

Ministry of Health

# COVID-19 Vaccine – Pre-Screening Assessment Tool for Health Care Providers

Version 3.0 - February 10, 2021

#### **Highlights of changes**

- Updated format to align with the Pre-Screening Assessment in COVax.
- Inclusion of Table 1: <u>Common Conditions and Vaccine Concerns and Implications for COVID-19 Immunization</u>

This guidance provides basic information only. It is not intended to provide medical advice, diagnosis or treatment or legal advice. Immunizers should take responsibility for ensuring they have up to date knowledge using appropriate guidelines and resources such as the applicable vaccine product monographs and the Canadian Immunization Guide (Canadian Immunization Guide - Canada.ca).

Please check the Ministry of Health (MOH) <u>COVID-19 website</u> regularly for updates to this document, list of symptoms, other guidance documents, Directives and other information.

The following tool is intended for health care providers who will be administering the Pfizer-BioNTech or Moderna COVID-19 vaccine.

Under the *Health Care Consent Act, 1996* (HCCA) consent is required prior to administration of the vaccine.

A **contraindication** is a situation in which COVID-19 vaccine should not be administered because the risk outweighs any potential therapeutic benefit. Both the Pfizer-BioNTech and the Moderna COVID-19 vaccines are contraindicated in individuals with a history of anaphylaxis after previous administration of the vaccine. The COVID-19 vaccine is also contraindicated in persons with proven immediate or anaphylactic hypersensitivity to any component of the vaccine or its packaging.

All individuals administering the vaccine should be aware of the contraindications listed above and should not defer administration of the vaccines because of conditions or circumstances that are not contraindications. All efforts should be made



to immunize individuals who are willing to receive a COVID-19 vaccine in the absence of contraindications.

A **precaution** is a condition that may increase the risk of an adverse event following immunization (AEFI) or that may compromise the ability of the COVID-19 vaccine to produce immunity. In general, vaccines are deferred when a precaution is present. However, there may be circumstances when the benefits of giving the vaccine outweigh the potential harm, or when reduced vaccine immunogenicity may still result in significant benefit to a susceptible, immunocompromised host. For example, individuals with a history of severe allergic reactions (i.e., anaphylaxis) not related to vaccines, or injectable medications (e.g., food, pets, latex, environmental), should be offered the COVID-19 vaccine with an extended post-immunization observation period of 30 minutes.

Screening procedures for precautions and contraindications include, at a minimum, asking questions to elicit a history from the individual of possible adverse events following the administration of the first dose of COVID-19 vaccine and determining if any existing precautions or contraindications are present.

# **Section 1: Before Vaccine Administration**

- 1. Confirm patient information (e.g., name, date of birth, contact information).
  - a. If there is another individual who will provide consent on behalf of the patient, confirm their status (i.e., parent, legal guardian, substitute decision maker).
- 2. Confirm that patient is seeking to receive a COVID-19 vaccine.
- 3. Ask the patient "Is this your first or second dose of the vaccine?"
  - a. If this is their second dose, ask for the date of the first dose, which vaccine product they received and if any side effects were experienced after the first dose.
    - If minor side effects were experienced, the second dose of COVID-19 vaccine should be offered after the rest of the assessment is completed.
    - If symptoms of an immediate allergic reaction (this includes an allergic reaction that occurred within 4 hours after receiving the vaccine that caused hives, swelling, or respiratory distress, including wheezing as well as anaphylaxis), confirm if they have already



consulted with a health care provider (e.g., primary care provider or allergist/immunologist) on whether it is safe to receive a second dose.

If they have not been evaluated by an allergist/immunologist, vaccine administration should be deferred until they speak with their health care provider.

b. For individuals receiving their second dose, the same vaccine product (either Pfizer-BioNTech or Moderna) that was given for the first dose should be used.

**For Pfizer-BioNTech vaccine**: In order for your body to build up protection against the virus, you will need to receive TWO DOSES of this vaccine. The recommended interval for the second dose is 21 -28 days. If there is a need to extend the dose interval, it should be no more than 42 days after the first dose.

Note: Residents in long-term care, high-risk retirement and First Nations eldercare homes should receive the second dose of vaccine on schedule. The dosing schedule should be maintained at 21-27 days.

**For Moderna vaccine:** In order for your body to build up protection against the virus, you will need to receive TWO DOSES of this vaccine. The second dose should be given 28 days after the first dose.

You may experience some mild side effects in the day or two after receiving the vaccine. Common side effects can include pain, redness and swelling where the needle was given, tiredness, headache, muscle pain, joint pain, chills, mild fever, and/or swollen glands. These side effects often get better on their own within several days after immunization. As with medications and other vaccines, allergic reactions are rare, but can occur after. You cannot get COVID-19 from the vaccine.



# Section 2: Assessment for Conditions or Concerns prior to Vaccine Administration

Table 1 on <u>Common Conditions and Vaccine Concerns and Implications for COVID-19 Immunization</u> provides additional information related to the questions below. If required, more information can also be found in the <u>COVID-19 Vaccination</u> <u>Recommendations for Special Populations</u> guidance.

I need to ask you a few questions about your medical history to see if you can receive the COVID-19 vaccine today.

#### 1. Do you have symptoms of COVID-19 or feel ill today?

**If yes**: Immunization should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with symptoms of COVID-19. They should be referred for COVID-19 testing.

Residents of long-term care, retirement or First Nations elder care homes that are currently in self-isolation and if their symptoms are resolving, can be immunized on site under Droplet and Contact Precautions. Residents who are asymptomatic cases or self-isolating after admission to the home, can be immunized on site if at least 72 hours has passed since their specimen collection to decrease the likelihood that they are not pre-symptomatic cases.



2. Have you previously had a severe allergic reaction (i.e., anaphylaxis) to a previous dose of a COVID-19 mRNA vaccine or to any of its ingredients or its container?

**If yes**: This is an absolute contraindication and these individuals should not receive the COVID-19 vaccine.

Ingredients		Pfizer-BioNTech Vaccine	Moderna Vaccine
Medical	mRNA	• mRNA	• mRNA
Non-	Lipids	<ul> <li>ALC-031</li> <li>ALC-0159 - a polyethylene glycol (PEG)</li> <li>1,2-Distearoyl-sn- glycero-3- phosphocholine (DSPC)</li> <li>Cholesterol</li> </ul>	<ul> <li>1,2-distearoyl-sn- glycero-3- phosphocholine (DSPC)</li> <li>Cholesterol</li> <li>PEG2000 DMG SM-102</li> </ul>
medical	Salts	<ul> <li>Dibasic sodium phosphate dihydrate</li> <li>Monobasic potassium phosphate</li> <li>Potassium chloride</li> <li>Sodium chloride</li> </ul>	<ul><li>Acetic acid</li><li>Sodium acetate</li><li>Tromethamine</li><li>Tromethamine hydrochloride</li></ul>
	Sugar	• Sucrose	• Sucrose
		Water for injection	Water for injection

3. Do you have a suspected hypersensitivity, or have you had an immediate allergic reaction (within 4 hours) to any ingredients in the COVID-19 vaccine?

**If yes**: Precaution should be taken and these individuals should not receive the COVID-19 vaccine, unless they have been evaluated by an allergist/immunologist before getting the vaccine. Documentation of a discussion with the health care provider to be provided at the clinic.



4. Have you ever had a severe (e.g., anaphylaxis) or other immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbates)?

If yes to severe allergic reaction: Precaution should be taken and these individuals should not receive the COVID-19 vaccine, unless they have been evaluated by a heath care provider (e.g., primary care provider or allergist/immunologist) before getting the vaccine. Documentation of a discussion with the health care provider to be provided at the clinic.

**If yes to immediate allergic reaction:** Precaution should be taken as the risk of developing a severe allergic reaction is unknown and should be balanced against the benefits of immunization. Documentation of a discussion with the health care provider to be provided at the clinic.

5. Have you ever had a severe allergic reaction (i.e. anaphylaxis) not related to vaccines or injectable medications- such as food, pets, venom, the environment, latex, etc.?

**If yes**: These individuals should be offered a COVID-19 vaccine. Post-immunization observation period should be extended to 30 minutes.

6. Have you received any other vaccines (not a COVID-19 vaccine) in the past 14 days?

**If yes**: COVID-19 vaccine administration should be deferred if another vaccine was received in the past 14 days. The COVID-19 vaccine should not be administered with other vaccines.



#### 7. Are you or could you be pregnant?

**If yes**: COVID-19 vaccine should be offered at anytime if they are eligible and no contraindications exist.

#### 8. Are you currently breastfeeding?

**If yes**: COVID-19 vaccine should be offered at anytime if they are eligible and no contraindications exist.

9. Do you have any problems with your immune system or are you taking any medications that can affect your immune system (e.g., high dose steroids, chemotherapy, etc.)?

**If yes**: This is a precaution and these individuals should have a thorough risk/benefit discussion with their health care provider prior to getting immunized.

If you are unsure of the therapies or medications you are taking, you should consult with their treating health care provider prior to getting immunized.

#### 10. Do you have an autoimmune disease?

**If yes**: This is a precaution and these individuals should have a thorough risk/benefit discussion with their health care provider prior to getting immunized.

If you are unsure of the therapies or medications you are taking, you should consult with your treating health care provider prior to getting immunized.

11. Do you have a bleeding disorder or are you taking medications that could affect blood clotting (e.g., blood thinners)?

**If yes and have a bleeding disorder**: In individuals with bleeding disorders, the condition should be optimally managed prior to immunization to minimize the risk of bleeding. COVID-19 vaccine should be offered.

If yes and on anticoagulant therapy: COVID-19 vaccine should be offered.



# 12. Have you ever felt faint or fainted after receiving a vaccine or medical procedure?

**If yes**: COVID-19 vaccine should be offered. Post-immunization observation period could be extended to 30 minutes.

# 13. Do you have any questions?



#### Table 1: Common Conditions and Vaccine Concerns and Implications for COVID-19 Immunization

Individuals who are unsure of the therapies or medication they are taking, should consult with their treating health care provider prior to getting immunized.

Condition or	Concern	Implication	Comments	Documentation to be presented at clinic
covid-19 symptoms or acute illness			Immunization should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with symptoms of COVID-19. They should be referred for COVID-19 testing.¹  Immunization should be delayed until all symptoms of acute illness have completely resolved in order to avoid attributing any complications resulting from infection with SARS-CoV-2 to vaccine-related AEFI and to minimize the risk of COVID-19 transmission at an immunization clinic/venue.¹	N/A

<sup>&</sup>lt;sup>1</sup> The National Advisory Committee on Immunization (NACI) <u>Statement on the Recommendations on the use of COVID-19 Vaccines</u>



Condition	or Concern	Implication	Comments	Documentation to be presented at clinic
immediate allergic reaction	Anaphylaxis to a previous dose of COVID-19 vaccine or any of its ingredients or its container		These individuals should not receive the COVID-19 vaccine.¹ Referral to an allergist/immunologist may be considered.	N/A



Condition or Concern		Implication	Comments	Documentation to be presented at clinic
Anaphylactic or immediate allergic reaction	Immediate reaction to a previous dose of COVID-19 vaccine or any of its ingredients or its container	Precaution	These individuals should not receive the COVID-19 vaccine, unless they have been evaluated by an allergist/immunologist before getting the vaccine so that a thorough risk/benefit discussion can take place, and where necessary, a collaborative plan for immunization is established (e.g., under observation, or in a setting with advance medical care available).  Polyethylene glycol (PEG) is a non-medical ingredient that is in the vaccines.  PEG rarely causes allergic reactions and is found in products such as medications, bowel preparation products for colonoscopy, laxatives, cough syrups, cosmetics, skin creams, medical products used on the skin and during operations, toothpaste, contact lenses and contact lens solution. PEG can also be found in foods and drinks but is not known to cause allergic reactions from food or drinks.  Consultation with an allergist/ immunologist is advised.	Patient needs to provide documentation from health care provider.  Documentation should include an immunization care plan and indicate what type of parameters the clinic should meet to provide safe vaccine administration (e.g., availability of advanced medical care).



Condition or	Concern	Implication	Comments	Documentation to be presented at clinic
Anaphylactic or immediate allergic reaction	Polysorbate	Precaution	indicated due to the potential cross-reactive hypersensitivity with PEG.  Consultation with an allergist/immunologist is advised.	Patient needs to provide documentation from health care provider.  Documentation should include an immunization care plan and indicate what type of parameters the clinic should meet to provide safe vaccine administration (e.g., availability of advanced medical care).



Condition or Concern		Implication	Comments	Documentation to be presented at clinic
Anaphylactic or immediate allergic reaction	To any other vaccine or injectable therapy (i.e., intramuscular, intravenous or subcutaneous vaccines or therapies)	Precaution	These individuals should not receive the COVID-19 vaccine, unless they have been evaluated by a health care provider before getting the vaccine so that a thorough risk/benefit discussion can take place, and where necessary, a collaborative plan for immunization is established (e.g., under observation, or in a setting with advance medical care available).	Patient needs to provide documentation from health care provider.  Documentation should include an immunization care plan and indicate what type of parameters the clinic should meet to provide safe vaccine administration (e.g., availability of advanced medical care).
Anaphylactic or immediate allergic reaction	Known allergies to food, pets, venom, the environment, latex, etc.	Safe	These individuals should be offered a COVID-19 vaccine.  Post-immunization observation period should be extended to 30 minutes.	N/A



Condition or	Concern	Implication	Comments	Documentation to be presented at clinic
Non-anaphylactic allergies	Known allergies to COVID-19 vaccine ingredients	Precaution	Polyethylene glycol (PEG) is a non-medical ingredient that is in the vaccines.  PEG rarely causes allergic reactions and is found in products such as medications, bowel preparation products for colonoscopy, laxatives, cough syrups, cosmetics, skin creams, medical products used on the skin and during operations, toothpaste, contact lenses and contact lens solution. PEG can also be found in foods and drinks but is not known to cause allergic reactions from food or drinks.  Consultation with an allergist/ immunologist is advised.	Patient needs to provide documentation from health care provider.  Documentation should include an immunization care plan and indicate what type of parameters the clinic should meet to provide safe vaccine administration (e.g., availability of advanced medical care).



Condition or Concern		Implication	Comments	Documentation to be presented at clinic
Non-anaphylactic allergies	Polysorbate	Precaution	If suspected hypersensitivity or non- anaphylactic allergy to polysorbate, investigation is indicated due to the potential cross-reactive hypersensitivity with PEG.	Patient needs to provide documentation from health care provider.
			Consultation with an allergist/immunologist is advised.	Documentation should include an immunization care plan and indicate what type of parameters the clinic should meet to provide safe vaccine administration (e.g., availability of advanced medical care).
Non-anaphylactic allergies	Known allergies to food, pets, venom, the environment, latex, etc.	Safe	These individuals should be offered a COVID-19 vaccine.  Post-immunization observation period should be extended to 30 minutes.	N/A



Condition or	Concern	Implication	Comments	Documentation to be presented at clinic
Pregnancy		Safe	COVID-19 vaccine may be offered to pregnant individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and if informed consent includes discussion about the insufficiency of evidence on the use of COVID-19 vaccine in this population. <sup>1</sup>	Attestation needed at clinic
Breastfeeding		Safe	COVID-19 vaccine may be offered to individuals in the authorized age group who are breastfeeding, if a risk assessment deems that the benefits outweigh the potential risks for the individual and the infant, and if informed consent includes discussion about the insufficiency of evidence on the use of COVID-19 vaccine in this population. <sup>1</sup>	N/A



Condition or	Concern	Implication	Comments	Documentation to be presented at clinic
Autoimmune conditions		Precaution	COVID-19 vaccine may be offered to individuals with an autoimmune condition in the authorized age group after:  • Receiving counselling by their treating provider and if a risk assessment deems that the benefits outweigh the potential risks for the individual, and • If informed consent includes discussion about the insufficiency of evidence on the use of COVID-19 vaccine in this population. <sup>1</sup>	N/A



Condition or	Concern	Implication	Comments	Documentation to be presented at clinic
Immunosuppressed due to disease or treatment	CAR-T therapy, chemotherapy, immune checkpoint inhibitors, monoclonal antibodies, other targeted agents (e.g., CD4/6 inhibitors, PARP inhibitors, etc.), stem cell transplant		COVID-19 vaccine may be offered to individuals who are immunosuppressed due to disease or treatment in the authorized age group after:  • Receiving counselling by their treating provider, and  • If a risk assessment deems that the benefits outweigh the potential risks for the individuals, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population.¹	Attestation needed at clinic



Condition o	· Concern	Implication	Comments	Documentation to be presented at clinic
Immunosuppressed due to disease or treatment	Organ Transplant	Precaution	COVID-19 vaccine may be offered to transplant recipients who are immunosuppressed due to disease or treatment in the authorized age group after:  • Receiving counselling by their treating provider, and  • If a risk assessment deems that the benefits outweigh the potential risks for the individuals, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population. <sup>2</sup> These individuals may choose to receive the vaccine after counselling by their treating provider.	N/A

<sup>&</sup>lt;sup>2</sup> Canadian Society of Transplantation <u>National Transplant Consensus Guidance on COVID-19 Vaccine</u>



Condition or	Concern	Implication	Comments	Documentation to be presented at clinic
Immunosuppressed due to disease or treatment	Rheumatic Disease	Precaution	COVID-19 vaccine may be offered to individuals who are immunosuppressed due to rheumatic disease or treatment in the authorized age group after:  • Receiving counselling by their treating provider, and  • If a risk assessment deems that the benefits outweigh the potential risks for the individuals, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population. <sup>3</sup> These individuals may choose to receive the vaccine after counselling by their treating provider.	N/A
Immunocompetent	Stable infection (e.g., HIV)	Safe	People living with HIV that are considered immunocompetent may be vaccinated. <sup>1</sup>	N/A

<sup>3</sup> Canadian Rheumatology Association <u>Canadian Rheumatology Association Position Statement on COVID-19 Vaccination</u>



Condition or Concern		Implication	Comments	Documentation to be presented at clinic
Bleeding Disorder		Precaution	In individuals with bleeding disorders, the condition should be optimally managed prior to immunization to minimize the risk of bleeding. <sup>1</sup>	N/A
			The vaccine should be administered through the intramuscular (IM) route with a small gauge needle and apply firm and prolonged pressure to the injection site for approximately 5 minutes.	
Concurrent medication, including biologics	Antibiotic therapy	Safe	COVID-19 vaccine should be offered if they are eligible and no contraindications exist.	N/A



Condition or Concern		Implication	Comments	Documentation to be presented at clinic
Concurrent medication, including biologics	Anticoagulation	Safe	Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy. <sup>1</sup> The vaccine should be administered through the intramuscular (IM) route with a small gauge needle and apply firm and prolonged pressure to the injection site for approximately 5 minutes.	N/A
	Antiviral therapy	Safe	COVID-19 vaccine should be offered if they are eligible and no contraindications exist.	N/A
	Other vaccine(s)	Deferral	COVID-19 vaccine administration should be deferred if another vaccine was received in the past 14 days. The COVID-19 vaccine should not be administered with other vaccines. <sup>1</sup>	N/A



Condition or	Concern	Implication	Comments	Documentation to be presented at clinic
Neurologic disorders	History of syncopal episodes (fainting)	Safe	If the individual is anxious about getting immunized, offer reassurance and encourage them to breathe slowly and deeply, or provide a distraction such as asking them to count to ten. They can also be immunized lying down, remaining seated in immunization clinic setting, and being accompanied when leaving clinic.  Post-immunization observation period could be extended to 30 minutes.	N/A

#### **Additional Resources:**

Canadian Association of Gastroenterology: <a href="https://www.cag-acg.org/images/publications/CAG-COVID-19-Vaccines-in-IBD-Patients.pdf">https://www.cag-acg.org/images/publications/CAG-COVID-19-Vaccines-in-IBD-Patients.pdf</a>

The Society of Obstetricians and Gynaecologists of Canada (SOGC):

 $\underline{https://sogc.org/common/Uploaded\%20 files/Latest\%20 News/SOGC\_Statement\_COVID-19\_Vaccination\_in\_Pregnancy.pdf}$ 

Thrombosis Canada: <a href="https://thrombosiscanada.ca/wp-uploads/uploads/2020/12/National-Release-VACCINES-Final-Dec-22.pdf">https://thrombosiscanada.ca/wp-uploads/uploads/2020/12/National-Release-VACCINES-Final-Dec-22.pdf</a>



## **Section 3: After Vaccine Administration**

Please **wait for 15 minutes** after receiving your vaccine. If you feel unwell while waiting, please let one of the clinic staff know. Longer waiting times of 30 minutes may be recommended if there is a concern about a possible vaccine allergy or if you have previously fainted after having a vaccine administered.

While waiting inside the clinic, please keep your mask on (unless you are unable to wear a mask due to a medical condition) and continue to practice physical distancing (2 meters) from others.

You may experience some mild side effects that are common after receiving a vaccine in the day or two after receiving the vaccine. These usually go away on their own. You can take pain or fever medication, such as acetaminophen (Tylenol) or ibuprofen (Advil or Motrin), or apply a cool damp cloth where the vaccine was given. If you have any questions or concerns, please contact your health care provider.

Keep the Vaccine Information Sheet and immunization records in a safe place.

It is very important that, even after you receive the vaccine, you continue to follow the recommendations of local public health officials to prevent the spread of COVID-19. This includes wearing a mask, staying at least 2 metres from others and limiting/avoiding contact with others outside your immediate household. While we are confident that the vaccine reduces your risk of becoming sick with COVID-19, it does not eliminate your risk. In addition, we do not know yet if it stops transmission. In other words, you may carry the virus and not get sick, but still be able to pass it on to others.

### If this is the patient's first dose:

Make an appointment now to ensure you receive the second vaccine dose at the right time. You need 2 doses, spaced properly apart for the best protection.

When you return for your second dose of the vaccine, tell your health care provider if you develop any side effects after today.