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SYDNEY

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INFORMED CONSENT STATEMENT

Gastroenterologist Perceptions of Faecal Microbiota Transplantation

(Manuscript No 17929)

All respondents provided written informed consent acknowledged by completion and return of the voluntary anonymous survey

Regards

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GASTROENTEROLOGIST “FAECAL MICROBIOTA TRANSPLANTATION” (FMT) PERCEPTIONS SURVEY

Thank you for kindly taking the time to complete this voluntary short survey assessing the perceptions of Gastroenterologists with regards to Faecal Microbiota Transplantation (FMT) as a medical therapy. Completion and submission of this voluntary anonymous survey will be taken as informed consent.

Please only complete and submit this survey once (either paper copy or online).

Please circle your selected answer.

1: How would you best describe yourself? (may select more than one option)

- a: General Gastroenterologist
- b: Hepatology subspecialist
- c: Inflammatory Bowel Disease subspecialist
- d: Advanced / Therapeutic endoscopy subspecialist
- e: Gastroenterology trainee
- f: Other; please describe in space below

2: What is the nature of your practice / work? (may select more than one option)

- a: Staff Specialist
- b: Public Hospital Visiting Medical Officer
- c: Private Practice
- d: >40% Medical Research
- e: Other; please describe in space below

3: Have you been consulted by a patient who has had FMT before? If yes please circle the indication for the FMT (may select more than one option)

- a. No
- b: *Clostridium difficile*
- c: Ulcerative Colitis
- d: Crohn’s disease
- e: Irritable bowel syndrome
- f: Other; please describe in space below

4: Have you ever referred a patient for FMT before?

a: Yes – please elaborate in space below (indication, number of referrals, outcome)

b: No

5: Please select which of the following indications, if any, you would consider referring for FMT if easily available (may select more than one option)

a: *Clostridium difficile*

b: Ulcerative Colitis

c: Crohn’s disease

d: Irritable bowel syndrome

e: Other; please list in space below

f: I would not consider referring for FMT for any indication

6: If a patient saw you and expressed interest in undergoing FMT would you (you may select more than one option)

a: Advise against it

b: Remain ambivalent

c: Acknowledge their interest and refer them for FMT

d: Only refer them for FMT for the indication of recurrent *Clostridium difficile*

e: Suggest they only participate in clinical trials involving FMT

f: Other; please describe in space below

7: Please select your response in answer to each of the following potential concerns with FMT

a: I don’t believe in FMT and I don’t think it is an effective therapy

| | | | |
|-------------------|-------------------|----------------|----------------|
| Strongly Disagree | Somewhat Disagree | Somewhat Agree | Strongly Agree |
|-------------------|-------------------|----------------|----------------|

b: While FMT may work at present there is inadequate evidence for efficacy

| | | | |
|-------------------|-------------------|----------------|----------------|
| Strongly Disagree | Somewhat Disagree | Somewhat Agree | Strongly Agree |
|-------------------|-------------------|----------------|----------------|

c: There is a significant infection risk from donor stool despite screening

| | | | |
|-------------------|-------------------|----------------|----------------|
| Strongly Disagree | Somewhat Disagree | Somewhat Agree | Strongly Agree |
|-------------------|-------------------|----------------|----------------|

d: I have other safety concerns regarding non-infectious adverse reactions with FMT

| | | | |
|-------------------|-------------------|----------------|----------------|
| Strongly Disagree | Somewhat Disagree | Somewhat Agree | Strongly Agree |
|-------------------|-------------------|----------------|----------------|

e: There is a risk of disease exacerbation with FMT

| | | | |
|-------------------|-------------------|----------------|----------------|
| Strongly Disagree | Somewhat Disagree | Somewhat Agree | Strongly Agree |
|-------------------|-------------------|----------------|----------------|

f: I don't think my patients would contemplate or consent to FMT

| | | | |
|-------------------|-------------------|----------------|----------------|
| Strongly Disagree | Somewhat Disagree | Somewhat Agree | Strongly Agree |
|-------------------|-------------------|----------------|----------------|

g: "Yuck" factor

| | | | |
|-------------------|-------------------|----------------|----------------|
| Strongly Disagree | Somewhat Disagree | Somewhat Agree | Strongly Agree |
|-------------------|-------------------|----------------|----------------|

h: Lack of availability / accessibility to FMT

| | | | |
|-------------------|-------------------|----------------|----------------|
| Strongly Disagree | Somewhat Disagree | Somewhat Agree | Strongly Agree |
|-------------------|-------------------|----------------|----------------|

i: Other; please describe in space below

8: What is your greatest concern, if any, regarding FMT? Please select only one

a: Lack of efficacy

b: Lack of evidence

c: Infection risk from donor stool despite screening

d: Non infectious adverse reaction and lack of safety data

e: Possible disease exacerbation

f: "Yuck" factor of donor stool

g: None; I have no concerns regarding FMT

h: Other; please list in space below

9: How do you feel the potential risks of FMT compare with blood transfusion or other biologic product administration?

- a: More risk with blood transfusion than FMT
- b: More risk with FMT than blood transfusion
- c: Not sure
- d: Other; please describe in space below

10: What do you think is the optimal modality through which to deliver FMT?

- a: Transcolonoscopic
- b: Enema based
- c: Nasoduodenal/jejunal
- d: Other; please list in space below
- e: I don't have an opinion

11: If your patient had exhausted all other medical options and was facing surgery for refractory disease in which FMT has been suggested as a potential therapeutic option, would you consider FMT as a last resort therapy?

- a: Yes
- b: Yes but only for *Clostridium difficile*
- c: Yes but only in a clinical trial
- d: Not sure
- e: No
- f: Other; please describe in space below

12: Do you think FMT holds promise as a potential future therapy for certain gastrointestinal diseases?

- a: Yes
- b: No
- c: Not Sure
- d: Other; please describe in space below

13: Would you be willing to enroll your patients in clinical trials assessing FMT?

- a: Yes
- b: No
- c: Not Sure
- d: Other; please describe in space below

14: In the next 3 years, do you foresee a situation where you would consider referring a patient for FMT outside a clinical trial if a trusted service was available? Please select your answer for each of the following indications

- a. No, I would not consider referring for FMT for any indication
- b: Recurrent *Clostridium difficile* infection

| | | | |
|---------------|-----------------|-------------------|-----------------|
| Highly Likely | Somewhat Likely | Somewhat Unlikely | Highly unlikely |
|---------------|-----------------|-------------------|-----------------|

c: Ulcerative Colitis

| | | | |
|---------------|-----------------|-------------------|-----------------|
| Highly Likely | Somewhat Likely | Somewhat Unlikely | Highly unlikely |
|---------------|-----------------|-------------------|-----------------|

d: Crohn's disease

| | | | |
|---------------|-----------------|-------------------|-----------------|
| Highly Likely | Somewhat Likely | Somewhat Unlikely | Highly unlikely |
|---------------|-----------------|-------------------|-----------------|

e: Irritable bowel syndrome or other functional gut disorder

| | | | |
|---------------|-----------------|-------------------|-----------------|
| Highly Likely | Somewhat Likely | Somewhat Unlikely | Highly unlikely |
|---------------|-----------------|-------------------|-----------------|

15: With regards to FMT, please select your response to the following statements

- a: I already offer FMT as a therapeutic option in my practice
- b: I have an interest in learning how to process and administer FMT so that I or my institution can arrange such therapy for our patients independently

| | | | |
|-------------------|-------------------|----------------|----------------|
| Strongly Disagree | Somewhat Disagree | Somewhat Agree | Strongly Agree |
|-------------------|-------------------|----------------|----------------|

c: I believe a few select centres that satisfy appropriate regulatory requirements should be available in my city to offer FMT

| | | | |
|-------------------|-------------------|----------------|----------------|
| Strongly Disagree | Somewhat Disagree | Somewhat Agree | Strongly Agree |
|-------------------|-------------------|----------------|----------------|

d: I don't believe the therapy should be available for routine clinical use

| | | | |
|-------------------|-------------------|----------------|----------------|
| Strongly Disagree | Somewhat Disagree | Somewhat Agree | Strongly Agree |
|-------------------|-------------------|----------------|----------------|

16: After reviewing the attached FOCUS study letter of invitation, protocol summary and selection criteria

a: Are you likely to refer patients who meet selection criteria to this study?

| | | | |
|---------------|-----------------|-------------------|-----------------|
| Highly Likely | Somewhat Likely | Somewhat Unlikely | Highly unlikely |
|---------------|-----------------|-------------------|-----------------|

b: Do you have any actual patients in mind that you would consider referring to this study?

| | | | |
|---------------|-----------------|-------------------|-----------------|
| Highly Likely | Somewhat Likely | Somewhat Unlikely | Highly unlikely |
|---------------|-----------------|-------------------|-----------------|

17: Any other comments regarding FMT that you wish to make?

Thank you for kindly taking the time to complete this survey

Dr Sudarshan Paramsothy on behalf of the FOCUS Study Group

Prof Michael Kamm
Prof Thomas Borody
Prof Hazel Mitchell
Prof Rupert Leong
Dr Alissa Walsh
Dr Douglas Samuel
Dr Susan Connor
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