

Screening of faecal microbiota transplant donors during the COVID-19 outbreak: suggestions for urgent updates from an international expert panel



As the outbreak of coronavirus disease 2019 (COVID-19), caused by 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 have been released, as the potential for transmission of COVID-19 through transplant is not yet known. Several institutions have recommended interim precautions to screen new donors. The US Food and Drug Administration has suggested considering a donor's history of travel to areas of outbreak, cohabitation with infected individuals, or diagnosis or suspicion of COVID-19 within the 28 days before recovery of donor tissue.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 potential donors who have been diagnosed with COVID-19, and waiting at least 21 days before donation in those with a history of high-risk travel or contact.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 RT-PCR assays of nasopharyngeal swab samples (or bronchoalveolar lavage in deceased individuals).⁶

Faecal microbiota transplantation is a novel treatment that has rapidly earned a major role in the management of recurrent *Clostridioides difficile* infection because of its clear advantages over antibiotics.⁷ It is becoming increasingly more widespread and standardised around the world. Last year, an international expert panel, including several authors of this Comment, released recommendations on how to screen faecal microbiota

transplant donors, including a medical history and blood and stool examinations.⁸

Given the global COVID-19 outbreak, we, as an international group of experts in faecal microbiota transplantation 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 faecal microbiota transplantation might be higher than that in other tissue transplants. Evidence has shown that the SARS-CoV-2 can be found in faeces, and that stool samples can remain positive for the virus even when it is no longer detectable in the respiratory tract, suggesting the possibility of a faecal-oral route of transmission.⁹ This concept is supported by the presence of gastrointestinal symptoms in some patients affected by COVID-19.¹⁰ Another relevant issue is that faecal microbiota transplantation is not classified in the same way worldwide, as some countries regulate these transplants as a drug (eg, the USA, the UK, and France), some as a tissue (eg, Italy), and others do not provide specific regulation (eg, Australia).⁸ This discrepancy results in a confusing scenario, in which some countries will apply rules for human cells, tissues, or cellular or tissue-based products, and others will not, potentially contributing to the spread of the infection. A more alarming issue is represented by the uncontrolled practice of homemade faecal microbiota transplantation, which is widespread among patients who want to try this treatment for indications outside of clinical guidelines or clinical trials.¹¹

To prevent SARS-CoV-2 transmission, we propose additions to the current donor screening measures. In all countries, before each donation, physicians should screen for two main items: the presence of typical COVID-19 symptoms (including fever, fatigue, dry cough, myalgia, dyspnoea, and headache) within the previous 30 days; and the donor's history of travel to regions known to be affected by COVID-19 or close contact with individuals with proven or suspected infection, within the previous 30 days. If either of these items is positive, the potential donor should either be

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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 they are asymptomatic or do not have a history of high-risk travel or contact. 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 retrospectively check the health status of the donor before using frozen faeces, according to local epidemiology, to avoid further potential spreading of SARS-CoV-2. These suggestions should be tailored to local health-care organisations, and should be updated accordingly as further insight into COVID-19 and SARS-CoV-2 is gained.

We declare no competing interests.

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- 1 Xiao Y, Torok ME. Taking the right measures to control COVID-19. *Lancet Infect Dis* 2020; published online March 5. [https://doi.org/10.1016/S1473-3099\(20\)30152-3](https://doi.org/10.1016/S1473-3099(20)30152-3).
- 2 US Food and Drug Administration. Important Information for human cell, tissue, or cellular or tissue-based product (HCT/P) establishments regarding the 2019 novel coronavirus outbreak. 14 Feb, 2020. <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/important-information-human-cell-tissue-or-cellular-or-tissue-based-product-htcp-establishments> (accessed March 6, 2020).
- 3 Global Alliance of Eye Bank Associations. ALERT: Coronavirus (COVID-2019) and ocular tissue donation. Feb 3, 2020. <https://www.gaeba.org/2020/alert-coronavirus-2019-ncov-and-ocular-tissue-donation/> (accessed March 6, 2020).
- 4 Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee. Coronavirus infection. 2020. <https://www.transfusionguidelines.org/dsg/wb/guidelines/coronavirus-infection> (accessed March 6, 2020).
- 5 European Society for Blood and Marrow Transplantation. Coronavirus disease COVID-19: updated EBMT recommendations. 2020. <https://www.ebmt.org/ebmt/news/ebmt-recommendation-coronavirus-disease-covid-19> (accessed March 6, 2020).
- 6 Ministero Della Salute. Oggetto: aggiornamento delle misure di prevenzione della trasmissione dell'infezione da nuovo coronavirus (SARS-CoV-2) in Italia attraverso il trapianto di organi, tessuti e cellule. March 3, 2020. http://www.trapianti.salute.gov.it/imgs/C_17_cntAwvisi_231_0_file.pdf (accessed March 6, 2020).
- 7 Ianiro G, Murri R, Sciumè GD, et al. Incidence of bloodstream infections, length of hospital stay, and survival in patients with recurrent *Clostridioides difficile* infection treated with fecal microbiota transplantation or antibiotics a prospective cohort study. *Ann Intern Med* 2019; **171**: 695–702.
- 8 Cammarota G, Ianiro G, Kelly CR, et al. International consensus conference on stool banking for faecal microbiota transplantation in clinical practice. *Gut* 2019; **68**: 2111–2121.
- 9 Xiao F, Tang M, Zheng X, Liu Y, Li X, Shan H. Evidence for gastrointestinal infection of SARS-CoV-2. *Gastroenterology* 2020; published online March 3. DOI:10.1053/j.gastro.2020.02.055.
- 10 Wang D, Hu B, Hu C, et al. Clinical characteristics of 138 hospitalized patients with 2019 novel coronavirus-infected pneumonia in Wuhan, China. *JAMA* 2020; published online Feb 7. DOI:10.1001/jama.2020.1585.
- 11 Ekekezie C, Perler BK, Wexler A, Duff C, Lillis CJ, Kelly CR. Understanding the scope of do-it-yourself fecal microbiota transplant. *Am J Gastroenterol* 2020; published online Jan 10. DOI:10.14309/ajg.0000000000000499.