

Module 11: Fecal Microbiota Transplantation

From *C. diff* rescue to the frontier of microbiome medicine.

Tracks: Core, Clinical, Advanced | Duration: 55 min

KEY TAKEAWAYS

- FMT for rCDI is one of the most successful microbiome interventions: >85% cure rate.
- Two FDA-approved products now exist — marking the transition from artisanal to regulated.
- FMT for IBD is promising but heterogeneous; pooled donor, anaerobic preparation, and intensive dosing improve outcomes.
- Defined consortia (e.g., SER-109) represent the future — standardized, scalable, safer.

EVIDENCE-GRADED CLAIMS

FMT cures recurrent <i>C. difficile</i> infection in >85% of cases	A — Clinically established	Multiple RCTs; guideline-recommended after ≥2 recurrences.
FMT induces remission in ulcerative colitis	C — Promising, preliminary	Pooled-donor, intensive protocols show benefit; effect sizes modest, durability uncertain.
FMT converts immunotherapy non-responders to responders	C — Promising, preliminary	Small Phase I/II trials show signals; larger trials needed.
FMT is safe without screening	F — Misleading or false	Transmitted MDR infections reported; rigorous donor screening is mandatory.

CLINICAL CASE

DIY FMT from the internet

A 32-year-old with recurrent *C. difficile* (3rd episode) is frustrated with antibiotic retreatment. She found a YouTube tutorial on preparing home FMT using her husband's stool and an enema kit. She asks your opinion before trying it.

How would you discuss the real risks of unscreened FMT (transmitted MDR infections, deaths reported), the availability of FDA-approved alternatives, and appropriate referral pathways?

SUMMARIES

For Patients

Fecal transplant (FMT) involves transferring stool from a healthy donor to restore a patient's gut microbiome. It works remarkably well for recurring *C. diff* infections — curing over 85% of cases. The FDA has now approved two products based on this approach. Researchers are testing it for other conditions like IBD and to boost cancer treatment response, but that evidence is still early.

For Clinicians

FMT for rCDI: multiple RCTs (van Nood 2013, PUNCH CD3, ECOSPOR III) demonstrate >85% cure rate; superior to vancomycin alone. FDA-approved: Rebyota (rectal, live biotherapeutic, 2022) and Vowst/SER-109 (oral capsules, spore-based, 2023). For IBD, pooled RCTs in UC show higher remission with intensive, pooled-donor FMT (FOCUS trial: 27% vs 8% remission at 8 weeks); Crohn's data is sparser. Cancer immunotherapy: Phase I/II FMT trials in anti-PD-1 non-responders show signals (Davar 2021, Baruch 2021).

REFERENCES

- Duodenal infusion of donor feces for recurrent *C. difficile* — van Nood E et al., NEJM 2013 [\[Link\]](#)