about optimal recipient selection and management, donor assessment, material preparation and administration, and other key elements of FMT delivery.
ii. To provide specific guidance about best practice for an FMT service within the context of the regulatory framework for the intervention as it currently exists in the UK and beyond.

Whilst this is not a guideline specifically addressing the management of *Clostridium difficile* infection (CDI), the working group will include consideration of where FMT should be considered within the conventional treatment algorithm of patients with CDI (specifically, in which patients it should be considered, and at which point in their care).

The working group agreed that for the purposes of this guideline, faecal microbiota transplant would be defined as treatment that involves the administration of manipulated

whole stool. There is a growing literature of the use of 'bacteriotherapy' originally deriving from healthy donor stool as a potential alternative to FMT (including commensal bacteria, spores, bacteriophages and/ or bacterial proteins or metabolites). However, the working group considered this to still be at the research stage, and would not be considered further.

2.1. Population

2.1.1. Groups that will be covered

Adults (≥18 years) in whom:
i. FMT has been used as treatment for CDI.
ii. FMT has been used as treatment for a non-CDI indication.

Given the variability in the means used to diagnose CDI within different studies, the working group agreed to consider the suitability of the definition used on a study-by-study basis.

2.1.2. Groups that will not be covered

Children and young people (<18 years).

2.2. Healthcare setting

All settings in which National Health Service care is received, and/ or clinical trials are undertaken.

2.3. Clinical management

2.3.1. Key clinical issues that will be covered

a) Appropriate selection of patients with CDI for FMT, and best practice in their management post-FMT.
b) Optimal selection of donors of faecal material, and maintenance of a donor pool.
c) Identification of the preferred means of preparation and administration of FMT to recipients.
d) Evaluation of the safety and efficacy of FMT in treating non-CDI indications.
e) Best practice in the delivery of an FMT service.

2.3.2. Clinical issues that will not be covered

a) General management of CDI.

b) General management of non-CDI conditions in which FMT may have a role in therapy.

2.4. Main outcomes

Recommendations for practice

a) Patient/ recipient selection, and peri-FMT management
b) Donor selection
c) Preparation and administration of FMT
d) Provision of an FMT service
e) Efficacy and safety of FMT for non-CDI indications

2.5. Economic aspects

There are no significant anticipated additional costs. The expectation of the working group is that the publication of this guideline may encourage provision of FMT as treatment for recurrent or refractory CDI. This has consistently been shown to be cost-effective in comparison with anti-*C. difficile* antimicrobial therapy, and so costs associated with treating the condition may actually decrease. Furthermore, there may be changes to the practice of clinicians already offering the service. For example, encouraging the use of healthy unrelated donors (who can provide multiple stool donations after one screening) reduces the cost of screening when compared to the use of an FMT recipient's relative as donor, who is likely to provide one donation only.

2.6. Status

2.6.1. Scope

This is the final scope.

2.6.2. Timing

The development of the guideline recommendation will begin in July 2017.

3. Related NICE guidance

National Institute for Health and Care Excellence. *Faecal microbiota transplant for recurrent Clostridium difficile infection.* NICE Interventional Procedures Guidance IPG485. London: NICE; 2014. Available at: https://www.nice.org.uk/guidance/ipg485 [last accessed 19th December 2017].

4. Further information

Guideline development process

Scottish Intercollegiate Guidelines Network. *SIGN 50: a guideline developer's handbook.* Revised edition. Edinburgh: Healthcare Improvement Scotland; 2014. Available at: http://www.sign.ac.uk [last accessed December 2017].

Appendix B. Declarations of interest

B.1. *Introduction*

All members of the Working Group were required to make formal declarations of interest at the outset, and these were updated throughout the development process. No interests were declared that required any actions.

B.2. *Tariq Iqbal*

First meeting 19/07/17: no declarations of interest; second meeting 04/10/17: no change.

Third meeting 06/02/17: consultant, advisor or speaker for Pharmacosmos and Shield Therapeutics.

B.3. *Simon Goldenberg (co-chair)*

First meeting 19/07/17

Advisory board and/ or consultancy and/ or speaker fees: Astellas, MSD, Pfizer.

Second meeting 04/10/17; third meeting 19/10/17: no change.

No action required.

B.4. *Ailsa Hart*

First meeting 19/07/17

Advisory board and/ or consultancy and/ or speaker fees: AbbVie, Atlantic, Bristol-Myers Squibb, Celltrion, Falk, Ferring, Janssen, MSD, Napp Pharmaceuticals, Pfizer, Pharmacosmos, Shire and Takeda. Global steering committee for Genentech.

Second meeting 04/10/17; third meeting 19/10/17: no change.

No action required.

No declared conflict of interests for the other participants.

Appendix C. Clinical evidence tables

C.1. Reviewed case series of FMT for recurrent or refractory CDI

Additional Appendices

Paper	Study and patient characteristics	Donor characteristics	FMT characteristics	Outcomes	Adverse events	CRD
Aas et al Clinical Infectious Diseases 2003	Case series Number of patients = 18 Male: 5; Female: 13 Age(mean/median) = 73+/-9 (range 53-88) Comorbidities = 1 patient with Crohn's colitis, 1 leukaemia CDI features = Recurrent (at least 2 x lab confirmed CDI after initial abx treatment) CDI diagnosis confirmation =Cytotoxin A and B positivity Pre-FMT antibiotics = MTZ +/- vanc (not defined)	Donors were 15 were family members, 3 clinical volunteers. Working in healthcare = Yes - for 3 Donor demographics = Not defined Donor screening: Questionnaire = Not explicity stated Travel and antibiotic exclusion peroid = No abx for 6 months prior; nil stated re travel. Screening bloods = HAV, HBV, HIV-1/-2, HCV, syphilis Screening stools = C difficile, enteric pathogens, OCP	Amount of stool per transplant / administered to patients = 30g stool in 50-70ml normal saline; only 25ml of total administered to patient Diluent used to prepare = Normal Saline Diluent used to store if frozen = N/A - fresh Preparation methods = Homogenised in domestic blender, coffee filter Time from preparation to transplant (fresh) = 6 hours Time period for storage (frozen) = N/A Route administered: Upper GI = All NG (18) Lower GI = (N/A) Number of infusions = Single infusion for all patients Bowel purgative = N/A PPI = 20mg omeprazole on day 0 and day -1 Antimotility = N/A Prokinetics = N/A Time before CDI treatment was stopped before FMT = Continued until d0.	Overall cure within stated follow up period = 15 out of 18 Cure with 1 infusion alone = 15 out of 18 Total follow up period = 90 days.	Minor GI adverse events = Not stated Minor non-GI adverse events = Not stated Serious adverse events = Not stated Deaths = 2 - one related to ESRF, one related to COPD.	Selection/eligibility reported = Yes Consecutively recruited = Yes Prospectively recruited = No Loss to follow up explained = Yes At least 90% followed up = No - 89%

Additional Appendices

Agrawal et al Journal of Clinical Gastroenterology 2016	Case series Number of patients = 146 Male: 46; Female: 100 Age(mean/median) = 78.6 (range 65-97) Comorbidities = Immunosupression 15 (3 CD, 2UC, 1 renal transplant) CDI features = 89 Recurrence CDI diagnosis confirmation =As per ACG guidelines Pre-FMT antibiotics = MTZ,Fidax,Vanc (not defined)	Donors were Identified by the patient or if not available provided by the physician. Working in healthcare = Not stated Donor demographics = No ABx for last 3/12. Excluded if significant GI disease, metabolic syndrome, chronic illness, immunocompromise, recent travel, high risk lifestyle in last 3/12 Donor screening: Questionnaire = Excluded if significant GI disease, metabolic syndrome, chronic illness, immunocompromise, recent travel, high risk lifestyle in last 3/12 Travel and antibiotic exclusion peroid = Area of high incidence of infectious diarrhoea. No ABx for last 3/12. Screening bloods = HAV, HBV, HIV-1/-2, HCV, syphilis Screening stools = C difficile, enteric pathogens, OCP,giardia, Cryptosporidium,isospora, H. pylori, Rotavirus	Amount of stool per transplant / administered to patients = 60-100g of fresh stool Diluent used to prepare = Normal saline 75-200mls upper :Lower 250-400mls : Enema 150-200ml Diluent used to store if frozen = N/A - fresh Preparation methods = Handstirred and blender, sifted through gauze Time from preparation to transplant (fresh) = Not stated Time period for storage (frozen) = Route administered: Upper GI = Upper (16) Lower GI = lower GI (130) Number of infusions = 1, 2nd infusion given with vancomycin so data unable to be extracted Bowel purgative = PEG D-1 PPI = No Antimotility = Loperamide D0 Prokinetics = no Time before CDI treatment was stopped before FMT = Between D-3 D-1.	Overall cure within stated follow up period = N/a Cure with 1 infusion alone = 121/146 (83%) Total follow up period = Mean follow up was 12.3 months (range 1-48 months).	Minor GI adverse events = none Minor non-GI adverse events = none Serious adverse events = 2x Microscopic colitis, 1x Sjogrens, 1x scalp follicular lymphoma, 1x contact dermatitis and idiopathic Bence-Jones gammaglouburia, 1x scc 1x ileus (died 2 weeks after ileus) 1x colonic perforation secondary to CMV colitis and subsequent death after 1 year, (All CA patients had pre-existing risk factors) Deaths = 10 (4 Decompensated HF, 3 CA, 1 Dementia, 1Stroke, 1Pneumonia) 19 days to 7 months post FMT.	Selection/eligibility reported = yes Consecutively recruited = yes Prospectively recruited = no Loss to follow up explained = no At least 90% followed up = no

Additional Appendices

Alrabaa et al Transplant Infectious Diseases 2017	Case series Number of patients = 13 Male: 5; Female: 8 Age(mean/median) = 69 median (range 59-74) Comorbidities = Yes - 4 OLT, one kidney/ liver tx, one lung trasnplant, one HIV+ with CD4 count of 453. One immunocompromised with IBS, one immunocompetent with IBS; nil IBD CDI features = Not clear if recurrent or refractory. Mean of 4 previous episodes of CDI prior to FMT CDI diagnosis confirmation =PCR Pre-FMT antibiotics = All oral vanc, seven prev MTZ (either with or without vanc), 5 received fidaxo with or after oral vanc.	Donors were Unrelated. Working in healthcare = No Donor demographics = As per OpenBiome Donor screening: Questionnaire = As per OpenBiome Travel and antibiotic exclusion peroid = As per OpenBiome Screening bloods = FBC, HAV, HBV, HCV, LFTs, HIV, HTLV-1/-2, syphilis. Screening stools = C diff toin, MCP, OCP, H pylori stool Ag	Amount of stool per transplant / administered to patients = 12.5g of stool in 28.5g of product Diluent used to prepare = normal saline - diluted to approx 100-150ml to administer Diluent used to store if frozen = Not clear Preparation methods = As per OpenBiome Time from preparation to transplant (fresh) = N/A Time period for storage (frozen) = As per OpenBiome - not described in paper Route administered: Upper GI = Nasoduodenal (13) Lower GI = () Number of infusions = One routinely, but retreated if relapsed after primary outcome. However - one renal tx patient received 2 doses of FMT on consecutive days - successful Bowel purgative = Bowel preparation used - GoLytely (PEG) PPI = 40mg pantoprazole night before and morning of procedure Antimotility = loperamide 4mg 1hr post FMT Prokinetics = N/A Time before CDI treatment was stopped before FMT = See last box.	Overall cure within stated follow up period = 11/13 at eight weeks post-FMT Cure with 1 infusion alone = 13/13 at 5 days Total follow up period = Follow up up to 8 weeks described. .	Minor GI adverse events = Several patients transient cramps and/ or diarrhoea Minor non-GI adverse events = Nil noted Serious adverse events = One patient had episode of CMV reactivation at the time of FMT - thought unrelated. One patient had episode of mild transplant rejection 2/12 after FMT - thought unrelated. Deaths = None described.	Selection/eligibility reported = Yes Consecutively recruited = Not clearly described Prospectively recruited = No Loss to follow up explained = Yes At least 90% followed up = Yes

Additional Appendices

Brandt et al American Journal of Gastroenterology 2012	Case series Number of patients = 77 Male: 21; Female: 56 Age(mean/median) = 65+/-17 (range 22-87) Comorbidities = Not stated CDI features = All recurrent/ refractory CDI diagnosis confirmation =Not clear Pre-FMT antibiotics = 62 MTZ, 76 vanc (25 tapered vanc), 17 rifaximin	Donors were 45 spouses/ partners; 21 relatives; 1 unknown person. Working in healthcare = No Donor demographics = No antibiotics within past 3 months Donor screening: Questionnaire = Not stated Travel and antibiotic exclusion peroid = Area of high incidence of infectious diarrhoea. No ABx for last 3/12. Screening bloods = HIV 1, HIV 2, HAV, HBV, HCV, Syphillis Screening stools = iff toxin (if unavailable then EIA), MC&S, Giardia, Cryptosporidium, OCP, Hpylori, Acid Fast stain for cyclospora, isospora	Amount of stool per transplant / administered to patients = 6 tablespoons of stool up to entire donation; 300-700ml of transplant administered Diluent used to prepare = Normal saline Diluent used to store if frozen = N/A - fresh Preparation methods = Hand blender used to prep Time from preparation to transplant (fresh) = Within 8 hours Time period for storage (frozen) = N/A Route administered: Upper GI = (0) Lower GI = All colonoscopic (77) Number of infusions = 77 patients had one (patients that had second not included because given with concurrent vanc) Bowel purgative = All patients given prep but no details PPI = N/A Antimotility = N/A Prokinetics = N/A Time before CDI treatment was stopped before FMT = d-3.	Overall cure within stated follow up period = N/A Cure with 1 infusion alone = 70/77 Total follow up period = .	Minor GI adverse events = Not stated Minor non-GI adverse events = Not stated Serious adverse events = Nil Deaths = 7 deaths (cause unknown in one case, one metastatic CRC (present from pre-FMT), one metastatic ovarian Ca, one LRTI (non-enteric org), one MI, one CVA, one sepsis five months after FMT. .	Selection/eligibility reported = Yes Consecutively recruited = Not clear Prospectively recruited = No Loss to follow up explained = Reported but not explained At least 90% followed up = No - only 77%

Additional Appendices

Brumbaugh et al, J Pediatr, 2017	Case series Number of patients = 42 Male: 19; Female: 23 Age(mean/median) = median 9 years (range 1 -18) Comorbidities = 31% had IBD (4 Crohn's, 9 UC); 29% 'medically complex', including oncological, metabolic, cardiopulmonary or neurological diagnoses. CDI features = all children at least one course of vancomycin previously Recurrent - at least 2 episodes CDI diagnosis confirmation =Diarrhoea, haematochezia and/ or crampy abdominal pain in combination with positive *C difficile* PCR Pre-FMT antibiotics = Not stated	Donor: OpenBiome-supplied FMT. Working in healthcare = no. Donor demographics = Donor screening: Questionnaire = As per OpenBiome Travel and antibiotic exclusion peroid = As per OpenBiome Screening bloods = As per OpenBiome Screening stools = As per OpenBiome	Amount of stool per transplant / administered to patients = 30ml OpenBiome aliquot/ capsule, although not defined re stool quantity. Diluent used to prepare = As per OpenBiome Diluent used to store if frozen = As per OpenBiome. Preparation methods = As per OpenBiome Time from preparation to transplant (fresh) = None given fresh Time period for storage (frozen) = Route administered: Upper GI = 41, nasogastric administration (some children used pre-existing gastrostomy). Lower GI = Capsule = 1 (1 x 30 capsules). Number of infusions = 1 routinely Bowel purgative = Not stated PPI = Rantidine for 24hrs prior to FMT Antimotility = N/A Prokinetics = N/A Time before CDI treatment was stopped before FMT = 48 hours, after minimum of 5 days of vancomycin.	Overall cure within stated follow up period = 30/42 (71%) Cure with 1 infusion alone = 30/42 (71%) - remission in 16/17 otherwise healthy children, 7/13 with IBD, 9/12 medically complex. Success in 71% of children when via NGT, and 67% via gastrostomy (NS). Total follow up period = 5 patients with initial failure opted for 2nd and 2 cured, so total success of 32/42 (76%)	Minor GI adverse events = 6/47 FMT administrations accompanied by vomiting within 24hrs; self-resolved. Minor non-GI adverse events = Serious adverse events = Deaths = .	Selection/eligibility reported = Yes Consecutively recruited = Yes Prospectively recruited = No Loss to follow up explained = Yes At least 90% followed up = Yes

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Chin et al Clinical Gastroenterology & Hepatology 2016	Case series Number of patients = 35 Male: ; Female: 16 (46%) female Age(mean/median) = 43 (8 -93) Comorbidities = IBD in all, 8 on steroids, 3 on Immunomodulators, 11 on biologics CDI features = Recurrent - at least 2 episodes CDI diagnosis confirmation =Not stated Pre-FMT antibiotics = Not stated	Donors were Age 18 - 50, no meds, BMI 18.5 - 25, . Working in healthcare = Donor demographics = Donor screening: Questionnaire = Adapted from US blood bank Travel and antibiotic exclusion peroid = No abx for 6 months Screening bloods = FBC, U&E, LFTs, CRP, ANA, HAV, HBV, HIV-1/-2, HCV, syphilis Screening stools = Faecal occult blood, rotavirus, bacterial pathogens, OCP, Acid fast stain for giardia and Cryptosporidium, C diff, H. pylori	Amount of stool per transplant / administered to patients = 41g of stool on average Diluent used to prepare = Normal Saline Diluent used to store if frozen = Frozen in 10% glycerol Preparation methods = Ambient air Time from preparation to transplant (fresh) = None given fresh Time period for storage (frozen) = Up to 156 days Route administered: Upper GI = (5 via NG) Lower GI = (3 colon) Number of infusions = Not stated Bowel purgative = Not routinely - just for colonoscopy 4 litres of PEG PPI = 7 on PPI not as premed Antimotility = N/A Prokinetics = N/A Time before CDI treatment was stopped before FMT = Day -2 stopped.	Overall cure within stated follow up period = N/A Cure with 1 infusion alone = Not stated Total follow up period = At least 2 months (range 2 to 6 months).	Minor GI adverse events = Minor non-GI adverse events = Serious adverse events = Deaths = .	Selection/eligibility reported = No Consecutively recruited = No Prospectively recruited = No Loss to follow up explained = No At least 90% followed up = No

Additional Appendices

Cohen et al Israel Medical Association Journal 2016	Case series Number of patients = 22 Male: 13; Female: 9 Age(mean/median) = 71.5 (range 16-92) Comorbidities = 1 IBD (colonoscopic group), ?2 patients on chemo, unclear why. CDI features = Both CDI diagnosis confirmation =Diarrhoea and toxin testing Pre-FMT antibiotics = 19 MTZ, 99 vanc (13 both together)	Donors were 13 unrelated, rest related. Working in healthcare = Yes - for unrelated Donor demographics = No details - just says screening similar to blood donors Donor screening: Questionnaire = No details Travel and antibiotic exclusion peroid = No abx for 6 months Screening bloods = No details Screening stools = No details	Amount of stool per transplant / administered to patients = 60g stool average (35-75g), 250ml total once mixed with saline (100 - 300ml range) Diluent used to prepare = Normal saline Diluent used to store if frozen = Some frozen - not stated if glycerol Preparation methods = Some fresh, some frozen Time from preparation to transplant (fresh) = Not stated Time period for storage (frozen) = No details Route administered: Upper GI = Nasoduodenal (10) Lower GI = Colonoscopic (10) Number of infusions = 1 FMT Bowel purgative = 3l of PEG if colonoscopic PPI = d-1 PPI if upper GI administration Antimotility = Prokinetics = Metoclopramide just prior to upper GI administration Time before CDI treatment was stopped before FMT = 12-24hrs.	Overall cure within stated follow up period = 16/22 at 2 months Cure with 1 infusion alone = 16/22 (5/10 upper (out of 7 analysed), 11/12 for lower GI (out of 11 analysed)) Total follow up period = Results reported at 2/12, but followed up to 6/12 (7 in the upper, 5 in the lower followed up to 6 months).	Minor GI adverse events = Five transient constipation/ abdo discomfort Minor non-GI adverse events = Not stated Serious adverse events = See deaths Deaths = 7 (one due to C diff colitis, one chronic resp disease, one related to dialysis, two pneumonia, one sepsis 10/7 post-FMT (aspiration of stool; had been gastroscopic administration), one died at home ?cause)..	Selection/eligibility reported = Consecutively recruited = Prospectively recruited = Loss to follow up explained = At least 90% followed up =

Additional Appendices

Costello et al Alimentary Pharmacology and Therapeutics 2015	Case series Number of patients = 20 Male: NA; Female: NA Age(mean/median) = Median age 69 Comorbidities = Not reported CDI features = All recurrent CDI diagnosis confirmation =Not stated Pre-FMT antibiotics = Conventional therapy with met, van and/or fidaxomicin had failed in all	Donors were 4 healthy volunteers. Working in healthcare = No Donor demographics = No details Donor screening: Questionnaire = Adapted from US blood bank Travel and antibiotic exclusion peroid = No travel to diarrhoea endemic areas for 6 months and no antibiotics for 3 months. Screening bloods = HIV type 1 and 2, HAV, HBV, HCV ab and syphillis Screening stools = CDiff toxin B PCR, routine MC&S, Faecal giardia antigen, fecal cryptosporidium, Acid-fast stain for Cyclospora, Isospora, ova cysts and parasites, Hpylori fecal antigen.	Amount of stool per transplant / administered to patients = Not specified Diluent used to prepare = Normal saline Diluent used to store if frozen = 10% glycerol Preparation methods = Anaerobically prepared Time from preparation to transplant (fresh) = Time period for storage (frozen) = 16 ptns had stool stored for < 2 months. 4 ptns had stool stored > 2 months Route administered: Upper GI = 1 () Lower GI = 19 () Number of infusions = 17 - 1, 3 - 2 Bowel purgative = Not reported PPI = Not reported Antimotility = Not reported Prokinetics = Not reported Time before CDI treatment was stopped before FMT = Not reported.	Overall cure within stated follow up period = NA Cure with 1 infusion alone = 17/20 (85%) Total follow up period = Minimum 3 months (but up to 14 months).	Minor GI adverse events = None Minor non-GI adverse events = None Serious adverse events = None Deaths = None.	Selection/eligibility reported = Yes Consecutively recruited = Yes Prospectively recruited = No Loss to follow up explained = Yes At least 90% followed up = Yes

Additional Appendices

Dubberke et al Clinical Infectious Diseases 2016	Prospective case series Number of patients = 34 Male: 11; Female: 23 Age(mean/median) = 66.8 (range 26.7-89.6) Comorbidities = 21 GI. 19cardiovasc,18GU,9psychiatric CDI features = Recurrent - at least 2 episodes CDI diagnosis confirmation =presence of diarrhiea and at least 1 +ve stool test for c.diff or its toxins, or colonoscopic ot histopathologic findings of pseudomembarbous coltis as per society of america clinical practice guidelines Pre-FMT antibiotics = vancomycon, fidaxomicin. All recieved standard dose vancomycin 125mh oral qds followed by 24-48 hour wash out period before drug given	Donors were 4 unrelated donors. Working in healthcare = NS Donor demographics = NS Donor screening: Questionnaire = "comprehensive initial health and lifestyle questionnaire" Travel and antibiotic exclusion peroid = NS Screening bloods = HIV,HEPA,HEPB,HEPC, syphilis Screening stools = c.diff toxin, norovirus,rotavirus,adenovirus, ova,parasites,VRE, MRSA,vibrios,listeria and enteric pathogens	Amount of stool per transplant / administered to patients = 50g of himan stool/150ml of 0.9% saline/polyethelene glycol 3350 vehicle Diluent used to prepare = 150ml 0.9% nacl/polyethelene glycol Diluent used to store if frozen = polyethelene glycol Preparation methods = A sample was retained from each donor the pooled with other smples from the same donor and subjected to repeat testing at 45 day intervalsproduct stored frozed at -80 in a secure location then thawed prior to shipment to clinical site. cam then be stored at room tmp for 2 days prior to transplant Time from preparation to transplant (fresh) = NS Time period for storage (frozen) = ns Route administered: Upper GI = 0 (0) Lower GI = 0 (34 enema) Number of infusions = 16 =1 enema, 15=2 enemas Bowel purgative = no PPI = Not reported Antimotility = no Prokinetics = no Time before CDI treatment was stopped before FMT = 24-48 hrs.	Overall cure within stated follow up period = 27(87.1%) after 8 week Cure with 1 infusion alone = 16(51.6%) of those that recieved a second infusion 11/14(78%) were considered a success Total follow up period = 6 month follow up in 31 patients on safety.	Minor GI adverse events = Mild to moderate diarrhoea, flatulence, abdominal pain/cramping, and constipation, all of which were self-limited. Of the AEs, 58.5% (n = 110) were determined to be possibly, probably, or definitely related to CDI. Minor non-GI adverse events = Infections were second most common group of complications - Serious adverse events abdo pain, UTI, COPD resulting in hospitalisation. Deaths = 1 death.	Selection/eligibility reported = Yes Consecutively recruited = Yes Prospectively recruited = No Loss to follow up explained = Yes At least 90% followed up = No

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Emanuelsson et al Scandanavian Journal of Infectious Diseases 2014	Case series Number of patients = 23 Male: 9; Female: 14 Age(mean/median) = Mean age 66 years Comorbidities = CDI features = CDI diagnosis confirmation =Culture and/or toxin EIA Pre-FMT antibiotics = Metronidazole and/or Vancomycin	Donors were . Working in healthcare = Donor demographics = Donor screening: Questionnaire = Travel and antibiotic exclusion peroid = Screening bloods = HIV 1 and 2, hepatitis C virus, and hepatitis B surface antigen Screening stools = Salmonella, Shigella, Campylobacter, enterohemolytic Escherichia coli, and Clostridium difficile	Amount of stool per transplant / administered to patients = 50g in 500mls Diluent used to prepare = Normal saline Diluent used to store if frozen = NA Preparation methods = Anaerobically prepared Time from preparation to transplant (fresh) = Not stated Time period for storage (frozen) = NA Route administered: Upper GI = () Lower GI = 23 () Number of infusions = 22-1, 1-2 Bowel purgative = NS PPI = NS Antimotility = NS Prokinetics = NS Time before CDI treatment was stopped before FMT = NS.	Overall cure within stated follow up period = NS Cure with 1 infusion alone = 15/23 (65%) Total follow up period = Median follow up of 18 months (range 0-201 months).	Minor GI adverse events = None Minor non-GI adverse events = None Serious adverse events = None Deaths = None.	Selection/eligibility reported = Consecutively recruited = Prospectively recruited = Loss to follow up explained = At least 90% followed up =

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Fischer et al Inflammatory Bowel Diseases 2016	Case series Number of patients = 67 Male: 28; Female: 39 Age(mean/median) = mean 45.42+/- 17.33 Comorbidities = 5 patients PSc, 4 liver transplant 3 end stage liver disease concurrent IBD in all (31 C5 CD 31 UC 1 IC) CDI features = 17/54 average of 4.2 +/- 2.1 episodes CDI diagnosis confirmation =stool culture negative by PCR Pre-FMT antibiotics = metrronidazole 47, vancomycin 63, vancomycin taper 38, fidaxomicin 7, rifaxamin 7	Donors were patient directed donor or unrelated healthy volunteer. Working in healthcare = not stated Donor demographics = not stated Donor screening: Questionnaire = As per faecal microbiota transplant group (Bakken JS et al. treatng clostridium difficile infection with faecal microbiota transplantation. clin gastroenterol hepatol. 2011;9:1044-1049 Travel and antibiotic exclusion peroid = No travel within last 6 months where diarrheal illnesses are endemic or risk of travelers diarrhea is high/ antibiotics within 3 months Screening bloods = HiV 1&2, HAV, HBV,HCV, syphilis Screening stools =	Amount of stool per transplant / administered to patients = lower-25-50ml, upper 250-500ml Diluent used to prepare = preservative-free normal saline or 4%milk Diluent used to store if frozen = should not be frozen Preparation methods = household blender,homogenized and removal of paticle matter with gauze,/urine stone strainers biohazard 2 Time from preparation to transplant (fresh) = certainly within 24 hours and preferably within 6 Time period for storage (frozen) = n/a Route administered: Upper GI = 0 (0) Lower GI = 67 () Number of infusions = 53 had one infusion. 14 had 2 Bowel purgative = standard bowel preparation not specified PPI = ppi if upper evening before and morning of the procedure Antimotility = loperamide optional for lower Prokinetics = NS Time before CDI treatment was stopped before FMT = 24-48 hrs.	Overall cure within stated follow up period = 60(90%) within 3 months Cure with 1 infusion alone = 53 (79%) Total follow up period = average length 10.4 months (range 3-36).	Minor GI adverse events = 1 IBD flair managed as o/p Minor non-GI adverse events = URTI in 4 Serious adverse events = 1 colectomy for refractory IBD,7 hospitalised, 2:CDi recurrence, 2IBD exacerbation, 1SBO,1CMV colitis Deaths = none.	Selection/eligibility reported = yes Consecutively recruited = no Prospectively recruited = no Loss to follow up explained = n/a At least 90% followed up = n/a

Additional Appendices

Fischer et al American Journal of Gastroenterology 2016	Case series Number of patients = 328 Male: 87; Female: 241 Age(mean/median) = 61.4 +/- 19.3 Comorbidities = 77 immunocompromised(3 IGa def, 71 on immunosupressants(20 for solid organ transplant,29for IBD,6 for RA, 2 for lupus 1 for pemphigoid 1 for COPD 1 for psoriasis)11 chemo for malignancy,63 IBD,(25 UC:33 CD)118 diverticulosis CDI features = 0vs286 CDI diagnosis confirmation =postive stool C.difficile toxin or PCR Pre-FMT antibiotics = vancomycin	Donors were 130(40%) patient directed donors 198 universal (60%). Working in healthcare = not stated Donor demographics = not stated Donor screening: Questionnaire = not specified Travel and antibiotic exclusion peroid = not specified Screening bloods = not specified Screening stools = not specified	Amount of stool per transplant / administered to patients = not specified Diluent used to prepare = not specified Diluent used to store if frozen = both but not specified Preparation methods = NS Time from preparation to transplant (fresh) = NS Time period for storage (frozen) = NS Route administered: Upper GI = ns (ns) Lower GI = 249(76.9%) () Number of infusions = ns Bowel purgative = ns PPI = ns Antimotility = ns Prokinetics = ns Time before CDI treatment was stopped before FMT = ns.	Overall cure within stated follow up period = 1 month 81.4%, 1-3 months 97.3% Cure with 1 infusion alone = NS Total follow up period = ns.	Minor GI adverse events = ns Minor non-GI adverse events = ns Serious adverse events = ns Deaths = ns.	Selection/eligibility reported = yes Consecutively recruited = no Prospectively recruited = no Loss to follow up explained = n/a At least 90% followed up = n/a

Additional Appendices

Fischer et al Gut Microbes 2017	Case series Number of patients = 57 Male: 23; Female: 34 Age(mean/median) = 72(60-79;25-99) Comorbidities = CDI features = CDI diagnosis confirmation =positive stool c.difficle PCR Pre-FMT antibiotics = vancomycin, fidaxomicin, rectal vancomycin,iv metronidazole	Donors were screened patient selected donor in first 29. 28 from openbiome stool bank. Working in healthcare = ns Donor demographics = ns Donor screening: Questionnaire = patient selected Fecal microbiota transplant working group-see above open biome questionnaire Travel and antibiotic exclusion peroid = Screening bloods = patient selected donor-HiV 1&2, HAV, HBV,HCV, syphilis. open biome-HIV,hep ABC, Treponema pallidum, HTLV1 and 2 FBC and differential, hepatic function Screening stools =	Amount of stool per transplant / administered to patients = Diluent used to prepare = Diluent used to store if frozen = Preparation methods = Time from preparation to transplant (fresh) = Time period for storage (frozen) = Route administered: Upper GI = () Lower GI = () Number of infusions = Bowel purgative = PPI = Antimotility = Prokinetics = Time before CDI treatment was stopped before FMT = .	Overall cure within stated follow up period = Cure with 1 infusion alone = Total follow up period = .	Minor GI adverse events = Minor non-GI adverse events = Serious adverse events = Deaths = .	Selection/eligibility reported = Consecutively recruited = Prospectively recruited = Loss to follow up explained = At least 90% followed up =

Additional Appendices

Fischer et al Alimentary Pharmacology and Therapeutics 2015	Case series Number of patients = 29 Male: 12; Female: 17 Age(mean/median) = Mean overall of 65.2 years+/-17.9 (25-92 years); mean 60.8 (26-87) in severe; 67.6 (60-78) in severe/complicated Comorbidities = 3 Crohn's, 2 UC, 1 hypogammaglobulinaemia, one ESKD, one ESLD, one renal transplant, one liver transplant, four on immunosuppressive meds. 12/19 of pts treated in ITU at the time with following complications: 5 pts toxic megacolon (caecal diam >12cm or rectosigmoid>6.5cm diam); 7 AKI and hypovol/ septic shock, 4 of which required vasopressors, 3 with change in mental status, 2 patients ventilated. 22 with pseudomembranes at first FMT. CDI features = 9 patients with first episode of CDI; all others with previous episodes	Donors were Either patient selected-donor or universal donor; screening in all cases. If patient-directed, same donor used for subsequent FMTs if required. 44 FMTs in all - patient-selected for 16, universal donor for 28.. Working in healthcare = Not clear Donor demographics = Not clear Donor screening: Questionnaire = As per FMT working group Travel and antibiotic exclusion peroid = As per FMT working group Screening bloods = As per FMT working group Screening stools = As per FMT working group	Amount of stool per transplant / administered to patients = 50-200g of stool Diluent used to prepare = 300ml of saline Diluent used to store if frozen = No - all fresh Preparation methods = No additional details Time from preparation to transplant (fresh) = Six hours Time period for storage (frozen) = N/A Route administered: Upper GI = (0) Lower GI = Flexi or colon either proximal or distal to the splenic flexure at the discretion of the endoscopist. Oral vanc (125mg qds) continued 24-48hr post-FMT for at leat 5 days if pseudomembranes. In practice - prox to splenic flexure in 18 FMTs, distal in 26. (44) Number of infusions = As many as per protocol until end point. 16 x 1 FMT (7 severe, 9 comp), 11 x 2nd FMT (3 severe, 8 compl), 2 x 3rd FMT (0 severe, 2 compl) Bowel purgative = Split dose 4l Golytely if no ileus/ obstruction PPI = N/A Antimotility = N/A Prokinetics = N/A Time before CDI treatment was stopped before FMT = 12-24hr prior to FMT.	Overall cure within stated follow up period = By 3/12 - 18/29 in remission Cure with 1 infusion alone = 7/10 in severe arm; 9/19 in severe/ complicated arm Total follow up period = Up to 3 months f/u.	Minor GI adverse events = Not specifically stated Minor non-GI adverse events = Not specifically stated Serious adverse events = N/A Deaths = 2 deaths by 1 month - one death from sepsis within 24hr of FMT); death following collectomy after 3x failed FMT in patients 6/52 post-OLT. By 3 months - two further deaths from CDI recurrence, one death from cirhosis, one death from heart failure, one death from resp failure, one death from aspiration.	Selection/eligibility reported = Yes Consecutively recruited = Yes Prospectively recruited = Yes Loss to follow up explained = Yes At least 90% followed up = Yes

Additional Appendices

	CDI diagnosis confirmation =Diarrhoea (at least 3 loose stools/d) and positive toxin. Pre-FMT antibiotics = Not described					

Additional Appendices

Garborg et al Scandanavian Journal of Infectious Diseases 2010	Case series Number of patients = 40 Male: 19; Female: 21 Age(mean/median) = Mean age 75 (range 53-94) years Comorbidities = 1 Wegener's, 1 AML/ repeated abx, not formally described CDI features = Not described CDI diagnosis confirmation =Diarrhoea and + C diff toxin (testing for A and B) Pre-FMT antibiotics = All patients at least two courses of po mtz (500mg tds) or vanc (125mg po qds)	Donors were Close relatives/ household members. Working in healthcare = N/A Donor demographics = Not defined Donor screening: Questionnaire = "Symptoms of GI disease or hx of chronic infectious disease" Travel and antibiotic exclusion peroid = No details Screening bloods = HAV, HBV, HCV, HIV. Screening stools = MCS, Yersinia. No routine paraiste screening ("low prevalence in Norway")	Amount of stool per transplant / administered to patients = 50-100g Diluent used to prepare = 250ml sterile normal saline Diluent used to store if frozen = All fresh Preparation methods = Stool placed on gauze pad and strained; flushed with saline; drawn up into synriges ready for administration Time from preparation to transplant (fresh) = Same day Time period for storage (frozen) = N/A Route administered: Upper GI = OGD with delivery in distal duodenum (38) Lower GI = Colonoscopy (2) Number of infusions = One at baseline; follow up if 'did not respond' although not specifically defined Bowel purgative = Not used - even for colon PPI = Not described Antimotility = Not decribed Prokinetics = Not descirbed Time before CDI treatment was stopped before FMT = Evening prior.	Overall cure within stated follow up period = 33/40 Cure with 1 infusion alone = 29/ 40 (28 in duodenum, 1 in colon) Total follow up period = Up to 80 days.	Minor GI adverse events = Not described Minor non-GI adverse events = Not described Serious adverse events = Not described Deaths = Five deaths within 3 weeks - 2 months post-FMT but none attributable to FMT. Two frailty, one advanced Wegener's, one AML/ abx, one patients with advanced CV disease who had fulminant colitis, underwent colectomy, but died. .	Selection/eligibility reported = Yes Consecutively recruited = Yes Prospectively recruited = No Loss to follow up explained = Yes At least 90% followed up = Yes

Additional Appendices

Girotra et al Digestive Diseases and Sciences 2016	Case series Number of patients = 29 Male: 23; Female: 6 Age(mean/median) = 80.1+/-6.49 years mean (13 patients 70-79, 14 patients 80-89, 2 patients > 90 years) Comorbidities = 8 DM, no mention GI comorbs/ immunosuppression CDI features = No specific details - purely sx > 6 months, failed at least 3 abx regimens. CDI diagnosis confirmation =At least 3 unformed stools in 24hr and positive stool C diff test by toxin (by ELISA) or toxin gene B (by PCR). All patients here defined RCDI by sx >6 months and at least x3 failed abx. Pre-FMT antibiotics = Not indicated	Donors were Patient-selected family or friend. Working in healthcare = No Donor demographics = Not defined Donor screening: Questionnaire = PUD/GORD, IBS, IBD, polyps, malignancy, abx/ hospital < 3 months Travel and antibiotic exclusion peroid = No details Screening bloods = e Screening stools = MCS/OCPx3, Crypto, Microscpora, C diff toxin	Amount of stool per transplant / administered to patients = 450cc - 270cc via colonoscopy AND 180cc into jejunum via enteroscopy Diluent used to prepare = Saline - whole stool sample (>30g) mixed with 50-70ml of sterile saline, made up to 5 x 90cc aliquots Diluent used to store if frozen = Fresh Preparation methods = Stool mixed with saline, homogenised in blender for <4 mins, filtered x2 with coffee filter paper. Time from preparation to transplant (fresh) = Within 6 hrs Time period for storage (frozen) = N/A Route administered: Upper GI = enteroscopy into jejunum (29) Lower GI = colonoscopy (29) Number of infusions = 1 Bowel purgative = No PPI = 20mg omeprazole evening before/ morning of procedure Antimotility = N/A Prokinetics = N/A Time before CDI treatment was stopped before FMT = >12 hrs.	Overall cure within stated follow up period = 29/29 Cure with 1 infusion alone = 29/29 Total follow up period = Reported 25.37+/- 12.8 mo f/u (range 8-50 months). Also report 60% weight gain, 40% stable weight, 75% improved 'failure to thrive' (defined as decrease of weight >10% from baseline, with no improvement despite medical Rx of CDI and nutritional Rx)..	Minor GI adverse events = Bloating 3/29. Minor non-GI adverse events = Fever 2/29 (resolved in transiently in 1/7). Serious adverse events = N/A Deaths = 0.	Selection/eligibility reported = Yes Consecutively recruited = Yes Prospectively recruited = No Loss to follow up explained = N/A At least 90% followed up = Yes

Additional Appendices

Hagel et al Deutsches Arzteblatt Internatio nal 2016	Case series Number of patients = 133 Male: 47; Female: 86 Age(mean/median) = Median 75, IQR 59.5 - 81.5 Comorbidities = 3 chemo, 19 immunosuppressants, 5 solid organ transplant, 1 allogeneic stem cell transplant, 43 GI comorbs (no details) CDI features = Median 3 recurrences (IQR 1-4); no specific details re recurrent vs refractory CDI diagnosis confirmation =As per 2014 ESCMID guidelines Pre-FMT antibiotics = 4 MTZ only, 13 vanc only, 2 fidaxo only, 61 MTZ/vanc, 8 vanc/ fidaxo, 34 MTZ/vanc/fidaxo, 11 unknown	Donors were No details. Working in healthcare = No details Donor demographics = No details Donor screening: Questionnaire = No details Travel and antibiotic exclusion peroid = No details Screening bloods = Rapid plasma reagin and fluorescent treponemal antibody-absorbed Screening stools = No details	Amount of stool per transplant / administered to patients = No details Diluent used to prepare = No details Diluent used to store if frozen = Yes, in some cases - no details given Preparation methods = No details Time from preparation to transplant (fresh) = No details Time period for storage (frozen) = No details Route administered: Upper GI = 4 OGD, 0 NG, 40 enteroscopy, 19 NG tube (63) Lower GI = 55 'endoscopic' (no further details); 0 enema. (55) Number of infusions = 1 Bowel purgative = Yes - 117 (no details given) PPI = Yes - 31 (no details given) Antimotility = Yes - 31 (no details given) Prokinetics = No details given Time before CDI treatment was stopped before FMT = No details.	Overall cure within stated follow up period = See last box Cure with 1 infusion alone = No diarrhoea 30 days 101/120; no diarrhoea 90 days 72/92. Total follow up period = Median follow up 141 days (IQR 50-353 days).	Minor GI adverse events = 5 nausea, 3 abdo pain, 2 belching, 2 vomiting, 2 'food intolerance', 1 IBS Minor non-GI adverse events = 3 fever, 2 throat discomfort Serious adverse events = 1 aspiration pneumonia, 1 haemorrhage (during endoscopy - no details), 1 loss of tooth, 1 polyneuropathy, 1 weight gain > 10kg in 12 months post-FMT Deaths = 7 died during follow up, 2 within 90 days of FMT. In 6 cases, def not related to CDI (in one patient, recurrence of CDI 7/7 after FMT contributed to her death (but stroke described as primary cause of death)..	Selection/eligibility reported = Yes Consecutively recruited = Not clear Prospectively recruited = No Loss to follow up explained = No At least 90% followed up = Yes

Additional Appendices

Hamilton et al American Journal of Gastroenterology 2012	Case series Number of patients = 43 Male: 12; Female: 31 Age(mean/median) = 59+/-21 Comorbidities = 14 IBD CDI features = recurrent CDI diagnosis confirmation =toxin positive with at least two subsequent recurrences Pre-FMT antibiotics = all had vancomycin, 17 patients had addition of vancomycin and 2 weeks of rifaximin (one of these 17 had 4 weeks of rifaximin) 3/43 took 2-4 weeks of nitazoxanide	Donors were 6 related, 2= spouse,2=friends rest unrelated ultimately 30/33 were universal and 3 were patient selected. Working in healthcare = ns Donor demographics = ns Donor screening: Questionnaire = Before recruitment, the donors were required to submit available medical records and have a separate medical history interview away from the recipient patient. The history included assessment of infectious risk, including identification of known risk factors for HIV and Hepatitis, current communicable diseases, and recent travel to areas of the world with a higher prevalence of diarrheal illnesses Travel and antibiotic exclusion peroid = recent travel to areas where high prevelence of diarrheal illness (not specified) Screening bloods = HIV,HEBB/C Screening stools = c.diff, ova, parasites, diardia, cryptosporidium	Amount of stool per transplant / administered to patients = 50g Diluent used to prepare = 250ml sterile, non-bacteriostatic normal saline Diluent used to store if frozen = 10% glycerol Preparation methods = related stool was oassed through stainless steel tea strainers , stool from universal donors was transported on ice to the lab, and processed within 2h. Material was weighed and homogenised in commercial blender uner N2 gas. Slurry then passed through 2.0,1.0.0.5 and 0.25mm stainless steel lab sieves. resulting material then cetrifuged at 6000g for 15m and resuspended to one-half the original vulmine in normal saline Time from preparation to transplant (fresh) = 1-2h Time period for storage (frozen) = 1-8 weeks Route administered: Upper GI = 0 (0) Lower GI = majority into TI or caecum with a small proportion into colonic areas (43) Number of infusions = 1=37, 2=6 Bowel purgative = yes golytely or moviprep PPI = no Antimotility = no Prokinetics = no Time before CDI treatment was stopped before FMT = 2 days.	Overall cure within stated follow up period = 95% within 2 months follow-up Cure with 1 infusion alone = 86%% Total follow up period = 2 months follow FMT and 3 months in one patient.	Minor GI adverse events = 1/3rd reported flatulance and excessiive bowel movements follwoing procedure Minor non-GI adverse events = none Serious adverse events = none Deaths = none.	Selection/eligibility reported = yes Consecutively recruited = yes Prospectively recruited = yes Loss to follow up explained = no At least 90% followed up = yes

Additional Appendices

Hefazi et al, 2017, Mayo Clinic Proceedings	Case series Number of patients = 23 Male: 10; Female: 13 Age(mean/median) = Median 66 years (range 23-88). Comorbidities = 13 patients had haematological malignancy (4 DLBCL, 2 Hodgkin's lymphoma, 1 CML, 1 follicular lymphoma, 1 stage IV cutaneous T cell lymphoma, 1 B cell ALL, 1 hairy cell leukaemia, 1 CLL, 1 severe aplastic anaemia); 1 with active disease at time of FMT, 2 with recent chemotherapy use, 2 with neutropenia within 12 weeks prior to FMT. 10 patients with solid organ malignancy (4 breast, 2 anal, 1 colon, 1 pancreatic, 1 tonsillar, 1 non-small cell lung. 5 with metastasis at time of FMT, 3 recent chemotherapy use, 1 with recent neutropenia. Other comorbidities include 1 x COPD, 1 x ESRF on haemodialysis, 1 GvHD on	Donors = Fresh stool from family/ friends in 10 patients, frozen stool from standard donors in 13 patients. Working in healthcare = NS Donor demographics = NS Donor screening: As per Patel et al, 2013. Travel and antibiotic exclusion peroid = As per Patel et al, 2013. Screening bloods = As per Patel et al, 2013. Screening stools = As per Patel et al, 2013.	Amount of stool per transplant / administered to patients = Approximately 50g. Diluent used to prepare = 250ml normal saline. Diluent used to store if frozen = NS Preparation methods = As per Patel et al, 2013. Time from preparation to transplant (fresh) = Not defined. Time period for storage (frozen) = Not defined. Route administered: Upper GI = 0 (0) Lower GI = 23 colonoscopy into caecum. Number of infusions = 1 Bowel purgative = NS PPI = NS Antimotility = NS Prokinetics = NS Time before CDI treatment was stopped before FMT = 24 hours.	Overall cure within stated follow up period = 11/12 of haematological malignancy patients (other patient died), 8/10 solid malignancy patients. Cure with 1 infusion alone = 19/22 by primary outcome criteria Total follow up period = 1 CLL patient recurred at 22 months post-FMT in context of ibrutinib and coamoxiclav; successfully treated with 10 days of MTZ. 1 tonsillar cancer patient recurred at 14 months after exposure to cefalexin; successfully treated with 10/7 vanc then 10/7 fidaxo. (In all - 10 more chemo and 8 more abx after FMT).	Minor GI adverse events = 3 x chronic diarrhoea for at least 6/12 (despite negative C diff lab tests), transient diarrhoea in 8, abdominal cramps in 3, faecal urgency in 2, constipation in 2, nausea in 1. Minor non-GI adverse events = none Serious adverse events = none Deaths = 1 death after cardiac arrest of Hodgkin patient at day 5 (multiple medical comorbs thought likely cause, not FMT); 2 deaths at > 60 days related to the underlying malignancy progressing.	Selection/eligibility reported = yes Consecutively recruited = yes Prospectively recruited = no Loss to follow up explained = yes At least 90% followed up = yes

	immunosuppression, 1 granulomatosis with polyangiitis on immunosuppression, 1 hypogammaglobulinaemia on IVIg, 1 inflammatory arthritis on corticosteroids. CDI features = recurrent CDI diagnosis confirmation =Not explicitly defined, but definitions of recurrent, severe and complicated CDI as per American College of Gastroenterology Pre-FMT antibiotics =all additional vancomycin until 24hrs prior to FMT. Median of 2.5 standard treatment courses per patient (defined as at least ten days of metronidazole, vancomycin or fidaxomicin), 1 previous vancomycin taper, and four total treatment courses for CDI).					

Additional Appendices

Hirsch et al BMC Infectious Diseases 2015	Case series Number of patients = 19 Male: 6; Female: 13 Age(mean/median) = 26-92 mean 61 Comorbidities = 3 AF, htn 8,cardiomyopathy 1, Coronary artery disease 2, Diebetes 2, hypothyroid,2,PCOS1, thyroid nodule1, obesity 2, chrnic pan2, IBS 3, divertic 1, lymphoma 1, AML1, renal ca1, psoriasis1 dementia 3, parkinsons 1, stroke 1, chronic pain 3,anxiety 1, depression 2, asthma 2 Chronic renal failure 1, CDI features = refractory and recurrent (2 or more episodes) CDI diagnosis confirmation =ns Pre-FMT antibiotics = metronidazole, vancomycin +/or fidaxomicin	Donors were 3 unrelated. Working in healthcare = ns Donor demographics = exluded if-BMI>25, diabetes, psychiatric hz, IBD, IBS, Donor screening: Questionnaire = standarrd questionnaire-not specified Travel and antibiotic exclusion peroid = travel outside the USA excluded 30 days prior Screening bloods = HIV, HEP A, B,C, Treponema, syphilis, HTLV-1 Screening stools = C.diffe,campylobacter,salmonella, shigella, campylobacter, e.coli, Yersinia, vibrio,aeromonas, plesiomonas,	Amount of stool per transplant / administered to patients = 2.3g Diluent used to prepare = 350ml in 0.9% nacl Diluent used to store if frozen = 15% glycerol Preparation methods = strict environmental contol <6 hrs after defecation. All sterile, wet weight of stool was homogenised in 350ml 0.9% nacl and liquoted, samples then centrifudged at 200g for 10 mins. supernatent decated and centrifuged at4600g for 15mins. supernatant removed and re-suspended in 0.9% nacl with glycerol. typical concentration was 0.5g/ml.Resulting FMT slurry was put in 5-10ml syringes and frozen at -80 Time from preparation to transplant (fresh) = frozen Time period for storage (frozen) = 1-3 weeks Route administered: Upper GI = 0 (0) Lower GI = 0 (0) Number of infusions = 8-12 capsules (one only took 6) Bowel purgative = no PPI = yes evening and morning of procedure Antimotility = no Prokinetics = yes encouraged to drink 4 ounces of Kefir fermented mild BD and a list of probiotics to consume for 3 days Time before CDI treatment was stopped before FMT = day prior to FMT.	Overall cure within stated follow up period = see previous Cure with 1 infusion alone = 13(68%) 90 days Total follow up period = primary outcome 90 days secondary 6 weeks after this.	Minor GI adverse events = abdominal pain 5 (4 self resolved one required opiates and was hospitalised) Minor non-GI adverse events = none Serious adverse events = none Deaths = 1- died from respiratory failure after failing FMT treatment.	Selection/eligibility reported = yes Consecutively recruited = Not clear Prospectively recruited = no Loss to follow up explained = no At least 90% followed up = yes

Additional Appendices

Ianiro et al Clinical Microbiology and Infection 2017	Case series Number of patients = 64 Male: 25; Female: 39 Age(mean/median) = mean 74 Comorbidities = not reported CDI features = 65 Recurrent CDI- all patients had 3 recurrences on average range (2-6) CDI diagnosis confirmation =defined using the escmid guidelines Pre-FMT antibiotics = metronidazole, vancomycin or fidaxomicin	Donors were 36 unrelated and 28 from related. Working in healthcare = no Donor demographics = not mentioned Donor screening: Questionnaire = questionnaire containing possible risk factors for potentially transmittable diseases due to their medical history and lifestyle habits. The donors could not have taken antibiotics in the previous 6 months or exhibited significant intestinal symptoms of other intestinal diseases. Travel and antibiotic exclusion period = less 3 months Screening bloods = hepatitis A, B and C, antibodies to HIV-1 and -2,Epstein–Barr virus, Treponema pallidum, Strongyloidesstercoralis and Entamoeba histolytica. Blood cell countsand measurements of transaminase, C-reactive protein,albumin and creatinine Screening stools = C. difficile (culture and toxin),enteric bacteria, protozoa and helminths of the large andsmall bowel, VRE (vancomyc in-resistant Enterococci),MRSA (methicillin-resistant Staphylococcus aureus), and Gram-negative MDR (multi-	Amount of stool per transplant / administered to patients = not reported Diluent used to prepare = 500ml of saline 0.9% Diluent used to store if frozen = fresh Preparation methods = after dilution the solution was blended and supernatant strained and poured into sterile container Time from preparation to transplant (fresh) = 6 hrs Time period for storage (frozen) = not specified Route administered: Upper GI = 0 (0) Lower GI = 64 (0) Number of infusions = 44=1, 20 had multiple (undefined) Bowel purgative = 4l macrogol on last 1 or 2 days of antibiotcs treatment PPI = no Antimotility = not reported Prokinetics = not reported Time before CDI treatment was stopped before FMT = FMT given on last 1 or two days of CDI treatment.	Overall cure within stated follow up period = 97% at 8 weeks Cure with 1 infusion alone = 44/64 (69%) Total follow up period = 8 weeks.	Minor GI adverse events = not reported Minor non-GI adverse events = not reported Serious adverse events = no reported Deaths = not reported.	Selection/eligibility reported = yes Consecutively recruited = yes Prospectively recruited = yes Loss to follow up explained = yes At least 90% followed up = yes

		drug-resistant) bacteria.				

Additional Appendices

Kassam et al Archives of Internal Medicine 2012	Case series Number of patients = 27 Male: 14; Female: 13 Age(mean/median) = 69.4 years (mean) Comorbidities = Not reported CDI features = Both CDI diagnosis confirmation =Inclusion criteria were (1) laboratory-confirmed C difficile toxin using enzyme immunoassay with no other cause for diarrhea; (2) refractory CDI (defined as ongoing diarrhea despite antimicrobial treatment) or recurrent CDI (defined as symptom resolution for at least 2 days after discontinuation of treatment with recurrence of diarrhea); Pre-FMT antibiotics = All had at least metronidazole; 19 had subsequent vancomycin monotherapy. 8 had combination metronidazoleand vancomycin therapy.	Donors were Two healthy volunteers. Working in healthcare = Not specified Donor demographics = Not reported Donor screening: Questionnaire = Not explictly reported Travel and antibiotic exclusion peroid = 6 months antibiotic exclusion. Screening bloods = Blood was screened for hepatitis B surface antigen, hepatitis C antibody, Helicobacter pylori and syphilis serologic markers, human immunodeficiency virus types 1 and 2, and human T-lymphotropic virus types I and II. Screening stools = Stool was processed for enteric bacterial pathogens, C difficile toxin, and ova and parasites.	Amount of stool per transplant / administered to patients = 150g of stool Diluent used to prepare = 300mls sterile water Diluent used to store if frozen = NA Preparation methods = Not reported Time from preparation to transplant (fresh) = Not reported Time period for storage (frozen) = NA Route administered: Upper GI = () Lower GI = (27 via retention enema) Number of infusions = 22 -1, 5 - 2 Bowel purgative = No PPI = No Antimotility = No Prokinetics = No Time before CDI treatment was stopped before FMT = At least 24 hours before.	Overall cure within stated follow up period = NA Cure with 1 infusion alone = 22/27 (81%) Total follow up period = Mean follow-up at 427.3 days after transplant. .	Minor GI adverse events = Not reported Minor non-GI adverse events = Not reported Serious adverse events = Not reported Deaths = Not reported .	Selection/eligibility reported = Yes Consecutively recruited = yes Prospectively recruited = no Loss to follow up explained = No At least 90% followed up = yes

Additional Appendices

Kelly et al Journal of Clinical Gastroenterology 2012	Case series Number of patients = 26 Male: 2; Female: 24 Age(mean/median) = 59 years (mean) Comorbidities = CDI features = CDI diagnosis confirmation =Method of CDI diagnosis not stated;mean duration of diagnosis of CDI prior to FMT 12.6 M (range 4 to 84 M); Pre-FMT antibiotics = clind, cipro, metro, moxiflox, levoflox, azithro, cefurox, amox, augmentin; treatment for CDI-all had metronidazole, Sacchromyces bourladii, 4 had lactobacillus, 2 had IV IG, 19 had had rifaximin; pre-FMT all had 2 weeks of metronidazole or vanc, discontinued 2-3 days before FMT	Donors were 25/26 family members; 1 friend. Working in healthcare = No Donor demographics = Donor screening: Questionnaire = Travel and antibiotic exclusion peroid = No antibiotics for preceeding 90 days Screening bloods = blood for HAV, HBV, HCV, HIV 1&2, trepenoma pallidum Screening stools = stool for culture for bacteria, stain for ova and parasites, C. diff. toxin A and B	Amount of stool per transplant / administered to patients = "6=8 tablespoons of donor stool" Diluent used to prepare = 1litre of sterile water passed through gauze. Aliquoted in 60ml syringes. Diluent used to store if frozen = NA Preparation methods = Time from preparation to transplant (fresh) = 6 hours prior to transplant Time period for storage (frozen) = NA Route administered: Upper GI = () Lower GI = 26 via colonoscopy () Number of infusions = not explicitly stated but imples single infusion for all patients Bowel purgative = polyethelene glycol bowel prep night before transplant PPI = Antimotility = Prokinetics = Time before CDI treatment was stopped before FMT = .	Overall cure within stated follow up period = Cure with 1 infusion alone = 24/26 (92.3%) Total follow up period = follow up mean 10.7 months ranged from 2-30 months.	Minor GI adverse events = mild diarrhoea post FMT in 3 patients Minor non-GI adverse events = No Serious adverse events = No Deaths = No.	Selection/eligibility reported = Yes Consecutively recruited = Yes Prospectively recruited = Yes Loss to follow up explained = Yes At least 90% followed up = Yes

Additional Appendices

Kelly et al American Journal of Gastroenterology 2014	Case series Number of patients = 80 Male: 38; Female: 42 Age(mean/median) = ((75 adults ,5 children)mean age adults 53 years range (20-88) mean age paediatrics 10.9 (range 6.5–16) Comorbidities = 36 IBD, 19 solid organ transplant 3 HIV/AIDS, 7 Cancer, 4RA, 1 adrenal insufficiency 6 Cirrhotics, 1 esrf,1 panhypopituatarism, 1 endstage copd,i esrd on hd and allograft failure 1 sjogens CDI features = 9 (11%) refractory 44(55%) recurrent CDI diagnosis confirmation =https://www.nature.com/ajg/journal/v108/n4/full/ajg20134a.html NOT CLEAR BUT AS PER AMERICAN GUIDELINES Pre-FMT antibiotics = vancomycin 67 (84%),fidaxomicin 23 (29%), rifaximin 13 (16%), metronidazole 955 69%)	Donors were not mrntiond. Working in healthcare = not mentioned Donor demographics = not mentioned Donor screening: Questionnaire = not reported Travel and antibiotic exclusion peroid = Not reported Screening bloods = not reported Screening stools = Not reported	Amount of stool per transplant / administered to patients = Not reported Diluent used to prepare = Not reported Diluent used to store if frozen = not reported Preparation methods = not reported Time from preparation to transplant (fresh) = Not reported Time period for storage (frozen) = Not reported Route administered: Upper GI = not specified (not specified) Lower GI = not specified (not specified) Number of infusions = 62 (78%) had single, twelve(15%) had multiple Bowel purgative = ns PPI = ns Antimotility = ns Prokinetics = ns Time before CDI treatment was stopped before FMT = ns.	Overall cure within stated follow up period = 89% within a minimum of 12 weeks Cure with 1 infusion alone = 62(78%) Total follow up period = 12 weeks post FMT.	Minor GI adverse events = 3 self limiting diarrhea, 3 bloating and abdo discomord, 1 CD flaire 1 nausea 1 minor mucosal tear at colonoscopy Minor non-GI adverse events = 1 fever, 1 hip pain, 1 petussis Serious adverse events = see next box Deaths = 2 deaths (1 pneumonia and 1 aspiration), 10 hospitalization (1 for fever encephalopathy and pancytopenia,1 abdo pain post FMT, 3 IBD flairs (2CD 1UC), 1 CVA, 1 colectomy, 1 fall and sustained hip fracture, 1 influenxa b and diarrhea, 1 catheter infection.	Selection/eligibility reported = yes Consecutively recruited = no Prospectively recruited = no Loss to follow up explained = yes At least 90% followed up = yes

Additional Appendices

Khoruts et al Clinical Gastroenterology & Hepatology 2016	Case series Number of patients = 272 Male: 83; Female: 189 Age(mean/median) = Mean 57.2+/-19.2 years; median 59.0 (range 16-100 years) Comorbidities = 10 dialysis, 22 established Crohns, 21 established UC, 15 lymphocytic colitis, 5 diagnosed CD during colonoscopy for FMT, 1 diagnosed UC during colonoscopy for FMT, 14 newly diagnosed lymphocytic colitis. 13 reclassified in terms of IBD 8 solid organ recipients, 30 patients in non-IBD arm with biologics (anti-TNF, rituximab), immunomodulators (MTX, purine analogues), and corticosteroids. CDI features = All patients had at least 2 spontaneous relapses of CDI following initial episode, defined as recurrence within 3 months of discontinuation of anti-CDI abx treatment in	Donors were As per Hamilton paper. Working in healthcare = As per Hamilton paper Donor demographics = As per Hamilton paper Donor screening: Questionnaire = As per Hamilton paper Travel and antibiotic exclusion peroid = As per Hamilton paper Screening bloods = As per Hamilton paper Screening stools = As per Hamilton paper	Amount of stool per transplant / administered to patients = As per Hamilton paper Diluent used to prepare = As per Hamilton paper Diluent used to store if frozen = As per Hamilton paper Preparation methods = As per Hamilton paper Time from preparation to transplant (fresh) = As per Hamilton paper Time period for storage (frozen) = As per Hamilton paper Route administered: Upper GI = () Lower GI = colonoscopy (272) Number of infusions = One routinely, more than one if required - specific criteria not defined. Bowel purgative = Yes - all had purgative 1/7 prior to procedure (see Hamilton paper) PPI = See Hamilton paper Antimotility = See Hamilton paper Prokinetics = See Hamilton paper Time before CDI treatment was stopped before FMT = 42773.	Overall cure within stated follow up period = Noted that 3 patients with IBD technically counted as successes in clearing CDI within 2/12 of FMT had spontaneous relapse without abx provocation within 6/12. Cure with 1 infusion alone = 74.4% in those with IBD whilst 92.1% in those without Total follow up period = 42898.	Minor GI adverse events = Not described Minor non-GI adverse events = Not described Serious adverse events = 11/43 of IBD patients diagnosed with FMT-related flare. Two patients hospitalised with IBD flare within 2 months of FMT. Clearance of CDI by FMT generally assocaited with improved control of IBD over the long term. 6 patients struggled with IBD despite optimisation of immunosuppressive Rx, 3 of whom underwent colectomies; ?=patients with IBD colonised with C diff rather than main driver. Deaths = Not described.	Selection/eligibility reported = Yes Consecutively recruited = Yes Prospectively recruited = No Loss to follow up explained = Yes At least 90% followed up = Yes

	conjunction with diarrheal sx . CDI diagnosis confirmation =Positive stool testing within 2 months of FMT - not clearly defined. Pre-FMT antibiotics = 206 MTZ, 270 vanc, 69 fidaxomicin, 71 rifaximin, 104 probiotics					

Additional Appendices

Lagier et al European Journal of Clinical Microbiology and Infectious Diseases 2015	Case series Number of patients = 61 Male: 21; Female: 40 Age(mean/median) = Mean 84 years (66-101) Comorbidities = No specific details CDI features = Some patients refractory/ recurrent; some during first CDI CDI diagnosis confirmation =PCR that detects tox and B genes, and tox C gene deletion that characterises 027. Pre-FMT antibiotics = Patients divided into 'tardive transplant' (i.e. only after 3xabx failures) or 'early transplant' (during first week of infection during first dx, accompanied by abx). Abx were for non-severe disease: mtz po tds 14/7, then vanc 125mg qds 14/7, then fidax 200mg bd 10/7; for severe disease (defined as AKI, paralytic ileus, or peritoneal fluid), used vanc and mtz for primary infection, then fidax if relapse/ failure	Donors were Preferentially used healthy family members, also used healthy volunteer students and residents. Working in healthcare = Yes - some residents Donor demographics = BMI<30, exclude active cancer, diarrhoea, current immunosuppressive drugs, abx within 3/12. Donor screening: Questionnaire = See last box. Travel and antibiotic exclusion peroid = Abx within 3/12 Screening bloods = HIV, HAV, HBV, HEV, HCV, active CMV, active EBB, TPHA-VDRL, HTLV Screening stools = Bacteria, parasites, toxigenic C diff'	Amount of stool per transplant / administered to patients = >30g Diluent used to prepare = Whole stool mixed with 400ml N/saline, homogenised for 10 mins Diluent used to store if frozen = Fresh Preparation methods = 10 mins of homogenisation in blender, filtered, put into a syringe at room temperature. Time from preparation to transplant (fresh) = <6hrs Time period for storage (frozen) = N/A Route administered: Upper GI = NG (61) Lower GI = () Number of infusions = In early FMT arm - one FMT routine; but offered 2nd FMT if relapse Bowel purgative = 4l Klean Prep/ two glasses of Fast Prep day before FMT PPI = No - but used 200ml 1.4% bicarb 15 mins before FMT Antimotility = N/A Prokinetics = Not mentioned Time before CDI treatment was stopped before FMT = Not stated.	Overall cure within stated follow up period = Global death rate of 3/16 in early transplant arm (day 20, day 37, day 166), 2/3 treated by tardive transplant (day 28, day 54). None of these patients died with evidence of CDI. Cure with 1 infusion alone = 1/3 treated by tardive FMT dead at day 31; 1/16 treated by early FMT dead at day 31 Total follow up period = No details on absolute length of follow up.	Minor GI adverse events = 24 diarrhoea (resolved d1), one nausea Minor non-GI adverse events = N/A Serious adverse events = 1 acute heart failure - no details Deaths = 3/16 in early transplant (vs 29/45 treated by abx only or tardive transplant). No sign of CDI at time of death (days 20, 37, 166)..	Selection/eligibility reported = Yes Consecutively recruited = No - not clearly stated Prospectively recruited = No Loss to follow up explained = Yes At least 90% followed up = Yes

Additional Appendices

Lee et al European Journal of Clinical Microbiology and Infectious Diseases 2014	Case series Number of patients = 94 Male: 41; Female: 53 Age(mean/median) = Mean 71.8 years, range 24-95 Comorbidities = Three IBD, 3 post-renal transplant, no specific details given CDI features = Some patients refractory (defined as ongoing diarrhea depsite Rx with at least 5 days of vanc po 125mg qds), or reccurent (symptom resolution for at least 2/7 after the discontinuation of Rx with recurrence of diarrhea). CDI diagnosis confirmation =Toxin pos by EIA or PCR Pre-FMT antibiotics = Average of 2.1 prev antiCDI abx courses prev (range 1-4), MTZ (79.3%), Vanc (75%), vanc taper (15.2%), probiotic monoRx (0.03%), concomitant MTZ/ vanc (17.4%).	Donors were Volunteers - no further details. Working in healthcare = Not specifically described Donor demographics = Not defined Donor screening: Questionnaire = Describes use of questionnaire but no details given - "similar to the Full Length Donor History Questionnaire documents (US Food and Drug administration, DHQ version 1.3, May 2008" Travel and antibiotic exclusion peroid = Not described. Screening bloods = HIV-1/-2, HTLV-1/-2, HAV IgG/M, HBsAg, HCV, Treponema pallidum Screening stools = OCP, MCS, C diff toxin, noro, adeno, rota.	Amount of stool per transplant / administered to patients = Not defined Diluent used to prepare = 300ml water Diluent used to store if frozen = N/A - fresh Preparation methods = Homogenisation of stool in water using a disposable spatula Time from preparation to transplant (fresh) = Not defined Time period for storage (frozen) = N/A Route administered: Upper GI = () Lower GI = retention enema (94) Number of infusions = No fixed number - as many as required to achieve remission. No clear definition of non-response. Bowel purgative = Not described PPI = Not described Antimotility = Not described Prokinetics = Not described Time before CDI treatment was stopped before FMT = Does not describe.	Overall cure within stated follow up period = At 6 months - 81 in remission after FMT, 5 in remission after FMT-abx-FMT, 8 non-responders Cure with 1 infusion alone = 45/94 with single FMT in remission at 6 months Total follow up period = 42898.	Minor GI adverse events = "10% experienced transient constipation and excess flatulence post-FMT" Minor non-GI adverse events = N/A Serious adverse events = None described Deaths = 6/8 patients not responding to FMT died (not clearly when). All "over 70 years of age", with multiple underlying signif comorbs, and passed away due to critical illnesses; none had deaths attributable to FMT or directly due to CDI. .	Selection/eligibility reported = Yes Consecutively recruited = Yes Prospectively recruited = No Loss to follow up explained = Yes At least 90% followed up = Yes

Additional Appendices

MacConnachie et al QJM 2009	Case series Number of patients = 15 Male: 1; Female: 14 Age(mean/median) = 81.5 median (range 68-95 years) Comorbidities = CDI features = CDI diagnosis confirmation =Not defined Pre-FMT antibiotics = All previous MTZ and vanc; 3 patients tapering vanc and IgG	Donors were: healthy related volunteers Working in healthcare = yes 3 where relatives could not be identified Donor demographics = not described Donor screening: = HIV-1/-2, HTLV-1/-2, HAV IgG/M, HBsAg, HCV, Treponema pallidum Questionnaire = not specified Travel and antibiotic exclusion peroid = not specified Screening stools = OCP, MCS, C diff toxin.	Amount of stool per transplant administered to patients = 30g or 2cm Diluent used to prepare = 0.9% nacl Diluent used to store if frozen = not applicable Preparation methods = stool sample less than 6 hours,add 50-70 ml of Nacl 0.9%, homogenise with handheld stool blender,gradually advance speed, continue for 2-4 mins until smooth, filter suspension in coffee filter paper Time from preparation to transplant (fresh) = 6 hrs Time period for storage (frozen) = not applicable Route administered: Upper GI = 18 Lower GI = 0 Number of infusions = 1 per patient assumed Bowel purgative = none given PPI = omeprazole 20mg eve before and on morning Antimotility = not given Prokinetics = not given Time before CDI treatment was stopped before FMT = Stopped evening before	Overall cure within stated follow up period = 15/18 (84%) “resolution Cure with 1 infusion alone = 84% Total follow up period = 90 days	Minor GI adverse events = 1 diarrhoea Minor non-GI adverse events =0 Serious adverse events = 0 Deaths =2 (felt not related) .	Selection/eligibility reported = yes Consecutively recruited = yes Prospectively recruited = yes Loss to follow up explained = yes At least 90% followed up = yes

Additional Appendices

Mattila et al Gastroenterology 2012	Case series Number of patients = 70 Male: 28; Female: 42 Age(mean/median) = Mean 73 (range 22-90 years) Comorbidities = No IBD, one adenoCa of colon diagnosed during colonoscopy for FMT CDI features = Mean of 3.5 prev episodes of CDI pre-FMT (range 1-12) CDI diagnosis confirmation =Positive culture and toxin Pre-FMT antibiotics = Mixture of MTZ, vanc, rifaximin - no patient-level data	Donors were 61 donors were close relatives/ other household members; in 9 cases, healthy volunteers. Working in healthcare = Not defined Donor demographics = No given age or BMI limits Donor screening: Questionnaire = "No abx and no intestinal sx within 6 months" Travel and antibiotic exclusion peroid = No abx past six months; no details re travel Screening bloods = HBsAg, HCV Ab, HIV-1/-2 Ab, Treponema pallidum plasma reagin test; total blood count, CRP, creatinine, liver enzymes Screening stools = C diff culture/ tox A/ B; MCS; OCP	Amount of stool per transplant / administered to patients = 20-30ml stool Diluent used to prepare = 100-200ml water; 100ml of suspension administered to caecum Diluent used to store if frozen = N/A - all fresh Preparation methods = N/A/ Time from preparation to transplant (fresh) = 6 hours Time period for storage (frozen) = N/A Route administered: Upper GI = () Lower GI = colonoscopy (70) Number of infusions = One Bowel purgative = 4l PEG (Colonsteril) PPI = No Antimotility = No Prokinetics = No Time before CDI treatment was stopped before FMT = Average of 36 hours.	Overall cure within stated follow up period = 4 of those with initial remission had relapse after receiving abx for unrelated cause; two successfully treated with 2nd FMT, 2 successfully Rxed with abx. Of 4 patients not responding to initial FMT - all 4 had 027 and other serious illness and died 1.5 - 3/12 after FMT. Cure with 1 infusion alone = 66/70 (34/34 of those with non-027, 32/36 with 027) Total follow up period = 1 year.	Minor GI adverse events = N/A Minor non-GI adverse events = N/A Serious adverse events = N/A Deaths = 4 patients infected with 027 did not respond to FMT and died within 3/12. 10 other patients died of 'unrelated illnesses' during one year f/u. .	Selection/eligibility reported = Yes Consecutively recruited = Not clear Prospectively recruited = No Loss to follow up explained = Yes At least 90% followed up = Yes

Additional Appendices

Meighani et al European Journal of Gastroenterology and Hepatology 2016	Case series Number of patients = 201 Male: 76; Female: 125 Age(mean/median) = Mean age 66.6+/-18.3 years Comorbidities = 37 cancer, 30 immunosuppressed, 26 CKD. Immunosuppressed defined as chemo wihtin 1 yr of FMT, HIV with CD4 < 200, or pred use greater than or equal to 20mg for more than 1 month. CDI features = 61 with refractory, 140 with recurrent CDI diagnosis confirmation =Positive toxin or PCR Pre-FMT antibiotics = Not defined	Donors were Not defined. Working in healthcare = Not defined Donor demographics = Not defined Donor screening: Questionnaire = Not defined Travel and antibiotic exclusion peroid = Not defined Screening bloods = Not defined Screening stools = Not defined	Amount of stool per transplant / administered to patients = Not defined Diluent used to prepare = Not defined Diluent used to store if frozen = Not defined Preparation methods = Not defined Time from preparation to transplant (fresh) = Not defined Time period for storage (frozen) = Not defined Route administered: Upper GI = NG (+5 through PEG) (76) Lower GI = 45 enema, 75 colon () Number of infusions = Some people received multiple FMT procedures- repeat FMTs within 90 days of previous FMT were still maintained as a 'single infection unit'. Bowel purgative = Not described PPI = Not described Antimotility = Not described Prokinetics = Not described Time before CDI treatment was stopped before FMT = 24hr - not specifically stated as antiCDI Rx.	Overall cure within stated follow up period = See previous. Cure with 1 infusion alone = Overall response rate of 176/201 Total follow up period = Each patient for 90 days.	Minor GI adverse events = Not described Minor non-GI adverse events = Not described Serious adverse events = Not described Deaths = 18 deaths in cohort but not timeframe not defined; not clear if any related to FMT. Describe mortality rate of 6.25% in response group, 28% in failure rate..	Selection/eligibility reported = Yes Consecutively recruited = Yes Prospectively recruited = No Loss to follow up explained = Yes At least 90% followed up = Yes

Additional Appendices

Meighani et al Dig Dis Sci 2017	Case series Number of patients = 201 Male: 77; Female: 124 Age(mean/median) = Mean 68.79+/-16.78 years for 181 non-IBD patients, mean 46.9+/-19.97 for the 20 IBD patients Comorbidities = 13/20 IBD patients immunosuppressed (no further details); no further specific details about immunosuppression. CDI features = Recurrent 13/20 of IBD patients, primary refractory 7/20. 1.90+/- 1.02 CDI infections in past three months for IBD patients, 1.79+/-1.17 CDI infections in past three months for non-IBD CDI diagnosis confirmation =GDH first, then toxin A and B; PCR used if discordance Pre-FMT antibiotics = Not defined for non-IBD; for IBD, 15 vanc alone, 5 vanc and po mtz.	Donors were Overally - typically family members, but small number of unrelated universal donors. Amongst IBD cohort - 6 patients had family members as donor, universal donor in other 14. Working in healthcare = Not defined Donor demographics = Not defined Donor screening: Questionnaire = Not defined Travel and antibiotic exclusion peroid = Not defined Screening bloods = Not defined Screening stools = Not defined	Amount of stool per transplant / administered to patients = Not defined Diluent used to prepare = Not defined Diluent used to store if frozen = Not defined Preparation methods = Not defined Time from preparation to transplant (fresh) = Not defined Time period for storage (frozen) = Not defined Route administered: Upper GI = 5 NG (IBD patients only; not described re non-IBD patients) (5) Lower GI = 13 colonoscopy (IBD patients only; not described re non-IBD patients); 2 retention enema (IBD patients only; not described re non-IBD patients) (15) Number of infusions = Any relapse beyond 90 days was defined as 'new infection'. However, not made clear if patients given more than one FMT. Bowel purgative = Nil PPI = Not described Antimotility = Not described Prokinetics = Not described Time before CDI treatment was stopped before FMT = No specific deails.	Overall cure within stated follow up period = As per primary outcome - difficult to give more specific info than already given. Cure with 1 infusion alone = 158/181 in non-IBD, 15/20 in IBD; but 31/181 non-IBD relapse within 90 days/ 25/180 beyond 90 days, and 5/20 IBD relapse within 90 days/ 4/20 beyond 90 days. 3/5 failures in IBD arm had newly-diagnosed IBD, other had severe active disease. Total follow up period = At least 90 days.	Minor GI adverse events = None Minor non-GI adverse events = None Serious adverse events = None Deaths = None.	Selection/eligibility reported = Yes Consecutively recruited = Yes Prospectively recruited = No Loss to follow up explained = Yes At least 90% followed up = Yes

Additional Appendices

Patel et al Mayo Clinic Proceedings 2013	Case series Number of patients = 31 Male: 14; Female: 17 Age(mean/median) = Mean 61.26+/19.34 years Comorbidities = 5 diverticulosis, 5 IBS, 3 UC, 1 Crohn's, 1 gastroparesis, 1 coloanal fistula, 3 prev sigmoid surgery for diverticulitis, 2 subtotal colectomy with ileosigmoid anastomosis, 1 L/hemicolectomy with colostomy, 3 long term steroids, 2 hypogammaglobulinaemia, 1 OLT, 1 renal tx, 1 long term methotrexate CDI features = Recurrent - mean +/- SD number of confirmed relapses before FMT of 4+/-1.4 (range 2-7) CDI diagnosis confirmation =At least 3x unformed stools/d, at least 2 x toxin pos episodes previously to participate. Pre-FMT antibiotics = All 31 prev MTZ, all 31 prev vanc, 6 prev fidaxo, 10 prev rifaximin, 23 prior	Donors were Healthy family/ contacts of recipients - 14 spouses, 9 children, 5 siblings, 3 parents, 1 niece, 1 friend.. Working in healthcare = Not stated Donor demographics = No stated age/ BMI limits Donor screening: Questionnaire = Exclude if: chronic GI disease, active PUD, GORD requiring daily PPI, IBS, IBD, hx of colon polyps/ cancer, , abx or hospitalisation in past 3/12. Travel and antibiotic exclusion peroid = No stated travel; 3/12 for abx Screening bloods = HAV IgM, HBsAg, HBc IgG/M, HCV Ab, HIV-1/-2 Ab, HTLV-1/-2 AB, RPR/ syphilis EIA. Screening stools = MCS, OCP, Crpyto Ag, microsporidia smear, C diff toxin (PCR or EIA)	Amount of stool per transplant / administered to patients = Whole stool - median transplanted weight of 115g (range 18-397g) Diluent used to prepare = N/saline - "added in 100ml increments until mixture suitable for instillation through working channel of colonoscope". Median volume of FMT 360ml (range 180-900). Diluent used to store if frozen = Fresh Preparation methods = Blender/ pitcher Time from preparation to transplant (fresh) = Six hours; kept at RT until processing. Time period for storage (frozen) = N/A Route administered: Upper GI = () Lower GI = Colonoscopy (31) Number of infusions = 1 initially Bowel purgative = Yes - PEG day before PPI = N/A Antimotility = 4mg loperamide either pre or immediately after colonoscopy Prokinetics = N/A Time before CDI treatment was stopped before FMT = Abx continued until 4hr before prep (i.e. stopped day prior to FMT).	Overall cure within stated follow up period = At 3 months - 21/23 said diarrhoea no longer present; at 1 year, 6/6 reported maintained improvement or resolution Cure with 1 infusion alone = Of 29 with diarrhoea - 7 reported improvement and 22 resolution of diarrhoea by median time of 3 days Total follow up period = One year.	Minor GI adverse events = Not described Minor non-GI adverse events = Not described Serious adverse events = Microperforation - caused by biopsy of an area of presumed ischaemic small bowle injury during the FMT procedure; managed conservatively. Deaths = One death at 3/12 - directly related to recently diagnosed metastatic pancreatic Ca, not related to FMT .	Selection/eligibility reported = Yes Consecutively recruited = Yes, implied that were Prospectively recruited = No Loss to follow up explained = Yes At least 90% followed up = Yes - at least as far as primary outcome

Additional Appendices

	probiotic					

Additional Appendices

Pathak et al Clinical & Experimental Gastroenterology 2013	Case series Number of patients = 12 Male: 4; Female: 8 Age(mean/median) = Mean 71.9; range 37 - 90 years Comorbidities = 1 UC, 1 renal transplant, one L/colon adenoCa and diverticulitis; one ruptured appendix; 2 ventilator-dependent CDI features = Recurrent; full details not given. CDI diagnosis confirmation =Not specifically defined Pre-FMT antibiotics = All vanc, 8 fidaxo, 4 MTZ	Donors were Preferrably family/ first degree relatives; family used in all cases here.. Working in healthcare = Not specifically addressed. Donor demographics = Not given. Donor screening: Questionnaire = Exposure to HIV, hepatitis, STDs; high risk sexual behaviour; drug use, tattoos/ piercings, imprisonment, other high risk behaviour; known current communicable disease; GI morbidities incl IBD or GI malignancy; abx use within 90 days Travel and antibiotic exclusion peroid = Abx < 90 days Screening bloods = HIV-1/-2, hep A/B/C, STDs Screening stools = MCS, OCP, C diff tox A and B	Amount of stool per transplant / administered to patients = About 6-8 tablespoond Diluent used to prepare = 1l of tap water Diluent used to store if frozen = N/A - all fresh Preparation methods = N/A Time from preparation to transplant (fresh) = 6hrs Time period for storage (frozen) = N/A Route administered: Upper GI = Nasoduodenal tube. (1) Lower GI = colonoscopy (11) Number of infusions = 1 initially Bowel purgative = PEG the night before PPI = No Antimotility = 2 tablets diphenoxylate/ atropine post-FMT Prokinetics = N/A Time before CDI treatment was stopped before FMT = 24hr.	Overall cure within stated follow up period = 43081 Cure with 1 infusion alone = 43051 Total follow up period = 2-26 months.	Minor GI adverse events = N/A Minor non-GI adverse events = N/A Serious adverse events = N/A Deaths = 1 death - patient with perforated appendix with abx; didn't respond to 6/12 Rx for CDI. Went to ITU. Donor was husband - no screening, no response to colon FMT. Next healthy volunteer donor FMT via ND tube - responded. UTI at nursing home few months later - abx, further CDI. Septic, ITU - declined Rx, died, 4 months after initial FMT..	Selection/eligibility reported = Yes Consecutively recruited = Yes, implied that were Prospectively recruited = No Loss to follow up explained = Yes At least 90% followed up = Yes

Additional Appendices

Rohlke et al Journal of Clinical Gastroenterology 2010	Case series Number of patients = 19 Male: 2; Female: 17 Age(mean/median) = Mean age 49 Comorbidities = CDI features = recurrent CDI diagnosis confirmation =Positive C diff toxin and consistently recurring sx over a span of six months Pre-FMT antibiotics = Not given in detail - all at least three courses of conventional Rx, including pulsed and tapered vancomycin	Donors were 4 family, 14 partner, 1 housemate. Working in healthcare = NA Donor demographics = Donor screening: Questionnaire = Travel and antibiotic exclusion period = NA Screening bloods = HIV, Hep A/B/C and trepenoma serology Screening stools = Cdiff, bacterial culture, OCP, Giardia, Cryptosporidium,	Amount of stool per transplant / administered to patients = 350mls Diluent used to prepare = saline Diluent used to store if frozen = NA Preparation methods = fresh Time from preparation to transplant (fresh) = not stated Time period for storage (frozen) = NA Route administered: Upper GI = () Lower GI = all given via colonoscopy Number of infusions = 1 in 19, 2 in 1 Bowel purgative = PEG PPI = NA Antimotility = loperamide post FMT Prokinetics = NA Time before CDI treatment was stopped before FMT = 1-3 days	Overall cure within stated follow up period = 20/20 (100%) Cure with 1 infusion alone = 19/20 (95%) Total follow up period = 6 months to 5 years	Minor GI adverse events = none reported Minor non-GI adverse events = none reported Serious adverse events = none reported Deaths = none reported	Selection/eligibility reported = yes Consecutively recruited = yes Prospectively recruited = no Loss to follow up explained = variable FU At least 90% followed up = yes

Additional Appendices

Rubin et al Anaerobe 2013	Case series Number of patients = 75 Male: 26; Female: 49 Age(mean/median) = 63 median (6-94 range) Comorbidities = 10 DM, 8 malignancy, 7 steroids in prior 3 months CDI features = Not stated CDI diagnosis confirmation =Not described Pre-FMT antibiotics = Oral MTZ or vanc alone or in combination for initial FMT in all cases; not clear exact breakdown/ use for recurrences	Donors were Healthy close household member of patient. Working in healthcare = Presumed not Donor demographics = Not described Donor screening: Questionnaire = Not described Travel and antibiotic exclusion peroid = As per Aas paper Screening bloods = As per Aas paper Screening stools = As per Aas paper	Amount of stool per transplant / administered to patients = 30g of stool Diluent used to prepare = Saline - details as per Aas paper. 25ml of stool/ saline mixture per FMT Diluent used to store if frozen = N/A Preparation methods = As per Aas paper Time from preparation to transplant (fresh) = As per Aas paper Time period for storage (frozen) = N/A Route administered: Upper GI = 64 NG, 4 PEG, 7 OGD (75 administrations to 74 patients) Lower GI = () Number of infusions = One routinely Bowel purgative = Not described PPI = Evening prior to/ morning of procedure - no further details Antimotility = Not described Prokinetics = Not described Time before CDI treatment was stopped before FMT = Stopped day prior to procedure'.	Overall cure within stated follow up period = 59/75 Cure with 1 infusion alone = 59/75 Total follow up period = Up to 60 days.	Minor GI adverse events = No Minor non-GI adverse events = No Serious adverse events = No Deaths = No - up to 60 days.	Selection/eligibility reported = Yes Consecutively recruited = Yes Prospectively recruited = No Loss to follow up explained = Yes At least 90% followed up = Yes

Additional Appendices

Satokari et al Alimentary Pharmacology and Therapeutics 2015	Case series Number of patients = 49 Male: 15; Female: 34 Age(mean/median) = Overall with fresh: mean 52(22-81 range) years; frozen: 61(20-88 range) years Comorbidities = Not described in significant details CDI features = Recurrent - mean 4.6 (range 2-12) relapses in fresh, mean 4.9 (range 1-6) relapses in frozen CDI diagnosis confirmation ="Positive culture and toxin" Pre-FMT antibiotics = Describes using vanc with all, but no specific details	Donors were 15 fresh FMT with individual donor, 11 fresh FMT with universal donor, 23 frozen FMT with universal donor. Working in healthcare = Not stated Donor demographics = No clear age or BMI limits Donor screening: Questionnaire = "No abx in past six months and no intestinal sx" Travel and antibiotic exclusion peroid = No abx in past six months. Screening bloods = Total blood count, CRP, creatinine, LFTs, HBV, HCV, HIV-1/-1, Treponema. Screening stools = C diff culture and tox A/B test, MCS, OCP	Amount of stool per transplant / administered to patients = Fresh - approx 30g of stool Diluent used to prepare = Fresh - approx 150ml of tap water Diluent used to store if frozen = Frozen - 30g of stool added to 150ml N/saline, then glycerol added to final [] of 10%, followed by quick spatula mix, then freezing at -80 degrees. Preparation methods = As described. Time from preparation to transplant (fresh) = Fresh - less than 6 hours between delivery and admin; less than 15 mins between making FMT and delivery. Time period for storage (frozen) = Up to 16 weeks; thawed over 4-5 hrs at room temp or in 37 degree water bath Route administered: Upper GI = () Lower GI = colonoscopy (49) Number of infusions = Bowel purgative = 4l Colonsteril PEG/ 2l MoviPrep PPI = Not described Antimotility = Not described Prokinetics = not described Time before CDI treatment was stopped before FMT = Stopped at an average of 36 hrs prior to administration.	Overall cure within stated follow up period = Cure with 1 infusion alone = Total follow up period = .	Minor GI adverse events = N/A Minor non-GI adverse events = Mild transient fever in two patients with frozen FMT. Serious adverse events = N/A Deaths = One fresh faeces patient died within one year of FMT - not related; two frozen patients had relapse within one year, both Rx abx - one died CDI, one died of arterial thrombsosi. .	Selection/eligibility reported = Consecutively recruited = Prospectively recruited = Loss to follow up explained = At least 90% followed up =

Additional Appendices

Yoon et al Journal of Clinical Gastroenterology 2010	Case series Number of patients = 12 Male: 3; Female: 9 Age(mean/median) = Mean age 66 years (range 30 - 86 years) Comorbidities = 0 IBD, 0 CLD, 9 with diverticulosis (with 2 of these having diverticulitis as index infection) CDI features = 1 with first CDI, 2 with 2nd, 5 with 3rd, 1 with 4th, 1 with 5th, 1 with 6th, 1 with 8th CDI diagnosis confirmation =Toxin testing for either toxin A or B, or assessment of both via EIA Pre-FMT antibiotics = 12 had oral MTZ, 3 had IV MTZ, 12 had oral vanc, 4 x rifaximin, no mention of fidaxomicin	Donors were Spouses/ partners as 8/12; one son, two daughters, one granddaughter.. Working in healthcare = No Donor demographics = No details Donor screening: Questionnaire = No details Travel and antibiotic exclusion peroid = No details given Screening bloods = HBV, HCV, HIV Screening stools = C difficile toxin, enteric pathogens, OCP - at treating clinician's discretion	Amount of stool per transplant / administered to patients = Stool (unclear how much) mixed with 1l normal saline; approx 250-450cc of FMT administered in total. Diluent used to prepare = Normal saline Diluent used to store if frozen = N/A Preparation methods = Manually shaken then filtered through gauze. Time from preparation to transplant (fresh) = No details Time period for storage (frozen) = N/A Route administered: Upper GI = (N/A) Lower GI = 10-20cc of FMT administered every 5-10cm of withdrawal distance. (12) Number of infusions = Single Bowel purgative = All colonoscopic, but no specific details given PPI = No Antimotility = No Prokinetics = No Time before CDI treatment was stopped before FMT = d-3.	Overall cure within stated follow up period = 12/12 (with f/u ranging from 3/52 to 8 years at the time of publication) Cure with 1 infusion alone = Total follow up period = 3 weeks to 8 years - no details on relation to individual patients.	Minor GI adverse events = Nil described Minor non-GI adverse events = Nil described Serious adverse events = Nil described Deaths = Nil described.	Selection/eligibility reported = Yes Consecutively recruited = Yes Prospectively recruited = No Loss to follow up explained = No At least 90% followed up = Yes

Additional Appendices

Youngster et al JAMA 2014	Prospective case series Number of patients = 20 Male: 11; Female: 9 Age(mean/median) = Median age 64.5 yrs Comorbidities = not stated CDI features = both CDI diagnosis confirmation =Toxin and ELISA, PCR if toxin negative but ELISA is positive or indeterminate Pre-FMT antibiotics = Failed vancomycin taper and or fidaxomicin.	Donors were Unrelated adult volunteers . Working in healthcare = Not stated Donor demographics = Age range 18-50 years, BMI 18.5 - 25. Donor screening: Questionnaire = American Association of Blood Banks donor questionnaire Travel and antibiotic exclusion peroid = No abx for preceeding 6 months Screening bloods = antibodies to hepatitis A, B, and C; human immunodeficiency virus; and Treponema pallidum within 2 weeks of donations Screening stools = " enteric pathogens"	Amount of stool per transplant / administered to patients = 30 capsules (single treatment) - total 48g of stool Diluent used to prepare = saline in 1/10th volume Diluent used to store if frozen = NA Preparation methods = Fecal matter solution was pipetted into size 0 capsules (650 µL), which were closed and then secondarily sealed in size 00 capsules. Capsules were stored frozen at −80°C (−112°F) till use. Time from preparation to transplant (fresh) = NA Time period for storage (frozen) = Mean 113 days (30-252 days) Route administered: Upper GI = 0 (0) Lower GI = 0 (0) Number of infusions = 1 course (given as 15 capsules on 2 consecutive days). If failed, retreated at mean 7 days Bowel purgative = no PPI = no Antimotility = no Prokinetics = no Time before CDI treatment was stopped before FMT = 48hrs prior to fmt.	Overall cure within stated follow up period = 18/20 (90%) Cure with 1 infusion alone = 14/20 (70%) Total follow up period = 8 weeks.	Minor GI adverse events = Transient abdominal cramping and bloating in 6 patients (30%) that resolved in 72 hours Minor non-GI adverse events = Not described Serious adverse events = 1 hospitalised with a documented relapse of severe CDI after taking 15 capsules but had successful treatment after receiving the remaining 15 capsules after discharge. No other severe adverse events (grade 2 or above). Deaths = none.	Selection/eligibility reported = yes Consecutively recruited = yes Prospectively recruited = yes Loss to follow up explained = yes At least 90% followed up = yes

Additional Appendices

Youngster et al BMC Medicine 2016	Case series Number of patients = 180 Male: not mentioned; Female: not mentioned Age(mean/median) = 7–95 years (median 64) Comorbidities = not mentioned CDI features = three or more mild-to-moderate episodes of CDI or two episodes requiring hospitalization, were offered capsule FMT CDI diagnosis confirmation =not mentioned Pre-FMT antibiotics = not mentioned	Donors were Healthy volunteer donor: nonpregnant adults. Working in healthcare = not mentioned Donor demographics = 18-50 years of age, on no medications, with a normal body mass index Donor screening: Questionnaire = Initial screening using the American Association of Blood Banks donor questionaire for exposure to infectious agents. Travel and antibiotic exclusion peroid = No antibiotic use for 6 months Screening bloods = Blood was screened for antibodies to hepatitis A, B, and C; HIV; and Treponema pallidum within 2 weeks of donations. Screening stools = Donor feces were screened for enteric bacterial pathogens including rotavirus, Listeria monocytogenes, Vibrio cholerae, Escherichia coli O157, ova and parasites (including general microscopy, acid-fast staining, and/or antigen testing for Giardia, Cryptosporidium, Isospora, and Microsporidia), C.difficile, and Helicobacter pylori antigen.	Amount of stool per transplant / administered to patients = 90mls of thawed FMT (41g) Diluent used to prepare = Normal saline Diluent used to store if frozen = 10% glycerol Preparation methods = Homogenised using a commercial blender then passed through sieves Time from preparation to transplant (fresh) = NA Time period for storage (frozen) = The suspension was double-encapsulated in hypromellose capsules (Capsugel, Cambridge, MA) and stored at –80 °C for up to 6 months pending use Route administered: Upper GI = 0 (0) Lower GI = 0 (0) Number of infusions = 147-one infision, 20-two infisons, 3 had 3 infusions Bowel purgative = not mentioned PPI = not mentioned Antimotility = not mentioned Prokinetics = not mentioned Time before CDI treatment was stopped before FMT = 24–48 hours prior.	Overall cure within stated follow up period = 91% at 8 weeks Cure with 1 infusion alone = 147/190 (82%)% Total follow up period = 8 weeks for primary response.	Minor GI adverse events = 5 vomiting, 112 diarrhoea, 45 nausea/bloating,40 abdo pain Minor non-GI adverse events = 3 fever, 54 fatigue,mailaise,headache, 12 other complaints Serious adverse events = Related serious (1 fever, 2 NEW UC, 6 hospitalisations for CDI/diarrhiea,) Unrelated serious (26 hospitalisations, 14 deaths) Deaths = 14 (unrelated).	Selection/eligibility reported = yes Consecutively recruited = yes Prospectively recruited = no Loss to follow up explained = yes At least 90% followed up = yes

Additional Appendices

Zainah et al Digestive Diseases and Sciences 2014	Case series Number of patients = 14 Male: 5; Female: 9 Age(mean/median) = Mean age 73.4+/-11.9 years Comorbidities = No details given of these comorbs. 4 patients with cancer. One liver transplant patient. CDI features = 8 patients had had prev CDI episodes (2-5 prior) CDI diagnosis confirmation =Diarrhoea (at least 3 unformed stool/d for 2 consecutive days) + positive C diff EIA and/or PCR. All patients here severe by definition - defined here as age >60 years, alb <2.5mg/dl, temp at least 38.3 degrees, WBC > 15 within 48hr of CDI diagnosis; or at least one of the following: pseudomembranes, treatment in intensive care for CDI Pre-FMT antibiotics = 14 patients prior vanc, 12 prior MTZ too	Donors were Donor was family member, or unrelated if family members not available. 12 FMT from related donor (7 spouse, 5 children); rest unrelated.. Working in healthcare = Not stated Donor demographics = N/A Donor screening: Questionnaire = Not described Travel and antibiotic exclusion peroid = No details Screening bloods = HIV-1/-2, HAV IgM, Hep B serology, HCV Ab, syphilis (RPR and FTA-ABS). Screening stools = C diff toxin by PCR, stool OCP	Amount of stool per transplant / administered to patients = 30-50g Diluent used to prepare = Warm tap water Diluent used to store if frozen = N/A Preparation methods = Homogenised mixture, then filtered through gauze; 120-180ml of suspension if through NGT, 300-500ml if through colonoscopy. Time from preparation to transplant (fresh) = "Same day" Time period for storage (frozen) = N/A Route administered: Upper GI = NG administration in all but one patient (13 patients) Lower GI = Colonoscopic administration in one patient (1 patient) Number of infusions = One routinely; repeated if no response at 48-72hr Bowel purgative = No details PPI = Yes pre NG admin - no details given. Antimotility = Not described Prokinetics = Not described Time before CDI treatment was stopped before FMT = 24hr.	Overall cure within stated follow up period = 11/ 14 by seven days Cure with 1 infusion alone = 10/ 14 Total follow up period = Up to 100 days .	Minor GI adverse events = Not described Minor non-GI adverse events = Not described Serious adverse events = Not described Deaths = One within 7 days of FMT - but died of their malignancy..	Selection/eligibility reported = Yes Consecutively recruited = Yes Prospectively recruited = No Loss to follow up explained = Yes At least 90% followed up = Yes

C.2. Reviewed randomised studies of FMT for recurrent or refractory CDI

Paper	Study and patient characteristics	Donor characteristics	FMT characteristics	Outcomes	Adverse events
Camacho-Ortiz et al, PLOS ONE, 2017	Intervention = FMT (pooled from 3 donors) Number of patients = 9 Female:Male = 3:4 (data only presented for 7 patients) Age(mean/median) = 39.7 (+/- 24.8 years). Comparator = Vancomycin Number of patients = 10 Female:Male = 3:6 (data only presented for 9 patients) Age(mean/median) = 46.7 (+/- 15.8 years). Comorbidities = In FMT arm – 1 x abdominal abscess, 1 x Child B cirrhotic, 1x pulmonary TB; in vancomycin arm – 2 x haemodialysis, 1 x meningeal TB, 1 x 'abscessed squamous cell carcinoma'. CDI features = All first episode of CDI, occurring at least 48hrs after admission. CDI diagnosis confirmation: >3 bowel movements during the previous 24hr, a Bristol scale > 5, positive *C. difficile* EIA or PCR. Pre-FMT antibiotics = no antibiotics within FMT arm; 250mg every 6hrs for 10-14 days. Total follow up period = up to 1 year. Cochrane Collaboration risk of	Donors were >18 years, non-pregnant, BMI 20-25kg/m2 Working in healthcare = NS Donor demographics = >18 years. Donor screening: Questionnaire = rejected potential donors who in the past three months had had use of PPI, use of antibiotics, use of immunosuppressives, hospitalisation and/ or diarrhoea. Also excluded if high risk sexual behaviour, first degree relative with diabetes mellitus, abdominal surgery, and any GI disease/ cancer. Travel and antibiotic exclusion period = 3 months for antibiotics. Screening bloods = Normal full blood count and liver enzymes essential for inclusion. Also screened for HAV, HBV, HCV, HIV, CMV, EBV, *Trypanosoma, Brucella, Treponema pallidum*. Screening stools = Parasites, enteropathogenic bacteria, rotavirus.	Amount of stool per transplant / 45ml of pooled donor stool (from three donors), at ~0.19g/ml. Diluent used to prepare = 0.9% saline Diluent used to store if frozen = 15% v/v glycerol. Preparation methods = Stool from donors pooled, mixed, resuspended in saline, filtered to remove particles > 330um. Time from preparation to transplant (fresh) = N/A Time period for storage (frozen) = NS Route administered: Upper GI = 14 by OGD; 1 by nasojejunal tube. Lower GI = colonic (1; patient with anatomical abnormality due to head and neck neoplasia) Capsule = n/a (n/a) Number of infusions = routinely 1; patients not resolving after first FMT received 2nd FMT (as did patients not improving with vancomycin). Bowel purgative = NS PPI = NS Antimotility = NS Prokinetics = NS Time before CDI treatment was stopped before FMT = Nil given.	Treatment arm = FMT Overall cure rate = 5/7 (after 2 x FMT) Cure with 1 infusion alone = 4/7 Treatment arm = Vancomycin Overall cure rate = 8/9 (not clear if failed patient received FMT subsequently, as is described in protocol) Cure with 1 infusion alone = 8/9	Minor GI adverse events = nil stated Minor non-GI adverse events = nil stated Serious adverse events = nil stated Deaths = nil.

	bias assessment = uncertain risk of bias				

Cammarota et al Alimentary Pharmacology and Therapeutics 2015	Intervention = FMT Number of patients = 20 Female:Male = 12:8 Age(mean/median) = 71 (range 29-89) Comparator = Vancomycin Number of patients = 19 Female:Male = 11:8 Age(mean/median) = 75(range 49-93) Comorbidities = Not stated CDI features = All recurrent CDI diagnosis confirmation =Diarrhoea and CDT positive within 10/52 of prev abx treatment Pre-FMT antibiotics = Vanc taper 19+/- 1 metronidazole Total follow up period = 10 weeks Cochrane Collaboration risk of bias assessment = uncertain risk of bias	Donors were Less than 50 years old. Abx in last 6/12 Working in healthcare = no Donor demographics = less than 50 Donor screening: Questionnaire = No ABx for last 6/12. Excluded if significant GI disease, metabolic syndrome, chronic illness, immunocompromise, recent travel, high risk lifestyle in last 3/12 Travel and antibiotic exclusion period = 3 month travel exclusion period, 6 month antibiotic exclusion period Screening bloods = Hep ABC, HIV, EBV, syphilis, stongyloides,entomoeba histolytica, FBC,LFTs,Createnine, CRP, Screening stools = C. diffe cult and toxin, enteric bacteria, OSP, VRE,MRSA gram negative multi drug resistant bacteria	Amount of stool per transplant / administered to patients = not specified Diluent used to prepare = normal saline 500mls Diluent used to store if frozen = fresh Preparation methods = Blended and strained Time from preparation to transplant (fresh) = 6 hrs Time period for storage (frozen) = n/a Route administered: Upper GI = () Lower GI = colonic (20) Capsule = n/a (n/a) Number of infusions = 14 had 1 infusion, 4 had 2 infusions, 1 had 3 infusions and 1 had 4 infusions Bowel purgative = macrogol PPI = no Antimotility = no Prokinetics = no Time before CDI treatment was stopped before FMT = (D-5 to D-2)	Treatment arm = FMT Overall cure rate = 18/20 Cure with 1 infusion alone = 13/20 Treatment arm = Vancomycin Overall cure rate = Cure with 1 infusion alone = 42875	Minor GI adverse events = 19 diarrhoea, 12 bloating (all resolved at 12 hrs) Minor non-GI adverse events = Serious adverse events = none Deaths = 2- from c.diff related complications.

Allegretti et al Gastroenterology (DDW abstract) 2016	Intervention = Low dose FMT capsules (30 pills once) Number of patients = 10 Female:Male = ns Age(mean/median) = ns Comparator = High dose FMT capsules (30 pills daily on two consecutive days) Number of patients = 9 Female:Male = ns Age(mean/median) = ns Comorbidities = ns CDI features = ns CDI diagnosis confirmation =ns Pre-FMT antibiotics = ns Total follow up period = 8 weeks Cochrane Collaboration risk of bias assessment = uncertain risk of bias	Donors were unrelated donors from universal stool bank Working in healthcare = no Donor demographics = mean age 26, mean BMI 22.2 Donor screening: Questionnaire = As per open biome Travel and antibiotic exclusion period = As per open biome Screening bloods = As per open biome Screening stools = As per open biome	Amount of stool per transplant / administered to patients = 30 pills a day for one day Diluent used to prepare = none Diluent used to store if frozen = stored at -80 prior Preparation methods = capsules physically stable for 30 days at 25 degrees using an emulsion based production protocol Time from preparation to transplant (fresh) = ns Time period for storage (frozen) = ns Route administered: Upper GI = 0 () Lower GI = 0 (0) Capsule = (10 low-30 in one day) Number of infusions = 30 tablets (over one day) Bowel purgative = ns PPI = ns Antimotility = ns Prokinetics = ns Time before CDI treatment was stopped before FMT = ns	Treatment arm = Low dose FMT capsules (30 pills once) Overall cure rate = 7/10 Treatment arm = High dose FMT capsules (30 pills daily on two consecutive days) Overall cure rate = 7/9	Minor GI adverse events = none Minor non-GI adverse events = Serious adverse events = none Deaths = none.

Hota et al Clinical Infectious Diseases 2016	Intervention = FMT Number of patients = 16 Female:Male = 11 Age(mean/median) = Mean 75.7 Comparator = 6 week vanc taper Number of patients = 12 Female:Male = 8 Age(mean/median) = Mean 69.6 Comorbidities = CDI features = Recurrent CDI diagnosis confirmation =Symptoms and toxin or PCR detection Pre-FMT antibiotics = At least 1 course of vancomycin for min 10 days Total follow up period = 120 days Cochrane Collaboration risk of bias assessment = uncertain risk of bias	Donors were Not stated Working in healthcare = Not stated Donor demographics = >/= 18yrs Donor screening: Questionnaire = self-screening questionnaire of behaviours associated with risk for blood borne pathogens Travel and antibiotic exclusion period = Not mentioned Screening bloods = Done but not specified Screening stools = Done but not specified	Amount of stool per transplant / administered to patients = 50g Diluent used to prepare = 500mls N Saline Diluent used to store if frozen = NA Preparation methods = Stomacher Lab Blender Time from preparation to transplant (fresh) = 48 hrs Time period for storage (frozen) = Route administered: Upper GI = () Lower GI = (16) Capsule = () Number of infusions = All had 1 infusion Bowel purgative = none PPI = none Antimotility = none Prokinetics = none Time before CDI treatment was stopped before FMT = day before	Treatment arm = FMT Overall cure rate = 7/16 Cure with 1 infusion alone = 7/16 Treatment arm = 6 week vanc taper Overall cure rate = 7/12	Minor GI adverse events = abdominal pain, tenderness and bloating, equal in both groups Minor non-GI adverse events = Serious adverse events = 1 developed anasarca from liver disease, 1 had perf bowel from diverticulitis 35 days post FMT Deaths = None.

Jiang et al Alimentary Pharmacology and Therapeutics 2017	Intervention = Fresh Number of patients = 25 Female:Male = 21 Age(mean/median) = Mean 75 (19-97) Comparator = Lyophilised Number of patients = 23 Female:Male = 13 Age(mean/median) = 63 (20-87) Comparator = Frozen Number of patients = 24 Female:Male = 18 Age(mean/median) = 62.5 (33-88) CDI features = recurrent CDI diagnosis confirmation =Not explicitly stated but includes CDI toxin Pre-FMT antibiotics = Not stated Total follow up period = 2 months Cochrane Collaboration risk of bias assessment = high risk of bias	Donors were Not stated Working in healthcare = Not stated Donor demographics = "Normal BMI" Donor screening: Questionnaire = As per van Nood Travel and antibiotic exclusion period = As per van Nood Screening bloods = As per van Nood Screening stools = As per van Nood	Amount of stool per transplant / administered to patients = 50g Diluent used to prepare = Normal saline Diluent used to store if frozen = none Preparation methods = mix stool with n.saline (1:10), aerobic conditions, Stomacher to homogenise Time from preparation to transplant (fresh) = not specified Time period for storage (frozen) = not specified Route administered: Upper GI = 0 () Lower GI = all (0) Capsule = 0 (0) Number of infusions = 1 Bowel purgative = PEG night before PPI = no Antimotility = 4mg loperamide 3hrs before Prokinetics = no Time before CDI treatment was stopped before FMT = not specified	Treatment arm = Fresh Overall cure rate = 25/25 (100%) Cure with 1 infusion alone = 25/25 (100%) Treatment arm = Frozen Overall cure rate = 20/24 (83%) Cure with 1 infusion alone = 20/24 (83%) Treatment arm = Lyophilised Overall cure rate = 18/23 (78%) Cure with 1 infusion alone = 18/23 (78%)	Minor GI adverse events = no differences in the three groups. mild transient abdo pain and diarrhoea in 86% of patients. 6 experiences fatigue and 4 had a headache. 2 gained weight Minor non-GI adverse events = Serious adverse events = none Deaths = none.

Kao et al, JAMA, 2017	Intervention= oral FMT capsules Number of patients= 116 Female:Male= 79:37 Age: (mean/standard deviation)=58(19) Comparitor= Colonoscopy delievered FMT Number of patients: 59 Female:Male=36:13 Age (median/standard deviation)=57.4 (19.1) Comparitor= Oral FMT capsules Number of patients=57 Female:male=43:14 Age (median/standard deviation)=58.7(18.5) CDI features = Recurrent CDI diagnosis= recurrence of diarrhea (>3 unformed bowel movements every 24 hours) within 8 weeks of completing a prior course of treatment, with either a positive C difficile toxin by glutamate dehydrogenase and C difficiletoxins A/B (C diff QuikChek Complete; Techlab) or by detection of glutamate dehydrogenase and C difficile cytotoxin B gene (Cepheid), plus resolution of diarrhea for the current episode Pre-FMT antibiotics=Vancomycin po 125mg BD up to 24hrs before FMT	Donors were unrelated volunteers Working in healthcare = Not stated Donor demographics = not stated Donor screening: Questionnaire = As per Kelly *et* al Travel and antibiotic exclusion lperiod = Not mentioned Screening bloods = As per Kelly *et* al Screening stools = As per Kelly *et* al	Amount of stool per transplant / administered to patients = 80-100g Diluent used to prepare = Normal saline Diluent used to store if frozen = 100% glycerol Preparation methods = mix stool with 200 cc of n.saline, and filtered using a Stomacher to homogenise 180cc of faecal slurry Time from preparation to transplant (fresh) = up to 2 months frozen collected fresh within 12 hours Time period for storage (frozen) = up to 2 months Route administered: Lower GI = 59 (colonoscopy) Capsule = 57 Number of infusions = 1 colonoscopy, 40 capsules as one off Bowel purgative = PEG night before PPI = no Antimotility = NS Prokinetics = nS Time before CDI treatment was stopped before FMT = 24 hours	Treatment arm = Oral FMT capsules = 51/53 (96.2%) absence of CDi at 12 weeks Cure with 1 treatment alone = 51/53 (96.2%) Treatment arm = FMT via colonoscopy=50/52 (96.2%) Cure with 1 infusion alone = 50/52(96.2%)	Minor GI adverse events = capsule group= 3 nausea, 2 vomiting, 1 abdominal pain Colonoscopy group=1 nausea,1 vomiting, 1 fever, 5 abdominal pain Minor non-GI adverse events = one developed confusion in the colonoscopy group between time of screening and delivery of FMT. This was not communicated to team and despite an uneventful FMT she died 3 days later from heart failure Serious adverse events = none Deaths = one in each group from cardiopulmonary disease (see above for colonoscopy). The other patient developed *staphylococcus epidermis* bacteraemia 10 weeks after capsules

	Total follow-up period= 12 weeks				and died from sepsis.

Kelly et al Annals of Internal Medicine 2016	Intervention = Donor FMT Number of patients = 22 Female:Male = 18 Age(mean/median) = Mean age 48 (SD 16) Comparator = Autologous FMT Number of patients = 24 Female:Male = 19 Age(mean/median) = Mean age 55 (SD 14) Comorbidities = CDI features = Recurrent CDI diagnosis confirmation =≥3 unformed stools over 24 hours for 2 consecutive days and either a positive stool test result for C difficile or pseudomembranes on colonoscopy Pre-FMT antibiotics = Total follow up period = 8 week outcome follow up, 6 month safety follow up Cochrane Collaboration risk of bias assessment = low risk of bias	Donors were Not specified for the donor FMT arm Working in healthcare = Not stated Donor demographics = Not stated Donor screening: Questionnaire = Potential donors also completed a modified AABB full-length donor history questionnaire, and those with risk factors for infectious agents were excluded Travel and antibiotic exclusion period = No antibiotics for preceeding 90 days Screening bloods = Testing for HIV-1 and HIV-2 was performed within 2 weeks before donation for FMT. Other serologic testing was performed within 1 month before FMT and included testing for hepatitis A, B, and C viruses; testing for Treponema pallidum; Screening stools = polymerase chain reaction (PCR) testing for detection of C difficile toxin; culture for enteric pathogens (Esch- erichia coli, Salmonella, Shigella, Yersinia, Campylobac- ter, Listeria monocytogenes, Vibrio parahaemolyticus, and V cholerae); testing for fecal Giardia and Cryptosporidium antigens; acid-fast stain for detection of Cyclospora and Isospora; ova and parasite testing; and enzyme immunoassay for detection of Rotavirus.	Amount of stool per transplant / administered to patients = Mean stool dose of 64 g (SD, 25 g; range, 20 to 100 g) Diluent used to prepare = 100g of stool in 500mls of normal saline Diluent used to store if frozen = NA Preparation methods = not reported Time from preparation to transplant (fresh) = 6 hours Time period for storage (frozen) = Route administered: Upper GI = 0 () Lower GI = all patients in both groups Capsule = () Number of infusions = 1 infusion only Bowel purgative = polyethylene glycol (PEG) PPI = No Antimotility = Not described Prokinetics = No Time before CDI treatment was stopped before FMT = continued therapy until 2 to 3 days before the procedure	Treatment arm = Donor FMT Overall cure rate = 20 / 22 (90.9%) Cure with 1 infusion alone = 20 / 22 (90.9%) Treatment arm = Autologous FMT Overall cure rate = 15/24 (62.5%) Cure with 1 infusion alone = 15/24 (62.5%)	Minor GI adverse events = Rates of other solicited AEs (fever, abdominal pain, bloating, nausea, vomiting, diarrhea, flatulence, anorexia, and constipation) did not differ significantly between groups. Minor non-GI adverse events = Serious adverse events = None described Deaths = None.

Lee et al JAMA 2016	Intervention = Frozen Number of patients = 108 Female:Male = 72 Age(mean/median) = Mean age 73 years Comparator = Fresh Number of patients = 111 Female:Male = 74 Age(mean/median) = Mean age 73 years Comorbidities = CDI features = Both CDI diagnosis confirmation =Toxin and PCR Pre-FMT antibiotics = Metronidazole and Vancomycin Total follow up period = 13 weeks Cochrane Collaboration risk of bias assessment = low risk of bias	Donors were Unrelated volunteers Working in healthcare = Not specifically described Donor demographics = Not defined Donor screening: Questionnaire = Blood donor screening questionnaire Travel and antibiotic exclusion period = Exclusion:Travel (within the last 6 months) to areas of the world where diarrheal illnesses are endemic or risk of traveler's diarrhea is high and antibiotics within the preceeding 3 months Screening bloods = Clostridium difficile toxin B by PCR; if unavailable, then evaluation for toxins A and B by EIA. Routine bacterial culture for enteric pathogens Fecal Giardia antigen Fecal Cryptosporidium antigen Acid-fast stain for Cyclospora, Isospora and, if antigen testing unavailable, Cryptosporidium Ova and parasites Screening stools = HIV, type 1 and 2 HAV IgM HBsAg, anti-HBc (both IgG and IgM), and anti-HBs. HCV Ab RPR and FTA-ABS	Amount of stool per transplant / administered to patients = 100g of stool Diluent used to prepare = 300mls of water Diluent used to store if frozen = no solvents used for storage Preparation methods = 100g of stool homogensied and mixed in 300mls of water. Time from preparation to transplant (fresh) = If fresh administered within 24hrs. Time period for storage (frozen) = If frozen kept for 30 days at -20C. Route administered: Upper GI = 0 () Lower GI = all in both groups Capsule = 0 (0) Number of infusions in frozen 57 - 1 infusion, 24 - 2 infusions, rest >2; in fresh 56 - 1 infusion, 22 - 2 infusions, rest >2 Bowel purgative = Nil PPI = Nil Antimotility = Nil Prokinetics = Nil Time before CDI treatment was stopped before FMT = Discontinued 24 to 48 hours prior to FMT.	Treatment arm = Frozen Overall cure rate = 98/109 (90.7%) Cure with 1 infusion alone = 57/108 (52.8%) Treatment arm = Fresh Overall cure rate = 95/111 (85.6%) Cure with 1 infusion alone = 56/111 (50.5%)	Minor GI adverse events = Transient diarrhoea (70%), abdominal cramps (10%), nausea (5%) in 24 hours post FMT; constipation (20%) and flatulence (25%) in follow up period. No difference between the two groups Minor non-GI adverse events = Serious adverse events = 12 patients required hospitalization because of ilnesses unrelated to FMT Deaths = 6 deaths in frozen and 13 deaths in fresh arm (unrelated to FMT).

van Nood et al New England Journal of Medicine 2013	Intervention = FMT + vanc + bowel lavage Number of patients = 16 Female:Male = 8 Age(mean/median) = 73 +/- 13 Comparator = vanc Number of patients = 13 Female:Male = 7 Age(mean/median) = 66+/-14 Comparator = vanc + bowel lavage Number of patients = 13 Female:Male = 3 Age(mean/median) = 69+/-16Comorbidities = Not stated CDI features = Recurrent CDI diagnosis confirmation =Toxin and PCR Pre-FMT antibiotics = At least one course of adequate antibiotic therapy (>=10 days of Vancomycin at a dose of >=125mg four times a day or >=10 days of Metronidazole at a dose of 500mg three times per day). Total follow up period = After first infusion at 10 weeks; follow up was extended to 10 weeks after the second infusion Cochrane Collaboration risk of bias assessment = low risk of bias	Donors were Healthy volunteers Working in healthcare = No Donor demographics = <60 years of age Donor screening: Questionnaire = Questionnaire adressing risk factors for potencially transmissible diseases Travel and antibiotic exclusion period = Not mentioned Screening bloods = Blood was screened for HIV; human T-cell lymphotropic virus types 1 and 2; hepatitis A,B, and C; cytomegalovirus; Epstein-Barr virus; Treponema pallidum; Strongyloides stercoralis; and Entamoeba histolytica. Screening stools = Donor feces were screened for parasites, including Blastocystis hominis and Dientamoeba fragilis; C.difficile, and enteropathogenic bacteria	Amount of stool per transplant / administered to patients = A mean (+-SD) of 141+-71g of feces was infused. Diluent used to prepare = Feces were diluted with 500mls of sterile saline 0.9% Diluent used to store if frozen = NA Preparation methods = The solution was stirred, and the supernatant strained and poured in a sterile bottle Time from preparation to transplant (fresh) = The mean time from defecation to infusion was 3.1+-1.9 hours Time period for storage (frozen) = NA Route administered: Upper GI = 16 Lower GI = 0 (0) Capsule = (NA) Number of infusions = 16 patients had 1 infusion; 3 who did not respond in this group had 2nd infusion. Bowel purgative = 4 liters of macrogol solution (Klean-Prep) on the last day of antibiotic treatment. PPI = NA Antimotility = NA Prokinetics = NA Time before CDI treatment was stopped before FMT = 24 hours	Treatment arm = FMT + vanc + bowel lavage Overall cure rate = 15/16(94%) Cure with 1 infusion alone = 13/16 (81%) Treatment arm = vanc Overall cure rate = 4/13 (31%) patients at 10 weeks Treatment arm = vanc + bowel lavage Overall cure rate = 3/13 (23%) patients at 10 weeks	Minor GI adverse events = 94% immediate diarrhoea, 31% abdominal pain with cramping, 19% belching - resolved within 3 hours. During follow up 3 patients had constipation (19%). Minor non-GI adverse events = Serious adverse events = Nil described Deaths = None.

Youngster et al Clinical infectious diseases 2014	Intervention = Colonoscopy Number of patients = 10 Female:Male = 6 Age(mean/median) = Mean 50.4 Intervention = NG Number of patients = 10 Female:Male = 5 Age(mean/median) = Mean 58.6 Comorbidities = CDI features = Relapsing or recurring (having at least 3 episodes of mild-to-moderate CDI OR at least 2 episodes of severe CDI resulting in hospitalization and associated with significant modbidity CDI diagnosis confirmation =Toxin: initial GDH enzyme-linked immunosorbent assay, followed by PCR only if the GDH test is positive or indeterminate Pre-FMT antibiotics: treatment failures of a 6- to 8-week taper with Vancomycin (95% of patients) with or without an alternative antibiotic, including Fidaxomicin (70% of participants). Total follow up period = 8 weeks follow up for primary response Cochrane Collaboration risk of bias assessment = uncertain risk of bias	Donors were Healthy volunteer donor: nonpregnant adults Working in healthcare = No Donor demographics = 18-50 years of age, on no medications, with a normal body mass index Donor screening: Questionnaire = Initial screening using the American Association of Blood Banks donor questionnaire for exposure to infectious agents. Travel and antibiotic exclusion period = No antibiotic use for 6 months Screening bloods = Blood was screened for antibodies to hepatitis A, B, and C; HIV; and Treponema pallidum within 2 weeks of donations. Screening stools = Donor feces were screened for enteric bacterial pathogens including rotavirus, Listeria monocytogenes, Vibrio cholerae, Escherichia coli O157, ova and parasites (including general microscopy, acid-fast staining, and/or antigen testing for Giardia, Cryptosporidium, Isospora, and Microsporidia), C.difficile, and Helicobacter pylori antigen.	Amount of stool per transplant / administered to patients = 90mls of thawed FMT (41g) Diluent used to prepare = Normal saline Diluent used to store if frozen = 10% glycerol Preparation methods = Homogenised using a commercial blender then passed through sieves Time from preparation to transplant (fresh) = NA Time period for storage (frozen) = Inocula were stored frozen for up to 156 days, range, 29-156 days Route administered: Upper GI = 10 Lower GI = 10 (0) Capsule = NA (NA) Number of infusions = Colonoscopy : 8 - 1 infusion, 2 - 2infusions; NG: 7 - 1 infusion, 3 - 2infusions Bowel purgative = For colonic route - 4 liters of PEG solution PPI = 20mg, of omeprazole orally for 48 hours prior Antimotility = single dose of oral loperamide prior to procedure Prokinetics = Nil Time before CDI treatment was stopped before FMT = Patients were required to discontinue all antibiotics at least 48 hours prior to the procedure	Treatment arm = Overall Overall cure rate = 18/20 (90%) Cure with 1 infusion alone = 14/20 (70%) Treatment arm = Colonoscopy Overall cure rate = 10/10 (100%) Cure with 1 infusion alone = 8/10 (80%) Treatment arm = NG Overall cure rate = 8/10 (80%) Cure with 1 infusion alone = 6/10 (60%)	Minor GI adverse events = Mild abdominal discomfort and bloating in 4 patients (20%). One child treated colonoscopically had a transient fever of 38.8 C on day 2 that resolved spontaneously Minor non-GI adverse events = Serious adverse events = 1 new diagnosis of malignancy, 1 hospitalisation for Fournier gangrene Deaths = 2 deaths (unrelated).

C.2. Reviewed randomised studies of FMT for non-CDI indications

Paper	Study and patient characteristics	Donor characteristics	FMT characteristics	Outcomes	Adverse events
Moayyedi et al Gastroenterology 2015	Intervention = FMT Number of patients = 38 Female:Male = 20:18 Age(mean/median) = 42.2+/-15.0 Comparator = Water enema Number of patients = 37 Female:Male = 11:26 Age(mean/median) = 35.8 +/- 12.1 Primary outcome = Remission at week 7, defined as full Mayo score < 3 and complete healing of mucosa at flex sig (endoscopic Mayo score = 0). Secondary outcome = Clinical response (at least 3 point reduction in Mayo score), change in Mayo, IBD Questionnaire scores, EQ-5D scores. Inclusion criteria = >18 years with UC - Mayo at least 4 with endoscopic subscore at least 1 (included patients with severe disease). Exclusions - abx/ probiotics in past 30 days, concomitant C diff/ other enteric pathogens, disease severity requiring hospitalisation, pregnancy, unable to give informed consent. Concomitant medications =Stable dose thiopurines, mesalamine, corticosteroids, anti TNF allowed as long as stable dose for at least 12 weeks (4 weeks for steroids) Total FU period =Up to 12 months Cochrane Collaboration risk of bias assessment = low risk of bias	Donors were Unrelated volunteers - six donors used. Plus - one patient in active treatment arm had spouse as donor (treatment failure) Working in healthcare = Not specifically stated Donor demographics = 18-60 Donor screening: Questionnaire = Yes Travel and antibiotic exclusion period = Retesting of stool whenever donor travelled outside North America. No abx within 3/12. Screening repeated regardless every 6 months. Screening bloods = HIV, HAV IgM, HBsAg, HCV, syphilis, HTLV-1/-2 Screening stools = MCS, OCP, C diff toxin, VRE, MRSA	Amount of stool per transplant / administered to patients = 8.3g of stool per enema Diluent used to prepare = 50g of stool mixed with 300ml of commercial bottled drinking water, then 50ml of mixture administered as enema Diluent used to store if frozen = No glycerol. FMT administered either fresh, or stored at -20 degrees. 21 received frozen, 15 received fresh, 1 mixture of fresh and frozen Preparation methods = Not anaerobic. Single donor per FMT. Time from preparation to transplant (fresh) = Processing within 5hr of collection Time period for storage (frozen) = Not stated Route administered and frequency: Upper GI = () Lower GI = Enema - weekly for 6 weeks. Aimed to retain for at least 20 mins (38) Capsule = (No PEG) Bowel purgative = No PEG PPI = Antimotility = Prokinetics =	FMT arm Remission rates = 9/38 Clincial response rates = 15/38 had reduction in full Mayo score of at least 3 points Quality of Life Assessment = Yes - IBDQ and EQ-5D not significantly different between groups Water enema arm Remission rates = 2/37 (p=0.03) Clincial response rates = 9/37 had reduction in full Mayo score of at least 3 points (p=0.16)	FMT arm Minor GI adverse events = Two patients developed patchy inflam in the colon and also rectal abscess formation - resolved with abx Minor non-GI adverse events = NoneSerious adverse events = Two patients had dx changed to Crohn's colitis, one was C difficile toxin pos at end of therapy Deaths = None. Water enema arm Minor GI adverse events = One patient developed patchy inflam in the colon and also rectal abscess formation - resolved with abx Minor non-GI adverse events = NoneSerious adverse events = One patient changed diagnosis from UC to Crohn's colitis; one admitted with hospital with active severe colitis and required colectomy Deaths = None.

Rossen et al Gastroenterology 2015	Intervention = Donor feces Number of patients = 23 Female:Male = 12:11 Age(mean/median) = Median age 40 (33-56) Comparator = Autologous feces Number of patients = 25 Female:Male = 14:11 Age(mean/median) = Median age 41 (30 - 48) Primary outcome = Clinical remission: (defined as a SCCAI score 2) in combination with 1-point improvement on the combined Mayo endoscopic score of the sigmoid and rectum, as compared with baseline sigmoidoscopy, 12 weeks after the first treatment. Secondary outcome = Endpoints at 6 and 12 week were clinical response (defined as a reduction of 1.5 points on the SCCAI),11 clinical remission (defined as a SCCAI of 2), endoscopic response, change in median (Inflammatory Bowel Disease Questionnaire12 [IBDQ]) score from baseline to shortly after treatment (week 6), and adverse events Inclusion criteria = enteric infection, use of biologics within 8 weeks or MTX within 4 weeks Concomitant medications =stable doses of thiopurines, mesalamine, or corticosteroids 10 mg/d for the 8 weeks before inclusion. Total FU period =12 weeks Cochrane Collaboration risk of bias assessment = low risk of bias	Donors were Healthy partners, relatives, or volunteers Working in healthcare = Not stated Donor demographics = >18 yrs Donor screening: Questionnaire = Dutch Red Cross Questionnaire addressing risk factors for potential transmissible diseases used for screening of blood donors in The Netherlands Travel and antibiotic exclusion period = No antibiotics within 8 weeks Screening bloods = CMV (IgG + IgM), EBV (IgG + IgM), Hep A (total antibody), Hep B (HBsAg), Hep C (hepatitis C virus antibody), HIV (1+2 antibodies/antigen), HTLV (I + II antibodies), Entamoeben (antibodies against Entamoeba histolytica), strongyloides (strongyloides ELISA). Screening stools = Multiplex PCR containing probes against enteral viruses (rotavirus, norovirus, enterovirus parechovirus, sapovirus, adenovirus 40/41/52, astrovirus), FT + TFT II: PCR op Giardia, SSYC, Clostridium toxine	Amount of stool per transplant / administered to patients = 120g Diluent used to prepare = N saline Diluent used to store if frozen = not stated Preparation methods = Not anaerobic Time from preparation to transplant (fresh) = not stated Time period for storage (frozen) = not stated Route administered and frequency: Upper GI = Nasoduodenal route. 2 infusions three weeks apart. () Lower GI = 0 Capsule = 0 Bowel purgative = Macrogol before both infusions PPI = no Antimotility = no Prokinetics = no	Donor faeces arm Remission rates = 0.3 Clincial response rates = 47.8% at 12 weeks Quality of Life Assessment = IBDQ only calculated based on responders vs nonresponders Autologous faeces arm Remission rates = 0.2 Clincial response rates = 52% at 12 weeks	Minor GI adverse events = 78.3% of donor stool and 64% of autologous stool experienced side effects post FMT : transient borborygmus, diarrhoea, vomiting, fever Minor non-GI adverse events = NoneSerious adverse events = 4 overall (SB perforation - was Crohns, CMV infection, abdominal pain, cervical carcinoma Deaths = nil.

Paramsothy et al Lancet 2017	Intervention = FMT Number of patients = 41 Female:Male = 19:22 Age(mean/median) = 35.6 (27.8-48.9) Comparator = Placebo-isotonic saline with added colourant odourant and glycerol cryoprotectant (concentration 10%) Number of patients = 40 Female:Male = 15 Age(mean/median) = 35.4 (27.7-45.6) Primary outcome = The primary outcome was a composite of steroid-free clinical remission and endoscopic remission or response at week 8, which we defined as a total Mayo score of 2 or less, with all Mayo subscores of 1 or less, and at least a 1 point reduction from baseline in the endoscopy subscore. Secondary outcome = Secondary outcomes were: steroid-free clinical remission (defined as combined Mayo subscores of 1 or less for rectal bleeding plus stool frequency); steroid-free clinical response (defined as either a decrease of 3 points or more on the Mayo score, a 50% or greater reduction from baseline in combined rectal bleeding plus stool frequency Mayo subscores, or both); steroid-free endoscopic response (defined as a Mayo endoscopy subscore of 1 or less, with a reduction of at least 1 point from baseline); steroid-free endoscopic remission (defined as a Mayo endoscopy subscore of 0); quality of life (assessed with the IBDQ);10 and safety (assessed by adverse events).	Donors were between 3-7 unrelated donors Working in healthcare = no Donor demographics = not described Donor screening: Questionnaire = · Known HIV, hepatitis B or hepatitis C infection · Known exposure to HIV or viral hepatitis within the previous 12 months · High risk sexual behavior (e.g. sexual contact with anyone with HIV/AIDS or viral hepatitis, men who have sex with men, sex for drugs or money) · Use of illicit drugs · Tattoo or body piercing within the preceding 6 months · Incarceration or history of incarceration · Known current communicable disease (e.g. upper respiratory tract infection) · Risk factors for variant Creutzfeldt-Jakob disease · Travel within last 2 weeks to areas of the world where diarrhoeal illnesses are endemic or risk of traveler's diarrhea is hig · History of or current inflammatory bowel disease (IBD) · History of or current irritable bowel syndrome (IBS), chronic constipation, chronic diarrhea or other intrinsic gastrointestinal illness / condition · History of or current gastrointestinal malignancy or known polyposis or strong family history of colorectal cancer	Amount of stool per transplant / administered to patients = 37.5g of blended stool to isotonic saline volume of each infusion was 150ml Diluent used to prepare = isotonic saline with 10% glycerol cryoprecipitant Diluent used to store if frozen = -80 glycerol cryoprotectant (concentration 10%) Preparation methods = Donors had to provide faeces within 4 h of a bowel movement, which was inspected visually for suitability (formed stool, no blood or mucous). Donor stool homogenised for a given batch on each day in a biosafety cabinet in isotonic saline then filtered. Placebo infusions comprised isotonic saline. Brown food colourant, odourant, and glycerol cryoprotectant (concentration 10%) was added to all study infusions (investigational and placebo). The volume of each infusion was 150 mL. Infusions were stored at −80°C until dispensation to patients at fortnightly study visits for home freezer storage at −20°C before daily administration. Time from preparation to transplant (fresh) = not mentioned Time period for storage (frozen) = not mentioned Route administered and frequency: Upper GI = 0 Lower GI = 5 enemas per week following colonosopic delivery -5 days on two days off for 8 weeks (40 enemas per patient) Capsule = 0 Bowel purgative = yes but no details PPI = Not described Antimotility = Not described Prokinetics = Not described	Donor FMT arm Remission rates = 11 (27%)p =0.021 Clincial response rates = 22 (54%) p=0.04 Quality of Life Assessment = Not described Placebo arm Remission rates = 3 (8%) Clincial response rates = 9 (23%) Quality of Life Assessmemt = Not described	FMT arm Minor GI adverse events = Abdo pain 12 (29%), colitis 10 (24%), flatulance 10 (24%), bloating 8 (20%),nausea 2(5%), alt elevated 2(5%), vomiting 2 (5%),enterocolitis 1 (2%), diarrhoea 1 (2%),reflux 1 (2%), haemorrhoids 1 (2%), elective surgical procedure 1(2%) Minor non-GI adverse events = NoneSerious adverse events = 2(5%)- 1 clinical deterioration and colectomy, 1 needed intravenous Iv steroids Deaths = 0. Placebo arm Minor GI adverse events = abdo pain 11 (28%), colitis 9 (23%), flatulance 8 (20%), bloating 11 (28%), nausea 5 (13%), vomiting 1(3%), enterocolitis 3 (8%),anal fissure 1(3%),faecal incontinence 1 (3%), ALT elevated 2 (5%) Minor non-GI adverse events = NoneSerious adverse events = 1 (3%)-admitted to hospital (no details why) Deaths = 0.

	Inclusion criteria = 1.18-75 years, 2.UC for >3m 3. UC of any extent except isolated proctotis <5cm, 4. currently active mild-mod UC as mesured by a mayo score of 4-10, endoscopy score must be greater or equal to 1 and a physician global assessment score of less than or equal to 2. 5. Written consent. Concomitant medications =We permitted the following drugs as long as the dose was stable preceding enrolment: oral 5-aminosalicylates (stable dose for 4 weeks); thiopurines and methotrexate (on medication for ≥90 days and dose stable for 4 weeks); and oral prednisone (dose ≤20mg daily and stable for 2 weeks). During the study, patients remained on the same dose of 5-aminosalicylate, thiopurine, and methotrexate. For oral prednisone, we did a mandatory taper of up to 2·5 mg per week so that patients would be steroid-free by week 8 Cochrane Collaboration risk of bias assessment = low risk of bias	· History of major gastrointestinal surgery (e.g. gastric bypass, partial colectomy)h Antimicrobials (antibiotics, antivirals, antifungals), probiotics or proton pump inhibitors (PPIs) within the preceding 3 months · Major immunosuppressive medications (e.g. calcineurin inhibitors, biological agents, exogenous glucocorticoids) · Systemic anti-neoplastic agents · Household members with active GI infection Systemic autoimmunity (e.g. multiple sclerosis, connective tissue disease) · Atopic disease (e.g. moderate - severe asthma, eosinophilic disorders of the gastrointestinal tract) · Metabolic syndrome, obesity (BMI >30) or moderate to severe under-nutrition / malnutrition · Chronic pain syndromes (e.g. chronic fatigue syndrome, fibromyalgia) or neurologic / neurodevelopmental disorders · History of malignant illness or ongoing oncologic therapy Travel and antibiotic exclusion period = within last 2 weeks where diarrheal illnesses are endemic or risk of travelers diarrhea is high Screening bloods = complete blood count, electrolytes, urea and creatinine, lfts, esr, crp, HIV1 and 2, hep A IGM, HEp B sag, HEpB core antibocy (igm and lgg) hep v virus surface antibody, hep c antibody, rapid plasma reagin and/or fluorescent treponemal antibody-			

		absorbed, HTLV1 and HTLV2 Screening stools = C diffe PCR, faecal microscopy/culture/sensitivity with routine bacterial culture for enteric pathiogens, giardia antigen, cryptosporidium antigen, faecal ova/cysts/parasites including blastocystitis hominis and dientamoeba fragilis, norovirus			

Costello et al Journal of Crohn's and Colitis 2017	Intervention = Donor FMT Number of patients = 38 Female:Male = Not stated Age(mean/median) = Not stated Comparator = Control - autologous FMT in saline Number of patients = 35 Female:Male = Not stated Age(mean/median) = Not stated Primary outcome = Steroid-free remission of UC, as defined by total Mayo of 2 or less with an endoscopic Mayo score of 1 or less at week 8. Secondary outcome = Clinical response (at least 3 point reduction in Mayo score), clinical remission (i.e. SCCAI of 2 or less), endoscopic remission (Mayo 1 or less), and safety. Inclusion criteria = UC - Mayo 3-10 with endoscopic subscore at least 2 Concomitant medications =Stable dose immunomodulator, 5-ASA, biological, tapering prednisolone. Cochrane Collaboration risk of bias assessment = uncertain risk of bias	Donors were Healthy volunteers Working in healthcare = Not clear Donor demographics = Not described Donor screening: Questionnaire = Not described Travel and antibiotic exclusion period = Not described Screening bloods = Screening stools = Not described	Amount of stool per transplant / administered to patients = 50g of stool for first FMT, 25g of stool in subsequent enemas Diluent used to prepare = 65% saline Diluent used to store if frozen = Yes - frozen with 10% glycerol Preparation methods = Anaerobic prep, donor stool pooled from 3-4 donors Time from preparation to transplant (fresh) = N/A Time period for storage (frozen) = Not stated Route administered and frequency: Upper GI = () Lower GI = FMT via colonoscopy on day 0, followed by 2 enemas on day 7 (38) Capsule = (PEG before colonoscopy but not enema) Bowel purgative = PEG before colonoscopy but not enema PPI = Not described Antimotility = Not described Prokinetics = Not described	Donor FMT arm Remission rates = 12/38 in steroid-free remission at week 8 Clincial response rates = 21/38 Quality of Life Assessmemt = Not described Autologous FMT arm Remission rates = 3/35 in steroid-free remission at week 8 ($p< 0.01$) Clincial response rates = 7/35 ($p<0.01$) Quality of Life Assessmemt = Not described	Donor FMT arm Minor GI adverse events = Nil Minor non-GI adverse events = NoneSerious adverse events = Worsening colitis in 2 patients Deaths = Nil. Control - autologous FMT in saline arm Minor GI adverse events = Nil Minor non-GI adverse events = NoneSerious adverse events = Worsening colitis in 2 placebo patients. 1 patient requiring colectomy, 1 x pneumonia Deaths = Nil.

Johnsen et al Lancet Gastro and Hepatology, 2017	Intervention = Donor FMT Number of patients = 55 Female:Male = 36:19 Age(mean/median) = 44 Comparator = Control - autologous FMT Number of patients = 28 Female:Male = 19:9 Age(mean/median) = 45 Primary outcome = Symptom relief of more than 75 points assessed by IBS-SSS at 3 months after FMT. Inclusion criteria = 18-75 yrs of age, IBS with diarrhoea or mixed IBS according to the Rome III Exclusion criteria = participants with severe cardiac disease, pulmonary disease, or kidney failure, non-IBS type abdominal pain, immunodeficiency or on immunomodulating agents criteria Cochrane Collaboration risk of bias assessment = low risk of bias	Donors were two volunteers screened at start and at 7 months post donation. Working in healthcare = Not stated Donor demographics = Not described Donor screening: Questionnaire = new tattoos or piercings in the past 3 months; high-risk sexual behaviour; former imprisonment; or history of any of the following conditions: chronic diarrhoea, constipation, inflammatory bowel disease, IBS, colorectal polyps or cancer, immunosuppression, obesity, metabolic syndrome, atopic skin disease, or chronic fatigue Travel and antibiotic exclusion period = 3 months for antibiotics Screening bloods = Glycated haemoglobin; and serology for HIV, Treponema pallidum, and hepatitis A, B, and C Screening stools = Salmonella spp, Shigella spp, Campylobacter spp, Yersinia spp, and toxin-producing C difficile; faecal tests for Helicobacter pylori antigen, viruses (norovirus, rotavirus, Sapovirus, adenovirus), calprotectin.	Amount of stool per transplant / administered to patients = 50 to 80g of stool in 50mls Diluent used to prepare = 200ml isotonic saline and 50mls of 85% glycerol Diluent used to store if frozen = glycerol, only for autologous transplants Preparation methods = Aerobic, stool from both donors was mixed together Time from preparation to transplant (fresh) = 7 hrs Time period for storage (frozen) = 2-4 weeks Route administered and frequency: Upper GI = none Lower GI = Single infusion of FMT via colonoscopy Bowel purgative = Picoprep PPI = Not described Antimotility = Loperamide 8mg 2 hrs before Prokinetics = None	Donor FMT arm Remission rates = 36/55 (p=0.49) Quality of Life Assessmemt = Not described Autologous FMT arm Remission rates = 12/28 Quality of Life Assessmemt = Not described	FMT arm Minor GI adverse events = Self limiting intermittent abdominal pain 1, self limiting nausea and vertigo 1 Minor non-GI adverse events = 0 Serious adverse events = 0 Deaths = 0. Placebo arm Minor GI adverse events = Self limiting intermittent abdominal pain 2 Minor non-GI adverse events = 0 Serious adverse events = 0 Deaths = 0.

Bajaj et al Hepatology 2017	Intervention = Donor FMT Number of patients = 10 Female:Male = 0:10 Age(mean/median) = 64.5 +/- 5.1 Etiology (HCV / alcohol / HCV+alcohol / nonalcoholic fatty liver / others) = 2/4/2/2/0 Comparator = Standard of care Number of patients = 10 Female:Male = 0:10 Age(mean/median) = 62.9 +/- 9.8 Etiology (HCV / alcohol / HCV+alcohol / nonalcoholic fatty liver / others) = 1/5/2/1/1 Primary outcome = Proportion of participants with FMT-related serious adverse events (SAEs) at day 150, a composite endpoint of death, hospitalizations, emergency room visits or transmissible infections, as defined by the FDA. Secondary outcomes = Changes in cognitive function at day 20, cirrhosis severity (MELD score, albumin), changes in liver function and white blood cell (WBC) count, development of all adverse events (AEs), and changes in microbiota composition and function in the FMT arm compared to standard of care arm. Inclusion criteria = >/=18 yrs outpatients with cirrhosis and recurrent hepatic encephalopathy (HE) defined as at last two documented overt HE episodes requiring therapy. Exclusion criteria = MELD score >17, on oral or intravenous antimicrobial agents besides nonabsorbable	Single donor only - identified based on highest relative abundances of Lachnospiraceae and Ruminococcaceae (16s rRNA analysis) among a universal stool donor bank Working in healthcare = Not stated Donor demographics = Not described Donor screening: Based on OpenBiome screening. 178-point clinical assessment for infectious and microbiome-mediated diseases and 30 stool pathogen and serological tests before and after the stool is collected Screening bloods = HIV 1/2 Antigen and Ab, Hepatitis A/B/C, Treponema pallidum (Syphilis), Hepatic Function Panel, Complete Blood Count (CBC) (Includes Differentials and Platelets), HTLV-I/II Ab, with Reflex to Confirmatory Assay. Screening stools = Clostridium difficile Toxin B, qRTPCR, Cyclospora and Isospora Examination, Ova and Parasites Exam with Giardia Antigen EIA, Salmonella/Shigella/Campylobacter Culture, Shiga Toxins EIA with Reflex to E. coli O157 Culture and Vibrio Culture, Cryptosporidium Antigen EIA, Helicobacter pylori Antigen EIA, Stool Norovirus EIA, Stool Rotavirus Antigen Detection,	Amount of stool per transplant / administered to patients = 37.5g of stool Diluent used to prepare = 90mls glycerol saline buffer in total Diluent used to store if frozen = glycerol, Preparation methods = Aerobic Time from preparation to transplant (fresh) = NA Time period for storage (frozen) = not stated Route administered and frequency: Upper GI = none Lower GI = Single infusion of FMT via enema Bowel purgative = Picoprep PPI = Not described Antimotility = Loperamide 8mg 2 hrs before Prokinetics = None Others = Lactulose and rifaximin were continued for all patients throughout the trial. A 5-day broad-spectrum coverage regimen was used (metronidazole 500 mg orally three times daily, ciprofloxacin 500 mg orally twice-daily, and amoxicillin 500 mg orally three times daily). All antibiotics were discontinued at least 12 hrs before FMT. This regime was not used in patients randomised to standard of care arm.	FMT arm Patients with SAEs at day 150 = 2 (20%) p=0.02 Total SAEs at day 150 = 2 (20%) p=0.01 Patients with altered mental status by day 150 = 0 p=0.03 Total HE episodes at day 150 = 0 p=0.03 Stroop OffTime+OnTime change (day 0 and day 20); positive indicates improvement = 29.1 +/- 27.9 p=0.04 PHES score change (day 0 and day 20); negative indicates improvement - 3.1+/-2.1 p=0.01 MELD score change (day 0 and day 35) = 0.1+/-2.0 (p=0.78) Standard of care arm Patients with SAEs at day 150 = 8 (80%) Total SAEs at day 150 = 11 Patients with altered mental status day 150 = 5 Total HE eps day 150 = 6 Stroop OffTime+OnTime change (day 0 and day 20); = -43.5 +/- 95.7 PHES score change (day 0 and day 20) = 0.0 +/- 3.1 MELD score change (day 0 and day 35) = 0.2 +/- 2.7 NB no significant difference in serum albumin, AST, ALT, WBC or Hb counts between the two groups	FMT arm Serious adverse events = 1 hospitalisation for acute kidney injury, and 1 was due to chest pain (all within 5 months post FMT) Deaths = 0. Standard of care arm Serious adverse events = 11 in total. 9 events linked to liver-related complications of which 4 needed hospitalisation. 1 patient developed pneumonia and 1 developed gastroenteritis. Deaths = 0.

	rifaximin, allergies to pretreatment antibiotics, immunosuppressive medications, positive C. difficile test, pregnancy, active infection, those with active alcohol abuse, and unable to provide informed consent Cochrane Collaboration risk of bias assessment = low risk of bias	Adenovirus Antigen Detection, Gastroenteritis EIA, Vancomycin-resistant Enterococcus Culture, Microsporidia Exam			
Tian et al PLoS ONE 2017	Intervention = Donor FMT (one for six days in a row) Number of patients = 30 Female:Male = 19:11 Age(mean/median) = 53.1 +/- 510.2 Comparator = Standard of care (education, behavioural strategies, oral laxaives; expressively told to avoid antibiotics. Macrogol permitted if no bowel movement for three days, and enema permitted if even this failed. Number of patients = 30 Female:Male = 21:9 Age(mean/median) = 55.4 +/- 12.1 Primary outcome = At least three complete spontaneous bowel movements (CSBMs) per week during the 12 week follow-up. Secondary outcomes = 1) Proportion of patients with average increase of at least 1 CSBM per week; 2) Number of CSBMs per week; 3) Colonic transit time (assessed via abdominal x-ray/ radiopaque markers); 4) subjective stool consistency; 5) Wexner constipation scale.	One universal donor used throughout (24 year old healthy university student). Working in healthcare = No Donor demographics = As above. Donor screening: Similar to FDA blood screening. Screening bloods = Full blood count, chemistry and iron profile, hepatitis A, B and C, HIV-1 and-2, CMV, EBV, HSV, VZV, and Treponema pallidum. Screening stools = *Yersinia spp, Salmonella spp, Shigella spp, Campylobacter jejuni, C difficile* toxin, helminths, ova, parasites, and *Helicobacter pylori.*	Amount of stool per transplant / administered to patients = 100g of stool Diluent used to prepare = Either 500mls normal saline, or normal saline amended with glycerol to final concentration of 10%. Diluent used to store if frozen = Glycerol. Preparation methods = Not stated. Time from preparation to transplant (fresh) = 2 hours. Time period for storage (frozen) = 1-4 weeks. Route administered and frequency: Upper GI = All via nasojejunal tube (originally placed endoscopically). Lower GI = Nil. Bowel purgative = Not described PPI = Not described Antimotility = Not described. Prokinetics = None.	Donor FMT arm Meeting primary outcome = 11/30 Meeting second outcomes: At least one more CSBM per week = 16/30 (p=0.04 vs control) Number of CSBMs per week = 3.2+/-1.4 Stool consistency score: 3.9+/-1.3 Colonic transit time (hrs): 58.5+/-9.8 Wexner constipation score = 8.6+/-1.5 Quality of Life Assessmemt = Not described Autologous FMT arm Meeting primary outcome = 4/30 Meeting second outcomes: At least one more CSBM per week = 6/30 Number of CSBMs per week = 2.1+/-1.2 Stool consistency score:	FMT arm 50 in total (1 x sedation contraindications, 22 x endoscopy-related respiratory difficulty, 12 x nausea, 5 x abdominal pain, 4 x diarrhoea, 4 x flatulence, 2 x transient fever). Placebo arm 4 in total (0 x sedation contraindications, 0 x endoscopy-related respiratory difficulty, 0 x nausea, 3 x abdominal pain, 0 x diarrhoea, 1 x flatulence, 0 x transient fever).

	Inclusion criteria = >/=18 yrs outpatients with cirrhosis and recurrent hepatic encephalopathy (HE) defined as at last two documented overt HE episodes requiring therapy. Exclusion criteria = At least 18 years, BMI of 18-25 kg/m2, and slow transit constipation defined as colonic transit time of >48hr, and symptoms unresponsive to dietary modification, enemas or biofeedback in the previous six months. Cochrane Collaboration risk of bias assessment = low risk of bias			2.4+/-1.1 Colonic transit time (hrs): 73.6+/-8.7 Wexner constipation score = 12.7+/-2.5 Quality of Life Assessmemt = Not described	

Appendix D. Excluded clinical studies

D.1. *Clostridium difficile* infection:

D.1.1. Studies excluded at Sift 2 by working group:

Paper:	Grounds for exclusion:
Allegretti JR, Allegretti AS, Phelps E, *et al.* Asymptomatic *Clostridium difficile* carriage rate post-fecal microbiota transplant is low: a prospective clinical and stool assessment. *Clin Microbiol Infect* 2017; doi: 10.1016/j.cmi.2017.10.022	Prospective case series of FMT for CDI, but insufficient patient data to fully populate data table (study primarily designed to evaluate *C. difficile* carriage post-FMT).
Aroniadis OC, Brandt LJ, Greenberg A, *et al.* Long-term follow-up study of fecal microbiota transplantation for severe and/or complicated *Clostridium difficile* infection: a multicenter experience. *J Clin Gastroenterol* 2016;50(5):398-402.	Case series of FMT for CDI, but insufficient patient data to fully populate data table.
Cammarota G, Ianiro G, Masucci L, *et al.* OC.12.9 Fecal microbiota transplantation for recurrent *C. difficile* infection: a 2-year experience from a European referral centre. *Dig Liver Dis* 2016;48 S2:e118.	Case series of FMT for CDI, but abstract only.
Dutta SK, Girortra M, Garg S, *et al.* Efficacy of combined jejunal and colonic fecal microbiota transplantation for recurrent *Clostridium difficile* infection. *Clin Gastroenterol Hepatol* 2014;12(9):1572-1576.	Prospective case series of FMT for CDI, but heterogenous primary endpoint (combination of clinical symptoms and *C difficile* toxin, but assessed between 1-3 months after FMT).
Ganc AJ, Ganc RL, Reimao SM, *et al.* Fecal microbiota transplant by push enteroscopy to treat diarrhea caused by *Clostridium difficile.* *Einstein* 2015;13(2):338-339.	Case series of FMT for CDI, but insufficient patient data to fully populate data table.
Ganc A, Ganc R, Frisoli Jr A, *et al.* Fecal transplantation – an original per-oral endoscopic technique with a pediatric colonoscope. *J Gastroenterol Hepatol* 2013;28 S3:115	Case series of FMT for CDI, but abstract only.
Jorup-Ronstrom C, Hakanson A, Sandell S, *et al.* Fecal transplant against relapsing *Clostridium difficile*-associated diarrhea in 32 patients. *Scand J Gastroenterol* 2012;47(5):548-552.	Case series of 'FMT' for CDI, but bacteriotherapy rather than true FMT.
Kao D, Roach B, Beck P, *et al.* A dual center, randomized trial comparing colonoscopy and oral capsule delivered fecal microbiota transplantation in the treatment of recurrent *Clostridium difficile* infection: preliminary results. *Am J Gastroenterol* 2015;110:S553.	Abstract of RCT of capsulised vs colonoscopic FMT for CDI, but same trial/ data set reported in more developed stage at later date[48], so this abstract excluded.
Mah XJ, Paramsothy R, Lo-Cao E, *et al.* Faecal	Case series of FMT for CDI, but

microbiota transplant (FMT) for recurrent and life threatening *Clostridium difficile* infection. *J Gastroenterol Hepatol* 2016;31:167-168.	abstract only.
Mandali A, Ward A, Tauxe W, *et al.* Fecal transplant is as effective and safe in immunocompromised as non-immunocompromised patients for *Clostridium difficile. Int J Colorectal Dis* 2016;31(5):1059-1060.	Case series of FMT for CDI, but insufficient patient data to fully populate data table.
Oprita R, Bratu M, Oprita B, *et al.* Fecal transplantation – the new, inexpensive, safe, and rapidly effective approach in the treatment of gastrointestinal tract disease. *J Med Life* 2016;9(2):160-162.	Prospective case series of FMT for CDI or UC, but insufficient patient data to fully populate data table.
Ott SJ, Waetzig GH, Rehman A, *et al.* Efficacy of sterile fecal filtrate transfer for treating patients with *Clostridium difficile* infection. *Gastroenterology* 2017;152(4):799-811.	Case series of 'FMT' for CDI, but only five patients. Furthermore, sterile faecal filtrate rather than true FMT.
Ray A, Jones C, Shannon B, *et al.* Does the donor matter? Results from PUNCH CD 2: a randomized controlled trial of a microbiota-based drug for recurrent *Clostridium difficile* infection. *Am J Gastro* 2016;111:S65-S66.	Abstract of RCT of treatment for CDI, but microbiota suspension rather than true FMT.
Ray A, Smith R, Breaux J. Fecal microbiota transplantation for *Clostridium difficile* infection: the Ochsner experience. *Ochsner Journal* 2014;14(4):538-544.	Case series of FMT for CDI, but heterogenous primary end point.
Rupali P, Mittal C, Deol A, *et al.* Fecal microbiota transplantation for *Clostridium difficile* infection in immunocompromised hosts: one easy strategy, one giant success. *Transplantation* 2014;98:687-688.	Case series of FMT for CDI, but abstract only.
Russell GH, Kaplan JL, Youngster I, *et al.* Fecal transplant for recurrent *Clostridium difficile* infection in children with and without inflammatory bowel disease. *J Pediatric Gastroenterol Nut* 2014;58(5):588-592.	Case series of FMT for CDI, but all children, and presented as separate cases rather than as group of 10 recipients.
Tauxe WM, Haydek JP, Rebolledo PA, *et al.* Fecal microbiota transplant for *Clostridium difficile* infection in older adults. *Ther Adv Gastroenterol* 2016;9(3):273-281.	Case series of FMT for CDI, but heterogenous primary end point.
True E, Tsoraides S, Wang H, *et al.* Predictors of failure with fecal microbiota therapy for recurrent *Clostridium difficile* colitis. *Dis Colon Rectum* 2014;57(5):e99-e100.	Case series of FMT for CDI, but abstract only.
Tvede M, Tinggaard M, Helms M. Rectal bacteriotherapy for recurrent *Clostridium difficile*-associated diarrhoea: results from a case series of 55 patients in Denmark 2000-2012. *Clin Micro Infect* 2015;21(1):48-53.	Case series of 'FMT' for CDI, but bacteriotherapy rather than true FMT.

D.1.2. Abstracts not fulfilling selection criteria:

Borody TJ, Wettstein A, Nowak A, Finlayson S, Leis S. Fecal microbiota transplantation (FMT) eradicates clostridium difficile infection (CDI) in inflammatory bowel disease (IBD). United Eur Gastroenterol J. 2013;1)(PG-A57):A57.

D.N. S, Seril DN, Shen B. Clostridium difficile infection in patients with ileal pouches. Am J Gastroenterol. B. Shen, Department of Gastroenterology/Hepatology-A31, Digestive Disease Institute, Cleveland Clinic Foundation, 9500 Euclid Avenue, Cleveland, OH 44195, United States. E-mail: shenb@ccf.org: Nature Publishing Group (Houndmills, Basingstoke, Hampshire RG21 6XS, United Kingdom); 2014;109(7):941–7.

Ganc AJ, Ganc RL. Fecal microbiota transplantation, by means of push enteroscopy. A novel endoscopic technique, for the treatment of chronic diarrhea associated with clostridium difficile-a pilot study. Gastrointest Endosc. 2014;1)(PG-AB380-AB381):AB380-AB381.

Garg S, Fricke WF, Girotra M, Dutta A, Von Rosenvinge EC, Dutta S. Recurrent clostridium difficile infection: A longitudinal study of alterations in fecal microbiome in patients-donor pairs before and after fecal microbiota therapy. Gastroenterology. 2013;1)(PG-S184-S185):S184–5.

Garg S, Fricke WF, Girotra M, Von Rosenvinge EC, Dutta A, Dutta SK. Emerging role of fecal microbiota therapy in the treatment of recurrent clostridium difficile infection in children. Gastroenterology. 2013;1)(PG-S45):S45.

Garg S, Song Y, Han MAT, Girotra M, Fricke WF, Dutta S. Post-infectious irritable bowel syndrome in patients undergoing fecal microbiota transplantation for recurrent clostridium difficile colitis. Gastroenterology. 2014;1)(PG-S83-S84):S83–4.

Girotra M, Bartlett J, Koerner K, Dutta S. Combined jejunal and colonic fecal bacteriotherapy in patients with recurrent clostridium difficile infection (RCDI). Am J Gastroenterol. 2011;106(PG-S162-S163):S162–3.

Girotra M, Dutta A, Koerner K, Bodner B, Dutta SK. Recurrent clostridium difficile infection (RCDI) in geriatric patients: A long-term follow up of simultaneous jejunal and colonic administration of fecal bacteriotherapy (FT). Gastroenterology. 2012;1)(PG-S130):S130.

Goyal A, Chu A, Calabro K, Firek B, Bush B, Morowitz M. Safety and efficacy of fecal microbiota transplant in children with inflammatory bowel disease. J Pediatr Gastroenterol Nutr. 2016;63(PG-S212):S212.

Goyal A, Kufen A, Jackson Z, Morowitz M. A study of fecal microbiota transplantation in pediatric patients with inflammatory bowel disease. Inflamm Bowel Dis. 2016;22:S74.

Graham D, Attumi T, Opekun A, Metcalf G, Muzny D, Hyde E, et al. Triple bacteroides fecal replacement therapy for relapsing clostridium difficile diarrhea (fecal transplantation sans feces). Am J Gastroenterol. 2013;108(PG-S170):S170.

Greenberg A, Aroniadis O, Shelton C, Brandt L. Long-term follow-up study of fecal microbiota transplantation (FMT) for inflammatory bowel disease (IBD). Am J Gastroenterol. 2013;108(PG-S540):S540.

Greenwald D, Patel T, Barto A. Fecal microbiota transplant for treatment of refractory C. Difficile colitis: Long-term follow-up of 58 patients. Am J Gastroenterol. 2014;109(PG-S679):S679.

Greig J, Swope LK, Calvin H. Shaking up clostidium difficile infections: Implementation of a fecal microbiota transplant program. Am J Infect Control. 2014;1)(PG-S4-S5):S4–5.

Grzesiowski P, Hermann A, Dubaniewicz A, Kasprzyk J, Pawlik D, Zak-Pulawska Z. Effectiveness of FMT in recurrent Clostridium difficile infection. Antimicrob Resist Infect Control Conf 3rd Int Conf Prev Infect Control ICPIC. 2015;4(no pagination PG-).

Gupta S, He SM, Noordhof C, Allen-Vercoe E, Petrof EO. Minimalist defined gut microbial ecosystem demonstrates protection against clostridium difficile toxin-mediated effects in vitro via toxin degradation. Gastroenterology. 2016;1)(PG-S544):S544.

Haran M, Tsang T, Kupfer Y, Tessler S. Intravenous immunoglobulins in severe clostridium difficile colitis. Chest Conf CHEST. 2011;140(4 MEETING ABSTRACT PG-). Gastroenterol. 2016;9(2 PG-229-239):229–39.

Harrison MJ, Burke D, Fleming C, McCarthy M, Shortt C, O'Callaghan G, et al. Clostridium difficile in adult cystic fibrosis (CF): Prevalence, ribotyping and toxigenic capability. A prospective study. J Cyst Fibrosis Conf 36th Eur Cyst Fibros Conf Lisbon Port Conf Start. 12(pp S6 PG-).

Holvoet T, Boelens J, Joossens M, Raes J, De Vos M, De Looze D. Fecal microbiota transplantation in irritable bowel syndrome with bloating: Results from a prospective pilot study. Gastroenterology. 2015;1)(PG-S963-S964):S963–4.

Holzwanger EA, Kaufman D, Foley A, Pellish R. Fecal microbiota transplantation via colonoscope: A single-center experience. Am J Gastroenterol. 2016;111(PG-S1232):S1232.

Hourigan S, Ann Chen L, Grigoryan Z, Laroche G, Weidner M, Sears CL, et al. Microbiome changes associated with sustained eradication of clostridium difficile after fecal microbiota transplantation in children with and without inflammatory bowel disease. Gastroenterology. 2015;1)(PG-S45):S45.

Hubble L, Joshua S, Glover PH, Trivedi A, Pfanner TP. Colonoscopic vs. Upper endoscopic placement of fecal microbiota transplant for recurrent clostridium difficile infection: A retrospective review. Gastroenterology. 2015;1)(PG-S728):S728.

Ihara S, Hirata Y, Serizawa T, Suzuki N, Kinoshita H, Nakagawa H, et al. Transforming growth factor-beta signaling on dendritic cells regulates bacterial communities and gut homeostasis. Gastroenterology. 2014;1)(PG-S-113):S-113.

Ihunnah C, Khoruts A, Fischer M, Afzali A, Aroniadis O, Barto A, et al. Fecal microbiota transplantation (FMT) for treatment of clostridium difficile infection (CDI) in immunocompromised patients ACG governors award for excellence in clinical research. Am J Gastroenterol. 2013;108(PG-S179-S180):S179–80.

Ishikawa D, Osada T, Haga K, Kodani T, Shibuya T, Watanabe S. Combination therapy of fresh faecal microbial transplantation and antibiotics for ulcerative colitis. J Crohn's Colitis. 2016;10(PG-S335-S336):S335–6.

Jain A, Parian AM, Dudley-Brown S, Lazarev M. Fecal microbiota transplantation is safe and effective for treatment of recurrent clostridium difficile infection in inflammatory bowel disease patients. Gastroenterology. 2015;1)(PG-S869):S869.

Jamot S, Kelly CR, Shah S. Won the battle, lost the war: Crohn's flare after fecal microbiota transplant (FMT) for recurrent C. Difficile infection. Am J Gastroenterol. 2016;111(PG-S833-S834):S833–4.

Kassam Z, Hundal R, Marshall JK, Lee CH. Fecal transplantation via retention enema is effective for recurrent or refractory clostridium difficile-associated diarrhea. Gastroenterology. 2010;1)(PG-S207-S208):S207–8.

Kellermayer R, Hollister EB, Nagy-Szakal D, Ihekweazu FD, Haynes A, Pitashny M, et al. Special considerations for fecal microbiota transplantation in pediatric recurrent clostridium difficile infection. Gastroenterology. 2015;1)(PG-S961-S962):S961–2.

Khanna S, Kashyap P, Rainey J, Loftus E, Pardi D. Outcomes from fecal microbiota transplantation in adults with C. difficile infection and inflammatory bowel disease. Am J Gastroenterol. 2013;108(PG-S508):S508.

Khanna S, Weatherly R, Kammer P, Pardi D. Management and outcomes of patients with failed fecal microbiota transplantation for recurrent clostridium difficile infection. Am J Gastroenterol. 2015;110(PG-S580):S580.

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Khoruts A, Hamilton MJ, Weingarden A, Sadowsky MJ. Treatment of C. difficile by fecal transplantation. Gastrointest Endosc. 2012;1)(PG-AB329):AB329.

Khoruts A, Rank KM, Viskocil K, Newman KM. Diagnostic value of colonoscopy in patients receiving fecal microbiota transplantation in treatment of refractory clostridium difficile infection. Gastroenterology. 2015;1)(PG-S729):S729.

Kukkadapu T, Chintalapally R, Daram S. Clostridium difficile infection in adult patients with acute myeloid leukemia: Incidence, recurrence, and outcomes. Am J Gastroenterol. 2015;110(PG-S590):S590.

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Kump PK, Wurm P, Grochenig HP, Reiter L, Hoffmann KM, Spindelboeck W, et al. Impact of antibiotic treatment before faecal microbiota transplantation (FMT) in chronic active ulcerative colitis. United Eur Gastroenterol J. 2015;1)(PG-A437):A437.

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Landy J, Al-Hassi HO, Mann ER, Peake ST, McLaughlin SD, Ciclitira PJ, et al. A prospective controlled pilot study of fecal microbiota transplantation for chronic refractory pouchitis. Gastroenterology. 2013;1)(PG-S897):S897.

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Appendix E. Peer review

Healthcare Infection Society

Consultation – The use of faecal microbiota transplant as treatment for recurrent or refractory *Clostridium difficile* infection and other potential indications: joint British Society of Gastroenterology (BSG) and Healthcare Infection Society (HIS) guidelines.

Closing date: 5pm on 18 January 2018

Organisation	**Royal College of General Practitioners**
Title (e.g. Dr, Mr, Ms, Prof)	**Drs**
Name	Clinical Adviser: Kevin Barrett Medical Director: Matthew Hoghton
Job title or role	As above
Address and post code	30 Euston square, London, Nw1 2FB
Telephone number	0203 188 7688
Email address	clinicaladvisers@rcgp.org.uk
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Section	Comments	Working group response
A	This is an important consultation of an important treatment for recurrent or refractory CDI. The recommendations are sensible and will help produce a universal service to patients across the UK.	Thank you for your comment.
B	Hudson et al doi: 10.1128/CMR.00049-16Clin. Microbiol. Rev. January 2017 vol. 30 no. 1 191-2311 January 2017 review suggests that faecal microbiotca transplant in the United States is used not only in refractory or recurrent Clostridium Difficile (CDI) but also in initial CDI and Ulcerative colitis	We cannot find mention of FMT use as treatment for initial CDI in this review. Updated searches have identified a small RCT evaluating the use of FMT as treatment for first CDI (Camacho-Ortiz *et al,* 2017), and this is now evaluated by the working group within the guideline (**Section 8.1.1.3**). All published RCTs evaluating the use of the FMT as treatment for ulcerative colitis have been reviewed by the working group within the guideline (**Section 8.6.2**).
C	There is a lack of GP representation on the working group (5.6) and this is reflected in the consultation with a lack of a suggested referral pathway for community based patients	We agree that the implications of this guideline for primary care were not well-described, and we have strengthened this within the guideline. In particular, we have more strongly highlighted the responsibility of microbiology staff in clinical laboratories to liaise proactively with primary care teams regarding the possibility of FMT when recurrent positive stool samples are received from the community on a particular patient (**Section 8.7.1**).
D	There has also been a reported case of the development of obesity following FMT from an overweight donor but this has not been substantiated in other studies. The BMI restriction on donors (8.3.2) may restrict donors.	The recruitment of suitable donors is relatively restrictive by necessity since FMT is an unlicensed and poorly-studied medicinal product. There is a growing literature base demonstrating an association between a high or low BMI and perturbation of the structure and/or function of the gut microbiota and subclinical chronic inflammation. The implications of this for the safety and efficacy of FMT are not well-defined. The suggested BMI range does not make it prohibitively difficult to find suitable donors. As such, the working group believes that their existing recommendation is reasonable.

Section	Comments	Working group response
E	It would be useful to have a standard UK pre and post questionnaire for patients to standardise recording (8.1.2.3)	We agree that the introduction of standardised questionnaires would have clear potential advantages for clinical care and/ or research. We now discuss this further in **Section 10**, 'further research'.
F	It may useful to consider measuring the micriobiol strains of donors to monitor the impact of combinations of specific microbial strains to understand the undefined nature of faecal preparations	We agree of the importance of this, and this is now discussed in more detail in **Section 10**, 'further research'.
G	The lack of universal definitions of cures (8.1.2.4) is likely to hamper future studies	We agree with this comment. **Section 10**, 'further research' has been amended accordingly. Furthermore, we expect that the attention generated by this guideline will highlight this inadequacy.
H	With the introduction of the clinical term SNOMECT across primary care in 2018 and secondary care in 2020 it is important to record faecal microbiota transplant so that long term sequaelae can be measured and patients can be potentially contacted in the future.	We agree that there should be specific procedure codes for FMT (according to route of administration), so that this can be accurately recorded in the patient's medical record. This would also lay the foundation for a future HRG code and tariff for the procedure which is not currently funded by CCGs. Members of the working group are in discussion with NHS England about this.

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Healthcare Infection Society

Consultation – The use of faecal microbiota transplant as treatment for recurrent or refractory *Clostridium difficile* infection and other potential indications: joint British Society of Gastroenterology (BSG) and Healthcare Infection Society (HIS) guidelines.

Closing date: 5pm on January 2018

Organisation	**NHS Highland**
Title (e.g. Dr, Mr, Ms, Prof)	**Dr**
Name	Alex Cochrane
Job title or role	Consultant Microbiology and Infectious Diseases
Address and post code	Raigmore Hospital, Perth Road, Inverness IV2 3UJ
Telephone number	01463 704000
Email address	Alexandra.cochrane@nhs.net
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Section	Comments	Working group response
8.1.1.1	I dont think you should limit FMT for first recurrence to those with specific risk factors. If clinicians wish to use FMT rather than fidaxomicin for the first recurrence on cost effectiveness grounds then that is reasonable. Suggest that you recommend FMT may be offered for the first or second or subsequent recurrences.	As FMT is currently an unlicensed medicinal product with poorly-studied long term sequelae, the working group considered that it should generally be reserved for patients who have had more than three episodes of infection. There are no studies directly comparing its effectiveness with some of the newer agents such as fidaxomicin or bezlotoxumab, hence this recommendation is made on the basis of safety. However, the working group felt that it may be reasonable in certain patient groups (with ongoing risk factors for

Section	Comments	Working group response
		further recurrence) to offer FMT after the second episode. Cost effectiveness analysis was outside the remit of the working group.
8.1.1.3 (ii)	I disagree that patients should have previously been treated with extended/pulsed vancomicin or fidaxomicin before being offered FMT. You dont present any evidence to show that these antibiotic treatment is superior to FMT. Where FMT is the preferred treatment for the first recurrence it is quite likely that the patient will not have had a prolonged or tapered course, and this should not be a barrier to giving FMT which as you say is highly efficacious.	As above, there are no studies comparing FMT to fidaxomicin or bezlotoxumab, and only one study comparing a vancomycin taper to FMT (Hota *et al,* 2017). The safety profile of these medications is well-established from large randomised controlled trials, whilst randomised studies involving FMT have tended to be smaller, and have more variable patient follow-up. As such, on the balance of safety, the working group agreed that antimicrobial/antitioxin therapy associated with reduced CDI recurrence should be considered prior to FMT. Reflecting the uncertainties in this area within the reviewed literature, the relevant recommendation is 'conditional' rather than 'strong'.
8.1.1.3 (iii)	You dont cite any evidence that fidaxomicin or bezlotoxumab have better cure rates than FMT. My practice has been not to use fidaxomicin in life threatening C. difficile due to lack of evidence of efficacy in this setting, though I may be out of date with this.	Pre-planned subgroup analysis of patients with severe CDI in a randomised trial demonstrated a significantly lower recurrence rate when treated with fidaxomicin (13.0%, *n*=12/92) than when treated with vancomycin (26.6%, *n*=29/209) (Louie *et al,* 2011); this finding was replicated in another randomised controlled trial, with 8.3% (n=4/48) and 32.6% (n=14/43) experiencing a recurrence respectively (Cornely *et al,* 2012). In a further randomised trial, bezlotoxumab (together with standard of care antibiotics) was shown to reduce recurrence of severe CDI compared to standard of care antibiotics alone (10.9% (*n*=6/55) vs 20% (*n*=13/65) respectively) (Wilcox *et al,* 2017). The working group noted that there are no studies comparing FMT to fidaxomicin or bezlotoxumab, and only one study comparing a vancomycin taper to FMT (Hota *et al,* 2017). The working group agreed that in the absence of this

Section	Comments	Working group response
		evidence, on the balance of safety and potential risks, consideration should be given to using antimicrobial/ antitoxin therapy associated with reduced CDI recurrence prior to considering the use of FMT.
8.5.1.1 (iii)	Is there adequate published material or experience to ensure the safety of loperamide? It is usually avoided in C. difficile disease due To increased risk of complications.	We agree that loperamide should not be used expressly for the treatment of CDI diarrhoea. However, a number of studies (references within the guideline) have used a single dose of loperamide after lower GI FMT to retention, and no potential safety issues associated with this use have been identified.

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Healthcare Infection Society

Consultation – The use of faecal microbiota transplant as treatment for recurrent or refractory *Clostridium difficile* infection and other potential indications: joint British Society of Gastroenterology (BSG) and Healthcare Infection Society (HIS) guidelines.

Closing date: 5pm on January 2018

Organisation	**NHS Lothian**
Title (e.g. Dr, Mr, Ms, Prof)	**Dr**
Name	Ewan Olson

Job title or role	Consultant Microbiologist
Address and post code	Royal Infirmary of Edinburgh 51 Little France Crescent Edinburgh EH16 4SA
Telephone number	O131 2326048
Email address	ewan.olson@luht.scot.nhs.uk
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Section	Comments	Working group response
8.3.4.	Laboratory Screening of donors "Whilst vancomycin-resistant *Enterococci* (VRE) carriage is relatively common in the community, they are of low pathogenicity, and screening for them was not felt to be justified." VRE can cause life threatening infections that are difficult to treat. Any patient who is VRE positive requires isolation in a sideroom with ensuite facilities. I would suggest that donors should be screened for VRE before accepting stool for donation. If there is a shortage of donor patients should be offered VRE positive donations only with informed	Whilst vancomycin-resistant *Enterococci* (VRE) carriage is relatively common in the community (probably related to food consumption) (Endtz *et al,* 1997), community strains of VRE are genetically distinct from (and generally of much lower pathogenicity than) those found nosocomially (Willems *et al,* 2005); as such, the working group felt that routine screening was not justified. However, the working group acknowledged that the potential infection risk from VRE (and MRSA) would vary regionally dependent upon local prevalence and pathogenicity, and as such recommended that a risk assessment was performed to assess whether screening for these organisms should be considered.

Section	Comments	Working group response
	consent.	

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Healthcare Infection Society

Consultation – The use of faecal microbiota transplant as treatment for recurrent or refractory *Clostridium difficile* infection and other potential indications: joint British Society of Gastroenterology (BSG) and Healthcare Infection Society (HIS) guidelines.

Organisation	**On behalf of European Study Group for C*. difficile* (ESGCD), and the National Donor Feces Bank at Leiden University Medical Center (drs. E. Terveer, drs. E. Boeije-Koppenol, prof. Hein Verspaget, dr. Y van Beurden, drs. R Ooijevaar, dr. Josbert Keller) and Department of Infectious Diseases, University of Koln (dr. Maria Vehreschild).**
Title (e.g. Dr, Mr, Ms, Prof)	**Prof. Dr.**
Name	Ed Kuijper
Job title or role	Head of Experimental Bacteriology
Address and post code	LUMC, Albinusdreef2, 2333 ZA, Leiden
Telephone number	31-71-5263574
Email address	e.j.kuijper@lumc.nl
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Section	Comments	Working group response
general	The literature was searched until April 2017, but please use the recently published document of E.M Terveer et al. entitled "How to: Establish and run a stool bank" and published in Clin Microbiol Infect. 2017 Dec;23(12):924-930. This document has considerable overlap with the proposed guideline, but also shows some important unresolved issues.	This reference has been added. Literature searches have been updated, to January 2018.
Lay summary, line 3	Capsules may also be prepared by use of non-freeze dried microbiota. Also, the possibility of using frozen products in general may be mentioned in this sentence.	We agree that these changes are important, and these amendments have been accordingly.
8.1.1.1	The authors are correct that CDI due to Type 07 responds less to FMT compared with CDI due to other PCR ribotypes. We register all infections by PCR ribotype to obtain more insights in successes and failures associated with strain characteristics and think that this is relevant for future recommendations, such as repeated FMT treatments for specific PCR ribotypes.	We agree that this is important, and further reference has been made to this in **Section 10**, further research.
recommendation	"FMT should be offered to patients with recurrent CDI who have had at least two recurrences, or those who have had one recurrence and have risk factors for further episodes, including severe CDI (strong)." Please elucidate how this risk assessment can be performed.	The working party noted that these risk factors are well-described in previous studies, and do not require further elucidation within the manuscript.
8.1.1.2	Refractory CDI is also considered as an indication for FMT. Can the authors please provide a recommendation on the number of FMTs	In **Section 8.2.1**, the working group reviewed the literature on contraindications to receiving FMT, and noted that certain

Section	Comments	Working group response
	that should be used? Are patients on Intensive Care Units with refractory CDI also eligible? in 8.2.1 IC admission can be considered as a contraindication, but there are sufficient publications supporting to apply it for patients with severe CDI at ICU.	studies have made 'admission to Intensive Care' such a contraindication. However, the working group have not themselves at any point stated that this is a contraindication to receiving FMT. As stated in **Section 8.1.1.2**, there are a relatively small number of cases reported in the reviewed literature of refractory CDI. As such, the working group are unable to give recommendations that patients with refractory CDI receiving FMT should be managed in any particular way differently to those with recurrent CDI.
8.1.1.3	Antibiotic treatment of rCDI. Though the literature search was until April 2017, please mention the recent trials of tapered doses of vancomycin and fidaxomicin (PMID 29273269, PMID: 28591789; PMID 29255732).	We agree that these trials are all relevant, and have updated the guideline accordingly.
	Recommendation II is less clear. How have the authors interpreted the literature that a tapered dosage of vancomycin before FMT increases the success rate of FMT? Are these studies also available for fidaxomicin?	There are no studies comparing FMT to fidaxomicin or bezlotoxumab, and only one study comparing a vancomycin taper to FMT (Hota *et al,* 2017). The safety profile of these medications is well-established from large randomised controlled trials, whilst randomised studies involving FMT have tended to be smaller, and have more variable patient follow-up. Furthermore, FMT remains (in the UK) an unlicensed medicine. As such, on the balance of safety, the working group agreed that antimicrobial/ antitioxin therapy associated with reduced CDI recurrence should be considered prior to FMT. Reflecting the uncertainties in this area within the reviewed literature, the relevant recommendation is 'conditional' rather than 'strong'.
	Recommendation iii is difficult to understand; do the authors recommend to treat severe and complicated CDI not with vancomycin, but with fidaxomicin or vanco+bezlo? If a recurrence	The wording of this recommendation has been amended, along with expansion of the explanatory text of **Section 8.1.1.4.**

Section	Comments	Working group response
	occurs, then followed by a FMT?	
	A recommendation for FMT treatment in severe (refractory), complicated CDI is missing (e.g. multiple sequential FMTs); should this also be accompanied with anti-CDI antibiotics? See review v. Beurden, Ther Advances in Gast, 2017 and Fischer, Ali Pharm Ther 2015	As stated in **Section 8.1.1.2**, there are a relatively small number of cases reported in the reviewed literature of refractory CDI. As such, the working group are unable to give recommendations that patients with refractory CDI receiving FMT should be managed in any particular way differently to those with recurrent CDI.
8.1.2.1	We suggest to differentiate between "non-responding" and "late failure". The latter can be defined as a relapse of CDI after an initial response to FMT. For instance, use of antibiotics in the first month after FMT may provoke a new episode of CDI. This new episode doesn't need a FMT and can be treated with conventional anti-CDI treatment, preferably microbiota sparing such as fidaxomicin.	We agree that this distinction is useful, and have amended the guideline accordingly.
8.1.2.2	Should a psychological questionnaire routinely be taken from recipients (before and after FMT) and from donors (regularly)? A ten-week follow-up is too short to recognize long term side-effects of FMT.	The working group did not consider that this was a priority.
8.1.2.3	We consider swallowing disorders a contraindication for upper GI delivery; death of a patient due to aspiration pneumonia with upper GI delivery has been described (PMID: 29026601); this patient had a swallowing disorder following oropharyngeal radiation after surgical removal of a maxillary carcinoma.	We note that this patient received a very large volume (500ml) of nasoduodenal FMT. This guideline recommends a much lower maximum volume with the specific aim of minimising this problem. Nevertheless, we agree that this is an important consideration, and have amended **Section 8.1.2.3** and **Section 8.5.2.2** accordingly.
8.2.1	What is the advice of the committee for coeliac patients with recurrent CDI?	The working group did not have any specific advice regarding patients with coeliac disease.
8.2.2	FMT in immunocompromised patients: we think that the presence of neutropenia ($<0.5 \times 10^9$/L) can be considered as a contraindiction for FMT, especially if hematological patients are treated with selective gut decontamination to prevent translocation and infections with aerobe Gram-negatives. Second, should donors and immunocompromised recipients be matched for the EBV and CMV	The working group have recommended that FMT is offered 'with caution' to immunosuppressed patients, reflecting the careful individualised assessment required for each patient. We agree with the comment regarding matching donors and immunosuppressed recipients for EBV and CMV status, and

Section	Comments	Working group response
	status to prevent a herpesvirus infection?	have updated **Section 8.2.2** and **Section 8.3.4** accordingly.
8.2.3	The effect of FMT on the IBD status for IBD patients with rCDI is under discussion. Is it possible that FMT will result in cure of CDI but an exacerbation of IBD. Should we differentiate UC from CD? Ref 71 suggests that IBD can worsen. The recommendation "strong" is debatable. Is the IBD group not a better candidate for vancomycin tapering, fidaxomicin (tapering) or bezlotoxumab before FMT is given?	We agree that there is evidence that FMT to treat CDI in patients with IBD may be associated with a flare of IBD activity (Qazi *et al,* 2017); we have updated the recommendation accordingly.
8.3.2	Age and BMI of the donor. We agree with the BMI of the donor but have some difficulties with the age, We consider an age above 50 as a contraindication, based on the risks to develop colon carcinoma and metabolic (diabetes) diseases. Additionally, older people seems to have a less stable gut microbiota.	We note from a recent paper that *Bacteroides: Firmicutes* ratio and microbial diversity were similar in donors > 60 years compared to younger donors, and donations from older donors had similar efficacy and no higher rate of adverse outcomes (Anand *et al,* 2017). As such, the working group agreed to uphold their prior recommendation.
8.3.3.	Donor screening history. Donors should also undergo a long term follow-up to recognize microbiota related diseases, including colon malignancies, autoimmune diseases, metabolic diseases and psychiatric illnesses.	We agree with the principle of this statement, and allude to this in **Section 8.7.7.**
	Please consider to add to the recommendation/evidence: Potential donors should be extensively screened by a questionnaire and a personal interview concerning risk factors for transmissible diseases and factors influencing the intestinal microbiota	We agree with this suggestion, and have amended **Section 8.3.3** accordingly.
8.3.4	Screening of the donor. Table 4. The Dutch guideline advises screening donors for multi-drug resistant bacteria (MDR), including VRE, MRSA, CPE and ESBL-producing Gram-negatives, and quinolone/aminoglycoside resistant Enterobacteriaceae. Most of the patients with rCDI have much comorbidity and are frequently hospitalized or encounter nosocomially acquired infections, such as UTI. Infections with MDR are more difficult to treat, mostly with intravenously administered antibiotics. If these patients become colonized with MDR they should be nursed with specific infection	The working group reviewed their recommendation regarding screening for multi-drug resistant bacteria, and **Section 8.3.4** has been updated accordingly. We agree with the principle of a 'window period'/ quarantine prior to repeat donor screening in centres using frozen FMT; **Section 8.3.5** has been updated accordingly, and a new flow chart to illustrate the process (**Figure 1**) added.

Section	Comments	Working group response
	control precautions. We also apply a "window period"; donors stools samples are stored in quarantine for 2 months and only become available after a negative second screening. We additionally screen for: *Yersinia enterocolitica, Yersinia pseudotuberculosis, Plesiomonas shigelloides*, shiga toxin producing *E. coli* (not only 0157 E.coli), Astrovirus, Sapovirus, Adenovirus, Enterovirus, Parechovirus, Hepatitis E, *Entamoeba histolytica*, *Microsporidium* species, *Blastocystis hominis, Dientamoeba fragilis*, and Strongyloides (if a travel history to Middle and South America, Africa, or Asia is present). We advise to include carriership of *E. histolytica* and Strongyloides to the mandatory screening, because of the serious infections that occur in immunocompromised patients. We have detected unexpectedly a donor carrying *E. histolyica* (Terveer, CMI, 2017).	The working group agreed that recommendations should be made to test for Shiga toxin-producing *Escherichia coli,* hepatitis E IgM, *Entamoeba histolytica* serology and *Strongyloides stercoralis* IgG (**Table 3**). However, the consensus was that screening for the other tests suggested is not justified.
8.4.1	Recommendation i. Please elucidate how donors should deliver their stools. We favour the use of specific device systems to prevent contamination with environmental microorganisms. Recommendation ii. Processing within 6 hours is proven effective, consider changing 'conditional' to 'strong' recommendation Recommendation iii. A meta-analysis concludes that lless than 50 gram of feces is related to a 4-fold increase in recurrence rates. The recommendation status should be changed to 'strong'.	i. We think that the text as it stands gives sufficient information about best practice in this area. ii. We agree with this suggestion, and have amended **Section 8.4.1** accordingly. iii. We agree with this suggestion, and have amended **Section 8.4.1** accordingly.
8.4.2	An important advantage of frozen FMT is the possibility to use a "window period" of, for example, two months. When donors are screened after this window period, the results determine if the stored FMTs can be used.	We have cross-referenced **Section 8.4.2** to **Section 8.3.5**, where the concept of a window period/ quarantine is discussed in more detail.
8.4.3	We think that there is not enough evidence to state that feces	A trend towards decrease in the viability of certain gut

Section	Comments	Working group response
	suspensions can only be used up to six months from preparation. There is no sufficient data that show a decreased efficacy with feces suspensions stored over 6 months. Additionally, multiple stool banks set the expiration date at 1 year after storage.	bacterial groups was noted when faecal aliquots were frozen in 10% glycerol for six months (Costello *et al,* Alimentary Pharm & Ther, 2015), and as such, the working group agreed that six months was the acceptable limit for freezing of an FMT in glycerol. This rationale is now within the text.
	Good practice point: Thawing overnight in a 4C refrigerator is also a good and much used alternative.	None of the working group had sufficient experience with this means of thawing FMT, and as such were unable to make this good practice point.
8.5.1.1.	It is not clear, why the administration of a bowel lavage in upper GI administration, of PPI, of loperamide and of metroclopramide are recommended. There is no evidence to support their use, and all of them are drugs with known side effects. The only reason why they are used is that the first RCT used them. However, the RCT did not assess their importance, and there are many case series showing that FMT has a high success rate even without their use.	All of these interventions have a clear biological or practical rationale for their use. Significant side effects in association with a single dose of these medications are generally rare, and their use has not been associated with adverse outcomes in FMT studies. Our recommendations for their use are only conditional. As such, the working group uphold their recommendations.
8.5.2.1.	Not all capsules necessarily contain lyophylized microbiota, frozen preparations have also been shown to be effective.	We agree with this comment, and have updated the guideline accordingly.
8.5.2.2	Are there studies indicating that 50 ml for upper gastrointestinal have comparable efficacy as 250 ml? If not, this should be more pronounced mentioned, also in the research session. We use at least 50 gram suspended in 200 ml and a slow infusion of 10cc/min.	As described in the text, the working group considered that mass of stool was a more important consideration than volume of diluent. They also noted that as low as 25ml of FMT has been demonstrated to be effective as upper GI FMT (Aas *et al, Clin Infect Dis,* 2003). As such, the working group uphold their recommendation.
8.5.2.4.	The recommendation not to use capsules seems rather strong. It is unlikely that concerning transmission of infection, the risk would differ in any way from other ways of administration. Also, no safety concerns based on endoscopic complications can possibly arise. We would therefore not pronounce a recommendation against use.	We agree with this statement. Of note, whilst the Kao *et al,* 2017 study (RCT of capsulised vs colonoscopic FMT) was not published at the time of initial searches, it has been identified by updated searches and has now been reviewed by the working group. As such, the guideline has been updated accordingly.
8.6	Consider to add that specific donor microbiota may have better outcomes (e.g. donor B in Moayyedi, gastroenterology, 2015)	Reference to Donor B in this paper has been added to **Section 8.6.2.2.**

Section	Comments	Working group response
	FMT for other conditions than rCDI. Why have the authors not included the role of FMT to eradicate MDR from the intestinal tract?	In keeping with NICE methodology, for the consideration of FMT as treatment for non-CDI conditions, only RCTs could be considered. The working group are aware of case studies and case series using FMT to attempt gut decolonisation of multidrug resistant microorganisms. Members of the working party have themselves contributed to the literature in this field. But no RCTs currently exist.
8.6.3.	Consider adding: characterisation of specific CU patient population that would potentially benefit from FMT. "However, recommendations for clinical use for this indication cannot be made until there is clearer evidence of the most appropriate **CU patient characteristics**, methodology for its preparation, route of delivery, and intensity of administration of FMT"	We agree with this comment, and have updated the guideline accordingly.
8.7.2 and 8.7.4	FMT is considered as a medicinal product under supervision of MHRA and licensing should follow the GMP guidelines. The activities should be performed in a dedicated containment level 2 laboratory with personal protective equipment and a quality assessment system. Does this indicate that FMTs should be prepared under GMP conditions at the Pharmacy Department and not within the Medical Microbiology? Or is this statement too strong?	No. MHRA guidance does not specify where the manufacture should take place. This could be pharmacy, the microbiology laboratory, or another place.
8.7.6	Please consider to add that aliquots of donor FMT materials (and original feces samples) used for patients treatment should be stored, enabling to use these samples when adverse effects after FMT developed. This should also been included in 6.3 (auditing).	We agree, and we have updated **Sections 6.3** and **8.7.6** accordingly.
Table 4	PCRs are more sensitive than conventional microscopy and antigen tests for parasites. Second, can the authors please specify the parasites? There is some debate on the significance of Blastocystes spp. and Dientamoeba spp. Why is only E. coli 157 excluded and not	**Table 4** has been updated to specify Shiga toxin-producing *Escherichia coli* screening by PCR. The working group did not consider that specific screening for *Blastocystis spp* or *Dientamoeba spp* was justified.

Section	Comments	Working group response
	other STEC pathogens?	
Propose to add: Eligibility of patients for FMT	At the NDFB, all requests by the treating physician are evaluated by at least two clinical members of our feces bank board to determine the eligibility of the patient. It is required that patients have a laboratory documented episode of recurrent CDI following at least one course of adequate CDI antibiotic therapy. Recurrent CDI is defined as the re-appearance of diarrhoea (≥ 3 unformed stools per 24 hours for two consecutive days; or ≥ 8 unformed stools per 48 hours) within eight weeks after cessation of antibiotic therapy in combination with a positive diagnostic test for *C. difficile*. We strongly recommend a two-stage testing algorithm, as recently advised by the *C. difficile* working group/ESCMID (ESGCD). Using this algorithm, we reject approximately 20% of all requests for FMT. We would like to add our experience that of 79 candidate patients for FMT, only 75% were considered as suitable candidates for FMT treatment; most rejected requests were patients with underlying IBD who concomitantly carried *C. difficile.*	Thank you for this comment. Definitions of recurrent CDI are outside of the remit of this working group. Testing is discussed in **Section 8.1.1.,** where we refer to current ESCMID guidance.
Need for antimicrobial stewardship after FMT (also for 8.5.1.3)	After FMT, we advise that an infectious disease specialist or medical microbiologists should be involved for antibiotic treatment (or prophylaxis) of the patient during the first month after FMT, since 50% of our registered failures were patients who received antibiotics within one month after FMT. Interestingly, all patients responded to conventional anti-CDI treatment and did not need a second FMT. It can be considered to use microbiota sparing fidaxomicin after FMT.	We agree with this comment, and have updated **Section 8.5.1.3** accordingly.

Closing date: Please forward this electronically by 5pm on January 2018 at the very latest to consultations@his.org.uk

Consultation – The use of faecal microbiota transplant as treatment for recurrent or refractory *Clostridium difficile* infection and other potential indications: joint British Society of Gastroenterology (BSG) and Healthcare Infection Society (HIS) guidelines.

Closing date: 5pm on January 2018

Organisation	OpenBiome
Title (e.g. Dr, Mr, Ms, Prof)	Dr
Name	Majdi Osman
Job title or role	Clinical Program Director, OpenBiome; Visiting Assistant Professor, Harvard Medical School
Address and post code	200 Inner Belt Road, Somerville, MA 02143
Telephone number	+1 (617) 575-2201
Email address	majdi@openbiome.org
Please note: comments will only be accepted electronically on this proforma.	

Please provide comments on the draft guideline on the form below, putting each new comment in a new row. When feeding back, please note the section you are commenting on (for example, section 1 Introduction and line number). If your comment relates to the guideline as a whole then please put 'general'. Add extra rows if required.

Section	Comments	Working group response
8.1.1.1. Recurrent *Clostridium difficile* infection	***"FMT should be offered to patients with recurrent CDI who have had at least two recurrences, or those who have had one recurrence and have risk factors for further episodes, including***	We agree with this statement, and have updated the guideline accordingly.

Section	Comments	Working group response
	severe CDI (strong).” We agree however for full clarity we would recommend re-wording to: ***“FMT should be offered to patients with recurrent CDI who have had at least two recurrences, or those who have had one recurrence and have risk factors for further episodes, including severe and severe-complicated CDI (strong).”***	
8.1.1.2. Refractory Clostridium difficile infection:	***“FMT should be considered in cases of refractory CDI (conditional).”*** We agree.	Thank you for this comment.
8.1.1.3. Antimicrobial therapy prior to considering FMT for patients with CDI:	***i. FMT for recurrent CDI should only be considered after failure of antimicrobial anti-C. difficile therapy which has been administered for a minimum of 10 days (conditional).*** ***ii. Recipients of FMT as treatment for recurrent CDI should have previously been treated with extended/ pulsed vancomycin and/or fidaxomicin (conditional).*** ***iii. For those with severe or complicated CDI, which appears to be associated with reduced cure rates, consideration should be given to offering patients treatment with medications which are associated with reduced risk of recurrence (e.g. fidaxomicin and bezlotoxumab), before offering FMT (conditional).*** We suggest rewording point *iii*, that recommends fidaxomicin or bezlotoxumab should be offered to patients with severe or complicated CDI before FMT. There is little evidence on the role of bezlotoxumab and fidaxomicin in severe or severe-complicated CDI. Although the evidence base is similarly lacking for FMT in severe or	Pre-planned subgroup analysis of patients with severe CDI in a randomised trial demonstrated a significantly lower recurrence rate when treated with fidaxomicin (13.0%, *n*=12/92) than when treated with vancomycin (26.6%, *n*=29/209) (Louie *et al,* 2011); this finding was replicated in another randomised controlled trial, with 8.3% (n=4/48) and 32.6% (n=14/43) experiencing a recurrence respectively (Cornely *et al,* 2012). In a further randomised trial, bezlotoxumab (together with standard of care antibiotics) was shown to reduce recurrence of severe CDI compared to standard of care antibiotics alone (10.9% (*n*=6/55) vs 20% (*n*=13/65) respectively) (Wilcox *et al,* 2017). The working group noted that there are no studies comparing FMT to fidaxomicin or bezlotoxumab, and only one study comparing a vancomycin taper to FMT (Hota *et al,* 2017). The working group agreed that in the absence of this evidence, on the balance of safety and potential risks,

Section	Comments	Working group response
	severe-complicated disease, there is a growing body of evidence from trials, multiple case series and reports indicating the potential for FMT in this population. **Bezlotuxumab:** The performance of bezlotuxumab has not been evaluated in a severe or severe-complicated population. Results from MODIFY I and II suggest a modest 10% improvement in rates of sustained cure with bezlotoxumab. Importantly, only 15.6% were severe CDI. Based on the modest gains in efficacy and the few severe/severe-complicated patients in the MODIFY trials, we feel that further evidence is required before proposing bezlotuxumab be offered ahead of FMT in this patient population. In comparison, across similar patient populations FMT has demonstrated in several randomized controlled trials reduced risk of recurrence. Based on the available evidence we therefore feel that the statement that bezlotuximab is "associated with reduced risk of recurrence" compared to FMT is not supported by the evidence. **Fidaxomicin:** Similarly, there is a dearth of evidence on the role of fidaxomicin in the severe CDI population. We agree that it has demonstrated superior efficacy compared to vancomycin in the general CDI population. In an RCT comparing extended-pulsed fidaxomicin versus vancomycin for CDI, Guery et al (2017) observed increased recurrence in severe CDI compared to non-severe CDI with an odds ratio 0.57 (95% CI 0·36–0·91) p=0.019. We therefore recommend that fidaxomixin should be offered to patients with severe CDI. However, there is no evidence to suggest that the performance of fidaxomicin would be better than FMT. We acknowledge that access to fidaxomicin is likely to be more timely	consideration should be given to using antimicrobial/ antitoxin therapy associated with reduced CDI recurrence prior to considering the use of FMT.

Section	Comments	Working group response
	in settings where FMT is not readily available. **The role of FMT in severe CDI:** In their recent review, Van Beurden et al (2017) reviewed the literature on FMT in severe CDI and found 23 reports (12 case reports; 11 case series) about FMT as treatment for severe or complicated CDI. The patients described (n=200) all had severe or complicated CDI, did not respond to conventional CDI antibiotic treatment and received FMT as last resort treatment. In all studies, patients were treated with (sequential) FMT, whether or not followed by additional antibiotic treatment for CDI. FMT, with or without additional antibiotic CDI treatment, appears to be a promising curative treatment option in patients with severe and complicated CDI who do not respond sufficiently to conventional antibiotic treatment. FMT has been proposed by Fischer et al (2015) as an option utilizing an endoscopic response-guided approach, which may be particularly useful in non-surgical candidates. In an open-label cohort study (n = 17), FMT was delivered by colonoscopy. If pseudomembranes were identified, patients reinitiated oral vancomycin 24 hour after FMT and continued for 5 days. A repeat FMT by colonoscopy was given on day 7. If pseudomembranes persisted, vancomycin was restarted the following day for a 5 days course and a third FMT was offered on day 13. If pseudomembranes were absent during any colonoscopy, no further therapy was initiated. The results were promising with a combined clinical cure rate of 88%. In conclusion, we agree that there is a lack of evidence available to make a strong recommendation on the role of FMT in severe CDI. However, there is insufficient evidence to suggest that fidaxomicin or bezlotuximab would be superior to FMT in this population. On the contrary, the growing pool of experience in using FMT in severe	

Section	Comments	Working group response
	and severe-complicated CDI patients demonstrates that it appears to be generally safe and effective (quality of evidence: 3). We would therefore suggest re-wording point iii to: ***iii. For those with severe or complicated CDI, which appears to be associated with reduced cure rates, consideration should be given to offering patients treatment with medications which are associated with reduced risk of recurrence (e.g. fidaxomicin or bezlotuxumab), or offering FMT (conditional).*** Fischer M, Sipe BW, Rogers NA, et al. Faecal microbiota transplantation plus selected use of vancomycin for severe-complicated Clostridium difficile infection: description of a protocol with high success rate. Aliment Pharmacol Ther. 2015;42(4):470-476. doi:10.1111/apt.13290. Van Beurden YH, Nieuwdorp M, van de Berg PJEJ, Mulder CJJ, Goorhuis A. Current challenges in the treatment of severe Clostridium difficile infection: early treatment potential of fecal microbiota transplantation. Therapeutic Advances in Gastroenterology. 2017;10(4):373-381. doi:10.1177/1756283X17690480.	
8.1.2.1. Management of FMT failure:	***Further FMT should be offered after initial FMT failure (strong).*** We agree.	Thank you for this comment.
8.1.2.2. General approach to follow-up post-FMT:	***All FMT recipients should routinely receive follow-up. Given the relative novelty of FMT and the potential for unexpected sequelae, clinicians should follow-up FMT recipients for long enough to fully establish efficacy/ adverse events, and at least ten weeks in total (strong).***	Thank you for this comment. In light of other comments from the working group and stakeholders, this follow-up period has been adjusted to 'at least eight weeks in total'.

Section	Comments	Working group response
	We agree.	
8.1.2.3. Management of the FMT recipient:	***i. Immediate management after endoscopic administration of FMT should be as per endoscopy unit protocol (strong).*** ***ii. Patients should be warned about short term adverse events, in particular the possibility of self-limiting GI symptoms. They should be advised that serious adverse events are rare (strong).*** ***iii. After enteral tube administration, patients may have the tube removed and oral water given from 30 minutes post-administration (strong).*** We agree.	Thank you for this comment.
8.1.2.4. Definition of cure post-FMT for CDI:	***A decision regarding cure/remission from CDI should be recorded during follow-up. However, this has no uniformly-agreed definition, and should be decided on a case-by-case basis (strong).*** We agree.	Thank you for this comment.
8.1.2.5. Definition of treatment failure post-FMT for CDI:	***Treatment failure/recurrence should be defined on a case-by-case basis. Routine testing for C. difficile toxin after FMT is not recommended, but is appropriate to consider in the case of persistent CDI symptoms/suspected relapse (strong).*** When testing is to be performed, we would recommend clinicians follow the 2016 European Society of Clinical Microbiology and Infectious Diseases (ESCMID) guidelines for CDI testing, which state that no single commercial test can be used as a stand-alone test for diagnosing CDI, and recommend a 2-step approach (highly sensitive with reflex to highly specific test). These guidelines recommend performing an initial test with a high negative predicative value; therefore, if negative, no further testing needs to be done.	We agree on the use of ESCMID guidelines in CDI testing, and refer to these clearly in **Section 8.1.1.1**. However, **Section 8.1.2.5** specifically refers to diagnosing failure post-FMT for CDI rather than initial diagnosis of CDI, and no good uniform definition exists for this. We think that the guidance given, to define treatment failure on a case-by-case basis, is the most fair summary of the current literature on this topic.

Section	Comments	Working group response
	Specifically, they suggest glutamate dehydrogenase (GDH) EIA or NAAT/PCR testing. Our recommendation is GDH EIA as it is less expensive and has a slightly superior NPV at higher CDI prevalence compared with NAAT/PCR (98 vs 96 at hypothetical CDI prevalence of 50%), and an NPV of 100% at lower CDI prevalence. The second test should be a test with a high positive predictive value, such as EIA for toxin A/B. Obtaining CDI testing at each suspected CDI recurrence and working with institutional laboratories to use an appropriate testing algorithm is a key component to ensuring appropriate patient selection for FMT. As currently worded, the recommendations risk encouraging over testing in a context where patients may develop post-infectious IBS. This concept is highlighted by evidence suggesting that up to 25% of patients referred to an FMT center for "C difficile infection" were found to have an alternative diagnosis, with younger patients being more likely to have a non-CDI diagnosis (Jackson 2016). Jackson M, Olefson S, Machan JT, Kelly CR. A high rate of alternative diagnoses in patients referred for presumed clostridium difficile infection. J Clin Gastroenterol. 2016 Oct;50(9):742-6.	
8.2.1. General approach to co-morbidities and FMT:	***FMT should be offered with caution in patients with decompensated chronic liver disease and should be avoided in those with anaphylactic food allergy (strong).*** The authors may want to consider the approach recommended by Allegretti et al (2017). In patients with a severe food allergy, a potential option for FMT could be from a patient identified donor living with the patient (e.g. spouse) who avoids the same allergens. Allegretti JR, Kassam Z, Osman M, Budree S, Fischer M, Kelly CR.	The working group thought it important to emphasise the 'good practice point' that in patients with true anaphylaxis, the risks of FMT administration were likely to outweigh the benefits. As such, this suggestion has not been incorporated.

Section	Comments	Working group response
	The 5D framework: a clinical primer for fecal microbiota transplantation to treat Clostridium difficile infection. Gastrointest Endosc [Internet]. 2017 Jul 26; Available from: http://dx.doi.org/10.1016/j.gie.2017.05.036	
8.2.2. Immunosuppression and FMT:	***FMT should be offered with caution to immunosuppressed patients, in whom FMT appears efficacious without significant additional adverse effects (strong).*** We agree.	Thank you for this comment.
8.2.3. Other co-morbidities and FMT:	***Recommendation:*** ***i. FMT should be offered to those with recurrent CDI and inflammatory bowel disease (strong).*** ***ii. FMT should be considered for appropriate patients with recurrent CDI regardless of other comorbidities (conditional).*** We agree.	Thank you for this comment.
8.3.1. General approach to donor selection:	***Related or unrelated donors should both be considered acceptable. However, where possible, FMT is best sourced from a centralised stool bank, from a healthy unrelated donor (conditional).*** We agree.	Thank you for this comment.
8.3.2. Age and BMI restrictions for potential donors:	***People should only be considered as potential FMT donors if they are ≥18 and ≤60 years old, and have a BMI of <30 kg/m^2 (conditional).*** We agree.	Thank you for this comment.
8.3.3. General approach to the donor screening assessment:	***A donor-screening history/ questionnaire is mandatory (Table 2) (strong).*** ***1. Receipt of antimicrobials within the past three months.***	

Section	Comments	Working group response
	2. *Known prior exposure to HIV and/ or viral hepatitis, and known previous or latent tuberculosis.* 3. *Risk factors for blood-borne viruses - including high risk sexual behaviours, use of illicit drugs, any tattoo/ body piercing/ needlestick injury/ blood transfusion/ acupuncture, all within previous six months.* 4. *Receipt of a live attenuated virus within the past six months.* 5. *Underlying gastrointestinal conditions (e.g. history of IBD, IBS, chronic diarrhoea, chronic constipation, coeliac disease, bowel resection or bariatric surgery).* 6. *Family history of any significant gastrointestinal conditions (e.g. family history of IBD, or colorectal cancer).* 7. *History of atopy (e.g. asthma, eosinophilic disorders).* 8. *Any systemic autoimmune conditions.* 9. *Any metabolic conditions, including diabetes and obesity.* 10. *Any neurological or psychiatric conditions, or known risk of prion disease.* 11. *History of chronic pain syndromes, including chronic fatigue syndrome and fibromyalgia.* 12. *History of any malignancy.* 13. *Taking particular regular medications, or such medications within the past three months, i.e. antimicrobials, proton pump inhibitors, immunosuppression, chemotherapy* 14. *History of receiving growth hormone, insulin from cows, or clotting factor concentrates.* 15. *History of receiving an experimental medicine or vaccine within the past six months.*	

Section	Comments	Working group response
8.3.4. Laboratory screening of potential donors:	***Blood and stool screening of donors is mandatory (Tables 2 and 3) (strong).*** ***Table 3: Recommended blood screening for stool donors:*** ***Pathogen screening:*** • ***Hepatitis A IgM*** • ***Hepatitis B (HBsAg and HBcAb)*** • ***Hepatitis C antibody*** • ***Hepatitis E IgM*** • ***HIV -1 and -2 antibodies*** • ***HTLV-1 and -2 antibodies*** • ***Treponema pallidum antibodies (TPHA, VDRL)*** • ***Epstein-Barr virus IgM*** • ***Cytomegalovirus IgM*** • ***Strongyloides stercoralis IgG*** • ***Entamoeba histolytica serology*** ***General/ metabolic screening:*** • ***Full blood count with differential.*** • ***Creatinine and electrolytes*** • ***Liver enzymes (including albumin, bilirubin, aminotransferases, gamma-glutamyltransferase and alkaline phosphatase).*** • ***C-reactive protein*** ***Table 4: Recommended stool screening for stool donors:*** • ***Clostridium difficile PCR*** • ***Campylobacter, Salmonella, and Shigella by standard stool culture and/ or PCR*** • ***Escherichia coli 0157 H7 by culture and/or PCR***	We agree with the comment regarding matching donors and immunosuppressed recipients for EBV and CMV status, and have updated **Section 8.2.2** and **Section 8.3.4** accordingly. The working group did not think that screening for adenovirus was justified. Whilst vancomycin-resistant *Enterococci* (VRE) carriage is relatively common in the community (probably related to food consumption) (Endtz *et al,* 1997), the form of VRE in the community is genetically distinct from that found nosocomially, with much lower pathogenicity in community forms (Willems *et al,* 2005). As such, the working group strongly opined that routine screening was not justified. However, it was acknowledged that the potential infection risk from VRE (and MRSA) would vary regionally depending on local prevalence and pathogenicity, and as such a local risk assessment has been recommended to decide whether screening for these organisms should be considered.

Section	Comments	Working group response
	• ***Multi-drug resistant bacteria, specifically carbapenemase-producing Enterobacteriaceae.*** • ***Stool ova, cysts and parasite analysis, including for Microsporidia.*** • ***Faecal antigen for Cryptosporidium and Giardia.*** • ***Acid fast stain for Cyclospora and Isospora.*** • ***Helicobacter pylori faecal antigen.*** • ***Norovirus and Rotavirus PCR.*** We recommend: **CMV and EBV:** Given the high rates of carriage for both EBV and CMV in a healthy, adult population, excluding EBV or CMV positive donors would make it prohibitively difficult to identify suitable donors to provide access to care (Bate et al). Moreover, excluding EBV or CMV positive candidates is not expected to provide a significant benefit to the majority of the patients that would be served by a centralized stool bank, who are not severely immunocompromised. Given the need to ensure a reliable supply of material for the vast majority of rCDI patients while protecting severely immunocompromised patients, until now OpenBiome has chosen not to test for EBV and CMV. Instead, we treat material as presumptively CMV and EBV positive and discourage use in severely immunocompromised patients who are seronegative for CMV or EBV. We are sensitive to the fact that this leaves clinicians with an additional challenge for managing these already difficult cases (severely immunocompromised rCDI patients). Should FMT be	

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	indicated then we would suggest that **in the immunocompromised patient at risk of CMV or EBV infection either: 1) CMV and EBV testing of the recipient to confirm positive serology, in which case FMT may be considered after extensive discussion of the risks, benefits, and alternatives in the informed consent process; or 2) the use of a directed donor with matching serology.** Bate SL, Dollard SC, Cannon MJ. Cytomegalovirus seroprevalence in the United States: the national health and nutrition examination surveys, 1988-2004. Clin Infect Dis. 2010;50:1439–1447. **Adenovirus:** We recommend including adenovirus on stool in addition to norovirus and rotavirus. **Vancomycin resistant enterococcus (VRE):** VRE should be specifically mentioned in "*Multi-drug resistant bacteria".* VRE is a leading cause for donor exclusion despite prospective donors having no known risk factors for colonization.	
8.3.5. Final donor checks prior to donation:	***Further final screening should take place prior to collection of a stool sample for processing into FMT (strong).*** We agree.	Thank you for this comment. In light of this and other comments, the recommendation on repeat screening has been strengthended.
8.4.1. General principles of FMT preparation:	***Recommendation:*** ***i. Donor stool collection should follow a standard protocol (strong).*** ***ii. Donor stool should be processed within 6 hours of defecation (conditional).*** ***iii. Both aerobically and anaerobically prepared FMT treatments should be considered suitable when preparing FMT for the treatment of recurrent CDI (strong).***	Thank you for this comment.

Section	Comments	Working group response
	iv. Sterile 0.9% saline should be considered as an appropriate diluent for FMT production, and cryoprotectant such as glycerol should be added for frozen FMT (strong). ***v. Consider ≥50g of stool for use in FMT preparation (conditional).*** ***Good practice points:*** ***i. Stool should be mixed 1:5 with diluent to make the initial faecal emulsion (conditional).*** ***ii. Homogenisation and filtration of FMT should be undertaken in a closed disposable system (conditional).*** We agree.	
8.4.2. Fresh vs frozen FMT:	***The use of banked frozen FMT material should be considered preferable to fresh preparations for CDI (strong).*** We agree.	Thank you for this comment.
8.4.3. Use of frozen FMT:	***Recommendation:*** ***FMT material stored frozen at -80^{o}C should be regarded as having a maximum shelf life of six months from preparation (strong).*** ***Good practice point:*** ***Consider thawing frozen FMT should at ambient temperature and using within six hours of thawing (conditional).*** We agree.	Thank you for this comment.
8.5.1. Use of specific medications in the period around FMT administration: **8.5.1.1. General**	***Recommendation:*** ***i. Bowel lavage should be administered prior to FMT via the lower GI route, and bowel lavage should be considered prior to FMT via the upper GI route; polyethylene glycol preparation is preferred (conditional).***	Thank you for this comment.

Section	Comments	Working group response
principles of FMT administration:	***ii. For upper GI FMT administration, a proton pump inhibitor should be considered, e.g. the evening before and morning of delivery (conditional).*** ***iii. Loperamide (or other anti-motility drugs) should be considered following lower GI FMT delivery (conditional).*** ***Good practice point:*** ***i. Prokinetics (such as metoclopramide) should be considered prior to FMT via the upper GI route (conditional).*** ***ii. Best practice for prevention of further transmission of CDI should be applied throughout when administering FMT to patients with CDI (nursing with enteric precautions, sporicidal treatment of endoscope, etc).*** We agree.	
8.5.1.2. Additional antibiotics pre-FMT:	***Consider further antimicrobial treatment for CDI for at least 72 hours prior to FMT (conditional).*** We agree.	Thank you for this comment.
8.5.1.3. Washout period between antibiotic use and FMT:	***To minimise any deleterious effect of antimicrobials on the FMT material, there should be a minimum washout period of 24 hours between the last dose of antibiotic and treatment with FMT (strong).*** We agree.	Thank you for this comment.
8.5.2.2. Upper gastrointestinal tract administration of FMT:	***Recommendation:*** ***i. Upper GI administration of FMT as treatment for recurrent or refractory CDI should be used where clinically appropriate (strong).*** ***ii. Where upper GI administration is considered most***	Thank you for this comment.

Section	Comments	Working group response
	appropriate, FMT administration should be via nasogastric, nasoduodenal, or nasojejunal tube, or alternatively via upper GI endoscopy. Administration via a permanent feeding tube is also appropriate (strong). ***Good practice point:*** ***It is recommended that no more than 50ml of FMT is administered to the upper GI tract (conditional).*** We agree.	
8.5.2.3. Lower gastrointestinal tract administration of FMT:	***Recommendation:*** ***i. Colonoscopic administration of FMT as treatment for recurrent or refractory CDI should be used where appropriate (strong).*** ***ii. Where colonoscopic administration is employed, consider preferential delivery to the caecum or terminal ileum, as this appears to give the highest efficacy rate (conditional).*** ***iii. FMT via enema should be used as a lower GI option when colonoscopic delivery is not possible (strong).*** We recommend rewording point *iii*. Although there is limited data, flexible sigmoidoscopy may be the preferred route of delivery where colonoscopic delivery is not possible. Several experts have advised less invasive modalities such sigmoidoscopy in high risk patients (Brandt 2013; Kelly 2014). This may provide a more effective method for delivering material as proximally as possible and improving retention. We therefore recommend re-wording point *iii* to: ***FMT via enema should be used as a lower GI option when colonoscopic or flexible sigmoidoscopy delivery is not possible***	We agree with this suggestion, and have updated the guideline accordingly.

Section	Comments	Working group response
	(strong). Brandt LJ, Aroniadis OC. An overview of fecal microbiota transplantation: Techniques, indications, and outcomes. Gastrointest Endosc. 2013 Aug;78(2):240-9. Kelly CR, Ihunnah C, Fischer M, Khoruts A, Surawicz C, Afzali A, et al. Fecal microbiota transplant for treatment of clostridium difficile infection in immunocompromised patients. Am J Gastroenterol. 2014 Jul;109(7):1065-71.	
8.5.2.4. Capsulised FMT:	***Capsulised FMT holds promise as a treatment option for recurrent CDI, but further evidence regarding its safety and efficacy is awaited, and it should not be considered for use at present (conditional).*** There is a growing body of evidence on encapsulated FMT and the delivery modality presents a potential option in circumstances where it may be inappropriate, contraindicated, or contrary to patient preferences to deliver material via traditional routes of administration for CDI. In terms of patient perceptions, Zipursky and colleagues report that more aesthetically appealing FMT formulations, such as capsules, would both eliminate potential barriers to treatment and reduce the necessity for healthcare resources and procedure time for clinicians. Capsules appear well tolerated. For example, the mean time of 30 capsule administration is approximately 20 minutes (range 10-30 minute) (Allegretti, unpublished data). Although the optimal dose is still under investigation (as with other FMT delivery modalities), there have been several studies that have	We largely agree with this comment. Whilst the Kao *et al,* 2017 study was not published at the time of initial searches, it has been identified by updated searches and has now been reviewed by the working group. The guideline has been updated accordingly.

Section	Comments	Working group response
	shown equivalent efficacy rates. Youngster and colleagues reported their experience with a capsule formulation that averaged 1.6 grams of stool per capsule in which they dosed 15 capsules on 2 consecutive days. They reported a 70% cure rate after an initial dose in a cohort of 140 patients. Those that failed to achieve cure were re-treated, bringing the cumulative cure rate up to 90%. Similarly, Hirsch and colleagues demonstrated a clinical cure rate of 68% in the 19 participants, using capsules containing purified, concentrated, and cryopreserved fecal bacteria and this increased to 89% with retreatment. Allegretti and colleagues conducted the first dose-finding study for FMT capsules (0.75 grams of stool per capsule with upper GI release) assessing 30 capsules once (low dose) versus 30 capsules on 2 consecutive days (high dose). Efficacy rates between the groups were similar on initial dose (70%) and there were no adverse events reported. Lastly the largest randomized control trial to date of FMT used encapsulated FMT with good safety and efficacy outcomes equivalent to colonoscopy FMT. In Kao et al's non-inferiority randomized clinical trial (cited in the guidelines) that included 116 adults with rCDI, the proportion without recurrence over 12 weeks was 96.2% after a single treatment in a group treated with oral capsules and in a group treated via colonoscopy. Given this 1+ level of evidence, in addition to multiple smaller studies of encapsulated FMT, we feel that there is a good body of evidence to support the short-term safety of encapsulated FMT. We agree that further evidence is needed on optimal dosing and formulation, however this applies to all delivery modalities.	

Section	Comments	Working group response
	We agree that capsule availability is very limited in the UK at present however this shouldn't preclude guidelines recommending this as a potential FMT delivery option. We therefore recommend rewording the 8.5.2.4 to: ***Capsulised FMT holds promise as a treatment option for recurrent CDI and should be offered to patients as a potential treatment modality. Capsule preparations should follow a standard protocol. Further evidence regarding its optimal dosing and formulation is needed (conditional).*** Allegretti J*, Fischer M*, Papa E, Elliot R, Klank M, Mendolia G, et al. Fecal microbiota transplantation delivered via oral capsules achieves microbial engraftment similar to traditional delivery modalities: Safety, efficacy and engraftment results from a multi-center cluster randomized dose-finding study. Digestive Disease Week 2016. Hirsch BE, Saraiya N, Poeth K, Schwartz RM, Epstein ME, Honig G. Effectiveness of fecal- derived microbiota transfer using orally administered capsules for recurrent clostridium difficile infection. BMC Infect Dis. 2015 Apr 17;15:191,015-0930-z. Youngster I, Russell GH, Pindar C, Ziv-Baran T, Sauk J, Hohmann EL. Oral, capsulized, frozen fecal microbiota transplantation for relapsing clostridium difficile infection. JAMA. 2014 Nov 5;312(17):1772-8. Zipursky JS, Sidorsky TI, Freedman CA, Sidorsky MN, Kirkland KB.	

Section	Comments	Working group response
	Patient attitudes toward the use of fecal microbiota transplantation in the treatment of recurrent clostridium difficile infection. Clin Infect Dis. 2012 Dec;55(12):1652-8.	
8.6. What is the clinical effectiveness of faecal microbiota transplant in treating conditions other than Clostridium difficile infection?	***FMT is not currently recommended as treatment for inflammatory bowel disease. There is insufficient evidence to recommend FMT for any other gastrointestinal or non-gastrointestinal disease (strong).*** We agree.	Thank you for this comment.
8.7. Basic requirements for implementing a FMT service	***The development of FMT centres should be encouraged (strong).*** We agree.	Thank you for this comment.
8.7.5. FMT manufacturing:	***Ensure traceability of supply (strong).*** We agree.	Thank you for this comment.
FMT in patients with IBD	We recommend emphasizing the importance of counselling patients with IBD on the risk of flare or worsening IBD activity post-FMT.	We agree with this comment, and have updated **Section 8.2.3.** accordingly.
FMT in paediatric populations	A recommendation on paediatric FMT should be include. The evidence base is limited but safety and efficacy appears comparable to adult FMT. Patients and caregivers should be counselled on the unknown long-term risks of FMT. Recommendation: ***i. FMT should be offered to paediatric patients with recurrent CDI.*** ***ii. Paediatric patients and caregivers should be counselled on the unknown short and long-term risks of FMT.***	FMT in the paediatric setting is outside of the remit of this working group. We have updated **Section 5.4** to clarify this.

Closing date: Please forward this electronically by 5pm on January 2018 at the very latest to consultations@his.org.uk