Health Canada Santé Canada

March 13, 2020

Notice

Measures to Address the Potential Risk of Transmission of the novel coronavirus responsible for COVID-19 by Human Cells, Tissues and Organ Transplantation

Health Canada would like to bring to the attention of all source establishments under the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* (CTO Regulations) some considerations regarding the implementation of donor screening measures to address the risk of potential donor derived transmission of the novel coronavirus responsible for COVID-19 (officially named SARS-CoV-2 by the International Committee on Taxonomy of Viruses).

CTO establishments are urged to take into consideration clause 13.1.3 (k) of the Canadian Standards Association CAN/CSA-Z900.1-17 "*Cells, tissues, and organs for transplantation: General requirements*" standard which states that "*persons with infections that would pose a significant risk to the recipient if transmitted*" should be deferred from CTO donation.

At this time, it is recommended that CTO establishments adopt a precautionary approach and defer both living and deceased CTO donors with known or highly suspected active COVID-19.

It is recommended that donations from donors of fresh hematopoietic stem cells or living organ donors with a history of COVID-19 be postponed for 28 days after resolution of clinical symptoms of infection. It is recommended that deceased donors that have tested positive for SARS-CoV-2 in the past 28 days or are suspected of having been infected with SARS-CoV-2 and exhibited symptoms of COVID-19 in the past 28 days be deferred from donating organs or tissues.

Note that there are documented cases of patients in whom SARS-CoV-2 RNA was detectable by PCR for an extended period after full resolution of clinical symptoms. While detectable RNA does not necessarily mean that the donor has an active infection, it is possible that a donor with detectable SARS-CoV-2 RNA could be considered at potential risk of transmitting infection.

https://jamanetwork.com/journals/jama/fullarticle/2762452

Case by case consideration is necessary under these circumstances and should take into account the risk to the recipient and the urgency of the need for the transplant. If the

intended recipient's need for transplant is urgent and there are no suitable alternative donors, the Medical Director can consider the use of exceptional distribution prior to the end of the 28 day time period. In such cases RT-PCR testing of the donor is highly recommended. It may be necessary to re-evaluate deferral periods as the situation evolves and more studies looking at the potential for viremia and viral shedding become available. For individual cases, source establishments should consult with their Medical Director and infectious disease specialists to determine what length of deferral period to apply for living donors.

Establishments may also wish to consider under what circumstances and for what type of CTOs, risk factors for COVID-19 in a donor would pose a significant risk to recipients.

Establishments may consider implementing other voluntary donor screening measures for both deceased and living donors to address the risk of COVID-19, such as donor deferral criteria that are based solely on travel to at-risk areas, donor deferral criteria that are based on travel to at-risk areas in combination with symptoms of infection, or donor deferral criteria that are based on exposure to individuals with COVID-19. For example, source establishments may consider deferral of asymptomatic living donors for a minimum of 14 days in case of travel to an at-risk area or exposure to a known case of COVID-19. It is anticipated that any travel deferrals will require ongoing re-evaluation as the virus spreads and may cease to be appropriate if community transmission of the virus becomes widespread in Canada.

Currently there are no approved donor screening assays for SARS-CoV-2. However, diagnostic testing for SARS-CoV-2 may become more widely available as community transmission progresses and source establishments may consider developing algorithms to test donors at risk of transmitting SARS-CoV-2, particularly in the case of previously infected donors.

The following information and recommendations published by the American Association of Tissue Banks (AATB), the Eye Bank Association of America (EBAA), the World Marrow Donor Association (WMDA), the European Society for Blood and Marrow Transplantation (EBMT), the American Society of Transplantation (AST), and the United States Food and Drug Administration (FDA) can serve as valuable reference material for CTO establishments.

https://www.aatb.org/content/bulletin-20-3

https://restoresight.org/covid-19-updates/

https://share.wmda.info/display/DMSR/Coronavirus+-+COVID-19#/

https://www.ebmt.org/ebmt/news/ebmt-recommendation-coronavirus-disease-covid-19

https://www.myast.org/sites/default/files/COVID19%20FAQ%20Tx%20Centers%20030220-1.pdf

https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/important-information-human-cell-tissue-or-cellular-or-tissue-based-product-hctp-establishments

Establishments may also wish to consult the US Centers for Disease Control and Prevention (CDC) website and the Public Health Agency of Canada (PHAC) website for an updated list of destinations with community spread of COVID-19.

https://wwwnc.cdc.gov/travel

https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection.html

Note that all clinical decision making relating to specific cases, should be at the discretion of the source establishment's Medical Director.

NB: This notice is based on currently available information and may be subject to change as more information becomes available.

Questions or comments may be submitted to the Office of Policy and International Collaboration at the address below:

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Sincerely,

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