European FMT cost survey

Dear ,

Thank you for your agreement to participate in this survey about the activities and costs related to FMT. The survey is endorsed by the United European Gastroenterology (UEG) working group for FMT. A joint decision to conduct this survey was made by all attending working group members attending the UEG working group meeting in Barcelona at the 20th October 2019. The results of the survey will be presented at the next UEG working group meeting and published in a scientific journal, publicly available.

The survey consists of 7 sections with questions related to FMT. Each section covers specific parts of the value chain needed to provide FMT routinely. An additional section covers the country-specific regulation.

Please answer the questions to the best of your knowledge, and please provide all costs in your local currency.

If you have any questions related to the survey, please do not hesitate to contact me.

On behalf of the UEG stool bank working group
Kind regards,
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Demographic information

Country

- ◯ Austria
- ◯ Belgium
- ◯ Bulgaria
- ◯ Czech Republic
- ◯ Denmark
- ◯ Finland
- ◯ France
- ◯ Germany
- ◯ Hungary
- ◯ Iceland
- ◯ Ireland
- ◯ Italy
- ◯ Lithuania
- ◯ Netherlands
- ◯ Norway
- ◯ Poland
- ◯ Russia
- ◯ Spain
- ◯ Sweden
- ◯ Switzerland
- ◯ Turkey
- ◯ United Kingdom
- ◯ Other (specify)

Country (other), please specify

_____

Institution

_____

Responsible person, name	_____
Responsible person, medical specialty	◯ Gastroenterology ◯ Infectious diseases ◯ Clinical Microbiology ◯ Clinical Immunology ◯ Other
Other speciality, please specify	_____
Would you like to participate in the survey?	◯ No (survey ends) ◯ Yes, with name and institution in Acknowledgements ◯ Yes, anonymously

General comments

European FMT cost survey

Activity, modalities, and indications for FMT in 2019

Based on your activity in 2019, what is the

Total number of FMT procedures in 2019 in your centre

_____

Number of FMT procedures for Clostridioides (formerly Clostridium) difficile-associated disease in 2019, in your centre

_____

Number of FMT procedures for non-CDI-related conditions in 2019, in your centre

_____

Do you distribute FMT components to other centres or facilities?

◯ Yes ◯ No

If yes, how many components/treatments were distributed to other centres in 2019?

_____

Which administration modalities did you use for FMT?

(Please tick one or more as appropriate)

☐ Enema
☐ Colonoscopy
☐ Gastroscopy
☐ Nasogastric tube
☐ Nasoduodenal/nasojejunal tube
☐ Capsules (glycerol-based)
☐ Capsules (lyophilised)
☐ Other

Other modality, please specify

_____

Which is your most frequently used method of application?

(Please tick one)

◯ Enema
◯ Colonoscopy
◯ Gastroscopy
◯ Nasogastric tube
◯ Nasoduodenal/nasojejunal tube
◯ Capsules (glycerol-based)
◯ Capsules (lyophilised)
◯ Other

Other standard modality, please specify

_____

Is FMT used for routine and/or research purposes?

(Please tick one or more as appropriate)

☐ Routine clinical care outside of research protocols
☐ Randomised clinical trial
☐ Other protocol-based treatment

Routine indications for FMT (Please tick one or more as appropriate)	☐ Recurrent Clostridioides difficile ☐ Refractory Clostridioides difficile* ☐ Critically ill with Clostridioides difficile ☐ Index/first Clostridioides difficile ☐ Ulcerative colitis ☐ Crohn's disease ☐ Irritable bowel syndrome ☐ Pouchitis ☐ Multidrug resistance ☐ Antibiotics-associated diarrhea without Clostridioides difficile ☐ Graft versus host disease ☐ Obesity ☐ Spondylarthropathy ☐ Other (Refractory Clostridioides difficile defined as no clinical response to standard antibiotics within 6 days after prescription)
Other indications, please specify	_____
Experimental (within trials) indications for FMT (Please tick one or more as appropriate)	☐ Recurrent Clostridioides difficile ☐ Refractory Clostridioides difficile* ☐ Critically ill with Clostridioides difficile ☐ Index/first Clostridioides difficile ☐ Ulcerative colitis ☐ Crohn's disease ☐ Irritable bowel syndrome ☐ Pouchitis ☐ Multidrug resistance ☐ Antibiotics-associated diarrhea without Clostridioides difficile ☐ Graft versus host disease ☐ Obesity ☐ Spondylarthropathy ☐ Other (Refractory Clostridioides difficile defined as no clinical response to standard antibiotics within 6 days after prescription)
Other indications, please specify	_____
Do you have defined contraindications against FMT for Clostridioides difficile infection?	◯ Yes ◯ No
Please specify the contraindications against FMT for Clostridioides difficile infection	_____
Comments to this section	_____

Donor recruitment and donor screening

By which method do you recruit faeces donors?

(Please tick one or more as appropriate)

- ☐ No active recruitment is performed
- ☐ Public advertising
- ☐ Restricted advertising, i e. among students, societies
- ☐ Recruitment through personal contact in e.g. Blood centre
- ☐ Recruitment from other specific setting (specify)

Other recruitment method, please specify

_____

Do you perform an initial, questionnaire-based pre-screening on all potential donors?

◯ Yes ◯ No

Do you allow/practice dedicated donation, i.e. donation from a donor known to the patient?

(Please tick one)

- ◯ Only dedicated (known to the patient) donors is used
- ◯ Both dedicated and anonymous donors
- ◯ Only anonymous donors

Do you allow health care professionals as faeces donors in your institution?

◯ Yes ◯ No

Is your donor selection based on the absence of risk factors (clinical, biochemical, faecal) alone or do you also make a positive selection for e.g. microbiota patterns?

(Please tick one)

- ◯ Only absence of risk factors
- ◯ Absence of risk factors and positive selection (specify)

Donor selection method, please specify

_____

Comments to this section

Organisation of donation and laboratory processing

In which setting does donation and processing take place at your institution?

(Please tick one)

- ◯ Clinical microbiology
- ◯ Clinical immunology including blood centre
- ◯ Research laboratory
- ◯ Other

Other setting, please specify

_____

Which staff is directly involved in the laboratory processing of donor faeces?

(Please tick one or more as appropriate)

- ☐ Laboratory technicians
- ☐ Nurses
- ☐ Physicians
- ☐ Research assistants
- ☐ Other (specify)

Other staff, please specify

_____

What is the maximum time from defaecation to initiation of the laboratory processing?

(Please specify in hours)

_____

Do you perform a post-donation screening (blood and faeces tests)?

◯ Yes ◯ No

Is quarantine of FMT components until fulfillment of release criteria practiced?

◯ Yes ◯ No

Are routine quality controls performed?

◯ Yes ◯ No

Please describe your quality control measures

_____

Based on your institutions experience with handling donors for FMT, what is the:

Average faeces wet weight per donation

(In grams of faeces)

_____

Average number of faecal donations per round of donations before completing the post-donation screening

_____

Did you define a maximum length for the donation period, i.e. from the first to last faeces donation?

◯ Yes ◯ No

Maximum duration of donation period (In number of days from first to last faeces donation), if specifed?

_____

Do donors receive reimbursement following faeces donation?

(Please tick one or more as appropriate)

- ☐ No, reimbursement
- ☐ Yes, transportation
- ☐ Yes, fixed reimbursement per donation for all donors (specify)
- ☐ Yes, fixed reimbursement per donation for donors in clinical trials (specify)
- ☐ Yes, other reimbursement (specify)

Type and amount of reimbursement, please specify

_____

Based on your laboratory protocol for FMT components, what is the:

Amount of donor faeces used for one FMT component

(In grams of faeces)

_____

Do you use fresh and/or frozen donor faeces?

(Please tick one)

- ◯ Only fresh
- ◯ Only frozen
- ◯ Both fresh and frozen

At what temperature are FMT components kept?

(Please tick one or more as appropriate)

- ☐ No cryopreservation practiced
- ☐ Minus 20°C
- ☐ Minus 80°C
- ☐ Other (specify)

For how long is storage at -20°C allowed at your institution

(Please specify in months)

_____

For how long is storage at -80°C allowed at your institution

(Please specify in months)

_____

Other temperature, please specify

_____

Do you have a specific protocol for donation and FMT components for immunocompromised patients?

◯ Yes ◯ No

Protocol for immunocompromised patients, please specify

_____

Comments to this section

Organisation of clinical application

Do you have specific staff allocated to the clinical application of FMT, and whom?

(Please tick one or more as appropriate)

- ☐ No specific staff is allocated
- ☐ Physicians
- ☐ Nurses
- ☐ Laboratory technicians
- ☐ Research assistants
- ☐ Other (specify)

Other staff allocated to the clinical application of FMT, please specify

_____

Do you rountinely perform repeated administrations of FMT as a part of the same treatment?

(Please tick one)

- ◯ No, always single FMT
- ◯ Yes, occasional repeated FMT without predefined criteria
- ◯ Yes, by predefined criteria (specify)

Please state criteria for repeated FMT (patient type, risk factor, treatment protocol)

_____

Do you document follow-up in all patients who receive FMT?

◯ Yes ◯ No

How is your clinical follow-up practiced?

(Please tick one or more as appropriate)

- ☐ Clinical appointment
- ☐ Telephone call
- ☐ Medical record
- ☐ Other (specify)

Other form of follow-up, please specify

_____

What is the longest scheduled follow-up in patients who had FMT for Clostridioides difficile infection?

_____

(Please specify in weeks)

What is the longest scheduled follow-up in patients who had FMT for other indications?

_____

(Please specify in weeks)

Comments to this section

Regulation, audit, safety

Do you maintain a centralised database of FMT activity in your centre?

◯ Yes ◯ No

Has a formal auditing system been implemented in your centre?

◯ Yes ◯ No

Audit details please describe who carries out the audit, how often, and other elements?

_____

Do you have regulation from a national health authority?

(Please tick one or more as appropriate)

☐ No regulation
☐ Yes, dialogue with health authority
☐ Yes, formal regulation from tissue authority
☐ Yes, formal regulation from medicines authority
☐ Yes, Ethics Committee
☐ Yes, other regulation (specify)

Nature of other regulation, please specify

_____

Is FMT component processing performed and accredited according to GMP?

◯ Yes ◯ No

Are clinical trials conducted with GCP monitoring?

(Please tick one)

◯ Yes
◯ No
◯ Not applicable (no trials conducted)

Are adverse events recorded in a predefined manner?

◯ Yes ◯ No

Please describe the recording of adverse events

_____

Are adverse events reported to an external party?

◯ Yes ◯ No

Please specify to which external party

_____

Comments to this section