Fecal Microbiota Transplantation

Role of the Transfusion Network in Italy and in Europe

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Milan, Italy

SIMTI Congress, 2026

THE POOP OF OUR DONORS:

Safety, Selection and Regulation

Role of the Transfusion Network
in Italy and in Europe

SIMTI Congress, 2026

DONOR SELECTION → SCREENING & TESTING → PROCESSING & STANDARDIZATION → SAFETY & QUALITY → REGULATION & OVERSIGHT

SIMTI
SOCIETÀ ITALIANA DI MEDICINA TRASFUSIONALE E IMMUNOEMATOLOGIA

From a biological product to a therapeutic opportunity.

The Transfusion Network's next frontier.

Disclosures

I have received travel and research grants, speaking fees, and teaching fees from Diasorin, Diamed, Diatech Pharmacogenetics, Grifols, Immucor, Macopharma, Ortho Clinical Diagnostics, Terumo, Cerus.

Outline

1. Background and clinical rationale of FMT
2. Clinical indications: recurrent C. difficile, GvHD, and emerging indications
3. How Transfusion Medicine may contribute to FMT programs
4. The Italian regulatory framework
5. The Milano Experience of Stool Banking
6. European regulatory landscape: SoHO Regulation 2024/1938

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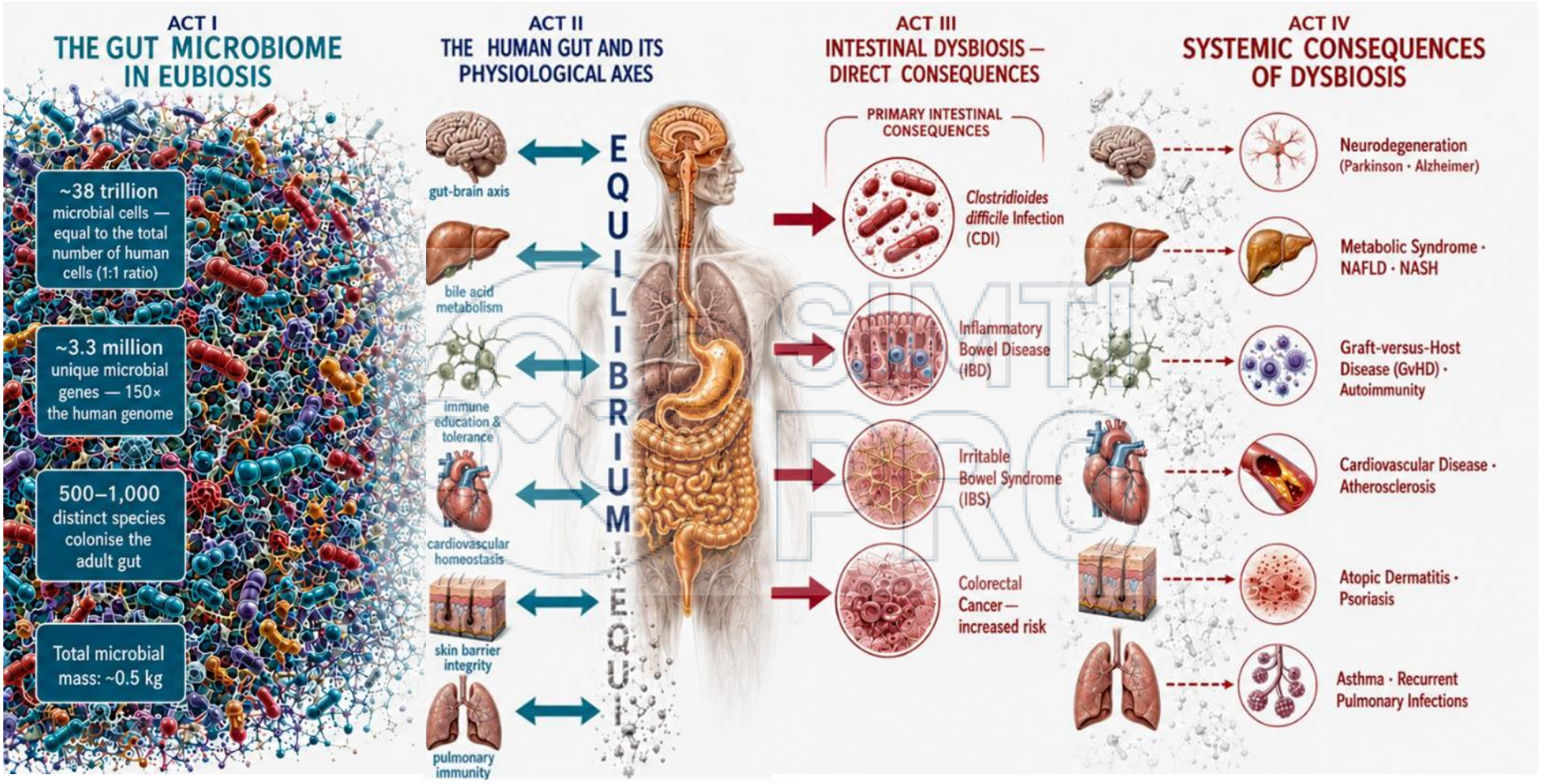


Fecal Microbiota Transplantation (FMT) — Evidence-based and emerging indications:

Clostridioides difficile (Level 1A) · Inflammatory Bowel Disease · Graft-versus-Host Disease · Immuno-oncology · Metabolic Syndrome

D. Prati 2026

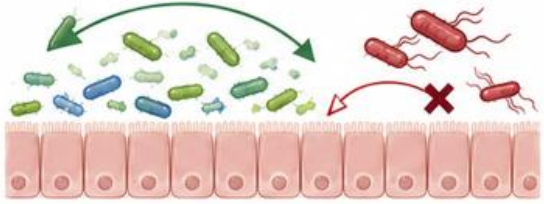
What is Fecal Microbiota Transplantation?

FMT consists in the transfer of fecal bacteria and other microorganisms from a healthy donor to a recipient with a disrupted gut microbiome. It can be administered via colonoscopy, enema, oral capsules, or nasoenteric tube.

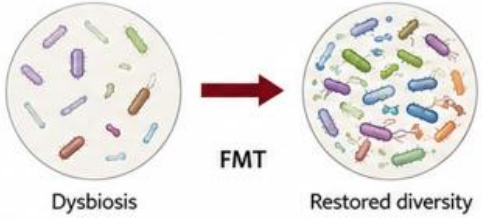
Routes of administration

Mechanisms of action

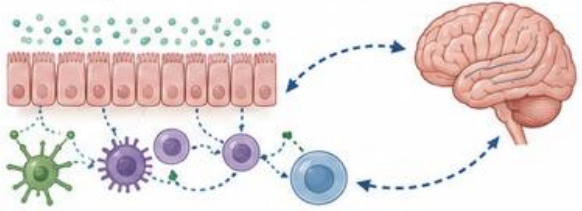
1. **Restoration of colonisation resistance:** the healthy microbiome outcompetes pathogenic species for ecological niches in the gut.



2. **Re-establishment of microbial diversity** depleted by antibiotics or by conditioning regimens before transplantation.



3. **Immune modulation through microbiome-host cross-talk,** including effects on intestinal T-cell populations and on the gut-brain axis.



Reference: Cammarota G et al., Gut 2017; Yadegar A et al., Clin Microbiol Rev 2024

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FMT Quick facts

~92%

Clinical resolution rate in recurrent CDI — superior to vancomycin in all RCTs (recurrence: 16% vs 42%)

Ray R et al., Cureus 2025 (15 RCTs, n=1,452 patients)

866+

Clinical trials registered on ClinicalTrials.gov using FMT as intervention (as of 2024; number growing)

Prati D et al., Blood Transfus 2025 (*data accessed 2024)*

~10%

Estimated share of European patients with FMT indication currently receiving treatment

Baunwall SMD et al., Lancet Reg Health Eur 2021

Aug 2027

EU SoHO Regulation 2024/1938 fully applies — intestinal microbiota explicitly in scope (Recital 7)

Regulation (EU) 2024/1938 OJ EU, 17 July 2024

Abbreviations: CDI: Clostridioides difficile Infection · FMT: Fecal Microbiota Transplantation · RCT: Randomised Controlled Trial · SoHO: Substances of Human Origin · RR: Relative Risk

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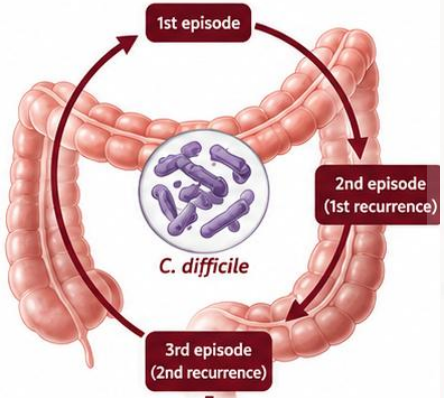
INDICATION 1 — RECURRENT CLOSTRIDIOIDES DIFFICILE INFECTION (rCDI)

Summary of evidence update 2024–2025

Recurrent CDI:
high relapse after standard antibiotic therapy



FMT restores microbial diversity and reduces recurrences

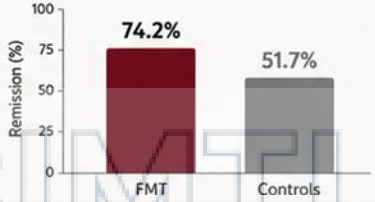
AGA GUIDELINE 2024 (definitive reference)

FMT recommended after the second CDI recurrence (third episode overall), or in selected high-risk patients after a first recurrence.

The threshold has NOT been lowered to ≥1 as a general recommendation.

The guideline also endorses FMT in severe/ fulminant CDI via lower GI route.

RCT analysis:
remission with FMT-based therapies



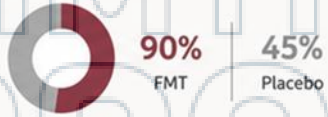
74.2% vs 51.7%

RR = 1.59
95% CI 1.27–2.00
FMT-only subgroup
RR = 1.97

Peery AF, Kelly CR, Kao D et al. Gastroenterology 2024;166:409–434. doi:10.1053/j.gastro.2024.01.008

EARLYFMT RCT (promising, not yet standard of care)

Randomised, double-blind, placebo-controlled trial (stopped early for superiority): FMT after vancomycin for first or second CDI episode.
Resolution of CDI-associated diarrhoea at 8 weeks:



Negative PCR at week 8:

85%

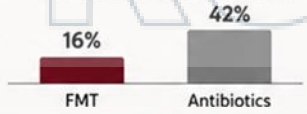
FMT

Baunwall SMD, Andreasen SE, Hansen MM et al. Lancet Gastroenterol Hepatol 2022;7(2):1083–1091. doi:10.1016/S2468-1253(22)00276-X

UPDATED META-ANALYSIS 2025 (vs antibiotics)

Systematic review and meta-analysis of 15 RCTs (n=1,452).

Recurrence rate
FMT vs standard antibiotic therapy



RR = 1.85

95% CI 1.62–2.11
p < 0.001

Ray R, Hack SA, Vij AK et al. Cureus 2025;17(8):e90614. doi:10.7759/cureus.90614

OBSERVATIONAL SERIES / REAL-WORLD DATA

Resolution rates of 85–95% consistently reported in open-label and observational studies, versus 74.2% in controlled RCTs.

85–95%
resolution rate with FMT (real-world)

74.2%
in controlled RCTs

Allegretti JR, Khanna S, Mullish BH, Feuerstadt P. Gastroenterology 2024; 167:885–902. doi:10.1053/j.gastro.2024.05.004

Bottom line:
FMT is the most effective therapy to prevent recurrences in rCDI.

Guideline-recommended after ≥2 recurrences

Superior to antibiotics in RCTs and meta-analyses

High effectiveness in real-world practice

Indication 2 — GvHD after Allogeneic HCT

Rapidly maturing evidence — 2023–2025 key publications

1 Rashidi et al. 2023 — Phase II RCT *(FMT vs placebo, alloHCT/AML)*

FMT safe and well tolerated. Primary endpoint (infection burden) not met. However: significantly improved microbiota diversity, restored anaerobic commensals, reduced *Enterococcus* expansion. Informs future trial design: GvHD prevention — not infection — as primary endpoint.

Safe | **Microbiota diversity ↑** | ***Enterococcus* expansion ↓**

Rashidi A et al. J Clin Oncol 2023;41;5306–5319

2 MaaT013 — ARES Phase III (ASH 2025, EHA 2025)

66 adult patients with GI-aGvHD refractory to steroids and ruxolitinib. Primary endpoint met.

62% GI overall response rate at Day 28 (95% CI 49–74%)

64% All-organ ORR

6.4 months median duration of response

Significantly exceeds historical control of 22% (p<0.0001) · 50 European sites

Malard F, Sanz J et al. Blood 2025;146(Suppl 1):817 [ASH 2025]

3 Morsink et al. 2025 — donor effect in FMT for GvHD prevention

Single-arm run-in phase (20 patients, 3 donor cohorts). FMT safe and effective in restoring microbiota diversity post-alloHCT. Microbiota engraftment correlated with better clinical outcomes. Identifies donor selection as the critical variable — implications for FMT donor matching.

Safe & effective | **Microbiota engraftment ↑ → better outcomes** | **Donor selection = key variable**

Morsink LM et al. Nat Commun 2025;16:873

4 EBMT European framework — regulatory navigation

Expert consensus from EBMT Cellular Therapy & Immunobiology Working Party. Clinical framework for microbiotherapy in haematology-oncology. Covers GvHD, MDRO decolonisation, immune reconstitution. Explicit guidance on SoHO vs ATMP dual regulatory track for pooled vs single-donor products.

European framework | **SoHO vs ATMP navigation** | **Pooled vs single-donor** | **GvHD • MDRO • immune reconstitution**

Malard F, Holler E, Peric Z et al. Bone Marrow Transplant 2025. doi:10.1038/s41409-025-02779-9

KEY TAKEAWAY: Evidence for FMT in GvHD is rapidly maturing — Phase III efficacy signals, mechanistic insights on donor matching, and regulatory frameworks now in place to guide clinical translation.

Indications 3–5 — IBD, Immuno-oncology, MDRO

State of evidence 2024–2025

1 Ulcerative Colitis — Cochrane 2023 + meta-analysis 2024

FMT effective for inducing clinical and endoscopic remission in mild-moderate UC — confirmed across 14 RCTs (600 patients): combined remission OR=2.25 (p<0.0001). Pooled donor and oral delivery associated with higher response.

OR 2.25 combined remission

OR 1.95 endoscopic remission

Imdad A et al. Cochrane Database Syst Rev 2023;4:CD012774 · Hussain et al. Gastroenterol Hepatol 2025

2 Immuno-oncology — FMT + anti-PD-1 (melanoma, Phase I)

FMT from healthy donors + nivolumab/pembrolizumab in 20 untreated advanced melanoma patients: ORR 65% including 4 complete responses. No grade 3 adverse events from FMT. Pooled ORR 43% across 10 studies (164 patients).

65% ORR Phase I (n=20)

43% pooled ORR meta-analysis (n=164)

Routy B et al. Nat Med 2023;29:2121–2132 · Meta-analysis PMC12147380

3 MDRO Decolonisation — complex picture (2024)

PREMIX RCT: significant ESBL reduction and replacement by susceptible strains after FMT. Key insight: decolonisation rates not consistently higher vs placebo at primary timepoint — but reduced invasive MDRO infections at longer follow-up. Study endpoint design needs reconsideration.

ESBL colonisation ↓

Invasive infections ↓ at follow-up

PREMIX trial: Emerg Infect Dis 2024;30(6) · Allegretti JR et al. Gastroenterology 2024;167:885

FMT evidence is expanding rapidly beyond CDI — IBD, immuno-oncology, and MDRO represent the next clinical frontier.

Safety Profile of FMT — Key Risks and Mitigations

General tolerability	Mild gastrointestinal symptoms (diarrhoea, cramping, bloating) are the most common adverse events, especially in the first days after transplantation.
MDRO transmission	Transmission of multidrug-resistant organisms is the most serious documented risk; rare fatal cases have been reported (DeFilipp Z et al., N Engl J Med 2019).
Immunocompromised patients	Higher infection risk requires careful patient selection and monitoring; serious infections have been documented in this population (DeFilipp Z et al., NEJM 2019).
Long-term safety data	Limited beyond rCDI; prospective outcome registries are needed — a key requirement of the EU SoHO Regulation (2024/1938).
Mitigation strategy	Rigorous donor screening, standardised processing, per-donation stool testing, and systematic patient follow-up are essential (Prati D et al., Blood Transfus 2025).

Abbreviations: MDRO: Multidrug-Resistant Organism · rCDI: Recurrent Clostridioides difficile Infection · SoHO: Substances of Human Origin

The FMT Process From Donor to Patient

Key steps in fecal microbiota transplantation — independent of institutional setting

1 Donor Recruitment

- Identify VNRD candidates
- Blood donors preferred
- Informed consent
- Anamnesis questionnaire

2 Donor Screening

- Blood & serology panel
- NAT (HIV, HBV, HCV)
- Stool pathogen panel
- (27 fecal tests)

3 Stool Collection

- Re-evaluation of anamnesis
- Home or hospital collection protocol
- Delivery within time limit
- Per-donation stool test

4 Processing & Biobanking

- Stool processing in lab
- FMT unit preparation
- Cryopreservation –80°C
- Quarantine pending release

5 Lot Release & QC

- Review all test results
- Donor + unit suitability
- Formal release decision
- Traceability documented

6 FMT Procedure

- Patient selection
- Route: colonoscopy / enema
- / oral capsule
- Follow-up & vigilance

At each step, the process can be interrupted if safety criteria are not met · Full traceability from donor to clinical outcome is required under EU SoHO Regulation 2024/1938

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FMT Needs What Transfusion Medicine has Built

Donor pools, biobanking, traceability, haemovigilance — the operational toolkit exists

What FMT requires

- Large pools of voluntary, non-remunerated donors
- Multi-step sequential biological screening
- Cryogenic biobanking at –80°C
- Lot quarantine and formal release procedures
- Full chain traceability from donor to patient
- Surveillance of serious adverse reactions and events

….What TM departments already have

- Pools of ~30,000 voluntary donors per large centre
- Validated sequential gate-screening SOPs
- Operating –80°C biorepositories (HPC, cellular therapy)
- ISO 15189-accredited quality management systems
- ISBT-coded traceability from donation to patient
- Haemovigilance infrastructure (SARE/SRC reporting)

Abbreviations: HPC: Haematopoietic Progenitor Cells · ISBT: International Society of Blood Transfusion · SARE: Serious Adverse Reactions and Events · SRC: Sistema di Sorveglianza delle Reazioni e degli Incidenti · SOP: Standard Operating Procedure

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Italy: Regulatory Framework — CNT as Competent Authority

EU Directive 2004/23/EC (Tissues & Cells) — Implementing Directives 2006/17/EC and 2006/86/EC

Stool is classified as a tissue preparation — not as a medicinal product.

- The CNT (Centro Nazionale Trapianti) is the competent authority for FMT in Italy, with the same oversight role it holds for solid organ and haematopoietic progenitor cell transplantation.
- FMT can only be performed in hospitals where the programme has been explicitly authorised by CNT; accreditation requires demonstrating quality management, validated procedures, and full traceability.
- Both donor and recipient must provide informed consent, and ethics committee approval is required before initiating a clinical FMT programme.
- Serious adverse reactions and events (SARE) are reported to CNT, mirroring haemovigilance obligations in the blood sector.
- Italy's approach is shared by the Netherlands (RIVM/CCTR) and Belgium (AFMPS), which also apply the Tissue & Cell pathway — unlike France and Germany, which classify FMT as a medicinal product.

Abbreviations: CNT: Centro Nazionale Trapianti · SARE: Serious Adverse Reactions and Events · RIVM: Netherlands National Institute for Public Health · CCTR: Centre for Cell and Tissue Research (Netherlands) · AFMPS: Belgian Federal Agency for Medicines · HPC: Haematopoietic Progenitor Cells

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THE EXPERIENCE OF THE POLICLINICO OF MILAN

THERAPIES BASED ON SUBSTANCES OF HUMAN ORIGIN (SoHO)

Review

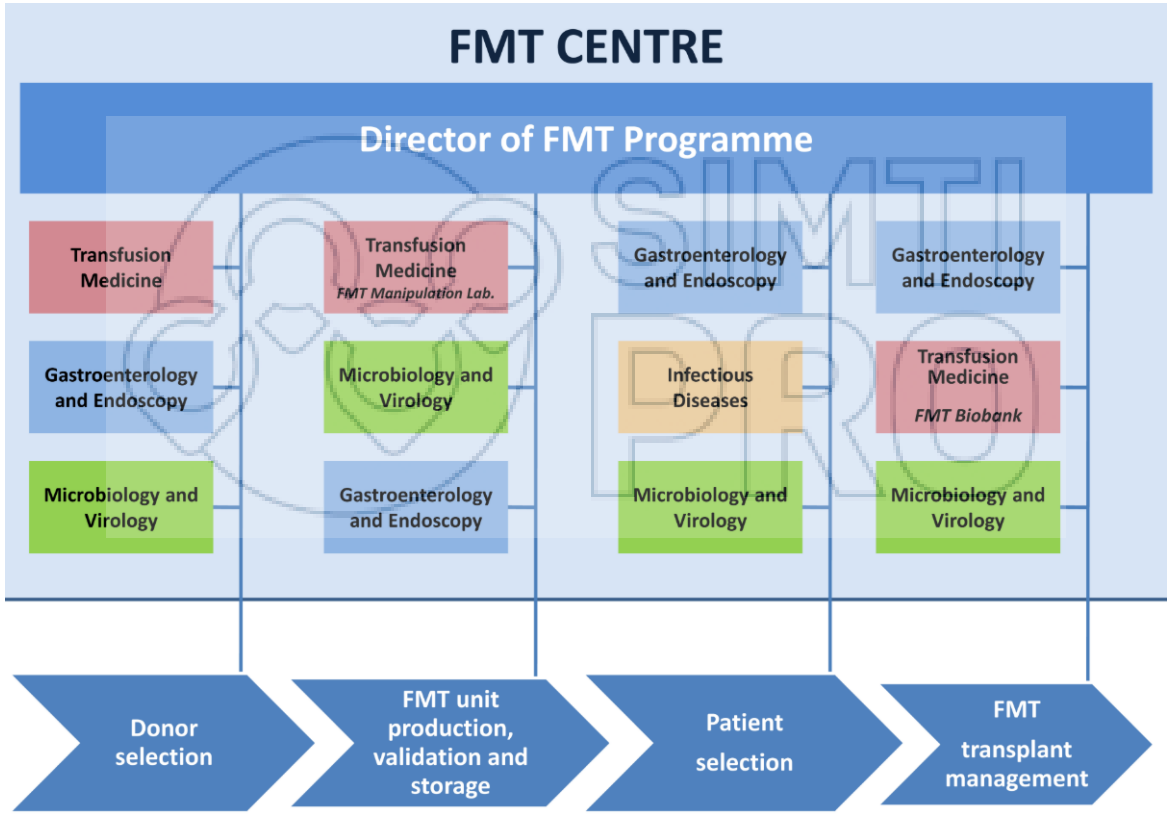
*Prati D. and Caprioli F. are co-first Authors

A "movement" worth making: why and how Transfusion Services can play a role in Fecal Microbiota Transplant programs

Daniele Prati[1,2,*], Flavio Caprioli[3,4,*], Luisa Stea[1], Alessandra Berzuini[1], Denise Pizzotti[1], Errica Petrillo[1], Elena Coluccio[1], Elisa Erba[1,5], Giuseppe Lamorte[1], Francesca Ferrari[1], Lisa Cariani[6], Chiara Amoroso[3], Anna C. Preti[7], Alessandra Bandera[4,8], Annapaola Callegaro[6], Silvana Castaldi[7,9], Massimo Cardillo[10], Maurizio Vecchi[3], Luca Valenti[1,4,**], Vincenzo De Angelis[2,**]

CNT Accreditation (Jul 2024): 2-year process authorized Policlinico's FMT under national safety standards.

The organizational structure of the FMT program at Ospedale Policlinico



Donor Selection Process for FMT

Step 1

Enrollment of Candidate Donors
among repeat blood donors

@Blood donation facility

Step 2

Microbiological Investigations & Suitability

Donor qualification tests

Step 3

Stool Donation
at the blood center

Dedicated toilet!

Step 4

Unit Preparation, Freezing and **Additional Validation Tests**

@Cell maipulation lab

Step 5

Final Review & Approval
lab/data review, clinical release

TRANSPLANT

FMT Unit Validation Tests (n=57!!)

- **Blood/Serum Panel (n=30)**
  - Tri-NAT: HIV RNA, HBV DNA, HCV RNA
  - Serologies: HBsAg, HIV-1/2 Ab/Ag, HCV Ab, anti-HBc (total/IgM), Treponema pallidum Ab, HAV/HEV IgM, CMV IgM, EBV IgM, Entamoeba histolytica Ab
  - General labs: CBC, ESR, CRP, glucose, albumin, creatinine, Na/K, transaminases, bilirubin (total/conjugated), γ-GT, alkaline phosphatase
  - **Risk-based** (if indicated): HTLV I/II, Strongyloides, Toxocara, Monkeypox PCR

- **Fecal Panel (n=27)**
  - **Immunoassays**: C. difficile toxin, H. pylori antigen
  - **Molecular**: enteropathogenic E. coli, Campylobacter, Salmonella, Shigella, Vibrio spp., Rotavirus, Norovirus, Astrovirus, Sapovirus, Adenovirus, Sapovirus, Giardia, Cryptosporidium, Cyclospora, Entamoeba, Dientamoeba, Blastocystis
  - **Culture**: Listeria, VRE, ESBL/CRE Enterobacteriaceae, MRSA, Carbapenem-resistant Pseudomonas & Acinetobacter
  - **Parasitology**: ova/cysts (helminths, microsporidia, Isospora)
  - **Other**: fecal occult blood; calprotectin (if risk factors)

Donor Recruitment at IRCCS Ca' Granda Policlinico di Milano

(as of may 2025)

- **Donor Pool:** ~30,000 regular blood donors
- **Program Launch:** March 2024

Stage	Number	%
Donors invited	41	
Donors accepting	41	100%
Completed screening	35	85%
Eligible for donation	9	25,7%

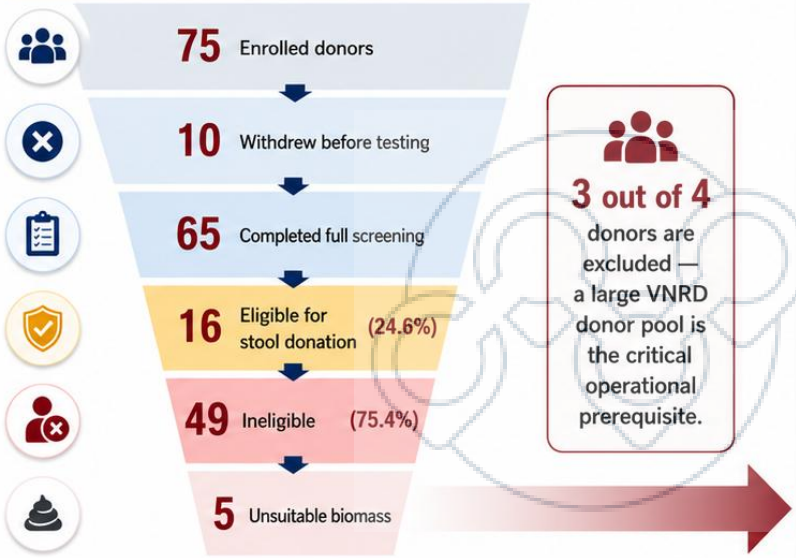
Reasons for Exclusion (26 donors)

- Bacterial: 6 E. coli, 3 H. pylori, 2 CR P. aeruginosa
- Parasitic: 1 Giardia lamblia, 8 D. fragilis, 6 B. hominis, 10 E. Coli (EAEC, EPEC), 1 Salmonella, 1 Campylobacter
- Other reasons: 7 donors

Donor Eligibility in FMT Stool Banking — Scale and Clinical Management

Ca' Granda Policlinico, Milan — data as of 2025

THE NUMBERS



3 out of 4 donors are excluded — a large VNRD donor pool is the critical operational prerequisite.

WHAT HAPPENS TO INELIGIBLE DONORS?

Multi-Resistant Bacteria
VRE, ESBL-producing Enterobacteriaceae, Carbapenem-resistant *P. aeruginosa*, MRSA, CRAB
→ No treatment required — donor deferred

Enteric Viruses
Adenovirus, Norovirus, Rotavirus, Sapovirus
→ No treatment required — donor deferred

Low-Impact Intestinal Parasites
Dientamoeba fragilis, *Blastocystis hominis*
→ No treatment required — donor deferred

Enteropathogenic Bacteria
Campylobacter, *C. difficile*, *E. coli* (EAEC/EPEC/STEC), Salmonella, Shigella
→ Infectious Diseases Specialist referral

Parasites / Helminths
Cryptosporidium, *Giardia*, *Ascaris*, *Strongyloides*
→ Infectious Diseases Specialist referral

H. pylori positive
→ Eradication therapy — GP referral

Calprotectin / Occult Blood in Stool
→ Gastroenterologist referral

Source: Prati D et al., Blood Transfusion 2025;23(3):275–282 · Prati D, ISBT Congress Milan, June 2025

KEY MESSAGE:
Donor exclusion is not only a logistical problem — it generates a clinically relevant yield of undiagnosed pathology in asymptomatic VNRD blood donors.

21% of donations excluded at per-donation testing even from asymptomatic eligible donors —
Ianiro G et al., Dig Liver Dis 2021

Source: Prati D et al., Blood Transfusion 2025;23(3):275–282 · Prati D, ISBT Congress Milan, June 2025

See Poster @SIMTI 2026!!!

FMT Clinical Outcomes (Dec 2024–Present)

- 11 FMT procedures performed since December 2024 for recurrent C. difficile infection
- 7 males, 4 females
- All patients achieved clinical recovery on follow-up

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European Regulatory Landscape Before 2027

EMA/HMA Horizon Scanning Report on FMT, 2022

Country / Region	Classification	Competent Authority
Italy · Netherlands · Belgium	Tissue & Cell (Directive 2004/23/EC)	CNT / RIVM / AFMPS
France	Medicinal product	ANSM — IND-equivalent required
Germany	Medicinal product (§13 AMG exemption)	BfArM / PEI
United Kingdom (post-Brexit)	Biological medicine	MHRA
EU — from August 2027	**SoHO Regulation (EU) 2024/1938**	**Unified harmonised framework**

Abbreviations: CNT: Centro Nazionale Trapianti · RIVM: Netherlands National Institute for Public Health · AFMPS: Belgian Federal Agency for Medicines · ANSM: Agence Nationale de Sécurité du Médicament (France) · BfArM: Bundesinstitut für Arzneimittel (Germany) · PEI: Paul-Ehrlich-Institut · MHRA: Medicines and Healthcare products Regulatory Agency (UK) · SoHO: Substances of Human Origin

EU SoHO Regulation 2024/1938 — A Regulatory Watershed

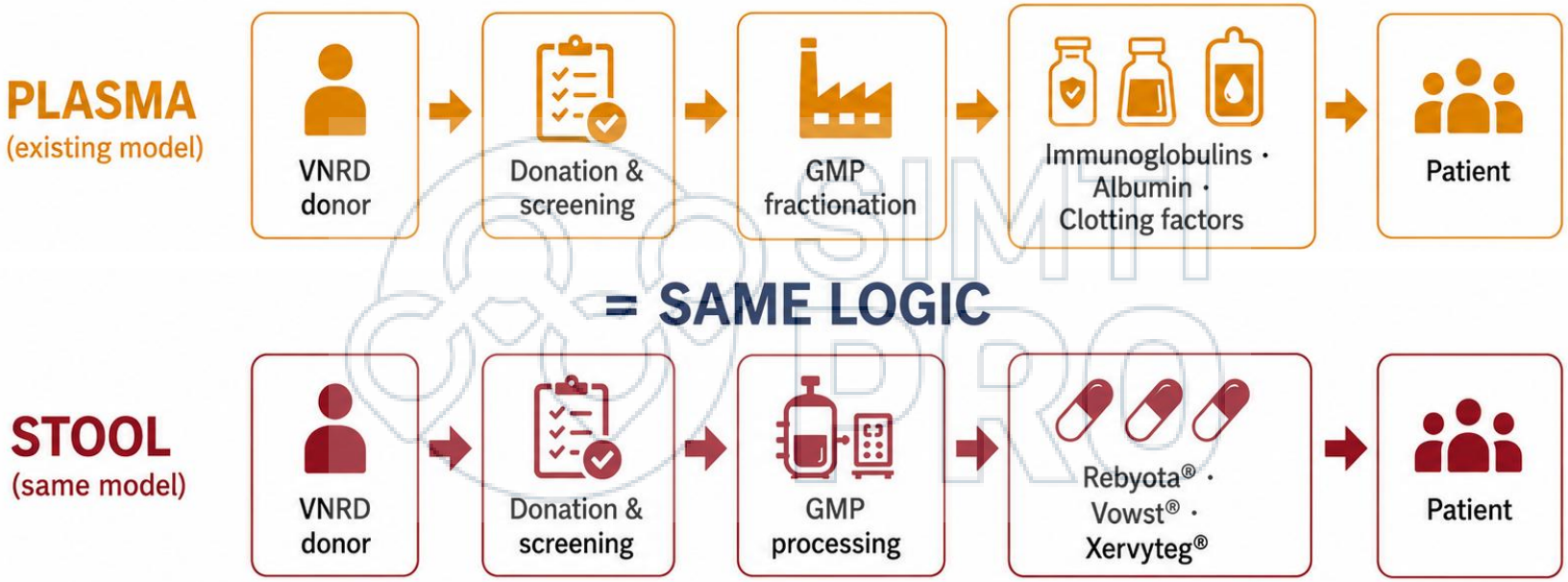
Published 17 July 2024 · In force August 2024 · Applies from 7 August 2027

Regulation (EU) 2024/1938 explicitly brings intestinal microbiota within the EU SoHO framework

- From August 2027, all Member States will operate under a common EU SoHO framework for donor selection, screening, traceability, and vigilance.
- Full traceability from donor registration to clinical outcome registration is mandatory, equivalent in scope to what is already required for blood components.
- Blood establishments already have mature infrastructures for donor management, traceability, biobanking, and vigilance that are directly adaptable to FMT programmes.
- Where intestinal microbiota is processed into a medicinal product (this is already the case for some preparations) the SoHO Regulation governs the upstream (donor to distribution); pharmaceutical legislation applies downstream.
- This new framework facilitates integration of stool banking within transfusion medicine departments.

Abbreviations: SoHO: Substances of Human Origin · BTC: Blood, Tissues and Cells · FMT: Fecal Microbiota Transplantation

From Voluntary Donation to Clinical-Grade Microbiota Products



EU SoHO Regulation 2024/1938 establishes voluntary and non-remunerated donation as the governing principle for intestinal microbiota — the standard the EU endorses also for plasma.

Reg. (EU) 2024/1938, Art. 54 • Feuerstadt P, NEJM 2022 • MaaT Pharma, June 2025

Open Policy Questions — Requiring Institutional Engagement

1. Traceability of pooled donor preparations

Products such as MaaT013 use pooled donors, meaning a single infusion cannot be attributed to one donor-recipient pair. The SoHO traceability model, designed for single-donor products, does not yet fully resolve this attribution challenge.

2. Cross-border flows after 2027

Harmonised SoHO quality standards do not automatically create mutual recognition of national entity authorisations. Cross-border stool banking at EU scale still requires bilateral agreements or a specific EU coordination mechanism.

3. Minimum dataset for clinical outcome registration

The SoHO Regulation mandates outcome registration but no agreed minimum dataset, follow-up duration, or attribution methodology has been established. These will be defined in delegated and implementing acts from the European Commission, currently awaited.

Abbreviations: SoHO: Substances of Human Origin

The Argument in Five Propositions

1

FMT efficacy is established

rCDI: Level 1A (van Nood E, NEJM 2013; Allegretti JR, Gastroenterology 2024). GvHD, IBD, MDRO decolonisation: rapidly maturing evidence.

2

Operational infrastructure is the bottleneck

Not biology — donor pools, multi-gate screening, cryogenic biobanking, traceability, and adverse event surveillance are the limiting factors.

3

TM competencies map directly to FMT requirements

The operational architecture of FMT closely mirrors that of transfusion medicine.

4

Italy provides a proof of concept of TM involvement

CNT National Programme (2020) + Policlinico (CNT accreditation July 2024, first 5 clinical procedures Dec 2024): viable, accredited, scalable.

5

SoHo Regulation recognises a framework where transfusion medicine expertise can support FMT

From August 2027, EU law requires TM-grade quality, traceability, and vigilance for all FMT across 27 member states.

Abbreviations: rCDI: Recurrent Clostridioides difficile Infection · IBD: Inflammatory Bowel Disease · MDRO: Multidrug-Resistant Organism · TM: Transfusion Medicine · SoHO: Substances of Human Origin · CNT: Centro Nazionale Trapianti

Conclusions: Advantages of TDM–FMT Integration

Logistical Advantages

- Single visit for blood + stool screening
- Consolidated sample transport & cold-chain
- Centralized lab processing reduces turnaround time

Quality & Regulatory Alignment

- SOPs, audits, and accreditation (ISO, GMP-like)
- Aligned with EU SoHO Regulation (2024/1938)
- Pharmacovigilance and adverse event reporting systems

Cost-Effectiveness

- Shared overhead lowers per-unit FMT cost
- Danish study: ~$590/unit via blood center vs. ~$1,600 independent (*Kragsnaes et al, Transfusion 2020*)
- Economies of scale in batch testing and processing

Research Opportunities?

nature genetics

Article

https://doi.org/10.1038/s41588-024-01719-2

Genome-wide association analyses highlight the role of the intestinal molecular environment in human gut microbiota variation

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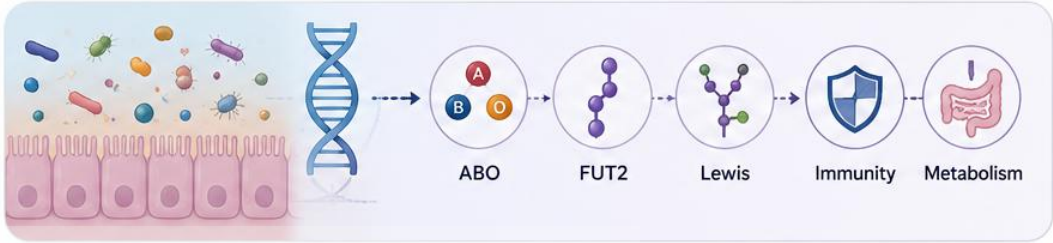
A list of authors and their affiliations appears at the end of the paper

Despite the importance of the gut microbiome to health, the role of host genetics in shaping gut microbiota composition remains incompletely understood.



Host genetics influences mucosal glycobiology and immune–metabolic pathways, shaping the gut microbial ecosystem.

1. Large-scale genetic study — Genome-wide association study (**>28,000 individuals**) identified human genetic loci that influence gut microbiota composition.

2. Key loci and pathways — Key loci included **ABO, FUT2 and Lewis-related pathways**, highlighting the link between blood group glycobiology and microbiome ecology.

3. Impact on host biology — Host genetic control of microbiota may influence **inflammation, metabolism** and **susceptibility to infection**.

4. Relevance for transfusion medicine — Particularly relevant because **ABO and Lewis antigens** regulate **mucosal glycosylation** and **microbial colonization**.

5. Future perspectives — Opens new perspectives on **donor biology, precision medicine** and possible microbiome-related effects on **transfusion outcomes**.

WHY IT MATTERS FOR TRANSFUSION MEDICINE

- Potential influence on donor health, infections and inflammation
- New biomarkers and stratification tools for donor selection and monitoring
- Towards personalized transfusion strategies and improved patient outcomes
- Microbiome as a novel biological factor in transfusion research


Harvey J. Alter
Nobel Prize in Physiology or Medicine 2020

The Gift of Good Poop

Not every hero wears cape or crown,

Some simply sit politely down.

A donor comes, discreet, well-bred,

With science, kindness, and fiber-fed.

Through safety checks and careful selection,

We guard each sample with due inspection.

EU regulation leads the way,

To keep bad bugs and chaos away.

So here's to donors, brave and true:

The world feels better...

thanks for your poo!

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