

Ministry of Health

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

Version 4.0 - March 11, 2021

### **Highlights of changes**

- Updated to align with the Pre-Screening Assessment in COVax.
- Updated to include the AstraZeneca and COVISHIELD vaccines.

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 on COVID-19 vaccines 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, Moderna, AstraZeneca or COVISHIELD COVID-19 vaccines.

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

A **contraindication** is a situation in which COVID-19 vaccine should not be routinely administered because the risk outweighs any potential therapeutic benefit. The Pfizer-BioNTech, Moderna, AstraZeneca and COVISHIELD COVID-19 vaccines are contraindicated in individuals with a history of anaphylaxis after the administration of a previous dose of the vaccine using a similar platform (mRNA or viral vector).

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. COVID-19 vaccine may be administered to individuals with a precaution. 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.

Screening procedures prior to vaccine administration should 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 client information (e.g., name, date of birth, contact information).
  - If there is another individual (substitute decision maker) who will provide consent on behalf of the client, confirm their status (i.e., parent, legal guardian, other substitute decision maker as specified in the <u>Health Care Consent Act</u>).
  - Confirm that the client is in the authorized age group and priority group (see Ontario's COVID-19 Vaccine Distribution Plan) to receive the vaccine.
- 2. Confirm that client is seeking to receive a COVID-19 vaccine.
- **3.** If the client is receiving **AstraZeneca and COVISHIELD vaccine** are they aware of the performance of this vaccine? Clients should consider:
  - · Vaccine trial information, including:
    - 1. Overall, vaccine effectiveness is lower than the other two approved products (76% as compared to 92% and 93% respectively), but still performs well.
    - 2. There is insufficient evidence of efficiency in adults over 65 years of age to make strong conclusions at this time.
    - 3. It has been shown to effectively prevent hospitalization for COVID-19, including in serious illness.
  - All approved vaccines are safe.



- The benefit of receiving the vaccine now, as opposed to in the future.
- **4.** Ask the client if this is their **first or second dose** of the vaccine?
  - If this is their second dose, ask for the date of the first dose, which vaccine product they received and if they experienced any side effects.
    - If minor side effects were experienced, the second dose of COVID-19 vaccine should be offered after the pre-screening assessment is completed.
    - If the client experienced a serious allergic reaction or a reaction within 4 hours to the COVID-19 vaccine), ask the client if they have 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, it is recommended that vaccine administration be deferred until they speak with their health care provider.
  - For individuals receiving their second dose, the same vaccine product (either Pfizer-BioNTech, Moderna, AstraZeneca or COVIDSHIELD) that was given for the first dose should be used.

For the Pfizer-BioNTech, Moderna, AstraZeneca and COVISHIELD vaccines: 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 4 months after the first dose.

Note: The following groups should continue to receive vaccine at the initial intervals as described in the product monographs as these groups are at highest risk from COVID-19:

- Remote and isolated First Nation communities (being supported by Operation Remote Immunity);
- Residents of long-term care homes, high-risk retirement homes, First Nation Elder Lodges and Assisted Living Facilities.

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 other vaccines, allergic reactions are rare, but can occur. 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 will ask a few questions, to make sure this COVID-19 vaccine is safe for you.

1. Have you been sick in the past few days? Do you have symptoms of COVID-19 or have a fever 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 had a serious allergic reaction or a reaction within 4 hours to the COVID-19 vaccine before?

If yes: Contraindication.

These individuals should not routinely receive the COVID-19 vaccine, unless they have been evaluated by an allergist/immunologist before getting the vaccine.

Documentation of a discussion with the allergist/immunologist to be provided at the clinic.



Ingred	lients	Pfizer-BioNTech Vaccine	Moderna Vaccine	AstraZeneca and COVISHIELD Vaccines
Medical	mRNA	• mRNA	• mRNA	Non-replicating viral vector (ChAd)
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>	<ul> <li>Disodium edetate dihydrate (EDTA)</li> <li>Ethanol</li> <li>L-Histidine</li> <li>L-Histidine hydrochloride monohydrate</li> <li>Polysorbate 80</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>	<ul><li>Magnesium chloride hexahydrate</li><li>Sodium chloride</li></ul>
	Sugar	• Sucrose	Sucrose	Sucrose
		Water for injection	Water for injection	Water for injection



## 3. Do you have allergies to polyethylene glycol, tromethamine (Moderna only) or polysorbate?

If yes: Precaution.

These individuals should not routinely receive the COVID-19 vaccine, unless they have been evaluated by an allergist/immunologist before getting the vaccine.

Documentation of a discussion with the allergist/immunologist to be provided at the clinic.

## 4. Have you had a serious allergic reaction to a vaccine or medication given by an injection (e.g., IV, IM), needing medical care?

If yes: Precaution.

Post-immunization observation period should be extended to a minimum of 30 minutes.

### 5. Have you received a 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.

### 6. Are you or could you be pregnant or breastfeeding?

If yes: Precaution.

Currently there is limited vaccine data for this population.

COVID-19 vaccine may be offered to these individuals in the authorized age group if no contraindications exist.

Pregnant individuals should have a thorough risk/benefit discussion with their treating health care provider prior to getting immunized. Verbal confirmation that this counselling was received should be provided prior to immunization.



# 7. Do you have a weakened immune system or are you taking any medications that can weaken your immune system (e.g., high dose steroids, chemotherapy)?

If yes: Precaution.

Currently there is limited vaccine data for this population.

Individuals on specific therapies should have a thorough risk/benefit discussion with their treating health care provider prior to getting immunized.

Verbal confirmation that this counselling was received should be provided prior to immunization for individuals receiving stem cell therapy, CAR-T therapy, chemotherapy, immune checkpoint inhibitors, monoclonal antibodies and other targeted agents.

### 8. Do you have an autoimmune condition?

If yes: Precaution.

Currently there is limited vaccine data for this population.

Individuals on specific therapies should have a thorough risk/benefit discussion with their treating health care provider prior to getting immunized.

## 9. Do you have a bleeding disorder or are you taking blood thinning medications?

**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.

## 10. 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 a minimum of 30 minutes.

### 11. 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.

For certain conditions or concerns, there is limited vaccine data currently available on the safety and efficacy of vaccine administration. These are indicated with an asterisk (\*) below.

Additional information on common conditions and concerns may be found in the references included below.



Condition or Conce	Implication for COVID-19 Vaccine Administration	Comments	Documentation to be presented at clinic
covid-19 symptoms or acute illness	Deferral	Immunization should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with respiratory symptoms. 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>1</sup> The National Advisory Committee on Immunization (NACI) <u>Statement on the Recommendations on the use of COVID-19 Vaccines</u>



Condition o	r Concern	Implication for COVID-19 Vaccine Administration	Comments	Documentation to be presented at clinic
Allergic reaction	Serious allergic reaction (e.g., anaphylaxis) or a reaction within 4 hours to a previous dose of COVID-19 vaccine	Contraindication	<ul> <li>The COVID-19 vaccine should not be offered routinely to individuals who:</li> <li>Have a history of severe allergic reaction after previous administration of a COVID-19 vaccine using a similar platform (mRNA or viral vector), or</li> <li>Are allergic to any component of the specific COVID-19 vaccine or its container.</li> <li>If a risk assessment deems that the benefits outweigh the risks for the individual and if informed consent is provided, an authorized COVID-19 vaccine using a different platform may be considered for re-immunization.</li> <li>Referral to an allergist/ immunologist is recommended.</li> </ul>	Client 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 o	r Concern	Implication for COVID-19 Vaccine Administration	Comments	Documentation to be presented at clinic
Allergic reaction	Mild to moderate allergic reaction after receiving a previous dose of COVID-19 vaccine	Precaution	<ul> <li>Immunization may be considered if:</li> <li>A risk assessment deems that the benefits outweigh the potential risks for the individual; and</li> <li>Informed consent is provided.</li> <li>These individuals should be evaluated by an allergist/immunologist before getting the vaccine, where a collaborative plan for immunization is established (e.g., under observation, or in a setting with advance medical care available).</li> </ul>	Client 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 for COVID-19 Vaccine Administration	Comments	Documentation to be presented at clinic
Allergic reaction	Allergies to polyethylene glycol (PEG), tromethamine or polysorbate	Precaution	If an individual has a known allergy or anaphylaxis to either PEG, tromethamine or polysorbate, they should be seen by an allergist/immunologist before getting either an mRNA or the AstraZeneca or COVISHIELD vaccines.	Client 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).



<b>Condition o</b>	Condition or Concern		Comments	Documentation to be presented at clinic
Allergic reaction	Proven serious allergic reaction to a vaccine or medication given by injection (e.g., IV, IM)	Precaution	These individuals should be offered a COVID-19 vaccine.  They should be observed for a minimum of 30 minutes after receiving their vaccine.	N/A
Allergic reaction	Known allergies to food, oral drugs, insect venom, environmental allergens, etc. or allergic rhinitis, asthma or eczema.	Safe	These individuals should be offered a COVID-19 vaccine.  They should be observed for a minimum of 15 minutes after receiving their vaccine.	N/A



Condition o	r Concern	Implication for COVID-19 Vaccine Administration	Comments	Documentation to be presented at clinic
Pregnancy*		Precaution	It is recommended that these individuals speak with their treating health care provider before receiving the vaccine.	N/A
			Verbal confirmation that this counselling was received should be provided prior to immunization.	
			COVID-19 vaccine may be offered to these individuals in the authorized age group if:	
			<ul> <li>A risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and</li> <li>Informed consent includes discussion about the insufficiency of evidence on the use of COVID-19 vaccine in this population.<sup>1</sup></li> </ul>	



Condition or Concern	Implication for COVID-19 Vaccine Administration	Comments	Documentation to be presented at clinic
Breastfeeding*	Precaution	<ul> <li>COVID-19 vaccine may be offered to these individuals in the authorized age group if:</li> <li>A risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and</li> <li>Informed consent includes discussion about the insufficiency of evidence on the use of COVID-19 vaccine in this population.<sup>1</sup></li> </ul>	N/A
Autoimmune conditions	Precaution	<ul> <li>COVID-19 vaccine may be offered to individuals with an autoimmune condition in the authorized age group if:         <ul> <li>A risk assessment deems that the benefits outweigh the potential risks for the individual, and</li> <li>Informed consent includes discussion about the insufficiency of evidence on the use of COVID-19 vaccines in these populations.<sup>1</sup></li> </ul> </li> </ul>	N/A



<b>Condition o</b>	r Concern	Implication for COVID-19 Vaccine Administration	Comments	Documentation to be presented at clinic
Immuno- suppressed 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	Precaution	It is recommended that these individuals speak with their treating health care provider before receiving the vaccine.  Verbal confirmation that this counselling was received should be provided prior to immunization.  COVID-19 vaccine may be offered to individuals who are immunosuppressed due to disease or treatment in the authorized age group if:  • A risk assessment with their treating health care provider determines that the benefits outweigh the potential risks for the individual, and  • Informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccines in this population and the possibility that individuals who are immunosuppressed may have a diminished immune response to any of the COVID-19 vaccines.¹	N/A



Condition o	r Concern	Implication for COVID-19 Vaccine Administration	Comments	Documentation to be presented at clinic
Immuno- suppressed due to disease or treatment	Organ Transplant	Precaution	<ul> <li>COVID-19 vaccine may be offered to transplant recipients who are immunosuppressed due to disease or treatment in the authorized age group if:         <ul> <li>A risk assessment deems that the benefits outweigh the potential risks for the individual, and</li> <li>Informed consent includes discussion about the insufficiency of evidence on the use of COVID-19 vaccines in these populations.<sup>2</sup></li> </ul> </li> </ul>	N/A

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



Condition o	r Concern	Implication for COVID-19 Vaccine Administration	Comments	Documentation to be presented at clinic
Immuno- suppressed due to disease or treatment	Rheumatic Disease*	Precaution	<ul> <li>COVID-19 vaccine may be offered to individuals who are immunosuppressed due to rheumatic disease or treatment in the authorized age group if:         <ul> <li>A risk assessment deems that the benefits outweigh the potential risks for the individual, and</li> <li>Informed consent includes discussion about the insufficiency of evidence on the use of COVID-19 vaccines in these populations.<sup>3</sup></li> </ul> </li> </ul>	N/A

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



Condition o	r Concern	Implication for COVID-19 Vaccine Administration	Comments	Documentation to be presented at clinic
Immuno- suppressed due to disease or treatment		Precaution	<ul> <li>COVID-19 vaccine may be offered to individuals who are immunosuppressed due to disease or treatment (and do not fall into other categories listed above) in the authorized age group if:         <ul> <li>A risk assessment with their treating provider determines that the benefits outweigh the potential risks for the individual, and</li> <li>Informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccines in this population and the possibility that individuals who are immunosuppressed may have a diminished immune response to any of the COVID-19 vaccines.¹</li> </ul> </li> </ul>	N/A
	Immuno- competent Stable infection (e.g., HIV)	Safe	People living with HIV that are considered immunocompetent may be offered the vaccine. <sup>1</sup>	N/A



Condition or Concern		Implication for COVID-19 Vaccine Administration	Comments	Documentation to be presented at clinic
Bleeding Disorder		Precaution	In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding. <sup>1</sup> The vaccine should be administered through the IM route with a small gauge	N/A
			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 for COVID-19 Vaccine Administration	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 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 for COVID-19 Vaccine Administration	Comments	Documentation to be presented at clinic
Concurrent medication, including biologics	Tuberculin skin testing (TST) or Interferon Gamma Release Assay (IGRA)	Deferral	There is a theoretical risk that mRNA or viral vector vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. If tuberculin skin testing or an IGRA test is required, it should be administered and read before immunization or delayed for at least 4 weeks after vaccination. Immunization with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing have been completed. <sup>1</sup>	N/A



Condition or Concern		Implication for COVID-19 Vaccine Administration	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 are concerned about any reactions you experience after receiving the vaccine, contact your healthcare provider. You can also contact your local public health unit to ask questions or report an adverse reaction.

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 any legal requirement specified in the *Reopening Ontario Act*, the recommendations of the Chief Medical Officer of Health and 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 client'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.