Ontario College of Family Physicians

Leaders for a healthy Ontario

COVID-19 Vaccination for Special Populations
Information for family doctors

Updated April 1, 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.

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Recent updates

- Guidance from NACI (March 3) has **extended the dose interval** for two-dose vaccines to up to 16 weeks. **Exceptions** identified by Ontario's Vaccine Advisory Clinical Group (March 26) include transplant recipients (including solid organ transplants and hematopoietic stem cell transplants) and those with malignant hematologic disorders and non-hematologic malignant solid tumors receiving active treatment (chemotherapy, targeted therapies, immunotherapy. Recommendation is for such individuals to receive second doses according to **product monographs** – 21 days for Pfizer-BioNTech (Pfizer), 28 days for Moderna, and four to 12 weeks for AstraZeneca-COVISHIELD (AZ). Evaluation is continuing for pregnant women and older people.
- NACI adjusted its guidance for **AZ vaccine** (March 29) to exclude people younger than 55, based on findings of associated rare Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) in individuals who received the vaccine. Ontario is following the latest NACI recommendation.
- Updated guidance related to timing for injectable bleeding disorders, transplant patients, osteoporosis medications, allergy shots and persons with IBD are outlined in this document.

Updates in February

- Verbal attestation 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. For those that require informed consent, here is a form a vaccinator may use at time of vaccination to capture verbal attestation of counselling.
- 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 a COVID-19 vaccine.
- Individuals with symptoms of confirmed or suspected COVID-19 infection should defer vaccination until recovered. Having prolonged COVID–19 symptoms (sometimes called "Long COVID") is not a contraindication to receiving the vaccine.
- **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', later in 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 (hay-fever), 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**." This information sheet from Unity Health and this decision aid from the Provincial Council for Maternal and Child Health are useful patient tools toward shared decision-making; and CMAJ has published this values-based framework for physicians and patients. MOH recommendations highlight that mRNA vaccines are not live vaccines and not expected to be a risk to the **breastfeeding** infant.

This form may be used to capture verbal confirmation by the patient that she received counselling by a healthcare provider familiar with the pregnancy as part of informed consent to receive the vaccine.

Children and adolescents: Children under the age of 18 (Moderna and AstraZeneca) and under 16 (Pfizer-BioNTech) were not part of the original clinical trials but are being studied by Moderna and Pfizer now. 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: Ontario Health – Cancer Care Ontario states: "Everyone should receive a COVID-19 vaccine, when available, unless contraindicated" and "Although the safety of COVID-19 vaccines in cancer patients has yet to be studied, prior experience with other protein-based or inactivated vaccines have not reported unique or major side effects in immunocompromised." This graphic summarizes Cancer and COVID-19 Vaccine Eligibility. CCO's patient resource says 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. Ontario's Vaccine Clinical Advisory Group (March 26, 2021) says certain cancer patients should receive the vaccine at the dose intervals indicated in the produce monographs (versus NACI's extended interval – see Recent Updates at the top of this document).

Specific immunosuppressed patients who must be counselled, as part of informed consent, about risks and benefits by 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). This form may be used at time of vaccination to capture verbal attestation of counselling.

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," and 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: Guidance from the Canadian Society of Transplantation (CST) (March 6, 2021) includes the AZ vaccine and recommends that "vaccine may be given to the pre- and post-transplant patient population when it is available to them. … the potential benefits of vaccine outweigh any theoretical risks or concerns about immunogenicity." CST lists several recommendations for optimum vaccine efficacy. Research, noted in JAMA, indicates transplant patients "may remain at higher early risk for COVID-19 despite vaccination" and Ontario's Vaccine Clinical Advisory Group (VCAG) points to emerging evidence of "poor immune response" to mRNA vaccines, affected by type of immunotherapy and timing of the therapy in relation to vaccine administration. VCAG recommends that dosing intervals for transplant patients not be extended beyond intervals authorized in product monographs.

Rheumatology: The Canadian Rheumatology Association (CRA) suggests vaccination in "persons with autoimmune rheumatic disease" – specifying that this is a "conditional recommendation" based on

"low certainty of the evidence," and notes that "for the majority of patients the potential benefits will probably outweigh potential harms." Other CRA recommendations:

- High-risk rheumatology patients, including 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."
- 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.
- Patients on medications for osteoporosis can receive the COVID-19 vaccine. Since intravenous zoledronate (Aclasta) or injected denosumab (Prolia) or romosozumab (Evenity) medications may also result in a flu-like reaction or local injection site reaction, it is advisable that these medications are not administered at the same time as the COVID-19 vaccine, although there is no safety risk if they are given at the same time. Osteoporosis Canada guidance (March 26, 2021) recommends an interval of one week between infusion of the intravenous bisphosphonate zoledronate (Aclasta) and 4 to 7 days between an injection of denosumab (Prolia) or romosozumab (Evenity) and the COVID-19 vaccination.

The American Association of Allergy, Asthma and Immunology (AAAAI) 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."

There is no definitive guideline for **allergy injections** but most allergists advise to avoid the shots on the same day, and the AAAAI recommends a 48-hour interval between shots, so that immediate or delayed reactions to either injection can be monitored.

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*** vaccine be given.

Crohn's and Colitis Canada's latest guidance (March 31, 2021) notes that none of the vaccines approved in Canada are 'live' vaccines and refers to NACI's recommendation of shared decision-making concerning the COVID-19 vaccine for people with autoimmune or immune mediated conditions and people who are immunosuppressed. "The Crohn's and Colitis Canada COVID-19 and IBD Task Force recommends **all of these COVID-19 vaccines be administered to patients with IBD at the earliest available opportunity**." This one-page IBD info sheet summarizes key points for patients and healthcare providers.

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, Chronic Inflammatory Demyelinating Polyneuropathy and Multifocal Motor Neuropathy: Vaccination guidelines (March 15, 2021) from GBS/CIDP Foundation of Canada includes recommendation of vaccination "as soon as possible … unless a patient has developed their disease within 6 weeks of any prior 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 findings on MS, GBS and Bell's Palsy.

ITP/Bleeding disorders: Reports of vaccine-induced prothrombotic immune thrombocytopenia VIPIT), specific to AZ vaccination, prompted NACI's March 29 recommendation to suspend AZ vaccine use in people age 55 and younger. This Science Brief on VIPIT from the COVID-19 Science Advisory Table lists the symptoms for which to monitor following vaccination.

In the U.S., where the AZ vaccine is not in use, the medical advisory board of the Platelet Disorder Support Association (PDSA) has stated (Feb.12, 2021) that for people **without pre-existing thrombocytopenia/ITP**, "the benefit to risk ratio strongly favors vaccination over avoiding vaccination for fear of thrombocytopenia of all eligible adults," even for those perceived to be at low risk of serious illness from COVID-19. It says the relationship between the cases of severe thrombocytopenia and the vaccine, if any, is uncertain. For **patients with pre-existing ITP,** PDSA says "it would seem prudent" to consult with a hematologist re platelet counts, and that these patients "should not hesitate to be vaccinated based on all available information but individual patients may choose to consult with their hematologist or another physician before proceeding."

Thrombosis Canada (March 18, 2021) states that "people who have COVID-19 are at much higher risk of developing blood clots" than for VIPIT from vaccination and "strongly recommends that people receive vaccinations for COVID-19, including the vaccine made by AstraZeneca."