Consensus guidance for eye and tissue donation and transplantation services during COVID-19 pandemic
Updated May 19, 2020

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

Background

On March 20, an urgent teleconference meeting of the Canadian Eye and Tissue Donation Community was held, bringing together eye and tissue donation and bank leaders from across the country. Participants included administrative, medical and quality directors from banks, donation organizations, regulatory and professional associations. Skype indicated 69 participants on that initial call. Weekly teleconferences are occurring each Friday to review, and update consensus and guidance based on the evolution of the pandemic and emerging evidence.

The aim of these meetings is to share information and develop a consensus which can be used by provincial donation organizations, eye and tissue banks to guide the administration of eye and tissue donation and bank services considering the COVID-19 pandemic. **It is understood that at this time each organization, program and jurisdiction will develop their own policies**.

These discussions and the consensus itself will continue to be informed by recommendations from Canadian Blood Services' advisory committees, Health Canada, Public Health Agency of Canada, WHO, provincial agencies, and international partners (including UK and Spain).

Guiding Principles

1. Tissue donation and transplantation is a life-enhancing service and, in certain conditions, is an essential life-saving and life-preserving service
2. In approaching COVID-19 we will assess operations through a risk/benefit profile, weighing patient and staff safety of acquiring COVID against the benefits of recovering and supplying tissue for transplantation.
3. *Modes of transmission of virus to recipients may include:*
    a. *Donor to recipient (unknown currently)*
    b. *Nosocomial*
        i. *via other patients, visitors*, health care staff
        ii. aerosolized and potential surface contamination

   c. Community acquired
4. Recommendations must balance the incidence trends in Canadian provinces and the risk posed to potential recipients versus the risks of suspending or delaying transplantation.
5. A consistent and principled approach for all jurisdictions is preferred.
6. Clear consistent communications are important and required

Key Considerations:

1. Elective surgeries are being cancelled to increase capacity for COVID19 patients.
2. Staffing, operating room, personal protective equipment and other hospital resources may be limited due to redeployment or due to infection.
3. Tissue grafts are banked and stored for extended periods of time for future use, except for corneas which require transplantation usually with 7-10 days of recovery
4. Current testing may not be validated or approved for post-mortem samples.
5. Asymptomatic patients may test negative as they are not yet shedding virus.
6. The transmissibility of the virus through blood, organ or tissues is unknown.
7. Guidance has been developed by the organ donation and transplantation community https://professionaleducation.blood.ca/en/organs-and-tissues/covid-19-update-organ-donation-and-transplantation-services

National Consensus Eye and Tissue Guidance

(as of April 30, 2020, 13:00 EST)

Recommendations for Eye and Tissue Banks

1. Jurisdictions to review and potentially suspend ocular and non-ocular tissue donation, recovery, and processing based on each Medical Director's discretion in relation to the specific risk in their region.
2. In approaching COVID-19 we will assess operations through a risk/benefit profile, weighing patient and staff safety of acquiring COVID against the benefits of recovering and supplying tissue for transplantation.
3. In relation to deferrals and testing 14 days is appropriate in terms of contact to a case or travel history as it aligns with public health recommendations.
4. Eye and Tissue banks expand screening questions to identify and exclude donors with potential COVID-19 or exposure.
5. Testing tissue donors for COVID-19 by nasopharyngeal and oropharyngeal PCR or serological (when available) testing is at the discretion of the program and Medical Director
6. The use of "exceptional release protocols" as per standards and regulations for tissue recovered and distributed during COVID-19 is appropriate. The use of exceptional release protocols is at the discretion of the program and Medical Director.

7. A traditional recovery of bone, soft tissue, skin, heart valves, ocular, and vascular tissues is reasonably handed with routine, masks, gowns, eye protection and shoe covers with underlying scrubs. If a bone saw is used as part of the recovery proves, the use of N-95 masks is not necessary, as there is no data that shows tissues carry the virus and therefore the virus will not be made atmospheric by using bone saws.
8. CBS will explore the development of a risk analysis for the transmission of COVID-19 transmission by ocular and tissue transplant to inform potential testing decisions and requirements.
9. CBS create and facilitate a national dashboard where programs can share and access information real time in relation to program status, resources and emerging issues.
10. CBS to maintain updates on eye and tissue banks operational status, COVID-19 testing practice and PPE practice.
11. CBS facilitate a weekly teleconference for the community to review and evolve this guidance as the situation changes and additional information comes to light.

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 increasing number of cases in Canada, the risk to Canadians is considered **high**.

There is likely an increased risk of more severe outcomes for Canadians:

- aged 65 and over
- with compromised immune systems
- with underlying medical conditions

People who are most likely to transmit COVID-19:

1. Those who live or have visited countries outside of Canada within the previous 14 days and show clinical symptoms compatible with COVID-19. However, the case epidemiology is now shifting towards local transmission. Asymptomatic or mildly symptomatic carriers are likely also serving as a source of community spread.
2. Confirmed donor or potential recipient cases of COVID-19 (for recovered patients, 2 negative swabs 24 hours apart confirms clearance).
3. Donors and potential recipients who have been exposed to a confirmed case within the previous 14 days and show clinical symptoms compatible with COVID-19. Exposure includes: having shared the ICU or any other hospital unit with a confirmed case of COVID-19 when appropriate infection control precautions were not used.

Modes of transmission:

1. Donor to recipient
    a. droplet/respiratory spread
    b. +/- viremia (unknown but presumed likely; viremia reported in up to 15% of cases but in a recent study of 300 patients, the viremia incidence is 1% (Wang et al., JAMA, 2020). Most viremic patients also have detectable virus in the respiratory tract.
    c. Virus present in organ (lung especially; but other organs possible).
2. Nosocomial
    a. other patients, visitors, health care staff
    b. droplet spread and potential surface contamination; the role of aerosolization is uncertain.
3. Community-acquired
    a. as described above in 2b.

COVID-19Testing

1. A nasopharyngeal (NP) swab and/or an oropharyngeal (OP) swab are often recommended for screening or diagnosis of early infection. A single NP swab has become the preferred swab, as it is tolerated better by the patient and is safer to the operator[i]. However, it appears there is no gold standard for sample collection, whether from NP or OP swabs, or both, given the lack of data available to accurately assess sensitivity[ii]. Some reports have shown that indication of viral pneumonia on a CT scan may precede a positive RT-PCR result in some patients[iii]. In some cases, lower respiratory tract specimens are more sensitive than upper tract specimens for the PCR detection of SARS-CoV-2[iv]. There is limited data on sensitivity and specificity in the setting of donor screening. CT chest has good sensitivity in patients with symptoms, but has lower sensitivity in asymptomatic individuals. The sensitivity and specificity in deceased donors is not known.
2. For intubated patients with COVID-19 respiratory failure, a broncho-alveolar lavage (BAL) has higher sensitivity than NPA- the BAL can be performed bronchoscopically which is an aerosol generating procedure, or can be performed as a modified 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.
3. Clearance criteria for confirmed cases may vary between settings. The Ontario Ministry of Health criteria for when to discharge someone from isolation outlines scenarios for home isolation, hospital, and healthcare workers. For hospitalized patients, it suggests using two negative NP PCR swabs that are 24 hours apart for clearing hospitalized patients from isolation[v]. There is growing evidence that patients may still be shedding virus after two PCR-negative swabs.[vi]
4. Rates of RNA-emia have been described as being possibly around one per cent.[vii] Increasing numbers of publications describe nucleic acid testing of serum or plasma. These assays may not be validated or available in all settings.[viii] It is also unclear if RNA detected in the blood represents viable virus or damaged virions or simply RNA. The clinical utility is uncertain, since it is expected that most or all viremic donors will have a positive respiratory sample.

5. Serology assays (IgG and IgM) are becoming available. They have higher sensitivity later in the course of disease. Their potential utility in donor screening has not been evaluated.

Health Canada communication on the use of exceptional release protocols in COVID-19

HC Communication April 14, 2020

Health Canada does not currently require testing of tissue donors for SARS-COV-2, nor have we recommended that tissue banks suspend all retrieval and processing of tissue during the pandemic.

Tissue banks are not prevented from determining tissues to be safe for transplantation when they are retrieved from donors that pass the COVID-19 specific donor screening requirements established by tissue banks to screen out potential donors at increased risk of COVID-19, such as donors that have been diagnosed with or suspected of having COVID-19 and those who have had close contact with individuals diagnosed with or suspected of having COVID-19.

However, in the event that tissue banks determine that factors such as the degree of community spread of SARS-COV-2 in their region make it such that they can no longer determine tissue to be safe for transplantation and they decide to scale back tissue retrieval and processing, it would be appropriate to use the exceptional distribution clauses in the Safety of Human Cells, Tissues and Organs for Transplantation Regulations (CTO Regulations) to distribute fresh tissue that has been retrieved for the purposes of meeting the demand for emergency surgery during the pandemic.

For instance, in the case of fresh tissue, such as corneas that require transplantation within a short period of time after recovery, one can meet the requirement in section 40 of the CTO Regulations that no other tissue be immediately available that has been determined safe for transplantation.

Please note that in the event of suspected cases of transmission of SARS-COV-2 by tissue transplantation the requirements for investigating and reporting adverse reactions are described in the Safety of Human Cells, Tissues and Organs for Transplantation Regulations (CTO Regulations), sections 47 to 49, 50 to 54, 62(2) and 74(2).

Canadian Consensus Recommendations for Deceased *Organ Donation and Transplantation* as of April 20, 2020

Recommendations for organ donor criteria

CRITERIA FOR DECEASED DONORS

1. Organs from donors with active COVID-19 should not be used.
2. Donors with a previous diagnosis of COVID-19 require two negative tests before being considered for donation and another negative test at the time of donation. Extreme caution is still recommended until more data are available.
3. All potential donors must be tested for COVID-19. The optimal choice of specimen for testing is unknown but options include NP swab, Broncho-alveolar lavage (BAL) (bronchoscopic or modified), or deep endotracheal aspirate or a combination of above. Concerns about aerosolization with bronchoscopic BAL sampling should also be taken into account. Current evidence of sensitivity and specificity in the setting of deceased donor screening is lacking. A reasonable screening may include two samples: a NP swab plus a lower respiratory tract specimen. The utility of CT chest screening in this setting is unknown but could provide added information especially for lung transplantation.
4. ICU/OR capacity allowing, a negative COVID-19 result must be available prior to proceeding (except in exceptional circumstances).
5. All organ offers from programs such as in the United States, where testing of donors may not have reliably occurred, should not be accepted.

Recommendations for ICU, OR and transplant services

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.

1) Adult and pediatric intensive care units are asked to test all patients that meet the following criteria:
   - **a)** They are admitted to intensive care;
   - **b)** The presenting condition is an acute community-acquired respiratory infection of any kind OR a febrile illness, regardless of known or suspected causative pathogen and clinical features. This includes ECMO active or eligible cases.
2) All health care personnel involved in organ donation and transplantation services should be fit-tested for masks and have personal protective equipment training.
3) 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.

4) We suggest all health care professionals deploy routine universal precautions (surgical masks, gloves) during the care of COVID-negative donors and recipients.
   - **a)** It is acknowledged that there is regional and institutional variability with respect to:
     - i) COVID-specific PPE
     - ii) Universal precautions
     - iii) No routine precautions
   - **b)** Given community spread, risk of asymptomatic carriage, limitations in NPA screening sensitivity and the inability to reliably distinguish COVID-positive from COVID-negative patients, many centers have adopted universal precautions for all health care professionals during all patient interactions.
   - **c)** Due to immunocompromised status, transplant recipients have heightened risk for adverse outcomes and mortality from COVID-19.
5) 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. As a result, during this time all transplant recipients should be advised of the increased risk.
6) Transplant candidates should be prioritized for testing. As new tests become available, each jurisdiction should consider how they can be used for this population to expedite access to results prior to transplant.

United States Food and Drug Association Consideration

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

American Association of Tissue Banks Donor Criteria Guidance

https://www.aatb.org/content/covid-19-updates

Recommendations on Personal Protective Equipment (PPE) for Tissue Bank Recovery and Processing Bulletin 20-11 April 23, 2020. The Panel on COVID-19 formed by the AATB Physicians Council has issued the following:

SARS-CoV-2 has demonstrated the capability to spread rapidly, predominantly by respiratory route, but also potentially via contact surfaces, leading to significant impacts on healthcare systems and causing societal disruption. To respond effectively to the COVID-19 outbreak, appropriate clinical management and infection control in conjunction with implementation of

community mitigation efforts are critical.[1] In tissue banking, deceased donors generally do not pose aerosolization risk because they are not speaking, coughing, or sneezing.

It is the intent of these recommendations to be practical and to consider the most appropriate PPE for tissue recovery, including when it is appropriate to use higher level personal protective equipment (PPE) (i.e. use of N-95 masks). N-95 masks require fit testing for optimization of intended use, and are not necessary for most tissue recovery operations.

Use of PPE in Tissue Recovery Operations and/or Processing

Universal and droplet precautions generally suffice for medical triage of possible COVID-19 cases, which should also be applied to tissue recovery and processing operations. This approach is consistent with the CDC recommendations for collecting specimens from deceased persons with COVID-19.

- A traditional recovery of bone, soft tissue, skin, heart valves, ocular, and vascular tissues is reasonably handled with routine masks, gowns, eye protection, and shoe covers with underlying scrubs.
- When electric oscillating saws are used, which may aerosolize and suspend viral particles during cutting of bone, PPE for aerosolizing procedures, including use of N-95 masks, should be used.
- Following standard procedures, all PPE should be removed and either discarded or placed in the appropriate areas for cleaning and decontamination.
- Any staff who has symptoms or an exposure to a known COVID-19 patient should discuss this issue with their healthcare provider and notify their manager so they can determine next steps with regard to the safety of other staff.
- The medical director for each tissue establishment should educate staff using these recommendations along with published CDC guidelines and in alignment with their organizations policies.

Bulletin #20-10 April 2, 2020

Bulletin #20-10: COVID-19 Update

The AATB Physicians Council formed a standing Panel, hereto known as PC Subgroup, to provide on-going surveillance of the emerging SARS CoV-2/COVID 19 situation. This PC Subgroup has been and will continue to collect data in order to assess, in real-time, the recommendations for our members for donor evaluation with the objective to protect recipients and recovery personnel, to the extent possible. Refer to previously issued Bulletins on the subject of COVID-19 (Bulletin No.20-3 of

January 31, 2020, Bulletin No.20-7 of February 25, 2020, Bulletin No.20-8 of March 4, 2020, and Bulletin No.20-9 of March 14, 2020).

This information will continue to be provided through Bulletins and by shared communications with the Physicians Council and tissue bank medical directors.

Update on Travel Recommendations:

On March 29, 2020, the CDC issued a Domestic Travel Advisory for New York, New Jersey, and Connecticut. In addition to the NY, NJ, and CT travel advisory, cases of coronavirus disease (COVID-19) have been reported in all states, with some areas experiencing sustained community spread of the disease.

The PC Subgroup met to discuss the relevancy of continuing to use the travel-based exclusion/deferral criterion. As a result of a thorough evaluation and discussion, the PC Subgroup unanimously agreed that the criterion might no longer be applicable but continues to recommend that each tissue bank medical director may consider travel-based criteria at their discretion and with information that may be available on a potential donor in regards to travel, residency in identified high community spread areas or close contact with individuals that may be considered as a *persons under investigation*[1] (PUI). In this process, medical directors may refer to the CDC on areas at risk for transmission and the latest travel advisories, both international and domestic, on a case-by-case basis as deemed necessary.

By a unanimous vote, the PC Subgroup also recommended to continue to retain clinical criteria. However, considering the changing situation with using travel-based criteria and the non-specific (if any) symptomatology of COVID-19, medical directors are advised to seek and evaluate available medical records for all sources of clinical data, including seemingly unrelated signs and symptoms, imaging studies, epidemiological circumstances, differential diagnosis notes and documented consultations, and others. It is understood that some cases will not be detected by clinical criteria, as a significant proportion of individuals have asymptomatic infection.

Update on Testing:

The PC Subgroup assessed the prospects for mitigating the risk relating to COVID-19 through laboratory testing of potential donors. Testing is currently available through a polymerase chain reaction (PCR) test of clinical samples, usually obtained through oropharyngeal or nasopharyngeal swab. These PCR platforms are diagnostic tests, i.e., not optimized for donor screening, and have not been validated for cadaveric samples. After a thorough discussion, considering possible risks and benefits, the PC subgroup has voted to recommend lab testing as part of donor screening using PCR testing obtained via swab, if available.

The PC Subgroup is monitoring the development and introduction of various new tests under the FDA emergency use authorization, some of which may be suitable for the purposes of donor screening. One of the testing platforms recently approved by the FDA may provide tissue banks with the option of rapid, portable point-of-care SARS-CoV-2 detection producing results on-site allowing for pre-recovery assessment. In addition, a test on serum or plasma validated for cadaveric donor screening may also be in development. The PC Subgroup will keep the entire Physicians Council informed about such new testing options as they become available.

During the preparation of this Bulletin for publishing, on April 1, 2020, the FDA issued the following statement:

> FDA is aware that some HCT/P establishments in the US are considering additional donor screening and testing measures in response to the COVID-19 outbreak.
> At this time, FDA does not recommend establishments use laboratory tests to screen asymptomatic HCT/P donors. Based on available information, it appears that SARS-CoV2 has only been detected in blood samples of a small percentage of severely ill patients.
> The HCT/P establishment's responsible person must evaluate a prospective donor and determine eligibility (21 CFR 1271.50). Based on the limited information available at this time, establishments may wish to consider, whether, in the 28 days prior to HCT/P recovery, the donor
> - cared for, lived with, or otherwise had close contact with individuals diagnosed with or suspected of having COVID-19 infection; or
> - been diagnosed with or suspected of having COVID-19 infection.

Considering that the FDA recommendation to not use laboratory tests "to screen asymptomatic donors" does not appear to apply to symptomatic donors, it would be up to the medical director responsible for donor eligibility determination to choose the risk mitigation methods and criteria for donors presenting with symptoms that may be attributed to COVID-19.

Recovery Personnel Safety

The PC Subgroup is also initiating an assessment and discussion about recovery personnel safety relating to COVID-19, including but not limited to, risks for personnel getting infected from an undiagnosed donor with COVID-19, risk for tissue contamination from asymptomatic personnel, as well as the role of the medical director in the process of developing personnel policies relating to COVID-19.

Medical Director's Discretion

As previously emphasized, the ultimate selection of risk-mitigation criteria pertaining to COVID-19, e.g., travel evaluation, symptomatology, exposure, close contact, infection status, and testing for COVID-19, is in the sole discretion of the medical director of the tissue bank responsible for donor eligibility determination as long as the intent of relevant standards, e.g. D4.120, D4.150, F1.120 and Appendix II is met.

AATB will inform its members if any material changes require additional measures. For additional information, please contact the AATB Executive Office, Dr. Roman Hitchev, AATB VP & Chief Science Officer.

[1]Person under Investigation (PUI): Refer to CDC Criteria to Guide Evaluation of PUI for COVID-19 - https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html

AATB Bulletin March 16, 2020 https://www.aatb.org/content/bulletin-20-9

- Travel within the last 28 days prior to donation to a country designated by the CDC as Warning Level 3 may constitute grounds for exclusion of a deceased donor regardless of symptoms, or deferral of a living donor for as much time is necessary to ensure at least 28 consecutive days without symptoms following the last travel date to the designated area. Risk relating to domestic

travel within the United States is to be evaluated and interpreted under the sole discretion of the medical director of the establishment responsible for donor eligibility determination.

- Fever with severe acute lower respiratory illness (e.g., pneumonia, ARDS) without alternative explanatory acceptable cause and without a negative SARS-CoV-2 diagnostic test evaluation, may constitute grounds for exclusion of a deceased donor, or deferral of a living donor for as much time is necessary to ensure at least 28 consecutive days without these syndromic symptoms.
- Close contact within the last 28 days prior to donation with a person who has confirmed COVID-19 infection or with a Person under Investigation (PUI) as defined by the CDC may constitute grounds for exclusion of a deceased donor, or a deferral of a living donor for as much time is necessary to ensure at least 28 consecutive days without symptoms[1] following the contact.
- Confirmed infection or designation of a Person under Investigation[2] (PUI) as defined by the CDC within the last 28 days prior to donation may constitute grounds for exclusion of a deceased donor or deferral of a living donor for as much time is necessary to ensure at least 28 consecutive days without symptoms after the PUI status is lifted.

Recommended DRAI Questions:

1. In the last 28 days, was he/she told by a healthcare professional he/she had coronavirus or was a *person under investigation*[2] (PUI) for the coronavirus infection? IF YES,
    a. When was he/she diagnosed or considered a *person under investigation*[2] (PUI)?
    b. Provide any contact information for the healthcare professional (e.g., name, group, facility, phone number, etc.)
2. In the last 28 days, was he/she within *close contact*[3] with a *person under investigation*[2] (PUI) for the coronavirus or diagnosed with coronavirus? IF YES,

    a. When was she/he diagnosed or first considered a *person under investigation*[2] (PUI) for coronavirus?

Eye Bank Association of America Donor Criteria Guidance

EBAA May 14, 2020 https://restoresight.org/covid-19-updates/

The EBAA Policy & Position Review Subcommittee of the Medical Advisory Board continues to update guidance and screening recommendations as the COVID-19 pandemic continues to evolve rapidly. Developments in our understanding of this novel SARS-CoV-2 virus and in our ability to screen donors should allow for the continued provision of safe corneal tissue to patients during this time. As we again proceed with elective corneal transplantation procedures across the US, the safety of corneal tissue may be supported by the following:

- There have been no reported cases of transmission of SARS-CoV, MERS-CoV, or any other coronavirus via transplantation of ocular tissue.
- Current Medical Standards of the EBAA requires use of a double povidone iodine donor prep; povidone iodine has documented in vitro viricidal activity against coronaviruses.
- Increased testing of patients in the hospital and outpatient settings for SARS-CoV-2, and greater understanding of COVID-19 symptoms will enhance donor screening and the safety of donor tissue.
- Medical Director review for final determination of donor eligibility in certain cases allows for further assessment of the full clinical picture and/or case specific scenarios.
- Donor eligibility criteria remain fluid and complex during the COVID-19 pandemic. Current guidance is more clearly presented in table format for use by eye banks and Medical Directors.

DONOR ELIGIBILITY CRITERIA

PCR Test Status[1]	COVID-19 Signs[2]	COVID-19 Symptoms[3]	Plausible Alternative Etiology of Signs or Symptoms	Close Contact[4]	Eligibility
Positive (in last 28 days)	Yes or No	Yes or No	Yes or No	Yes or No	**Not Eligible**
Negative (post-mortem or recent pre-mortem)	Yes	Yes or No	Yes	Yes or No	**Medical Director Review**
			No	Yes or No	**Not Eligible**
	No	Yes	Yes	Yes or No	**Medical Director Review**
			No	Yes or No	**Not Eligible**
		No	N/A	Yes	**Medical Director Review**
				No	**Eligible**
Not done	Yes	Yes or No	Yes or No	Yes or No	**Not Eligible**
	No	Yes	Yes	Yes	**Not Eligible**
				No	**Medical Director Review**
			No	Yes or No	**Not Eligible**
		No	N/A	No	**Eligible**

[1]RT-PCR SARS-CoV-2 test performed prior to or less than 24 hours after death. If performed, but result is indeterminate or inconclusive, then donor should be deferred.
[2]Development of one of the following signs consistent with possible COVID-19 infection within the 28 days prior to death:

- ARDS
- Pneumonia
- Pulmonary computed tomography (CT) showing "ground glass opacities" (regardless of whether another organism is present)

[3]Development of acute symptoms consistent with COVID-19 infection within the 28 days prior to death:

- One of the following:
- Cough
- Shortness of breath/difficulty breathing

OR

- Two of the following:
- Fever
- Chills
- Repeated shaking with chills
- Muscle Pain
- Headache
- Sore throat
- New loss of taste or smell

[4]Close contact is defined by the CDC as: being within approximately 6 feet (2 meters) of a COVID-19 case for a prolonged period of time; close contact can occur while caring for, living with, visiting, or sharing a health care waiting area or room with a COVID-19 case; ***OR*** having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on). ***IF*** such contact occurs while not wearing recommended personal protective equipment (PPE).

DONOR TESTING

At this time, the EBAA is not requiring eye banks to perform post-mortem nasopharyngeal (NP) RT-PCR testing for SARS-CoV-2. However, a negative PCR result may be necessary (in addition to a Medical Director Review) to release certain tissue (see Donor Eligibility Table). The decision to not require post-mortem NP RT-PCR testing for SARS-CoV-2 is based on several considerations including the variable false negative rates of current RT-PCR testing, ranging between 2-22%. Additionally, diagnostic RT-PCR tests for SARS-CoV have not been validated for cadaveric donors and are not intended for donor screening. Currently, the FDA does not recommend the use of laboratory tests to screen asymptomatic blood or plasma donors.[5]

The EBAA acknowledges that other associations, hospital systems, eye banks, departments of health, or governments may require that all donors be tested for COVID-19. Eye banks need to establish a protocol to ensure access to testing notification and results obtained by partner agencies. Results of such testing must be communicated to end-users on Tissue Report Forms or other supporting documents.

Eye banks *may* consider post-mortem testing of donors using currently available nasopharyngeal (NP) RT-PCR testing for SARS-CoV-2. Again, these tests have not been validated for cadaveric samples. If testing is performed, results must be obtained prior to release for transplantation and reported to end-users on Tissue Report Forms or other support documents. Tissue from donors with indeterminant, invalid, or inconclusive results should not be released for transplant. SARS-CoV-2 testing may reduce, but does not eliminate, the potential of transplanting tissue from a donor with COVID-19. Post-mortem testing must be performed within 24 hours of death. Considerations that may help guide the decision to initiate wide-spread donor testing should include epidemiologic factors such as the prevalence of disease within the recovery area, and the availability of supplies (e.g. swabs, viral transport media, reagents, etc.).

Finally, the EBAA does not suggest serologic testing for COVID-19 antibodies. Viral RNA can still be detected in patients despite development of antibodies against SARS-CoV-2.[6,7]

DONOR PREP

A recently published review[8] looked at the persistence of coronaviruses on inanimate surfaces as well as their inactivation with biocidal agents. Their review of the literature found that povidone iodine (0.23 – 7.5%) readily inactivated coronavirus (SARS-CoV and MERS-CoV) infectivity by approximately 4 $\log_{10}$ or more in vitro, with exposure times ranging between 15 seconds and 1 minute. Although we must be careful to extrapolate too much from these findings to the novel coronavirus, SARS-CoV-2, these results certainly support the current EBAA standards for ocular surface prep prior to recovery.

The European Centre for Disease Prevention and Control (ECDC) considers this a disinfection or microbial inactivation step that is validated for enveloped viruses. However, it is not known if infectious virus particles are present inside ocular surface cells or within deeper layers of the ocular tissue that may or may not be eliminated by povidone-iodine preparations.

[5]Kampf G, Todt D, Pfaender S, et al. Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents. *J Hosp Infection*. 2020 Mar;104(3):246-251.

[6]Updated Information for Human Cell, Tissue, or Cellular or Tissue-based Product (HCT/P) Establishments Regarding the Coronavirus Disease 2019 Pandemic". *US Food & Drug Administration*, US Department of Health & Human Services, 1 April 2020, https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/updated-information-human-cell-tissue-or-cellular-or-tissue-based-product-hctp-establishments.

[7]To KK, Tsang OT, Leung WS, et al. Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study. *Lancet Infect Dis.* 2020 Mar 23. doi: 10.1016/S1473-3099(20)30196-1.

[8]Zhao J, Yuan Q, Wang H, et al. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. *Clin Infect Dis*. 2020 Mar 28. doi: 10.1093/cid/ciaa344.

Update on Impact to Canadian 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. As they become available, we will share additional resources related to the COVID-19 pandemic on *Organ and Tissue Donation and Transplantation professional education website*. Additionally, a google doc and dropbox folder has been established for ease of sharing documents requiring limited access.