In the depths of the fecal microbiota: Unveiling the secrets of its production

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Context

Fecal microbiota transplants (FMT) production has been described in french hospital pharmacies since 2014 (1).
Several surveys (2-4) have examined the logistic of FMT but not specifically its pharmacotechnical aspects.

Objective

Compilation of FMT production practices in hospital pharmacies in 2024

Conclusion

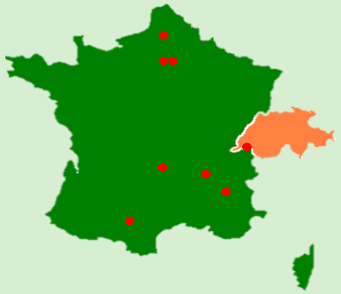
FMT are most commonly prepared in non-classified areas, consists of FM, 0.9% NaCl and glycerol, and are stored frozen.
Our survey highlighted local production variation emphasizing the need for guidelines to standardize production process.

Method

Survey
Google Forms
French language
57 questions concerning
- Fecal matter (FM) donation
- Production environnement
- Preparation and preservation methods of FM capsules and suspensions.

Broadcast : 27.03.24
A mail was sent to GFTF members (Groupe Français de Transplantation Fécale i.e. French group of Fecal transplantation) and 2.0 committee GERPAC
Available during 5 weeks

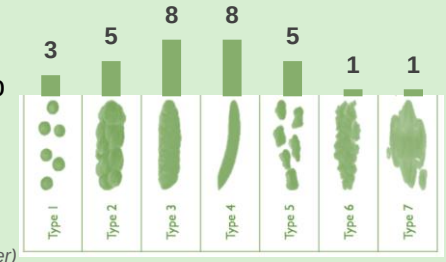
Results / Discussion



8 centers
FM suspensions (n=8)
FM capsules (n=4)
1.8 [0-3] allocated workers

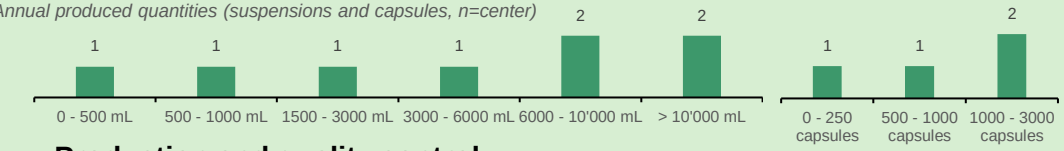
Non-classified and separated area dedicated to FMT production (n=7)

FM donation
- FM donation made on-site (n=6)
- Various donation periods (< 2 weeks to > 8 weeks)
- No pooling of donation (n=8)
- Less than 5 hours between emission and production (n=4)
- Acceptance criteria : Bristol type 3 and 4 (n=8)
- Exclusion criteria : blood and urine (n=8)



Bristol scale type considered conform (n=center)

Annual produced quantities (suspensions and capsules, n=center)



Production and quality control
- FM is homogeneised and diluted using non-pharmaceutical devices (cooking mixer, n=3), laboratory devices (Bag-Mixer®, n=3), pharmaceutical devices (Gako Unguator™, n=1) or manually (n=1)
- NaCl 0.9% as diluent (n=8), glycerol as cryoprotectant (n=8) in various quantities (suspension 5-20%, capsule 5-90%)
- Intermediate product (n=7, suspension to be repackaged) or ready-to-administer product (n=3, capsule, suspension in syringe or bags)
- FM donation are directly frozen by 2 centers
- Double encapsulation (type 0 in 00) is used for capsules to avoid inappropriate opening and ensure intestinal release
- Quality control : visual inspection (n=3), parametric data examination (n=3) and uniformity of mass (or other capsule mass control assay)
- FMT are stored at -80°C for up to 24 months.

Administration
Suspension : 20-60 g FM used (administration route and center-dependant)
Capsule : 50 g FM, 15 to 30 caps administered at D1-D2 or D1AM-D1PM

(1) ANSM. La transplantation de microbiote fécal et son encadrement dans les essais cliniques (03.2014) ; (3) Quraishi et al., 2017 doi.org/10.1016/j.jhin.2016.10.023 ; (2) Martel et al., 2019 doi.org/10.1016/j.pharma.2019.06.001
(4) Dahl Baunwall et al., 2021 doi.org/10.1016/j.lanepe.2021.100181
FM : fecal matter, FMT : fecal microbiota transplants - **Contact** : camille.stampfli@chuv.ch

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