

# DONOR SCREENING AND STOOL BANKING FOR FECAL MICROBIOTA TRANSPLANTATION: RESULTS FROM A PUBLIC ITALIAN CENTER.

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## Objectives

We aimed to report data from the first two years of stool donor screening and stool banking from the first public Italian fecal microbiota transplantation (FMT) center.

## Methods

We prospectively collected data from donor screening questionnaires, laboratory evaluations and donations. Donor screening has been performed according to the Italian Health Ministry regulation and the European consensus (1): potential donors, all aged below 50 years old, were screened for the presence of concomitant diseases, drugs intake and at-risk conditions for infectious diseases; the microbiological screening evaluated the colonization by potentially pathogenic microbes. Bacterial counts in terms of aerobic and anaerobic concentration [colony forming unit (CFU)/mL] from aliquots of each frozen fecal material were assessed after 1 week and subsequently monthly until 18 months from donation.

## Results

Two-hundred and 12 patients completed screening questionnaires. Of these, 29 (13.7%) were excluded for concurrent gastrointestinal symptoms (altered bowel habits) or diseases, 50 (23.6%) for concomitant systemic diseases, 8 (3.8%) for antibiotic intake in the previous 6 months. Finally, of the 120 donors clinically evaluated, 79 (37.3%) were excluded for at-risk conditions for infectious disease (e.g., use of illegal drugs, risky sexual behavior, recent body tattoo, piercing, travel in tropical countries, healthcare workers, etc.). Among the remaining 41 donors microbiologically screened, 19 (9%) were excluded for pathogens/potentially pathogenic bacteria (6 pathogenic *Escherichia coli*, 1 *Vancomycin resistant Enterococci*, 2 *Helicobacter pylori*, 1 *Rotavirus*, 1 *Giardia duodenalis*). Finally, 22 subjects (10.4%) were suitable for donation. Ten healthy donors actively donated stools (50% females), but 6 were excluded for pathogens/potentially pathogenic bacteria diagnosed during donation's screenings after a median of 3 donations. Among the

remaining 4 subjects, 2 discontinued the donation program due to the commitment requested. Aliquots evaluation showed no differences in aerobic counts until 18 months, while significant differences were found for anaerobic counts already after 1 month ( $1.33^{10}$  CFU/mL vs  $7.6^9$  CFU/mL at donation and after 1 month, respectively,  $p=0.028$ ).

## **Conclusions**

Only one on ten potential healthy donors are finally eligible for stool donation. Frozen stool samples showed a significant decrease in anaerobic concentration already after 1 month from storage, compared to fresh material.

1. Cammarota G., et al. Gut. 2017 Apr;66(4):569-580.