



Faecal Microbiota Transplantation for Recurrent *Clostridioides difficile* Infection in Patients on Long-Term Immunosuppression: A Review of Efficacy and Safety

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Abstract

*Faecal microbiota transplantation cures recurrent *Clostridioides difficile* infection more reliably than any antibiotic, but the trials that established it largely excluded the patients who recur most often. Transplanting a live, undefined microbial community into someone whose immune defences are pharmacologically suppressed raises a question the pivotal trials were never designed to answer.*

Objectives: To review the published evidence on the efficacy and safety of faecal microbiota transplantation for recurrent *C. difficile* infection in adults receiving long-term immunosuppression, and to set out what donor screening and follow-up that evidence supports.

Material and Methods: A narrative review. MEDLINE, Embase and the Cochrane Library were searched from January 2010 to May 2026 for randomised trials, controlled series, cohort studies and meta-analyses of faecal microbiota transplantation in recurrent *C. difficile* infection, together with regulatory safety communications and society guidance. Values were extracted from the primary reports and tabulated without pooling.

Results: In the first randomised trial, donor infusion resolved infection in 81% after one treatment and 94% overall, against 31% for vancomycin. Two licensed microbiota products have since shown more modest absolute gains against placebo. In immunocompromised cohorts, pooled resolution is 75.3% after a single transplant and 87.4% after repeated treatment, with recurrence in 23.9% and serious adverse events in 10.1%—rates comparable with immunocompetent series. The documented transmission events that prompted regulatory action in 2019 and 2020 both occurred in immunocompromised recipients, and one was fatal.

Conclusion: The efficacy signal in immunosuppressed patients is consistent and large, and the residual risk is concentrated in donor screening rather than in the procedure. Screening for multidrug-resistant organisms, a documented consent discussion about transmissible infection, and structured follow-up are what make transplantation defensible in this group.

Abbreviations: CDI – *Clostridioides difficile* Infection, rCDI – Recurrent CDI, FMT – Faecal Microbiota Transplantation, MDRO – Multidrug-Resistant Organism, ESBL – Extended-Spectrum Beta-Lactamase, IBD – Inflammatory Bowel Disease, SAE – Serious Adverse Event.

Keywords: Faecal Microbiota Transplantation; *Clostridioides difficile*; Immunosuppression; Donor Screening; Recurrent Infection

Introduction

Clostridioides difficile is the commonest cause of healthcare-associated diarrhoea, and its defining clinical problem is not the first episode but the second [1]. Roughly a fifth to a third of patients relapse after apparently successful antibiotic treatment, and each further recurrence makes the next one more likely. The mechanism is well understood: the antibiotic that clears the

organism also flattens the commensal community that would otherwise resist recolonisation, so treatment and relapse are driven by the same event.

Faecal microbiota transplantation was the first therapy to attack that mechanism rather than the organism, and the effect size was unusual. The trial that changed practice stopped early at interim analysis because continuing to randomise patients to

vancomycin alone had become difficult to justify [2]. Guidelines on both sides of the Atlantic now recommend it after the second or third episode [3,4,5].

Those recommendations rest on trials that mostly excluded severely immunocompromised patients. Of the randomised evidence assembled in the Cochrane review, five trials excluded them outright and only a handful of participants anywhere were on immunosuppressive therapy [6]. That exclusion is awkward, because immunosuppressed patients are precisely the group with the highest incidence of *C. difficile* infection, the highest recurrence rate and the worst outcomes from it —solid organ transplant recipients, patients on chemotherapy, and people with inflammatory bowel disease on biologic or thiopurine therapy.

The theoretical objection is easy to state. Transplantation delivers a live, incompletely characterised microbial community into a host with impaired capacity to contain it. The objection stopped being theoretical in 2019, when two immunocompromised recipients developed invasive infection with an extended-spectrum beta-lactamase-producing organism traced to a single unscreened donor, and one died [7]. This review asks what the accumulated evidence now supports in this population, and what conditions make transplantation reasonable.

Material and Methods

Search strategy:

MEDLINE, Embase and the Cochrane Library were searched from January 2010 to May 2026. Terms combined controlled vocabulary and free text for faecal microbiota transplantation, *Clostridioides difficile*, recurrence, immunocompromised host, solid organ transplantation, inflammatory bowel disease and donor screening. Regulatory safety communications and the reference lists of society guidance were hand-searched.

Eligibility and synthesis:

Randomised trials, controlled and uncontrolled cohort studies, systematic reviews with meta-analysis, registry reports and multisociety guidance were eligible. Single case reports and studies that did not report outcomes separately for immunocompromised participants were excluded. Values were extracted by one reviewer and checked by a second. The included studies differ in the definition of immunocompromise, the route of administration and the length of follow-up, so results are presented descriptively and no pooling was attempted. No individual patient data were accessed and ethics approval was not required.

Results

The efficacy signal in unselected patients

The randomised evidence is summarised in Figure 1 and Table 1. In the trial that established the treatment, duodenal infusion of

donor faeces resolved infection in 13 of 16 patients (81%) after a single administration and in 15 of 16 (94%) once a second infusion from a different donor was allowed, against 4 of 13 (31%) for a standard vancomycin course and 3 of 13 (23%) for vancomycin with bowel lavage [2]. Later randomised work has compared routes and preparations rather than re-testing the principle: capsules were non-inferior to colonoscopic delivery [8], frozen preparations performed comparably with fresh [9], and transplantation outperformed fidaxomicin and vancomycin in a three-arm trial [10].

Two cautions belong beside those numbers. Pooled estimates from controlled trials are lower than the 90% figures quoted from open series, and a systematic review restricted to randomised comparisons found cure rates well below what observational reports had suggested [11]. And two microbiota products have now been licensed on placebo-controlled trials whose absolute differences are far smaller than the early trials implied: a rectally administered consortium achieved treatment success in 70.4% against 58.1% for placebo [12], and an oral spore preparation left 88% free of recurrence at eight weeks against 60% [13]. The comparator in those trials was placebo after antibiotic therapy, not vancomycin alone, which accounts for much of the difference.

Between those two poles sits a body of smaller randomised work that is easy to overlook. Colonoscopic delivery was compared directly with a vancomycin course and resolved infection in the large majority of recipients against a minority of controls [29]. A trial that randomised patients to donor stool or to their own stool prepared identically —the closest thing to a placebo the field has produced —found donor material clearly superior, which matters because it isolates the transferred community from the bowel preparation and the act of administration [30]. An early controlled study established that a frozen inoculum from unrelated donors performed well enough to make stool banking viable, and it is that finding, more than any single efficacy result, which turned the procedure into a service deliverable at scale [31]. Pooled across the randomised and refractory-disease literature, resolution sits in the high eighties [33].

Evidence in immunosuppressed recipients

No randomised trial has been conducted in this population, so the evidence is a series of cohorts and the meta-analyses built on them (Figure 2, Table 2). The first multicentre experience assembled 80 immunocompromised patients and reported cure rates in the same range as immunocompetent series [14]. A systematic review of 44 studies covering 303 immunocompromised patients found resolution in 207 of 234 with reported follow-up (87%) after one treatment, rising to 93% with repeat treatment; there were two deaths, two colectomies and five treatment-related infections [15]. A larger and more recent meta-analysis of 44 studies, in which 1,208 of 3,476 participants were immunocompromised, gives the most usable current estimates:

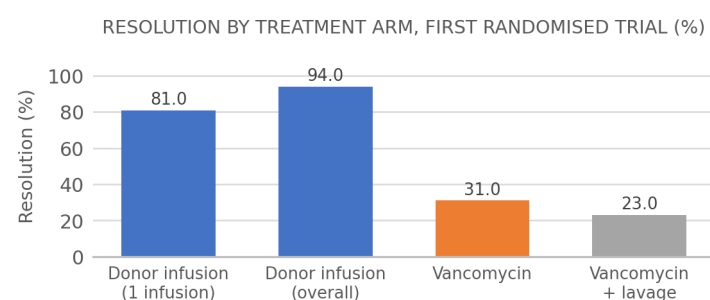


Figure 1: Resolution of recurrent *C. difficile* infection in the first randomised trial of donor faecal infusion, by treatment arm [2].

Study	n	Comparator	Principal result
van Nood 2013 [2]	43	Vancomycin ± lavage	81% after one infusion, 94% overall vs 31%
Kao 2017 [8]	116	Colonoscopy vs capsules	Capsules non-inferior to colonoscopic delivery
Lee 2016 [9]	219	Frozen vs fresh	Frozen preparation non-inferior to fresh
Hvas 2019 [10]	64	Fidaxomicin, vancomycin	Transplantation superior to both antibiotics
PUNCH CD3 [12]	267	Placebo	Treatment success 70.4% vs 58.1%
ECOSPOR III [13]	182	Placebo	88% free of recurrence at 8 weeks vs 60%

Table 1: Randomised and controlled evidence for faecal microbiota transplantation in recurrent *C. difficile* infection.

clinical resolution of 75.3% after a single transplant, 87.4% after consecutive treatments, recurrence of 23.9% and serious adverse events of 10.1% [16].

The subgroup data point the same way. Among solid organ transplant recipients, a multicentre series found cure rates consistent with the general population [17]. A single-centre immunocompromised cohort reported serious adverse events in 11.7% and three-month survival of 91.7% among those treated for severe or fulminant disease [18]. In inflammatory bowel disease, where the question is complicated by the difficulty of separating infection from a flare, meta-analysis and registry data show cure rates a little below those in patients without inflammatory bowel disease, with post-transplant flares reported in a minority [19,20].

The honest summary is that efficacy in immunosuppressed patients is slightly lower and requires repeat treatment more often, while the serious adverse event rate is somewhat higher than in immunocompetent series (Figure 3). Both differences are modest, and neither is clearly attributable to the transplant rather than to the underlying illness: a cohort defined by transplantation, chemotherapy or advanced immunodeficiency will generate hospitalisations and deaths at a higher baseline rate whatever is done to it. No controlled comparison exists to separate the two.

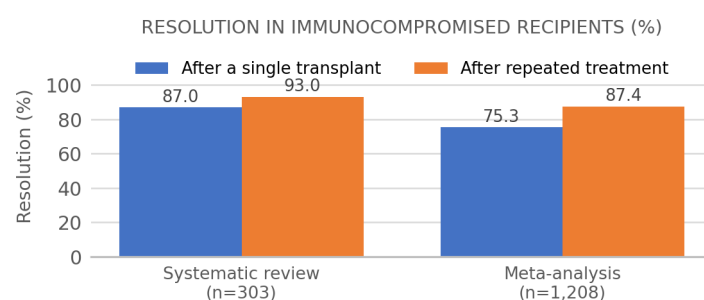


Figure 2: Reported resolution in immunocompromised recipients after a single transplant and after repeated treatment, from two systematic reviews [15,16].

Study	Population	n	Resolution	SAE
Kelly 2014 [14]	Mixed immunocompromised	80	Comparable to immunocompetent	–
Shogbesan 2018 [15]	44 studies, mixed	303	87% first, 93% repeat	5 infections
Cheng 2019 [17]	Solid organ transplant	94	Consistent with general cohorts	–
Suchman 2022 [18]	Single-centre cohort	94	Efficacious	11.7%
Meta-analysis [16]	44 studies, mixed	1,208	75.3% single, 87.4% repeat	10.1%

Table 2: Reported outcomes in immunocompromised recipients. Definitions of immunocompromise, route and follow-up differ between studies, so the figures are not pooled.

What actually went wrong, and where

The safety record is dominated by two clusters, and their pattern is more instructive than the aggregate rates (Figure 4, Table 3). In June 2019 the United States regulator reported that two immunocompromised adults given investigational transplants prepared from a single donor had developed invasive infection with extended-spectrum beta-lactamase-producing *Escherichia coli*; one died. Neither the donor stool nor the derived preparations had been tested for resistant Gram-negative organisms, and stored material from that donor subsequently grew an organism indistinguishable from the patients' isolates [7,21]. In March 2020 the same regulator described six patients infected with enteropathogenic or Shiga-toxin-producing *E. coli* after receiving material from one stool bank [22].

Both clusters were failures of donor screening rather than of the procedure. Neither involved an unexpected biological mechanism; in each case an organism present in the donor was transferred to a recipient less able to contain it. The regulatory response was correspondingly specific: mandatory screening for multidrug-resistant organisms, with additional testing added subsequently for other transmissible agents. Reviews of adverse events across the wider literature find that most reported harms are mild and self-limiting—transient diarrhoea, cramping, fever—with serious events concentrated in patients who were already severely ill [23,24].

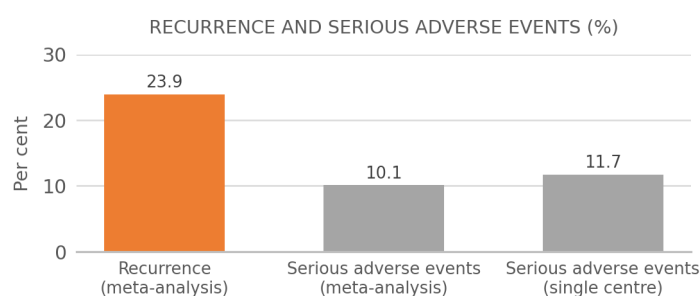


Figure 3: Recurrence and serious adverse event rates reported in immunocompromised cohorts [16,18].

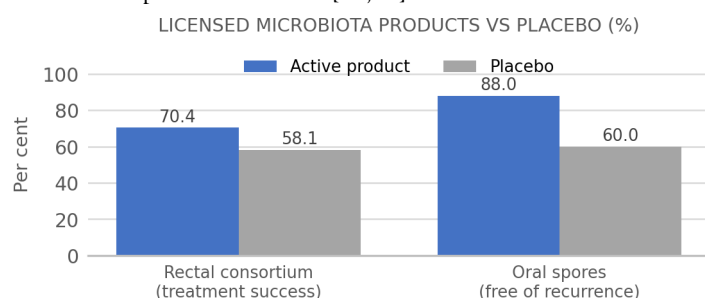


Figure 4: Absolute treatment effect of the two licensed microbiota products against placebo, on their own trial endpoints [12,13].

That distinction matters for how the risk should be presented. The residual hazard of transplantation in an immunosuppressed patient is not an intrinsic property of introducing a microbial community; it is the probability that a screening protocol missed something, multiplied by the recipient's reduced capacity to contain it. The first term is modifiable and has been substantially reduced. The second is not, which is why the same screening failure produces a mild colonisation in one recipient and a fatal bacteraemia in another.

Standardisation followed the same path. A European consensus process set out donor selection, screening intervals, preparation and traceability requirements before either regulator had licensed a product, and much of what is now routine in stool banking derives from that document rather than from statute [32]. The practical consequence for an immunosuppressed recipient is that the quality of the material is no longer a matter of local improvisation: a clinician can ask a supplier specific questions about what was tested for, and when.

What the guidance says

Society guidance has converged. The American College of Gastroenterology recommends transplantation for patients with two or more recurrences, and considers it in severe and fulminant disease refractory to antibiotics [3]. European guidance reaches the same position on recurrence [4], as does the American infectious diseases guidance [5,25]. The 2024 American Gastroenterological Association guideline addresses the immunocompromised question directly and supports microbiota-based therapy in this group after appropriate screening, while noting that the certainty of evidence is low [26]. None of these documents treats immunosuppression as a

Domain	Requirement	Basis
Indication	Two or more recurrences, or refractory severe disease	Society guidance [3,4,26]
Donor material	Programme screening for multidrug-resistant organisms	2019 ESBL cluster [7,21]
Additional screening	Enteropathogenic and Shiga-toxin-producing <i>E. coli</i>	2020 stool bank cluster [22]
Consent	Names transmissible infection and the effect of immunosuppression	Both clusters occurred in this group [7]
Follow-up	Structured review for delayed bacteraemia and recurrence	Registry practice [27]

Table 3: Conditions supported by the evidence for transplantation in a patient on long-term immunosuppression. contraindication; all treat it as a reason for care in donor selection and consent.

Registry data support that position in practice. The national registry established to follow recipients prospectively reported cure rates in real-world use consistent with the trials, with few serious events attributable to the procedure [27]. The remaining uncertainty is long-term: the theoretical concern that transferring a whole microbial community might alter metabolic or immune phenotypes years later has not been resolved by any study of adequate duration, and cannot be dismissed simply because short-term follow-up looks reassuring [28].

Discussion

For a patient on long-term immunosuppression with two or more recurrences, the evidence favours transplantation. The comparator is not a benign one: continued antibiotic cycling sustains the dysbiosis that causes recurrence, carries its own resistance and toxicity burden, and in this population is associated with hospitalisation and death rates that make the reported 10.1% serious adverse event rate look less alarming than it does in isolation [16]. The relevant question is not whether transplantation carries risk but whether it carries more risk than the alternative, and no dataset suggests it does.

Three conditions distinguish defensible practice. Donor material should come from a programme screening for multidrug-resistant organisms to current regulatory standards; the 2019 cluster arose specifically because that testing was absent [7]. Consent should record that the material is a biological product from a screened but not sterile donor, that transmission of an undetected organism is possible, and that the recipient's immunosuppression raises the consequence of that event. And follow-up should be structured rather than opportunistic, since the events that matter in this group present as bacteraemia weeks later rather than as procedural complications.

Two questions remain genuinely open. The first is whether defined products should now replace donor stool in immunosuppressed recipients: a manufactured consortium or purified spore preparation removes much of the transmission risk by construction, but the licensed products were tested against placebo in largely immunocompetent populations and their absolute effect is smaller [12,13]. Trading a better-characterised product for a less certain effect is a real trade, not an obvious improvement. The second is the durability question, which only long-horizon registry follow-up will answer.

Study limitations

This is a narrative rather than a systematic review: studies were selected against stated criteria but without duplicate screening of the full yield, and no risk-of-bias instrument was applied. The immunocompromised evidence is entirely non-randomised and drawn from cohorts that define immunosuppression inconsistently, so the pooled estimates carry more heterogeneity than their confidence intervals imply. Publication bias is likely, since successful series are more readily reported than unsuccessful ones. The review does not cover paediatric practice, transplantation for indications other than *C. difficile* infection, or the health economics of the licensed products.

Conclusion

Faecal microbiota transplantation works in immunosuppressed patients with recurrent *C. difficile* infection at rates close to those seen in immunocompetent recipients, needing repeat treatment somewhat more often and carrying a serious adverse event rate around 10% in a population whose baseline event rate is already high. The harms that have occurred were screening failures, not mechanistic surprises, and they fell on immunocompromised recipients because that is where an unscreened organism does the most damage. Transplantation should be offered to these patients after two or more recurrences, from a programme that screens for resistant organisms, with consent that names the transmission risk and follow-up that would detect it. What should not be inferred from the good efficacy data is that the procedure is low-risk in this group irrespective of how the donor material was obtained.

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