

Coronavirus COVID-19

BC Centre for Disease Control | BC Ministry of Health



Clinical Guidance on COVID-19 Vaccines for Solid Organ Transplant Recipients

This guidance is intended for healthcare providers and is based on known evidence as of September 8, 2022.

Background and Context

People who have received an organ transplant may require specific advice and counseling prior to COVID-19 immunization. There may be questions about the efficacy of vaccines in people who are immunosuppressed, and care considerations about the timing of immunization relative to treatment.^{1,2}

This guidance is based on a review of the vaccines approved by Health Canada for the prevention of COVID-19 disease caused by the SARS-CoV-2 virus:

- **mRNA vaccines:** tozinameran (COMIRNATY, Pfizer-BioNTech),³ elasomeran (SPIKEVAX, Moderna)⁴
- **Replication-defective adenoviral vector vaccine:** ChAdOx1-S (VAXZEVRIA, AstraZeneca),⁵ Ad26.COV2.S (Janssen COVID-19 Vaccine, Janssen)⁶
- **Recombinant protein vaccine:** NUVAXOVID (COVID-19 Vaccine [Recombinant protein, Adjuvanted], Novavax)⁷
- **Plant based virus-like particle vaccine:** Covifenz (Medicago)⁸

Currently, anyone in British Columbia who is 6 months and older is eligible for COVID-19 immunization. Health Canada has recently approved the mRNA vaccine SPIKEVAX (Moderna) for children ages 6 months to 4 years.⁹ Children aged 5 to 11 will be offered either COMIRNATY (Pfizer-BioNTech) or SPIKEVAX [Moderna] for children aged 6 to 11. NACI has released their statement for these age groups.^{10,11,12}

People who receive the mRNA vaccine (COMIRNATY [Pfizer-BioNTech] or SPIKEVAX [Moderna]) for their first dose, will be offered either mRNA vaccine for subsequent doses, with the exception of preferential recommendations based on age and immunosuppression.^{13,14} BC has taken the proactive step to expand booster doses for all individuals 12 years and older, not just those at high risk. However, it is particularly recommended for individuals 12-17 years of age who are at higher risk of severe illness due to COVID-19.¹⁵ All booster doses will be mRNA vaccines.¹⁶ For those who are not able, or willing, to receive mRNA vaccines, Novavax is available as an alternative.



Third doses:

To date, people who are moderately to severely immunocompromised have been observed to have generally lower antibody responses and lower vaccine effectiveness from COVID-19 vaccines compared to the general population.¹⁷ The National Advisory Committee on Immunization (NACI)¹⁸ has reviewed this evidence and recent studies that demonstrate that some people who are immunocompromised develop an improved antibody response after a third dose of vaccine.

As such, as of February 3, 2022, people (5 years and older) who are moderately to severely immunocompromised in B.C. are eligible to receive a third dose of an mRNA COVID-19 vaccine.¹⁹

A minimum interval of 28 days between dose 2 and dose 3 is recommended for those eligible for a third dose. As per the BC Immunization Manual, COMIRNATY (Pfizer-BioNTech) is recommended for those 5-11 years of age. For individuals 12 years of age and older, SPIKEVAX (Moderna) is preferred for the third dose; however, if SPIKEVAX (Moderna) is unavailable (or if the individual prefers), the COMIRNATY (Pfizer-BioNTech) vaccine may be provided.²⁰

Specifics on current eligibility for a third dose may be reviewed here: <https://www2.gov.bc.ca/gov/content/covid-19/vaccine/register#immunocompromised>

Second boosters (4th or 5th doses):

As part of a spring campaign, a second booster dose of COVID-19 mRNA vaccine continues to be offered to the following individuals at least 6 months after the first booster dose (minimum interval of 4 months)²¹

- Residents of long term care (LTC) and clients of alternate level of care awaiting placement in LTC
- Residents of assisted living facilities 70 years of age and older (or 55 years of age and older for Indigenous persons)
- Individuals 80 years of age and older in the community
- Individuals 70-79 years of age in the community (or 55-79 years of age in the community for Indigenous persons)

B.C. is making plans to offer everyone 12 years and older a fall booster dose. NACI has been clear this approach will provide the best protection in the fall and winter when we're all spending more time inside and respiratory illness is passed around our communities.²²

Intervals between doses:

Clients requesting a shorter interval between doses should be informed that this actually offers less optimal protection, but their request for an earlier dose should be granted, without need for Medical Health Officer approval, provided the minimum interval between doses has been observed.²³ This applies to doses in their primary series, between primary series and first booster dose and between booster doses.



Other vaccines:

VAXZEVRIA (AstraZeneca)⁵

The VAXZEVRIA (AstraZeneca)⁵ vaccine program has been stopped in B.C. for first doses, unless there is a contraindication to the mRNA vaccines, or as advised by the Medical Health Officer or an allergist,¹³ due to infrequent (1:50,000) but serious Vaccine-Induced Thrombotic Thrombocytopenia (VITT) blood clotting events after the first dose.²⁴ The Government of Canada is not securing additional VAXZEVRIA doses.

Janssen COVID-19 Vaccine (Janssen)⁶

The Janssen COVID-19 Vaccine (Janssen)⁶ one-dose viral vector vaccine is now available in limited supply in B.C. However, mRNA vaccines are preferred over viral vector vaccines due to better effectiveness and immunogenicity of mRNA vaccines and the possible adverse effects specifically associated with viral vector vaccines (e.g., Thrombosis and Thrombocytopenia Syndrome [TTS]). A viral vector COVID-19 vaccine should only be considered when all other authorized COVID-19 vaccines are contraindicated or have been refused, due to the reduced effectiveness and the possible adverse effects associated with viral vector vaccines (e.g., TTS).

NUVAXOVID (Novavax)⁷

NUVAXOVID⁷ was authorized for use on February 17, 2022 by Health Canada. NUVAXOVID is a different class of vaccination, a protein subunit vaccine that will give British Columbians another option to protect themselves against COVID-19. NUVAXOVID may be offered to individuals for whom COVID-19 mRNA vaccines are contraindicated or have been refused.²⁵ This vaccine is available to people aged 18 years and older. It is a two-dose vaccine and a limited number of doses will be available in B.C.²⁶

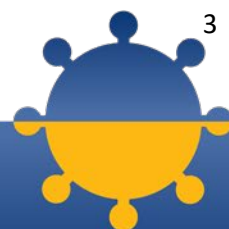
Medicago Covifenz (Medicago)⁸

Medicago⁸ was authorized for use on February 24, 2022 by Health Canada. Medicago is a different class of vaccination, a plant-based virus-like particle vaccine that will give British Columbians another option to protect themselves against COVID-19. Medicago is approved for people who are 18 to 64 years of age. It is a two-dose vaccine and a limited number of doses will be available in BC.⁸

Is COVID-19 immunization recommended for solid organ transplant recipients?

COVID-19 vaccines are not contraindicated and should be encouraged for people with solid organ transplants, including those who have had a COVID-19 infection. This recommendation is based on the following review:

- **Canadian Society of Transplantation** recommend that vaccine may be given to the pre- and post-transplant patient population when it is available to them, and they may receive any of the Health Canada approved vaccines that are available to them, if age requirements are met.²⁷



- **National Advisory Committee on Immunization** recommends that immunosuppressed individuals be offered the vaccine.^{13, 18}
- **Clinically worse outcomes from COVID-19 infection:** COVID-19 outcomes in organ transplant recipients have ranged from mild disease to the need for intensive care unit care and death.^{28,29} Whether COVID-19 is more severe due to immunosuppression or due to underlying disease or comorbid conditions associated with high COVID-19 risk (such as advanced age, chronic kidney disease, diabetes, and heart/lung disease) is unclear. Lung transplant patients also seem to be at particularly high risk of severe disease.²⁸

While data specific to the safety and efficacy of COVID-19 vaccines in solid organ transplant recipients is currently limited, there are data to suggest that the currently available COVID-19 vaccines have efficacy³⁰ and it is reasonable to anticipate that vaccination will offer some benefit. Thus, the authors of this guidance agree that the benefits of increased vaccine-induced immunity against COVID-19 for this population outweigh any theoretical risks of immunization.

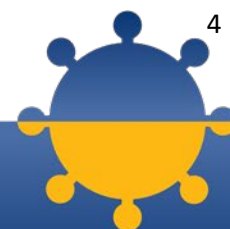
Is COVID-19 immunization efficacious and safe for solid organ transplant recipients?

Both adults and children who have had a solid organ transplant and people who are immunosuppressed in general were excluded from the clinical trials of the COVID-19 vaccines.³⁻⁷

Safety data for people with solid organ transplants are available in observational studies. The frequency and severity of adverse events following vaccination with an mRNA COVID-19 vaccine were comparable to that of non-immunosuppressed individuals in these studies and what was reported in clinical trials. Safety data in these populations following vaccination with a viral vector vaccine is not available.

As with most vaccines, there is a potential for blunted immune response in individuals who are immunocompromised due to their disease or treatment.^{1,2} Recently, multiple studies have been published examining the response to SARS-CoV2 mRNA-based vaccines in solid organ transplant (SOT) recipients.³¹⁻³⁷ Overall, these studies have shown a lower antibody response to vaccine among SOT recipients when compared to the general population. Emerging studies have shown a detectable SARS-CoV-2 specific T-cells response in some patients, despite a lack of antibody response. Therefore, SOT recipients might derive clinical benefit from the vaccine despite an absent antibody response. Studies to assess vaccine effectiveness, particularly for protection against severe COVID-19 as a clinical end-point in SOT, are still needed.³⁸ Studies evaluating immune response in pediatric and adolescent solid organ transplant recipients are ongoing. Early data suggests adolescent transplant recipients may have better antibody response compared to adult recipients.³⁹

There is one study that suggests that a third dose of COVID-19 vaccine in immunocompromised patients can increase antibody levels.⁴⁰ Small studies on third doses of the mRNA COVID-19 vaccines have shown that immunogenicity (immunity measured in the blood) may increase with a third dose. The impact of additional doses on the worsening of underlying disease or on rare adverse events, including the risk of myocarditis and/or pericarditis, is unknown at this time.¹⁸



Transplant recipients who are immunosuppressed from treatment should be informed that they may have a reduced immune response to any authorized COVID-19 vaccine series.¹³ However, they should also be reassured that expert consensus is that benefits of immunization outweigh the risks.^{13,28,29,31}

There is a theoretical vaccine side effect that COVID-19 immunization could cause graft rejection. While there is no data to suggest that the COVID-19 vaccines will lead to graft rejection at this time, and no cases have been reported, this should continue to be monitored until more data and certainty is available.

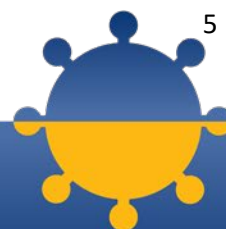
Are there any specific contraindications or exceptions for solid organ transplant recipients?

Individuals who have had a severe allergic reaction to an ingredient of one type of COVID-19 vaccine are still able to receive future doses of the other type of vaccine.⁴¹ BCCDC has a list of the individual components and their purpose in the vaccines (www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/vaccines-for-covid-19). For a complete list of components in the vaccine, consult the vaccine monographs found at:

- tozinameran (COMIRNATY, Pfizer BioNTech): <https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf>
- elasomeran (SPIKEVAX, Moderna): <https://covid-vaccine.canada.ca/info/pdf/covid-19-vaccine-moderna-pm-en.pdf>
- ChAdOx1-S (VAXZEVRIA, AstraZeneca): <https://covid-vaccine.canada.ca/info/pdf/astrazeneca-covid-19-vaccine-pm-en.pdf>
- Ad26.CO2.S (Janssen COVID-19 Vaccine, Janssen): <https://covid-vaccine.canada.ca/info/pdf/janssen-covid-19-vaccine-pm-en.pdf>
- COVID-19 Vaccine (Recombinant protein, Adjuvanted) (NUVAXOVID, Novovax): <https://covid-vaccine.canada.ca/info/pdf/nuvaxovid-pm-en.pdf>
- Medicago Covifenz COVID-19 vaccine: <https://covid-vaccine.canada.ca/info/pdf/covifenz-pm-en.pdf>

People with a history of anaphylaxis without known or obvious cause, and those with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, are advised to consult with an allergist prior to immunization. Health-care providers with patients with a history of severe allergic reactions should refer to the product monographs to review the full ingredient list.³⁻⁷ Potential allergens that are known to cause type 1 hypersensitivities in the mRNA vaccines include polyethylene glycol (PEG), and Polysorbate 80 in the VAXZEVRIA (AstraZeneca): viral vector vaccine.

Health Canada continues to monitor any adverse events following immunization through their post-authorization surveillance [process](#).



COVID-19 vaccines can be given concomitantly with, or any time before or after any other indicated vaccine including the seasonal influenza vaccine.⁴²⁻⁴⁵ This is a change from the previous recommendation for a 14-day interval before or after receipt of a COVID-19 vaccine. The original advice against co-administration was based on a cautionary approach, as specific studies of co-administration with other vaccines have not been performed. However, substantial data have now been collected regarding the safety of COVID-19 vaccines currently authorized by Health Canada. Extensive experience with non-COVID-19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone. The basis for this change in recommendation is referenced to general administrative guidance for vaccines and guidance from the US Advisory Committee on Immunization Practice (ACIP).

Patients should delay vaccination within the first month post-transplant, during acute rejection treatment (e.g., high dose steroids) or antibody mediated rejection protocols with rituximab - see below.²⁷

Are there specific recommendations or considerations for safe and/or most effective administration?

For the vast majority of solid organ transplant recipients, there are no specific recommendations that need to be considered for COVID-19 vaccine administration. A small subset of adult patients with specific timing considerations (those on the active transplant wait list, have recently had a solid organ transplant, or are undergoing acute rejection therapy) should be contacted directly by their transplant care teams to help with immunization timing.

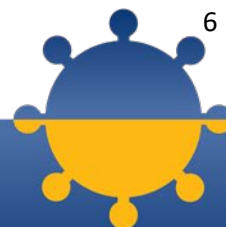
Pediatric transplant patients ages 5 and older are encouraged to be vaccinated. Pediatric patients who had solid organ transplant in the last month; have been treated for acute rejection therapy in the last month; or received rituximab in the last 3 months should contact their transplant care teams to help with immunization timing.

As part of vaccine surveillance for safety and efficacy, solid organ transplant patients should be encouraged to report any significant adverse event to their transplant clinics.

A very small group of pediatric and adult patients who are waiting to receive a solid organ transplant, have recently had a solid organ transplant, or are undergoing acute rejection therapy, will need to be specifically counselled by their post-transplant care teams on the appropriate timing of the COVID-19 vaccines. For these patients, it is recommended:^{27,28}

- Ideally, immunization should occur two weeks prior to transplant to allow for an immune response. If transplant happens before the second dose (for 2 dose vaccines), resume vaccination at least one month post-transplant.
- Wait at least one month after transplant to receive the COVID-19 vaccine regardless of induction therapy (basiliximab, anti-thymocyte globulin)
- Wait at least one month after active treatment for acute organ rejection (including steroid pulse even if no other drugs given)
- Wait at least three months after rituximab therapy (e.g. antibody-mediated rejection protocols)

Antibody testing is not recommended after vaccination. The levels of protective antibody and association with

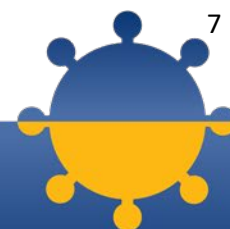


vaccine effectiveness are not known.³⁸

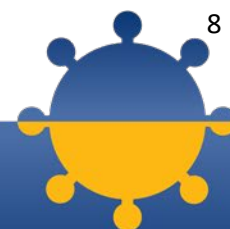
As all solid organ transplant recipients are immunosuppressed to varying degrees, vaccine efficacy is expected to be lower than for those who are not immunosuppressed. It is strongly recommended that patients (and their immediate household) continue to practice infection control measures while COVID-19 is circulating in the community. Household contacts and caregivers of the transplant recipient should also be immunized when possible.²⁷ Regardless of vaccination status, transplant recipients should follow any measures recommended by public health.

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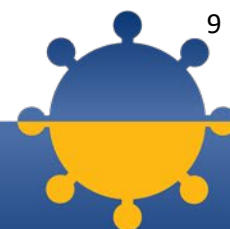
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