

Cell Therapy Transplant Canada
Position Statement on COVID-19 Vaccination

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There are currently four Health Canada approved vaccines for COVID-19, two based on mRNA technology (BNT162b2/tozinameran, [now referred to as Comirnaty](#), developed by Pfizer/BioNTech, and mRNA-1273, [now termed Spikevax](#), developed by Moderna), and two based on non-replicating adenoviral vectors (ChAdOx1, [now Vaxzevria](#), developed by AstraZeneca, and Ad26.COV2.S, developed by Janssen [and referred to as Janssen COVID-19 Vaccine](#)).¹ All four vaccines are authorized in Canada for individuals aged 18 and older, and both the Pfizer/BioNTech [and Moderna](#) vaccines can also be used for children aged 12 and older. [The FDA has given emergency authorization for use of the Pfizer/BioNTech vaccine in children aged 5-11, but Health Canada has not yet approved this indication in Canada.](#) Supplies are currently adequate to vaccinate all eligible Canadians.

COVID-19 infection in patients with hematologic malignancies, recipients of hematopoietic stem cell transplant (HSCT), or cellular therapies is associated with a high risk of poor outcomes and an overall mortality rate of 22-36% in adults,²⁻⁵ and 4-6% in children.^{3,4} These data highlight the importance of protecting patients with hematologic malignancies and recipients of stem cell transplantation and cellular therapy.

Immunocompromised patients were excluded from the phase III trials that provided the basis for approval of any of these four vaccines,⁶⁻⁹ and no studies that include this patient population are likely to be completed in the near future. Despite the lack of data, there is no evidence that these vaccines are more harmful than other inactivated (non-live) vaccines we currently administer to these patients, and there is no risk of developing COVID from these vaccine products.

Individual provinces have been vaccinating immunocompromised individuals based on the priority-based recommendations from the National Advisory Committee on Immunization (NACI), without any signal of significant toxicities.

As such, recipients of stem cell transplantation and cellular therapies were included among the highest priority and by this time many may have already received a full course of a particular (or mixed doses of) COVID-19 vaccine and may also have received a third (booster) dose of an mRNA vaccine as is recommended by Health Canada.¹⁰

Patients that are immunocompromised typically do not develop the same immunologic response to the vaccine and might not benefit to the same degree as a member of the general public, even after a third dose.¹¹ That said, in most patients, given the very

significant risk associated with COVID infection, the potential benefit associated with the vaccine is likely greater than any risks. [The timing of vaccination in HSCT recipients is critical, since patients that had been vaccinated prior to transplant would have no immunity to the virus post-transplant and should therefore receive a second course of vaccines. These patients may end up receiving up to 5 or 6 vaccination doses, depending on whether they were vaccinated pre-transplant.](#)

Given that the immune response to the vaccine might be impaired in these patients, a strategy that includes vaccinations of caregivers of stem cell transplant and cellular therapy patients is also critical, to mitigate any risk of transmission within the household. Many provinces have also implemented mandatory vaccination policies for high-risk settings and health-care workers.

Based on the above premises, we have the following recommendations. Our recommendations for vaccination are aligned with recommendations issued by the American and European cellular therapy societies.^{12,13}

We recommend:

1. Physicians should discuss the risks and benefits of COVID vaccines with their patients and weigh the potential risks and benefits of vaccination. It is expected that in most circumstances, the recommendation will be to proceed with vaccination, given the probable safety of vaccination and the very significant risks of COVID-19 infection.
2. Patients in the first 3-6 months following allogeneic stem cell transplant, autologous cell transplant, CAR-T therapy, or on active immunosuppression, [should receive a full course of mRNA vaccine post-transplant/therapy, independent of prior COVID-19 vaccination, and should include a third booster dose at the appropriate time. Re-vaccination should start 3-6 months after transplant, at the discretion of the centre. A more potent immune response will be obtained if the first vaccine dose is administered closer to the 6-month mark, but the timing of vaccination depends on many factors and should be considered on a case-by-case basis.](#)
3. For patients in the first 3-6 months following allogeneic stem cell transplant or CAR-T therapy, or on active immunosuppression, given uncertainty about the vaccine efficacy, vaccination of the health care teams providing care for them should be mandated. We also recommend encouraging caregivers and household contacts to get vaccinated. Household transmission is the most common mechanism for acquisition of COVID-19, and a similar strategy as is used in long-term care facilities (vaccination of all those

residing with high-risk patients) should be employed.

4. Eligible transplant and cellular therapy patients that have already received a full vaccination course should get a booster shot where available, to increase immunological response.
5. In general, most of the recommendations above could also apply to patients with other hematologic malignancies on active therapy, given their comparable risk.

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