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Donor screening for faecal microbiota transplantation in the COVID-19 outbreak era: suggestions for urgent updates from an international expert panel.

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Corresponding Author:	Gianluca Ianiro, MD Fondazione Policlinico Universitario Rome, ITALY
First Author:	Gianluca Ianiro, MD
Order of Authors:	Gianluca Ianiro, MD Benjamin H Mullish Colleen R Kelly Harry Sokol Zain Kassam Siew Ng Monika Fischer Jessica R Allegretti Luca Masucci Faming Zhang Josbert Keller Maurizio Sanguinetti Samuel P Costello Herbert Tilg Antonio Gasbarrini Giovanni Cammarota
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Title

Donor screening for faecal microbiota transplantation in the COVID-19 outbreak era: suggestions for urgent updates from an international expert panel.

Authors

Gianluca Ianiro¹, Benjamin H Mullish², Colleen R Kelly³, Harry Sokol^{4,5,6}, Zain Kassam⁷, Siew Ng⁸, Monika Fischer⁹, Jessica R Allegretti¹⁰, Luca Masucci¹¹, Faming Zhang¹², Josbert Keller^{13,14}, Maurizio Sanguinetti¹¹, Samuel P Costello¹⁵, Herbert Tilg¹⁶, Antonio Gasbarrini¹, Giovanni Cammarota¹

Affiliations

¹Digestive Disease Center, Fondazione Policlinico Universitario “A. Gemelli” IRCCS, Università Cattolica del Sacro Cuore, Rome, Italy

²Division of Digestive Diseases, Department of Metabolism, Digestion and Reproduction, Faculty of Medicine, Imperial College London, London, UK.

³Division of Gastroenterology, Alpert Medical School of Brown University, Providence, Rhode Island, United States of America

⁴Service de Gastroenterologie, Hôpital Saint Antoine, Sorbonne Université, Inserm, Centre de Recherche Saint-Antoine, Paris, France

⁵French Group of Fecal Microbiota Transplantation, Paris, France

⁶INRA, UMR1319 Micalis, AgroParisTech, Jouy-en-Josas, France

⁷Finch Therapeutics Group, Somerville, USA

⁸Institute of Digestive Disease and Department of Medicine and Therapeutics, State Key Laboratory of Digestive Disease, Li Ka Shing Institute of Health Sciences, CUHK Shenzhen Research Institute, The Chinese University of Hong Kong, Shatin, Hong Kong

⁹Department of Medicine, Indiana University, Indianapolis, Indiana, United States of America

¹⁰Division of Gastroenterology, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts, United States of America

¹¹Microbiology Unit, Fondazione Policlinico Universitario "A. Gemelli" IRCCS, Università Cattolica del Sacro Cuore, Rome, Italy

¹²Medical Center for Digestive Diseases, the Second Affiliated Hospital of Nanjing Medical University, China

¹³Department of Gastroenterology, Haaglanden Medical Center, The Hague, The Netherlands, and Leiden University Medical Center, Leiden, The Netherlands.

¹⁴Netherlands Donor Feces Bank, Leiden University Medical Center, The Netherlands

¹⁵Department of Gastroenterology, The Queen Elizabeth Hospital, University of Adelaide, Woodville, South Australia, Australia

¹⁶Department of Internal Medicine I, Gastroenterology, Hepatology, Endocrinology & Metabolism, Innsbruck Medical University, Innsbruck, Austria

Corresponding Author

Dr. Gianluca Ianaro; Digestive Disease Center, Fondazione Policlinico Universitario "A. Gemelli" IRCCS, Università Cattolica del Sacro Cuore, Largo A. Gemelli 8, 00168 – Rome, Italy. Tel/fax numbers: +39 06 30156265/+39 06 30157023; e-mail address: gianluca.ianaro@hotmail.it

Text

As the outbreak of coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has rapidly spread from China to other countries, governments and the medical community are taking steps to prevent transmission, from common sense recommendations to radical quarantine measures.¹

In that context, timely recommendations concerning the screening of donors of human cells, tissues, or cellular or tissue-based products (HCT/Ps) have been released, as the potential for transmission of COVID-19 through transplant is not known to date. Several institutions have recommended interim precautions to screen new donors. The U.S. Food and Drug Administration has suggested considering HCT/Ps donor history of travel to areas of outbreak, cohabitation with infected persons, or diagnosis/suspicion of COVID-19 within the 28 days before the visit.² Similar measures have been taken by the Global Alliance of Eye Bank Associations and by the Joint United Kingdom Blood Transfusion Services Professional Advisory Committee to rule out potential donors.^{3,4} The European Society for Blood and Marrow Transplantation has recommended excluding affected subjects, and waiting at least 21 days before donation in those with history of risky travels or contacts.⁵ In Italy, where the COVID-19 outbreak is spreading rapidly, the national transplant centre has taken stronger measures and has recommended testing all potential tissue and stem cell living donors, as well as dead donors, through real-time reverse transcriptase (RT) PCR assay for the nasopharyngeal swab (or by bronchoalveolar lavage in dead subjects).⁶

Faecal microbiota transplantation (FMT) is a novel treatment that has rapidly earned a paramount role in the management of recurrent *Clostridioides difficile* infection because of its clear advantages over antibiotics.⁷ FMT is becoming increasingly more diffused and standardized worldwide. Recently, an international expert panel, including several authors of this comment, have released recommendations on how to screen FMT donors, including a medical history, and blood and stool exams.⁸

Given the global COVID-19 outbreak, we, as an international group of experts in FMT and stool banking, believe that recommendations to update (at least temporarily) the screening of stool donors are urgently needed, as the risk of transmitting SARS-CoV-2 by FMT may be higher than in other tissue transplants. Recent evidence shows that the SARS-CoV-2 can be found in faeces, and that it can remain positive even after negativisation in the respiratory tract, suggesting that the faecal-oral route could be a potential route of transmission.⁹ This concept is supported by the presence of gastrointestinal symptoms in some affected patients.¹⁰ Another relevant issue is that FMT is not classified in the same way worldwide, as some countries regulate FMT as a drug (e.g. U.S., U.K., and France), some as a tissue (e.g. Italy), and others do not provide specific regulation (e.g. Australia).⁸ This discrepancy results in a confusing scenario, in which some countries will apply rules for HCT/Ps, and other will not, potentially contributing to the spread of the infection. A more alarming issue is represented by the uncontrolled practice of homemade FMT, which is widely diffused among patients who want to try this treatment for indications outside clinical guidelines or clinical trials.¹¹

To prevent SARS-CoV-2 transmission, we propose additional measures to the current donor screening. In all countries, the physicians should assess, before each donation: 1) the presence of typical COVID-19 symptoms, including fever, fatigue, dry cough, myalgia and dyspnea, headache, within the previous 30 days; 2) history of at-risk travels or close contacts with subjects with proven or suspected infection, within the previous 30 days. If one of these items is positive, the potential donor should either be rejected or tested with RT-PCR assay for SARS-CoV-2. In endemic countries, the RT-PCR assay should be considered in all donors, even if asymptomatic or without history of risky travels or contacts; alternatively, donor stools should be stored and quarantined for 30 days before use, and released only if the donor has not developed symptoms. Finally, stool banks should check retrospectively the health status of the donor before using frozen faeces, according to local epidemiology, to avoid further potential spreading of SARS-CoV-2. Obviously, these

suggestions should be tailored to local healthcare organizations, and should be updated accordingly with further discoveries on COVID-19 and SARS-CoV-2.

Declaration of interests

All authors declare no competing interests.

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