NICE National Institute for Health and Care Excellence

NICE guidance

Faecal microbiota transplant for recurrent Clostridium difficile infection

HealthTech guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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This guidance replaces IPG485.

This guidance is partially replaced by NG199.

1 Recommendations

1.1 Current evidence on the efficacy and safety of faecal microbiota transplant for recurrent Clostridium difficile infection is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 Only consider this procedure for a recurrent episode of C. difficile infection in adults who have had 2 or more previous episodes (as outlined in recommendation 1.1.10 in the NICE antimicrobial prescribing guideline on Clostridioides difficile). **[23 July 2021]**

1.3 Clinicians should ensure that a confidential record is kept of the donor and recipient of each faecal microbiota transplant.

1.4 NICE encourages further research into faecal microbiota transplant for C. difficile infection, specifically to investigate optimal dosage, mode of administration and choice of donor.

2 Indications and current treatments

2.1 Clostridium difficile is a bacterium that lives harmlessly in the gut of approximately 5% of healthy people. The use of broad-spectrum antibiotics and immunosuppressive agents can alter the balance of bacterial species in the gut, resulting in an overgrowth of C. difficile. Symptoms of mild C. difficile infections include purulent watery diarrhoea, abdominal cramps, nausea and dehydration. In more severe cases the infection can cause bloody diarrhoea and fever. In a few people C. difficile infection can lead to pseudomembranous colitis, sepsis, toxic megacolon, colonic rupture, and death. The risk of death increases in patients with multiple comorbidities.

2.2 First-line treatment involves rehydration and antibiotic therapy. Clinical responses are generally favourable but some people have recurrent or refractory C. difficile infections. For these people, further courses of antibiotics are used. An example of management algorithms can be found in Public Health England's Updated guidance on the management and treatment of C. difficile infection (June 2013).

3 The procedure

3.1 Faecal microbiota transplants aim to restore a healthy balance of bacteria in the gut of people who have recurrent Clostridium difficile infections by introducing enteric bacteria from the faeces of healthy donors.

3.2 Before the procedure, donors (who can be family members or unrelated) are screened for enteric bacterial pathogens, viruses and parasites. Donor faeces are taken and diluted with water, saline or another liquid such as milk or yogurt, and subsequently strained to remove large particles. The resulting suspension is introduced into the recipient's gut via a nasogastric tube, nasoduodenal tube, rectal enema or via the biopsy channel of a colonoscope. Recipients may receive a bowel lavage before transplantation, in order to reduce the C. difficile load in the intestines.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedures guidance overview.

4.1 A trial of 43 patients treated by faecal transplant versus vancomycin with a bowel lavage versus vancomycin only, reported a primary cure rate of 81% (13/16), 23% (3/13) and 31% (4/13) respectively at 10-week follow-up. The faecal transplant group had statistically significantly higher cure rates compared against the vancomycin with bowel lavage and vancomycin-only groups ($p<0.001$). Patients for whom an initial faecal transplant failed (n=3) had another transplant; 66% (2/3) of these patients were cured, resulting in an overall cure rate of 94% (15/16).

4.2 A systematic review of 25 studies, which included 289 patients with refractory Clostridium difficile infection treated by a faecal transplant, reported complete resolution of symptoms in 91% of patients at a mean follow-up of 12.6 months.

4.3 A non-randomised comparative study of 43 patients treated by faecal transplants using fresh stool from a related donor, transplants using fresh stool from an unrelated donor or transplants using frozen stool from an unrelated donor, reported resolution of symptoms with negative stool samples in 70% (7/10), 92% (11/12) and 90% (19/21) of patients respectively at 12-month follow-up. There were no statistically significant differences between the success rates of related and unrelated donor faeces or between the success rates of fresh and frozen faeces.

4.4 The randomised controlled trial of 43 patients treated by a faecal transplant, vancomycin with bowel lavage, or vancomycin only, reported relapses within 5 weeks of the start of therapy in 6% (1/16), 54% (7/13) and 62% (8/13) of patients respectively.

4.5 The systematic review of 25 studies reported that 2.4% (7/289) of patients had a relapse between 29 days and 4 years after faecal microbiota transplant.

4.6 The specialist advisers listed key efficacy outcomes as cure of infection and no

further relapses of C. difficile infection.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedures guidance overview.

5.1 Belching, abdominal cramps and abdominal pain, on the day of faecal transplant, were reported in 19% (3/16), 31% (5/16) and 13% (2/16) of patients respectively in the randomised controlled trial of 43 patients treated by faecal transplant, vancomycin with a bowel lavage or vancomycin only. In the same study, diarrhoea that was not considered to be due to Clostridium difficile infection was reported in 94% (15/16) of patients on the day of faecal transplant. Constipation (during the 10-week follow-up period) was reported in 19% (3/16) of patients.

5.2 Suspected peritonitis was reported in 1 patient (timing not reported), and 3 patients had symptoms of enteritis within 2 days of receiving a faecal transplant, in the systematic review of 25 studies.

5.3 The specialist advisers stated that theoretical adverse events include the transmission of biological agents and infections, and the administration of microbiologically uncharacterised material.

6 Committee comments

6.1 The Committee noted that religious beliefs, especially those related to diet, may influence the decision to donate or receive a faecal transplant.

6.2 The Committee recognised that the enteric infusion of donor faeces is not a transplant in the usual sense of transplanting body tissues, but it accepted that faecal microbiota transplant has become an accepted term to describe this procedure.

6.3 The Committee debated the theoretical risk of transmission of biological agents that may cause harm in the long term. It was mindful of the fact that patients having this procedure are typically very ill and standard treatments have not helped them. These considerations underpinned recommendations 1.1 and 1.3.

Update information

Minor changes after publication

January 2026: Interventional procedures guidance 485 has been migrated to HealthTech guidance 338. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.