Consensus guidance and recommendations for organ donation and transplantation services during COVID-19 pandemic

The most current version of this document will reside on the Organ and Tissue Donation and Transplantation professional education website.

Background

The COVID-19 pandemic continues to have a significant impact on the Canadian health care system, including organ and tissue donation and transplantation. To help guide the administration of organ and tissue donation and transplantation services in light of the COVID-19 pandemic, this guidance is informed by national discussions, expert consensus, and guidance from the Canadian Society for Transplantation, Canadian Blood Services' advisory committees, Health Canada, Public Health Agency of Canada, World Health Organization, provincial agencies, and international partners.

Recommendations marked with a double asterisk (**) were generated through the GRADE (Grading of Recommendations, Assessment, Development and Evaluations) process, a transparent framework for summarizing evidence in order to provide a systematic approach for making clinical practice recommendations. These recommendations have been published in the Clinical Practice Guideline for Solid Organ Donation and Transplantation During the COVID-19 Pandemic.[i]

This document was last **updated Nov. 4, 2021**, and will be updated as required.

Disclaimer:

> *The guidance provided in this document is not meant to replace clinical judgement. Because the pandemic is rapidly evolving, the guidance will likely change over time. Any clinical decisions should be made in consideration of the latest available information.*

Key Considerations

Guiding principles

1. Organ donation and transplantation is an essential life-saving and life-preserving medical intervention.

2. Guidance and recommendations must balance the incidence trends in provinces and territories, the risk posed to health care professionals and to potential recipients who will become immunocompromised, and the risks of suspending or delaying transplantation.
3. A consistent and principled approach for all jurisdictions across Canada is preferred.

Current level of risk

COVID-19 is a serious health threat, and the situation is evolving daily. The risk will vary between and within communities, but given the consistent number of cases in Canada, the risk to Canadians is considered **high**. Continued vigilance will be required.[ii]

The epidemiology of COVID-19 in Canada is continually evolving. Significant variation exists in COVID-19 symptomatology, including non-respiratory symptoms. In addition, there is evidence that asymptomatic or mildly symptomatic carriers can also serve as a source of community or institutional spread. There are also increasing reports of new emerging variants emerging in Canada and globally.

A recent systematic review of COVID-19 in solid organ transplant recipients found fever to be the most commonly reported symptom, followed by cough, shortness of breath, and diarrhea. In addition, the risk of hospital admission is higher for transplant recipients compared to the general population. However, rates of lower respiratory tract infection (based on abnormal imaging), intensive care unit (ICU) admission, and mortality are all comparable to the general population.[iii]

Potential modes of transmission:

1. Community-acquired
2. Nosocomial (in hospital):
    a. other patients, visitors, health care staff
    b. droplet spread, aerosolization and potential surface contamination
3. Donor to recipient*:
    a. Virus present in blood; there continues to be no evidence of blood-borne transmission of SARS-CoV-2
    b. Virus present in organ (lung especially; gastrointestinal tract; but other organs possible)

*** NOTE:** There has been at least one confirmed and published case of donor-to-recipient and donor-to-healthcare provider transmission via lung transplantation[iv], and at least one other confirmed case of donor-to-recipient transmission via lung transplantation[v]. Based on the available evidence, donor-to-recipient transmission is unlikely in non-lung organ transplants.

ICU, OR and transplant services

The decision to proceed with organ donation and transplantation is predicated on hospital capacity and resource considerations, and it is understood that it may be affected by provincial and facility incidence and severity of COVID-19.

Personal protection equipment

1. All health care personnel involved in organ donation and transplantation services should be fit-tested for masks and have personal protective equipment training.
2. N95 masks should be required for all ICU and OR staff, when deemed appropriate by hospital safety protocols (e.g. procedures that may lead to aerosolization of the virus such as intubation, bronchoscopy, surgical cautery, bone saw), and are not expected to be required for general care.
3. All health care professionals should wear personal protective equipment during all patient interactions. It is acknowledged that there is regional and institutional variability with respect to:
    a. COVID-specific PPE
    b. Universal precautions
    c. No routine precautions
4. All health care personnel involved in organ donation and transplantation services should be vaccinated against COVID-19 in accordance with hospital or organizational safety protocols.

Deceased donor programs

All deceased donation programs in Canada should consider potential donors on a case-by-case basis, considering hospital resource utilization and the severity of the pandemic in the local jurisdiction.

CRITERIA FOR DECEASED DONORS

1. We recommend PCR testing of all patients who are potential deceased organ donors (strong recommendation, low certainty of evidence).**
    a. We recommend both upper and lower PCR testing of all patients who are potential deceased organ donors within 24 hours prior to organ recovery (strong recommendation, low certainty of evidence).**We suggest that lower respiratory samples be collected by methods that produce the least risk of aerosol generation (e.g. endotracheal aspirate (ETT) as opposed to bronchoalveolar lavage (BAL)) (weak recommendation, low certainty of evidence).**

i) The BAL can be performed bronchoscopically or as a modified (blind) BAL, using an in line endotracheal tube suction catheter wedged deep into the airway.

b. We suggest against repeat PCR testing from the same collection site of patients who are potential donors (weak recommendation, low certainty of evidence).**

c. We recommend against routine thoracic computed tomography (CT) scans for COVID-19 screening for potential deceased organ donors (strong recommendation, low certainty evidence).**

d. We suggest that the results of PCR testing supersede any contradictory information from available thoracic computed tomography (CT) scan results (weak recommendation, moderate certainty evidence).**

e. We make no recommendation regarding the use of antibody screening to evaluate the risk of COVID-19 transmission from potential deceased organ donors to organ recipients.**

2. ICU/OR capacity allowing, a negative COVID-19 result must be available prior to proceeding (excluding exceptional circumstances).
3. We recommend against transplantation of solid organs retrieved from deceased donors with active COVID-19 infection, particularly in the case of lung transplantation (strong recommendation, very low certainty of evidence).**
4. We suggest proceeding with transplantation of solid organs retrieved from deceased donors with a resolved COVID-19 infection (weak recommendation, low certainty of evidence).**
5. All potential donors with a previous diagnosis of COVID-19 require:
   a. A minimum of one month since first diagnosis (i.e. first positive test)
   b. A negative NP swab AND either endotracheal tube (ETT) aspirate or BAL samples (BAL if lungs considered) within 48 hours of donation
   c. Review of each case by a Transplant Infectious Disease physician prior to consideration, if the patient's diagnosis is recent (less than 3 months).
6. All organ offers from programs where testing of donors may not have reliably occurred, should be considered on a case-by-case basis.

Living donor programs

It is suggested that all living donor kidney transplant programs in Canada should consider living donor transplants on a case-by-case basis, considering the recipient's medical need, hospital resource utilization, and the severity of the pandemic in the local jurisdiction.

CRITERIA FOR LIVING DONORS

1. All potential living donors must undergo a symptom screen and COVID-19 test as close as possible prior to donation (within 24–48 hours).
    a. It is acknowledged that there is regional and institutional variability relative to the precise timing of screening and testing, and the processes employed to administer both.
    b. Current data suggests the optimal test type in this ambulatory setting is a nasopharyngeal (NP) swab.
    c. Any donor with compatible symptoms should be deferred but should also be tested to allow for future planning.
2. A living donor is eligible to donate only if they have tested negative for COVID-19 with the testing taking place within 24–48 hours prior to surgery AND have a negative symptom screen AND have not travelled outside of Canada in the previous 14 days.
3. We suggest proceeding with transplantation of solid organs retrieved from living donors with a resolved COVID-19 infection (weak recommendation, low certainty of evidence).**
4. All living donors with a previous diagnosis of COVID-19 require:
    a. A minimum of one month since first diagnosis (i.e. first positive test)
    b. Complete resolution of symptoms
    c. Two negative NP swabs separated in time by a minimum of 72 hours, and one of the swabs should be within 48 hours of donation.
    d. Review by a Transplant Infectious Disease physician (or Infectious Disease physician) for clearance, if the patient's diagnosis is recent (less than three months).
5. All potential living donors who travelled outside Canada must wait at least 14 days before donating (as per Health Canada's *Measures to Address the Potential Risk of Transmission of the novel coronavirus responsible for COVID-19 by Human Cells, Tissues and Organ Transplantation)*.
6. All potential living donors should be advised to practice significant social distancing for 14 days prior to surgery. All living donors should not travel and be very careful to avoid contact with others who have respiratory or flu like symptoms in the 14 days prior to donation.

Transplant programs

1. Transplant programs should continue operations in accordance with their provincial and local operational plans. We suggest proceeding with transplantation instead of keeping transplant candidates on organ replacement therapies.**
2. During the pandemic, recipients of solid organ transplants should be fully informed at time of organ offer of the potential risk of severe complications should they contract the virus at the time of transplant, during the hospital stay, or once discharged from the hospital while being immunosuppressed. This informed consent should be clearly documented in the hospital chart.
    a. Health Canada regulations determine the criteria for “exceptional distribution” relevant to organ donation.
3. All transplant programs should, whenever possible, recover organs locally and ship them. For those centres that cannot recover organs locally, the decision to send a surgical team can be assessed on case-by-case basis, relative to recipient urgency.
4. If surgical recovery teams travel, the teams should be as small as possible. Every effort should also be made to minimize the team’s potential exposure to COVID-19. For example, upon arrival in locality, teams should go directly to the OR, they should avoid the emergency department whenever possible, and they should return directly to the plane as soon as they are able.
5. We suggest no modification to induction immunosuppression to prevent COVID-19 acquisition and/or severity.**
6. We suggest against pre-emptive adjustment of maintenance immunosuppression to prevent acquisition of COVID-19.**
7. We make no recommendation for or against prophylactic treatment for SARS-CoV-2. We recommend transplant recipients and those waiting for transplant should follow public health guidance available for the general population, including — but not limited to — physical distancing, hand hygiene, and wearing a mask.[vi]**
8. Based on current evidence, we suggest a temporary adjustment of maintenance immunosuppression for hospitalized patients with severe COVID-19. Data on optimal immunosuppression adjustment in patients with COVID-19 is lacking, may vary, and may not be required depending on disease severity and physician judgement.**
9. We make no recommendation for specific therapy for COVID-19. Transplant programs should follow national guidance pertaining to treatments in the general population.[vii]**

CRITERIA FOR RECIPIENTS OF DECEASED DONATION

1. All recipients of deceased donation must undergo a symptoms screen and a NP swab at the time they are called in for transplant. Those with a positive symptom screen or NP swab should be deferred.
2. In patients with a negative symptom screen, whenever possible, every attempt should be made to have the NP swab result available prior to proceeding with surgery.
3. All recipients with a previous diagnosis of COVID-19 require:
    a. A minimum of one month since first diagnosis (i.e. first positive test)
    b. Complete resolution of symptoms
    c. Two negative NP swabs separated by at least 72 hours, prior to listing
    d. Review of each case by a transplant-infectious disease physician for clearance prior to transplant, if the patient's diagnosis is recent (less than three months). Urgent transplants may be allowed sooner on a case-by-case basis.

CRITERIA FOR RECIPIENTS OF LIVING DONATION

1. All recipients of living donation should undergo a NP swab in the 24–48 hours prior to surgery. Those with a positive NP swab should be deferred.
2. All recipients with a previous diagnosis of COVID-19 require:
    a. A minimum of one month since first diagnosis (i.e. first positive test)
    b. Complete resolution of symptoms
    c. Two negative NP swabs separated by at least 72 hours, prior to transplant
    d. Review of each case by a transplant-infectious disease physician for clearance prior to transplant, if patient's diagnosis is recent (less than three months). Urgent transplants may be allowed sooner on a case-by-case basis.

Vaccination

Although further data is needed, experts believe the potential benefits of vaccine likely outweigh theoretical risks or concerns about immunogenicity.

1. Vaccine may be given to the pre- and post-transplant patient population, after informed consent, considering the risks vs. benefits, when it is available to them. However, one decision analysis suggests pre-transplant vaccination offers comparable to greater effectiveness than pursuing transplantation without delay [prior to vaccination].[viii]

   a. Additional guidance on the use of COVID-19 vaccines in transplant patients is available through the Canadian Society of Transplantation.

2. Transplant patients should be made aware of the limited safety and efficacy data and encouraged to report any adverse events. Efficacy may be lower in the immunosuppressed state.
3. Immunocompromised patients should continue to practice infection control measures against COVID-19.
4. Household contacts of the transplant recipient should also be vaccinated when possible.
5. All potential living donors should be vaccinated when possible.

NOTE: The vaccine is currently not approved for children under 12 years of age, but once approved, we expect similar guidance to apply to pediatric transplant recipients.

Impacts to Canadian Blood Services Kidney Paired Donation and Highly Sensitized Patient Programs

With the goal of ensuring the safety of both living donors and transplant recipients, the following decisions have been made:

1. Highly Sensitized Patient (HSP) Program:

   The HSP registry will continue to operate and be available to the country. The decision to proceed with accepting a kidney offer will be made by local/provincial programs based on their hospital's current policies and processes for deceased donor organ transplantation during the COVID-19 situation.

2. Kidney Paired Donation (KPD) Program:

   The KPD program has returned to normal operations. Local/provincial programs are participating based on their hospital's current policies, processes, and capacity.

   Programs will also be encouraged to ship and receive shipped kidneys, instead of asking donors to travel via public transportation, which currently is not advised. Some local travel by private vehicle may be possible at the discretion of programs.

Update on Impact to Blood Supply

Blood components are a vital resource supporting health care in Canada. Canadian Blood Services operates a national blood inventory and, in collaboration with our provincial and territorial partners, continues to monitor the impact of COVID-19 on the supply of these resources and will continue to keep the community apprised of the blood situation as it evolves.

Additional resources

1. Canadian Blood Services, the Canadian Society of Transplantation, and the Canadian Donation and Transplantation Research Program have compiled and published a brief summary of publicly available recommendations from organ donation and transplantation groups across the globe.[ix]
2. As they become available, additional resources related to the COVID-19 pandemic will be shared on the *Canadian Blood Services' professional education website.*

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[i] Weiss, M. J., Hornby, L., Foroutan, F., Belga, S., Bernier, S., Bhat, M., Buchan, C. A., Gagnon, M., Hardman, G., Ibrahim, M., Luo, C., Luong, M. L., Mainra, R., Manara, A. R., Sapir-Pichhadze, R., Shalhoub, S., Shaver, T., Singh, J. M., Srinathan, S., Thomas, I., … Mah, A. (2021). Clinical Practice Guideline for Solid Organ Donation and Transplantation During the COVID-19 Pandemic. Transplantation direct, 7(10), e755. https://doi.org/10.1097/TXD.0000000000001199

[ii] https://www.cidrap.umn.edu/sites/default/files/public/downloads/cidrap-covid19-viewpoint-part1_0.pdf and https://www.cmaj.ca/content/192/19/E497.long

[iii] Raja, MA., Mendoza, MA., Villavicencio, A., et al. COVID-19 in solid organ transplant recipients: A systematic review and meta-analysis of current literature. Transplantation Reviews (2021). https://doi.org/10.1016/j.trre.2020.100588

[iv] Kaul, D., Valesano, A., Petrie, J., et al. Donor To Recipient Transmission Of SARS-CoV-2 By Lung Transplantation Despite Negative Donor Upper Respiratory Tract Testing. American Journal of Transplantation (2021). https://doi.org/10.1111/ajt.16532

[v] Kumar, D., Humar, A., Keshavjee, S. and Cypel, M. (2021), A call to routinely test lower respiratory tract samples for SARS-CoV-2 in lung donors. Am J Transplant. https://doi.org/10.1111/ajt.16576

[vi] https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents.html

[vii] https://www.canadiancriticalcare.org/resources/Documents/AMMI-CCCS-PHAC-clinical-guidance-Aug21-EN-FINAL.pdf

[viii] Yanev I, Gagnon M, Cheng MP, Paraskevas S, Kumar D, Dragomir A, Sapir-Pichhadze R. Kidney Transplantation in Times of Covid-19: Decision Analysis in the Canadian Context. Can J Kidney Health Dis. 2021 Sep 14;8:20543581211040332. doi: 10.1177/20543581211040332.

[ix] Weiss MJ, Lalani J, Patriquin-Stoner C, Dieudé M, Hartell D, Hornby L, Shemie SD, Wilson L, Mah A. Summary of International Recommendations for Donation and Transplantation Programs During the Coronavirus Disease Pandemic. Transplantation. 2021 Jan 1;105(1):14-17. doi: 10.1097/TP.0000000000003520.