Consensus guidance 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 recommendations, 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.

This document was last updated Feb. 2, 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. Transplant recipients are, or are likely to become, immunocompromised, and may be at increased risk of more severe outcomes related to COVID-19. Several published series suggest that the risks of transplant recipients acquiring COVID-19 is higher than the general population. Mortality rates are also higher.

3. Patients on transplant waiting lists may be at increased risk of more severe outcomes related to COVID-19.
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.

5. 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.¹

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.

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 (theoretical)*:
   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 have been no confirmed published cases of donor-to-recipient transmission via solid organs or blood. Based on the available evidence, donor-to-recipient transmission is unlikely in non-lung organ transplants.

Recommendations for 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.
Recommendations for 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. We suggest all health care professionals 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

Recommendation for deceased donor programs

It is suggested that all deceased donation programs in Canada 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. All potential adult and pediatric deceased donors must be tested for COVID-19. It appears there is no gold standard for sample collection. Options include:
   a. A nasopharyngeal (NP) swab has become the preferred swab as it is positive early in the course of disease and is safer for the operator\(^i\). However, in some cases where lower respiratory tract infection is present, lower respiratory tract specimens are more sensitive than upper tract specimens for the polymerase chain reaction (PCR) detection of COVID-19\(^ii\).
   b. For intubated patients, a broncho-alveolar lavage (BAL) has higher sensitivity than a NP swab. 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. If a BAL is not performed, an endotracheal aspirate should be sent as an alternative. Concerns about aerosolization with bronchoscopic BAL sampling should also be considered.
   c. The utility of computed tomography (CT) chest screening in this setting is unknown but could provide added information especially for lung transplantation.
d. Reasonable screening may include two samples: a NP swab plus a lower respiratory tract specimen.

2. ICU/OR capacity allowing, a negative COVID-19 result must be available prior to proceeding (excluding exceptional circumstances).

3. Organs from donors with active COVID-19 should not be used.

4. 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).

5. All organ offers from programs where testing of donors may not have reliably occurred, should be considered on a case-by-case basis.

**Recommendation for 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. 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).

4. 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). Current public health guidelines require all returned travelers to self-isolate for 14 days.

5. 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.

Recommendations for transplant programs

It is suggested:

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. During the COVID-19 pandemic, the risk to potential transplant recipients is more significant in relation to the circumstances of transplantation and post-transplantation recovery than transmission from the donor.

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. Transplant recipients and those waiting for transplant should follow public health guidance, including — but not limited to — physical distancing, hand hygiene, and wearing a mask. We make no recommendation for or against prophylactic treatment for COVID-19.

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.

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.

Recommendations for vaccination

Currently, there are no efficacy, immunogenicity, or safety data available for transplant patients with any COVID-19 vaccine. Transplant recipients were not enrolled in phase three trials studying the vaccine. Although further data is needed, experts believe the potential benefits of vaccine likely outweigh theoretical risks or concerns about immunogenicity.

1. We recommend that the 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.
   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 lack of 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. In addition, household contacts of the transplant recipient should also be vaccinated when possible.

NOTE: The vaccine is currently not approved for children under 16 years of age, but once approved, we expect similar recommendations 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 recommended. 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 a brief summary of publicly available recommendations from organ donation and transplantation groups across the globe.

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