

Coronavirus COVID-19

BC Centre for Disease Control | BC Ministry of Health



Clinical Guidance on COVID-19 Vaccines for people with hematological malignancy at any stage of treatment and/or who have undergone hematopoietic stem cell transplant or CAR-T cell therapy in the past 6 months

This guidance is intended for healthcare providers and is based on known evidence as of April 18, 2023.

This document relates to people with hematological malignancies and those who have undergone hematopoietic stem cell transplant or CAR-T cell therapy. Please refer to other guidance document for people with solid cancers. For general information, please refer to BCCDC Guidance and information on [COVID-19 vaccines for providers](#).

Hematologic malignancies (blood cancers such as leukemias, myelodysplastic syndromes, myeloproliferative neoplasms, lymphomas and multiple myeloma) can be treated with chemotherapy, hematopoietic stem cell transplant (HSCT) or chimeric antigen receptor T-cell (CAR-T) therapies with either a curative intent or to prolong survival. The hematologic malignancy itself or the anti-cancer therapies can result in long-lasting immunodeficiency, and COVID-19 infection in this population is associated with a significantly higher risk of hospitalization and death.¹

There is still uncertainty as to whether the currently available COVID-19 vaccines are efficacious in adults and children with cancer or undergoing therapy for their cancer (cytotoxic chemotherapy, endocrine therapy, targeted therapy, immunotherapy) and/or radiation therapy (external-beam, brachytherapy, or systemic), as well as to the timing of immunization in relation to their cancer treatments.

Is the COVID-19 vaccine recommended for people with hematologic malignancies and HSCT and/or CAR-T recipients?

The risk of mortality from COVID-19 disease is higher in patients with cancer, including patients with hematologic malignancies and HSCT recipients.²⁻⁵ One study found that more severe forms of COVID-19 disease, including those requiring ICU admission, were more frequent in patients with hematologic malignancies hospitalized with COVID-19, and led to mortality nearly four times higher than that of the general population with COVID-19 and 41 times higher than that of hematologic malignancy patients without COVID-19.¹

There are data to suggest that the currently available COVID-19 vaccines have efficacy.⁶ COVID-19 vaccines should be encouraged for people with hematologic malignancies and HSCT and/or CAR-T recipients, as per BC Public Health recommendation for age eligibility and are not contraindicated. This recommendation is based on the following:

- The National Advisory Committee on Immunization (NACI) recommends that immunosuppressed individuals be offered the vaccine if the benefits of vaccines outweigh the potential risks.⁷

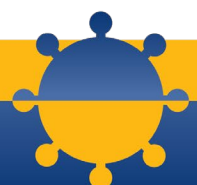
If you have fever, a new cough, or are having difficulty breathing, call 8-1-1.



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- Patients with blood cancer have an increased risk of death related to COVID-19 infection.¹⁻⁵
- The United Kingdom, the United States, France, and Australia have prioritized patients with cancer for COVID-19 vaccinations, highlighting the high COVID-19 risk faced by these patients.⁸

Is the COVID-19 vaccine efficacious and safe in people with hematologic malignancy patients and HSCT and/or CAR-T recipients?

There is still uncertainty about the efficacy of COVID-19 vaccines in patients with blood cancer and/or have undergone HSCT or CAR-T cell therapy in the last six months. As with most vaccines, there is a potential for diminished immune response in individuals who are immunocompromised due to their disease or treatment. In addition, patients with active cancer or undergoing active cancer treatment seemed to be generally excluded from the COVID-19 vaccine trials. However, in the COMIRNATY (Pfizer-BioNTech) vaccine trial, 3.9% of enrolled participants had a malignancy.⁹

There are currently no known factors that would predispose these individuals to adverse events associated with the vaccines. At the time of authorization, there are no known serious warnings or precautions related to the vaccines in patients with cancer.¹⁰⁻¹⁴

Small exploratory studies have shown lower antibody responses in patients with advanced cancer and haematological malignancies⁹ following vaccination compared to controls. However, it is unclear how much antibody is needed for protection and/or the role of other immunological responses.

There is one study that suggests that a third dose of COVID-19 vaccine in immunocompromised patients can increase antibody levels.¹⁵ 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 safety of a third dose is unknown at this time, but in these small studies reactions were found to be similar to that of prior doses.

The frequency and severity of adverse events following vaccination with an mRNA COVID-19 vaccine in these populations 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.¹⁶

Informed consent should include discussion about the possibility that individuals who are immunosuppressed may have a diminished immune response to any of the authorized COVID-19 vaccines.¹⁷

Observed short-term adverse effects with the mRNA-based COVID-19 vaccines have been similar to those seen with seasonal influenza vaccination. Still, they may be more pronounced after the second COVID-19 vaccine dose (e.g. injection site pain/erythema, fever, headache, fatigue, and myalgia/arthritis).^{2-9,18} Safety results in the allogeneic HSCT patient population seem comparable.¹⁵ Any long-term side effects of COVID-19 vaccines are not yet known, but Health Canada continues to monitor any adverse events following vaccination through their post-authorization surveillance process.

Immunocompromised patient populations are diverse and the relative degree of immunodeficiency will depend on the underlying condition, the progression of the disease, and the type and timing of treatment received. Therefore, the



balance of potential benefit and risk associated with COVID-19 vaccination should be assessed on an individual basis (Table 1).

Are there any specific contraindications or exceptions for those within the hematologic malignancy, HSCT and/or CAR-T recipient patient populations?

Blood counts

Patients with blood cancer and HSCT or CAR-T recipients may experience low blood counts, either due to their disease or treatment, which could impact individual decision-making around receipt of COVID-19 vaccinations and timing of vaccinations relative to their treatments. COVID-19 vaccination should be deferred in patients unwell with neutropenia until well,^{10,11} but may be considered in well patients with disease-related chronic neutropenia where neutrophil recovery is not expected.¹⁹

Allergy

The above noted COVID-19 vaccines are contraindicated in individuals with a history of severe allergic reaction to any component of the vaccines, including non-medicinal ingredients such as polyethylene glycol (PEG) or polysorbate-80, or a history of anaphylaxis after administration of a previous dose of COVID-19 vaccine using a similar platform (mRNA or viral vector).⁷ 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.²⁰ BCCDC has a list of the individual components and their purpose in the vaccines. For a complete list of components in the vaccine, consult the vaccine monographs found at: www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/vaccines-for-covid-19.

People with a history of anaphylactic reaction to a previous dose of an mRNA COVID-19 vaccine, re-vaccination (i.e., administration of a subsequent dose in the series when indicated) may be offered with the same vaccine or the same mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided. Prior to revaccination, consultation with an allergist or another appropriate physician (e.g., Medical Health Officer) is advised. If re-vaccination is going ahead, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis, with an extended period of observation of at least 30 minutes after re-vaccination.

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

Other vaccines

Currently, it is recommended that COVID-19 vaccines can be given concomitantly with, or any time before or after any other indicated vaccine.²¹⁻²⁴



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

1. Blood counts

Patients with blood cancer and HSCT or CAR-T recipients may have lowered blood counts related to the underlying disease or therapy. If blood counts (platelet count and neutrophil count) are low due to therapy and timing of recovery can be anticipated, e.g. 1 week prior to the next cyclical chemotherapy or maintenance cycle, the timing of vaccination should be scheduled accordingly (please see Table 1). However, where the timing of blood count recovery is unclear or not anticipated, e.g. marrow failure syndromes, then vaccination should not be delayed solely for this reason.

There is no consensus on an adequate platelet count for IM injections. Still, practical suggestions include using a platelet threshold of $>20 \times 10^9/L$, administering the vaccine after platelet transfusion if receiving regular transfusions, and applying firm pressure at the injection site for at least 5 minutes.²⁵

2. Anti-coagulant therapy

As per Thrombosis Canada recommendations,²⁶ anti-coagulation should not be a barrier for administering COVID-19 vaccination to patients on warfarin (INR monitoring not required prior to vaccination), novel oral anticoagulants (apixaban, dabigatran, edoxaban, rivaroxaban) or antiplatelet agents (aspirin, clopidogrel, ticagrelor). Patients on therapeutic dose low-molecular weight heparin (dalteparin, tinzaparin, enoxaparin, nadroparin) or fondaparinux may consider delaying their anti-coagulant dose on the day of vaccination until after the IM injection. For patients on any of the above, applying pressure to the injection site for 3 to 5 minutes post vaccination is recommended to reduce bruising.

3. Special considerations for immunotherapy

a. Therapies targeting B-cells including anti-CD20, CD19, CD22 targeting antibodies, or BiTEs: Patients receiving these agents may have a reduced immune response to vaccines in general that can extend to up to 6 months following treatment completion. If possible, patients should receive both doses of vaccine prior to starting these therapies. If patients are on, or have recently been treated with these agents, when they received the first 2 doses of vaccine, a 3rd dose is recommended to be administered at least 28 days after the 2nd dose, with consideration given to delaying to 3 months after therapy with B-cell directed therapies due to likelihood of impaired immune response.

b. Checkpoint inhibitors:

Previous studies have not signalled an increased risk of complications of COVID-19 for patients on checkpoint inhibitors such as CTLA-4 inhibitors (e.g., ipilimumab), PD-1 inhibitors (e.g., nivolumab, pembrolizumab) and PD-L1 inhibitors (e.g., atezolizumab, durvalumab). There have been theoretical concerns of an enhanced immune reaction, particularly with CTLA-4 inhibitors. However, given the seriousness of COVID-19 infection, vaccination is still recommended in this group even if a four-week window cannot be confirmed.

4. Timing of COVID-19 vaccines in relation to therapy

There are no known studies regarding the timing of COVID-19 vaccination in relation to therapy for blood cancer. The COMIRNATY (Pfizer-BioNTech), SPIKEVAX (Moderna) and VAXZEVRIA (AstraZeneca) vaccines are given as two injections with optimal protection assumed after the second dose for the general population.¹⁰⁻¹² Efficacy and duration of immunity are continuously being evaluated and recommendations are evolving rapidly. Therefore, patients should



follow current BCCDC guidance for the recommended number of and interval between COVID-19 vaccine doses.

In general, it is preferred that patients complete their COVID-19 vaccination series ideally 14 days prior to starting immunosuppressive therapy.²⁷

***However, life-saving or prolonging therapy should not be delayed solely to complete vaccination.**

Recommendations for timing of COVID-19 vaccination for patients with hematologic malignancies (either completed, starting or already receiving treatment) and patients who have undergone HSCT or CAR-T cell therapy in the past 6 months are described in Table 1 below.

Any other timing should involve a case-by-case assessment based on:

- Risk of morbidity related to COVID-19 infection (including local incidence of the pandemic, cancer type, comorbidities that confer higher risk categories in general population, etc.),
- Cancer-related morbidity due to delay of active treatment, and
- Suboptimal immunity due to insufficient time window between vaccination and immunosuppressive therapy.

Table 1. Suggested timing of COVID-19 vaccination in patients with hematologic malignancies²⁸⁻³¹

Therapy	Suggested timing of COVID-19 vaccine
Cyclical chemotherapy – <i>prior to starting</i> (including hypomethylating agents)	1) Ideally complete vaccination at least 2 weeks prior to starting* 2) Alternatively, complete vaccination between cycles of therapy if clinically not appropriate to wait to complete vaccination
Cyclical chemotherapy – <i>between cycles</i> (including hypomethylating agents)	Give vaccine dose(s) between cycles: <ul style="list-style-type: none"> Upon count recovery (<i>if anticipated to recover</i>)** about 1 week prior to starting subsequent cycle <i>Note: Avoid on same day as treatment</i>
Single agent small molecule inhibitors (e.g. kinase inhibitors or continuous oral chemotherapy, BTK inhibitors)	No specific timing
Immunomodulatory agents	Avoid on same day as treatment
Proteasome inhibitors (e.g. bortezomib)	Avoid on same day as treatment
Check point inhibitors	Avoid on same day as treatment
CD19, CD20, CD22 targeted therapy (e.g. monoclonal antibodies)	No specific timing †
Other monoclonal antibodies	No specific timing



Therapy	Suggested timing of COVID-19 vaccine
Systemic Corticosteroids	Cyclical corticosteroids as part of chemotherapy regimens – ideally vaccinate on days when not receiving corticosteroids Continuous corticosteroids – no specific timing ***
Autologous HSCT § ¥	Pre-HSCT: ≥ 2 weeks prior to starting conditioning chemotherapy Post-HSCT: > 3 months post-HSCT
Allogeneic HSCT § ¥	Pre-HSCT: ≥ 2 weeks prior to starting conditioning chemotherapy Post-HSCT: > 3 months post-HSCT †
CAR-T cell therapy §	Pre-CAR-T cell therapy: ≥ 2 weeks prior to starting lymphodepleting chemotherapy Post-CAR-T cell therapy: > 3 months post-CAR-T cell therapy
Aplastic Anemia	Not on therapy or completed therapy with counts in acceptable range: No specific timing required Post-therapy: > 3 months post-initiation of cyclosporine/ATG †
Intravenous immunoglobulin (IVIG) - Not COVID-19 specific	No specific timing
Under Observation - Not scheduled for therapy OR completed planned therapy	No specific timing

* In general, it is preferable to complete vaccination before starting immunosuppressive therapy if possible (based on timing of therapy and vaccine availability). However, life-saving or prolonging therapy should not be delayed solely to complete vaccination. Some immunity may be achieved following the first dose of the vaccine.

** Some patients may not have adequate counts either prior to or between cycles of therapy. The benefit likely outweighs the risk, and these patients should proceed to vaccination regardless of neutrophil count and with platelet transfusion support if required.

*** Ideally high dose systemic corticosteroids (> 0.5 mg/kg/day prednisone or equivalent) should be avoided or completed 28 days prior to vaccination; if this is not possible, proceed with vaccination.

† Due to likelihood of impaired immune response to vaccination within 3 months of receiving B-cell directed monoclonal antibodies and ATG, consider delaying to 3 months post-therapy.

§ Rationale for consideration of delaying COVID-19 vaccination for > 3 months after HSCT and CAR-T cell therapy includes:

- Vaccine response is expected to be sub-optimal;
- Antibody testing cannot be evaluated as standard of practice;
- Revaccination post-HSCT and CAR-T cell therapy is recommended. The attestation form for “Revaccination following Hematopoietic Stem Cell Transplant” can be obtained from transplant physicians.

¥ If local COVID-19 transmission rates are high, consider prioritization of COVID-19 vaccination. Routine post-HSCT vaccinations may be given at the same time as the COVID-19 vaccines but may be delayed at the discretion of the patient or medical professional.²⁸



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