COVID vaccination in lung transplant candidates

National consensus statement

Background and rationale

COVID-19 vaccinations are a safe and effective intervention to reduce serious COVID-19 infections. The development of these vaccines was based on substantial prior vaccine development for other viral pathogens (including SARS-CoV1). Over 80,000 voluntary participants enrolled globally in the COVID-19 vaccine trials. The vaccines that have been made available for Canadians are safe and effective.^{1–3} Across Canada, with over 93.1 million doses of COVID-19 vaccine administered, adverse reactions have occurred in only 0.056% of all vaccine recipients (as of November 11, 2022),⁴ with the majority of these being non-severe allergic reactions.

Immunocompromised solid organ transplant (SOT) recipients have significantly less immunologic response to COVID-19 vaccinations and therefore less protection when given post-transplant.^{5,6} Despite COVID-19 vaccination, In the initial phases of the pandemic, this led to a 25-30% mortality rate in patients who are infected with COVID-19 post-lung transplantation.^{7–9} Even with the B.1.1.529 (Omicron) SARS-CoV2 variant, risk of hospitalization and death remain significantly elevated in comparison to an immunocompetent population.¹⁰⁻¹² Lung transplant recipients require a high degree of immunosuppression compared to other organ groups in order to prevent rejection, which overall increases the risk of developing severe infections post-transplant. Studies have shown that a third dose of a COVID-19 vaccine increases the immunological response in this cohort of patients but, whether this confers protective immunity or not is not known.¹³

The best chance of protection from COVID-19 infection is vaccination prior to transplantation and the subsequent suppression of the immune system and the available data supports this.¹⁴ This strategy is not new. Across all Canadian lung transplant centers, there is a schedule of immunizations required for all SOT candidates.¹⁵ These vaccinations are required for all candidates prior to active listing to provide protection from preventable infections that have serious consequences for immunocompromised patients. Requiring the COVID-19 vaccine is consistent with existing policies, and reduces risk of severe infection to the individual as well as to other pre- and post-transplant recipients in the program who share the same space during clinic appointments and physical rehabilitation.

The availability of donors never meets the demand in Canada.¹⁶ As such, there is an ethical obligation to provide organs both to those most in need (beneficence) *and* who have the best probability of short- and long-term survival (utility). This obligation is not only to the recipient but also donor, the donor family and the other waiting candidates who could also benefit from a given donor organ.

It should be noted that refusal to be vaccinated against SARS-CoV2 is also non-adherence to medical care in the pre-transplant setting, which is a stated contraindication to lung transplant in the international published consensus document.^{17,18}

Consensus statement:

1. All patients listed for lung transplantation in Canada are required to be fully vaccinated against SARS-CoV2. This includes:

- a. All patients currently listed
- b. All prospective patients undergoing evaluation.

A fully vaccinated patient is defined as having completed a primary series of vaccinations against SARS-CoV2, as well as having had a recent booster within the appropriate recommended time frame as per provincial public health recommendations.

2. Patients actively listed or patients who are ready for activation who refuse vaccination against SARS-CoV2 will be made inactive on the waitlist and followed clinically by the program until they are ready to move forward with vaccination. Ongoing education and support regarding the rationale for vaccination will be provided to the patient and family.

3. Critically ill patients – either due to COVID-19 or otherwise – are required to be fully vaccinated or willing to receive at least the 1st dose of vaccination against SARS-CoV2 prior to being considered for lung transplant. In circumstances where a critically ill patient cannot engage in consent, their substitute decision maker may consent on their behalf.

This statement will be subject to re-evaluation in the future, should circumstances change. Any requests for medical exceptions to this statement should be reviewed on a case-by-case basis by the lung transplant program in the individual's jurisdiction.

This document has been reviewed and approved by all lung transplant programs across Canada*, and is consistent with the National Transplant Consensus Guidance on COVID-19 Vaccines, released by the Canadian Society of Transplantation, Version 5.1, updated January 9, 2022.¹⁹ **The issue is currently being actively examined in BC*

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