

# Coronavirus COVID-19

BC Centre for Disease Control | BC Ministry of Health



## Clinical Guidance on COVID-19 Vaccines for People with Thalassemia

This guidance is intended for health-care providers and is based on available evidence as of November 8, 2022.

### Background and Context

Thalassemia is an inherited blood cell disorder. Patients with both transfusion-dependent thalassemia (TDT) and non-transfusion dependent thalassemia (NTDT) may have risk factors associated severe SARS-CoV-2 infection including iron overload, endocrinopathies like diabetes, asplenia due to previous splenectomy, and coagulopathy.<sup>1</sup>

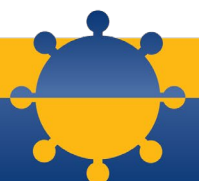
Some people with thalassemia are at a higher risk for severe COVID-19 infections than others. The Thalassemia International Federation has categorized “**highest risk**” and “**high risk**” thalassemia on the basis of age, disease, and comorbidity related factors.<sup>2</sup>

Persons with a diagnosis of thalassemia and any two of the following can be considered as high to highest risk:

- People over 50 years of age
- Transfusion dependent
- Non-transfused with hemoglobin values chronically below 70 g/L for the past two to three years
- People receiving iron chelation therapy
- Splenectomized persons or persons with asplenia
- Those with comorbidities including diabetes, pulmonary hypertension, endocrine, cardiac, or respiratory disease

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),<sup>3</sup> tozinameran and riltozinameran (COMIRNATY Bivalent original & BA.1, Pfizer-BioNTech),<sup>4</sup> tozinameran and famtozinameran (COMIRNATY Bivalent original & BA.4/BA.4, 1Pfizer-BioNTech),<sup>5</sup> elasomeran (SPIKEVAX, Moderna),<sup>6</sup> elasomeran and imelasomeran (SPIKEVAX Bivalent original & BA.1, Moderna)<sup>7</sup>
- **Viral vector vaccine:** ChADOx1-S (VAXZEVRIA, AstraZeneca),<sup>8</sup> Ad26.COVS.2.S (JCVODEN, Janssen)<sup>9</sup>
- **Recombinant protein vaccine:** COVID-19 Vaccine (recombinant protein, adjuvanted) (NUVAXOVID, Novavax)<sup>10</sup>
- **Plant based virus-like particle (VLP) vaccine:** COVID-19 Vaccine ([VLP], recombinant, adjuvanted) (COVIFENZ, Medicago)<sup>11</sup>



Currently, anyone in British Columbia (B.C.) who is aged 6 months and older is eligible for COVID-19 immunization. The mRNA vaccine SPIKEVAX (Moderna) and COMIRNATY (Pfizer-BioNTech) have been approved for children 6 months to 11 years of age, with young children getting a smaller dose of the same vaccine used for youth and adults.<sup>12</sup> National Advisory Committee on Immunization (NACI) has released their statement for these age groups.<sup>13,14,15</sup>

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.<sup>16,17</sup> B.C. has taken the proactive step to expand booster doses for all individuals 5 years and older, not just those at high risk. However, it is particularly recommended for individuals 5-17 years of age who are at [higher risk of severe illness](#) due to COVID-19 infection.<sup>18,19</sup> All booster doses will be mRNA vaccines.<sup>20</sup> For those who are not able, or willing, to receive mRNA vaccines, Novavax is available as an alternative for individuals 18 years of age and older.

### **Booster doses:**

As part of the Fall 2022 booster dose program, B.C. is making plans to offer everyone 5 years and older a 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.<sup>21</sup>

SPIKEVAX BIVALENT BA.1 (Moderna) (50 mcg) is the preferred product in B.C. for moderately to severely immunosuppressed individuals 12 years and older. SPIKEVAX original (Moderna) (100 mcg) primary series has been associated with a higher seroconversion rate among immunocompromised adult patients compared to COMIRNATY original (Pfizer-BioNTech) (30 mcg). In a general population of adults, booster vaccination with SPIKEVAX original (Moderna) (50 mcg) was also found to be more effective than COMIRNATY original (Pfizer-BioNTech) (30 mcg) during a period of Delta followed by Omicron variant dominance. However, these studies were conducted prior to the emergence of the Omicron BA.4/BA.5 Variant of Concern (VOC), and their applicability to all Omicron sublineages is uncertain.<sup>21</sup> Health Canada has recently authorized an adapted version of the SPIKEVAX (Moderna) COVID-19 vaccine that targets the Omicron BA.4/BA.5 subvariants.<sup>22</sup>

### **Patients who have tested positive for COVID-19:**

Booster doses may be deferred in those who have tested positive for COVID-19 until 3-6 months from symptom onset or, for asymptomatic cases, from the time of the positive test.<sup>23</sup> This suggested interval is based on immunological principles and expert opinion. When considering whether or not to administer vaccine doses following the suggested 3–6-month interval, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and severe disease should also be taken into account. As these intervals are to be used as a guide, clinical discretion is advised.

COVID-19 vaccination may be offered to individuals at any time following recovery from SARS-CoV-2 infection.

### **Intervals between doses:**

Individuals 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.<sup>24</sup>



The minimum interval between completion of the primary series, or a previous booster dose, and the Fall booster dose is 3 months. This revised minimum interval additionally applies to pregnant people and aligns with NACI's updated guidance on COVID-19 vaccines for individuals who are pregnant or breastfeeding. The exception to this is JCVODEN (Janssen) for which the minimum interval is 8 weeks between the single dose of JCVODEN (Janssen) and the booster dose.<sup>25</sup>

#### **Other vaccines:**

##### VAXZEVRIA (AstraZeneca)<sup>8</sup>

The VAXZEVRIA (AstraZeneca)<sup>8</sup> 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,<sup>16</sup> due to infrequent (1:50,000) but serious Vaccine-Induced Thrombotic Thrombocytopenia (VITT) blood clotting events after the first dose.<sup>26</sup> The Government of Canada is not securing additional VAXZEVRIA doses.

##### JCVODEN (Janssen)<sup>9</sup>

The JCVODEN<sup>9</sup> 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)<sup>10</sup>

NUVAXOVID<sup>10</sup> is a different class of vaccination, a protein subunit vaccine that will give British Columbians another option to protect themselves against COVID-19 infection. NUVAXOVID may be offered to individuals for whom COVID-19 mRNA vaccines are contraindicated or have been refused.<sup>27</sup> 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.<sup>28</sup>

##### COVIFENZ (Medicago)<sup>11</sup>

COVIFENZ<sup>11</sup> 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 infection. COVIFENZ 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 B.C.<sup>11</sup> This product is not yet available in Canada.



## Is COVID-19 immunization recommended for people with thalassemia?

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COVID-19 vaccines should be encouraged for adults and youth with thalassemia and are not contraindicated, including those who have had COVID-19 infection. This recommendation is based on the following review:

- A multicentre, retrospective, cross-sectional study from Iran including adult TDT and NTDT patients described a death rate of 26.6% in patients with confirmed COVID infection by PCR and 25% in those with suspected COVID infection.<sup>29</sup>
- A systematic review identified seven publications with a total of 34 adult beta thalassemia patients (76.5% had TDT) with a death rate of 26.5%.<sup>30</sup>

While data specific to the safety and efficacy of COVID-19 vaccines in people with thalassemia is currently limited, there are data to suggest that the currently available COVID-19 vaccines have efficacy.<sup>31</sup> The authors of this guidance agree that the benefits of COVID-19 immunization with these vaccines outweigh any theoretical risks of immunization.

## Are COVID-19 vaccines efficacious and safe for people with thalassemia?

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As thalassemia is considered to be a severe underlying medical condition, both adults and children with thalassemia were excluded from the COVID-19 vaccine clinical trials. Therefore, it is unknown if COVID-19 vaccines are as efficacious for patients with thalassemia as they were found to be for the clinical trial participants.

Many people with thalassemia have been splenectomised, which compromises immune function.<sup>32</sup> Chronic transfusion and iron overload are also thought to impair a person with thalassemia's immune response. As with most vaccines, there is a potential for blunted immune response in individuals who are immunocompromised due to their disease or treatment.<sup>33,34</sup> In one study, people with TDT produced protective antibodies comparable to healthy population following COVID-19 vaccination.<sup>35</sup> Therefore, it is possible that people with thalassemia may not respond as well to the vaccine as the general population, and should continue to follow local public health guidelines and adhere to precautionary procedures following vaccination for as long as SARS-CoV-2 continues to circulate at high rates in the community.

Currently, there are no serious warnings or precautions associated with the mRNA (COMIRNATY [Pfizer-BioNTech] or SPIKEVAX [Moderna]) vaccines in persons with thalassemia beyond those of the general population. If vaccination with the Janssen COVID-19 Vaccine (Janssen) vaccine is considered, clinicians should be aware of the rare potential for development of venous or arterial thrombosis accompanied by thrombocytopenia 4 to 30 days after vaccination.



## Are there any specific contraindications or exceptions for people with thalassemia?

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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.<sup>36</sup> 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](http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/vaccines-for-covid-19).

For individuals 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](#).

Thalassemia patients who have received gene therapy should be immunized in accordance with guidelines for patients who have received high-dose chemotherapy and autologous hematopoietic stem cell transplant.

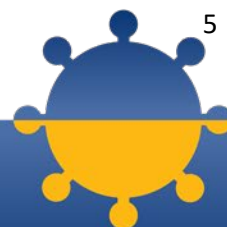
Otherwise, there are no contraindications or exceptions to immunization for individuals within the thalassemia population beyond those for the general population.

COVID-19 vaccines can be given concomitantly with, or any time before or after any other live or inactivated vaccine.<sup>37-40</sup>

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

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There are no specific timing considerations for the administration of the COVID-19 vaccine relative to treatment other than for patients who are receiving gene therapy. These patients should be immunized according to guidelines for autologous stem cell transplant recipients (e.g., two doses at least two weeks pre-treatment and more than three months post-treatment).



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