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 August 22, 2022.

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.

Background and Context

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

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), elasomeran (SPIKEVAX, Moderna)³
- **Replication-defective adenoviral vector vaccine**: ChADOx1-S (VAXZEVRIA, AstraZeneca), Ad26.COV2.S (Janssen COVID-19 Vaccine, Janssen)⁵
- **Recombinant protein vaccine**: NUVAXOVID (COVID-19 Vaccine [Recombinant protein, Adjuvanted], Novavax)⁶
- **Plant based virus-like particle vaccine**: Covifenz (Medicago)⁷

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.⁸ Children aged 5 to 11 will be offered either COMIRNATY (Pfizer-BioNTech) or SPIKEVAX (Moderna) for children aged 6 to 11. The National Advisory Committee on Immunization (NACI) has released their statement for these age groups.⁹,¹⁰,¹¹
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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. 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. All booster doses will be mRNA vaccines. For those who are not able, or willing, to receive mRNA vaccines, Novavax is available as an alternative.

**Second boosters:**

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):

- 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.

**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. The National Advisory Committee on Immunization 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.

A minimum interval of 28 days between dose 2 and dose 3 is recommended for those eligible for a third dose. 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.

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

**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
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minimum interval between doses has been observed. This applies to doses in their primary series, between primary series and first booster dose and between booster doses.

Other vaccines:

VAXZEVRIA (AstraZeneca)4

The VAXZEVRIA (AstraZeneca) 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, due to infrequent (1:50,000) but serious Vaccine-Induced Thrombotic Thrombocytopenia (VITT) blood clotting events after the first dose. The Government of Canada is not securing additional VAXZEVRIA doses.

Janssen COVID-19 Vaccine (Janssen)5

The Janssen COVID-19 Vaccine (Janssen) 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)6

NUVAXOVID 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. 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.

Medicago Covifenz (Medicago)7

Medicago 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.

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. 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.

There are data to suggest that the currently available COVID-19 vaccines have efficacy. COVID-19 vaccines are not contraindicated and should be encouraged for people with hematologic malignancies and HSCT and/or CAR-T recipients and as per BC Public Health recommendation for age eligibility. 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.
- Patients with blood cancer have an increased risk of death related to COVID-19 infection.
- 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.

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. 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.

Small exploratory studies have shown lower antibody responses in patients with advanced cancer and haematological malignancies 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. 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 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.
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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.13

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.19

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, 7, 34 Safety results in the allogeneic HSCT patient population seem comparable.34 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,2, 3 but may be considered in well patients with disease-related chronic neutropenia where neutrophil recovery is not expected.35

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).12 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.36 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:

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- **Medicago Covifenz COVID-19 vaccine:** [https://covid-vaccine.canada.ca/info/pdf/covifenz-pm-en.pdf](https://covid-vaccine.canada.ca/info/pdf/covifenz-pm-en.pdf)

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.³⁷-⁴⁰ 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.

**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 cycllical 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.

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If you have fever, a new cough, or are having difficulty breathing, call 8-1-1.
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There is no consensus on an adequate platelet count for IM injections. Still, practical suggestions include using a platelet threshold of >20 x 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.41

2. **Anti-coagulant therapy**

As per Thrombosis Canada recommendations,42 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.2-4 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.43

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

a. 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.),
b. Cancer-related morbidity due to delay of active treatment, and
c. Suboptimal immunity due to insufficient time window between vaccination and immunosuppressive therapy.

Table 1. Suggested timing of COVID-19 vaccination in patients with hematologic malignancies

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Suggested timing of COVID-19 vaccine</th>
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</table>
| Cyclical chemotherapy – prior to starting (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 – between cycles (including hypomethylating agents) | Give vaccine dose(s) between cycles:  
• Upon count recovery (if anticipated to recover)** about 1 week prior to starting subsequent cycle  
*Note: Avoid on same day as treatment |
| 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 |
| 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 † |
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<table>
<thead>
<tr>
<th>Therapy</th>
<th>Suggested timing of COVID-19 vaccine</th>
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<tbody>
<tr>
<td>CAR-T cell therapy §</td>
<td>Pre-CAR-T cell therapy: ≥ 2 weeks prior to starting lymphodepleting chemotherapy</td>
</tr>
<tr>
<td></td>
<td>Post-CAR-T cell therapy: &gt; 3 months post-CAR-T cell therapy</td>
</tr>
<tr>
<td>Aplastic Anemia</td>
<td>Not on therapy or completed therapy with counts in acceptable range: No specific timing required</td>
</tr>
<tr>
<td></td>
<td>Post-therapy: &gt; 3 months post-initiation of cyclosporine/ATG †</td>
</tr>
<tr>
<td>Intravenous immunoglobulin (IVIG) - Not COVID-19 specific</td>
<td>No specific timing</td>
</tr>
<tr>
<td>Under Observation - Not scheduled for therapy OR completed planned therapy</td>
<td>No specific timing</td>
</tr>
</tbody>
</table>

* 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.44

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