

COVID-19 Vaccination for Special Populations Information for family doctors

February 25, 2021

The OCFP has compiled current recommendations from various specialty groups to help guide vaccine discussions and decisions with special populations – such as those at risk of serious illness from COVID-19, as well as those groups excluded from clinical trials.

This information is specific to currently available mRNA vaccines: Pfizer-BioNTech and Moderna.

What's New:

- Verbal attestations by the patient of counselling by a primary provider on vaccine risk/benefits is required for the [two scenarios below](#):
 - Immunosuppressed if: receiving stem cell therapy, CAR-T therapy, chemotherapy, immune checkpoint inhibitors, monoclonal antibodies (e.g., rituximab) and other targeted agents (e.g., CD4/6 inhibitors, PARP inhibitors); and
 - Pregnancy.
- The MOH [pre-screening assessment tool](#) and [COVID-19 vaccine screening and consent form](#) can help determine conditions and concerns prior to vaccination. Here is the [form](#) the vaccinator can use to document verbal attestation when required.
- Patients who have had a **severe allergy / anaphylaxis** and those who have an allergic reaction within 4 hours of receiving a previous dose of the vaccine or any of its components, need [written documentation of counselling](#) from an allergist / immunologist.
- Updated [guidance](#) (page 6) states the Pfizer-BioNTech vaccine may be offered to individuals 12 to 15 years of age who are at very high risk of severe outcomes of COVID-19 and/or are at increased risk of exposure.

Who should not be vaccinated

- As a precautionary measure, acutely ill people should not receive the vaccine.
- Individuals with symptoms of confirmed or suspected COVID-19 infection should defer vaccination until recovered.
- Individuals who have received another vaccine in the past 14 days should not receive the vaccine.
- Children under the age of 12 should not be offered the vaccine (see 'children and adolescents', page 2 of this document).

Special Populations

Allergies: The [Canadian Society of Allergy and Clinical Immunology](#) identifies the risk for serious allergic reaction as low and [states](#), “the majority of individuals with a history of allergy will be able to safely receive vaccination for COVID-19”. [This includes](#) those with a history of serious allergic reactions or anaphylaxis to substances that are not an ingredient in this vaccine, and those with food allergy, eczema, allergic rhinitis (hayfever), asthma, or stinging insect allergy.

- An [extended period of observation](#) of 30 minutes post vaccination is recommended for individuals with a history of severe allergic reaction (i.e., anaphylaxis) not related to vaccines or injectable medications.
- **Polyethylene glycol (PEG)** has been identified as a potential allergen in the Pfizer-BioNTech vaccine but has not been confirmed as the cause of reaction for reported adverse reactions. PEG is found in many **common over-the-counter medications** (brand names Tylenol EZ tabs, Benadryl, Advil Liqui-gel and Reactine, for example) cosmetics and some food and drink; no cases of anaphylaxis to PEG in foods and drinks have been reported, according to the CSACI. People with a suspected hypersensitivity or who have had an immediate allergic reaction to PEG or polysorbate (the latter is not an ingredient in either vaccine but closely related to PEG) should not get either vaccine without being evaluated by an allergist / immunologist.
- **Allergic reaction to previous dose or component of the vaccine:** Patients who have had a severe allergy/anaphylaxis to a previous dose or any component of the vaccine and those who have an allergic reaction within 4 hours of receiving a previous dose of the vaccine or any of its components need [written documentation of counselling](#), **including a vaccination plan** from an allergist / immunologist.
- As needed for your patients, you can use [eConsult for COVID-19 vaccine allergy related consultations](#), or refer your patient to this [list of allergists / immunologists](#) prepared by the MOH.

Pregnancy/Breastfeeding: The [Society of Obstetricians and Gynaecologists of Canada](#) states that “the documented risk of not getting the COVID-19 vaccine outweighs the theorized and undescribed risk of being vaccinated during pregnancy or while breastfeeding and **vaccination should be offered.**” The MOH recommendations highlight that mRNA vaccines are not live vaccines are not expected to be a risk to the **breastfeeding** infant. This COVID-19 vaccine [information sheet](#) from Unity Health and this [values-based framework](#), published in CMAJ, may be helpful aids for shared decision making with this population.

- [Verbal attestation](#) by the patient of counselling by a healthcare provider familiar with the pregnancy must be documented before the vaccine is offered to a pregnant individual.

Children and adolescents: Children under the age of 18 (Moderna) and under 16 (Pfizer-BioNTech) were not part of the clinical trials. However, MOH [guidance](#) (page 6) states the Pfizer-BioNTech vaccine may be offered to individuals 12 to 15 years of age who are at very high risk of severe outcomes of COVID-19 (e.g., due to a pre-existing medical condition known to be associated with increased risk of hospitalization or mortality) AND/OR are at increased risk of exposure (e.g., due to living in a congregate care facility). Informed consent with the individual and the parent or guardian includes discussion with the treating provider of their medical condition about the insufficient evidence on the use of COVID-19 vaccines in this population.

Cancer: Cancer is a very broad and heterogeneous set of diseases and cancer treatments also vary in terms of impact on the immune system. The [Canadian Cancer Society](#) has not yet released specific guidance on COVID-19 vaccines but addresses the question of **immunization generally** with this statement: “Talk to your doctor or health care team if you have questions about immunizations during or after cancer treatment. Avoid vaccinations if you are being treated for cancer. ... Inactivated vaccines don’t pose a safety risk but likely won’t work as well if your immune system isn’t working properly”. [Cancer Care Ontario](#)’s patient resource notes the COVID-19 vaccine “is an important part of protecting people with cancer” and lists the groups of people with cancer most at risk from COVID-19.

If your patient is actively receiving cancer treatment, it may be best to **consult with their oncologist** about risks/benefits of vaccination.

Specific immunosuppressed patients requiring [verbal attestation](#) that they have received counselling about risks/benefits from their primary provider are those: receiving stem cell therapy, CAR-T therapy, chemotherapy, immune checkpoint inhibitors, monoclonal antibodies (e.g., rituximab) and other targeted agents (e.g., CD4/6 inhibitors, PARP inhibitors)

Diabetes: [Diabetes Canada](#) “encourages people living with type 1 or type 2 diabetes to receive the COVID-19 vaccine when it is accessible and with consultation with your healthcare provider.” It notes that “adults with diabetes (type 1 and type 2) who contract COVID-19 are at greater risk of serious complications ... and almost three times more likely to die in hospital.”

Liver disease: [Toronto Centre for Liver Disease:](#) “People living with liver disease are strongly encouraged to get vaccinated against COVID-19. This includes those with hepatitis B, hepatitis C, fatty liver, PBC, PSC, AIH, cirrhosis and other chronic liver diseases as well as those waiting for liver transplant and those who have already received a liver transplant.”

Organ transplantation: “There is no reason to suspect that adverse events will be any different than in the general population” and the “potential benefits of vaccine likely outweigh theoretical risks.” ([Canadian Society of Transplantation](#)). CST also lists several recommendations for optimum vaccine efficacy.

Rheumatology: Vaccination is recommended for high-risk rheumatology patients. Specifically, the [Canadian Rheumatology Association](#) states that people older than 70 should be considered for the vaccine regardless of the underlying condition, as should those who are at high risk for more severe illness, including those who are on corticosteroids. Those younger than 70 should be considered on a case-by-case basis and patients on DMARDs “do not appear to be at higher risk for more severe illness with COVID-19.”

Re timing of treatments: Of note, there are currently no data to make a recommendation of whether DMARDs should be withheld during COVID-19 vaccination. Concerns for potential disease flare should be considered when making these decisions.

The [American Association of Allergy, Asthma and Immunology](#) notes: “Daily oral steroids may interfere with the antibody response to the vaccine” and it may be reasonable to stop the dose for two weeks if that can be done safely. “**If the steroid cannot be stopped, we would not delay administration of the vaccine** as the risks associated with COVID infection outweigh the potential impaired response.”

Inflammatory bowel disease (IBD): The [Canadian Association of Gastroenterology](#) endorses CDC guidelines for receiving the mRNA vaccines and makes its recommendations based on the “certainty of evidence”: in patients with IBD who are not on immunosuppression therapy, CAG **recommends** the vaccine be given; in patients who are on immunosuppression therapy, CAG **suggests** that vaccine be given.

[Crohn’s and Colitis Canada](#) notes that the non-live vaccines are widely recommended for immunocompromised individuals, including people with IBD on immunosuppressing medications. Its recommendation is that: “People with IBD, whether on immunosuppressive medications or not, should be offered the COVID-19 vaccine after informed consent,” and further noting, “Reduced effectiveness due to immune suppression is NOT a reason to avoid these COVID-19 vaccines.”

Multiple sclerosis (MS): The Canadian Network of MS Clinics “feels strongly that immunization should be considered in all persons with MS”. Its [guidance for people living with MS](#) also states that people with progressive MS and others with MS and a higher risk for hospitalization due to COVID-19 should consider getting the vaccine as soon as it becomes available to them.

Guillain-Barré Syndrome (GBS): GBS is not contraindicated for COVID-19 vaccination, according to the [GBS/CIDP Foundation](#). It points to the [CDC statement](#) that “persons who have previously had GBS may receive an mRNA COVID-19 vaccine.”

Bell’s Palsy: A small number of cases of Bell’s Palsy were reported in the Pfizer-BioNTech vaccine study but, as noted in this [Ottawa Public Health patient FAQ](#) and by others, a direct connection has not been established. The [CDC notes](#) also that the “Food and Drug Administration (FDA) does not consider these to be above the rate in the general population” and has not concluded these cases were caused by the vaccination. Individuals who previously had Bell’s Palsy may receive an mRNA COVID-19 vaccine.

This [Neurology Today article](#) offers a good summary of the current findings on MS, GBS and Bell’s Palsy.

ITP/Bleeding disorders: The Platelet Disorder Support Association (PDSA) notes that the occurrence of severe thrombocytopenia in a person who received the vaccine is the “first such event reported after over 5 million vaccinations”, and that it is “uncertain whether the vaccination is causal or coincidental.” In summary, PDSA says the [opinion of its medical advisors](#) is: “our patients with ITP should not be hesitant to be vaccinated based on all available information.”