

Responding to concerns about the AstraZeneca COVID-19 vaccine

This document outlines key messages that you can use to respond to concerns raised by patients related to the safety of the AstraZeneca vaccine.

A key principle to effectively build vaccine confidence is to address the individual's concerns directly with facts and without introducing new concerns. For more information on how to effectively address vaccine hesitancy, refer to the [OMA's vaccine hesitancy toolkit](#) and [CEP's PrOTCT Framework](#).

Top-line key messages to share with patients:

See expanded details for physicians below

The best vaccine is the one that is available to you right now.

and

In response to patient concerns about efficacy of AstraZeneca COVID-19:

1. The clinical trials demonstrated the AstraZeneca vaccine is 100% effective at preventing severe disease, hospitalization and death
2. Studies have shown the AstraZeneca vaccine provides protection with just one dose
3. The AstraZeneca vaccine will help protect you during what is right now a very dangerous time in Ontario

In response to patient concerns about risk of blood clots:

1. Blood clots as a complication to the AstraZeneca vaccine are extremely rare
2. If they do happen, these blood clots are treatable and we know what to look for now
3. *If patient is concerned about a history of clots:* People with a history of blood clots are not at higher risk for blood clots from AstraZeneca (it's a different kind of clot)

In response to patient concerns about the changing guidance:

1. Scientific recommendations change to reflect new, emerging real-world evidence
2. Health Canada approved the use of the AstraZeneca vaccine for 18+

Tip: Telling personal stories about how you recommended the AstraZeneca vaccine to your family members or those close to you can also help to build vaccine confidence.

In response to patient concerns about efficacy of AstraZeneca COVID-19

Key messages and supporting evidence:

1. The clinical trials demonstrated the AstraZeneca vaccine is 100% effective at preventing severe disease, hospitalization and death
 - The clinical trials (with over 11,000 people) showed that with two doses it was close to 100% effective against severe disease, hospitalization and death, which is as effective as Pfizer and Moderna ([AstraZeneca product monograph](#); [Pfizer trial results](#); [Moderna trial results](#))

2. Studies have shown the AstraZeneca vaccine provides protection with just one dose
 - [Pooled analyses from four randomized trials](#) found a single dose of the AstraZeneca vaccine was 76% effective against primary symptomatic COVID-19 from day 22 to 90 post-vaccination
 - Refer to page 5 of the [MOH: Administration of AstraZeneca COVID-19 vaccine/COVISHIELD vaccine](#) for a summary of vaccine efficacies after the first and second doses

Note that both doses are required to maximize efficacy.

3. The AstraZeneca vaccine will help protect you during what is right now a very dangerous time in Ontario
 - Check the [OMA: Ontario COVID-19 Data Interactive Dashboard](#) for the latest COVID-19 case numbers, hospitalizations and deaths in Ontario and [PHO: Daily Epidemiological Summary](#) for current information on variants of concern case counts
 - B.1.1.7, the variant that originated in the UK, is now the predominant strain in Ontario. Emerging evidence suggests that the B.1.1.7 variant may be more transmissible (e.g. [NEJM, March 16, 2021](#); [The Lancet, April 12, 2021](#)) and increase the risk of mortality (e.g. [BMJ, January 26, 2021](#); [BMJ, March 10, 2021](#))
 - AstraZeneca vaccine works well against the B.1.1.7 variant that originated in the UK ([The Lancet, April 10, 2021](#))
 - Vaccines, including the AstraZeneca vaccine, along with public health measures in the UK have helped to [dramatically reduce COVID-19 case counts](#)

In response to patient concerns about risk of blood clots

Note the evidence in this area is changing rapidly. Ontario's Science Table is monitoring the situation and will update their Science Briefs as needed.

Key messages and supporting evidence:

1. Blood clots as a complication to the AstraZeneca vaccine are extremely rare
 - The AstraZeneca vaccine appears to be associated with autoimmune thrombosis that mimics heparin-induced thrombocytopenia
 - Cerebral sinus vein thrombosis (CSVT) and thrombocytopenia that occurs 4-28 days following AstraZeneca vaccination has been named vaccine-induced prothrombotic immune thrombocytopenia (VIPIT) or vaccine-induced immune thrombotic thrombocytopenia (VITT)
 - The Ontario Science Table notes the incidence of VIPIT appears to be 1/125,000 based on current evolving real-world data; there is greater risk of blood clots from birth control pills or flying than from the AstraZeneca vaccine
 - To learn more about VIPIT, read the [Ontario Science Table's brief](#) (access the version for [primary care physicians](#) and [lay summary](#))
 - The risk of blood clots if an individual contracts COVID-19 is high, with 30-70% of ICU patients developing blood clots in the deep veins of their legs or in the lungs

2. If they do happen, these blood clots are treatable and we know what to look for now
 - The arterial and/or venous blood clots of VIPIT (including CSVT) seem to occur 4 to 28 days after vaccination
 - Patients who receive the AstraZeneca vaccine should self-monitor for symptoms of VIPIT for 28 days after receiving the vaccine and seek immediate medical attention if they experience any symptoms (NOTE: if vaccinating patients, provide them with a copy of the [MOH: After Your COVID-19 Vaccine](#) handout)
 - Symptoms of VIPIT:
 - Persistent and severe headache, focal neurological symptoms, seizures, or blurred or double vision (suggesting CSVT or arterial stroke)
 - Shortness of breath or chest pain (suggesting pulmonary embolism or acute coronary syndrome)
 - Abdominal pain (suggesting portal vein thrombosis)
 - Limb swelling, redness, pallor or coldness (suggesting deep vein thrombosis or acute limb ischemia)
 - For information on diagnosing, treating and reporting VIPIT events, refer to the [Ontario Science's Table's brief](#)

3. *If patient is concerned about a history of clots:* People with a history of blood clots are not at higher risk for blood clots from AstraZeneca (it's a different kind of clot)
 - According to Ontario's Science Table, since VIPIT is immune-mediated, individuals with a history of arterial or venous clots would likely not be at an increased risk of VIPIT
 - [Thrombosis Canada](#) released a statement on April 2, 2021 that strongly recommends the AstraZeneca vaccine for all eligible adults, including people with a prior blood clot, those with blood clotting tendency (e.g. factor V Leiden mutation), and people who are receiving blood thinners
 - AstraZeneca is less preferred in individuals with a history of heparin-induced thrombocytopenia (HIT) and previous CVST

In response to patient concerns about the changing guidance

Key messages and supporting evidence:

1. Scientific recommendations change to reflect new, emerging real-world evidence
2. Health Canada approved the use of the AstraZeneca vaccine for 18+

Note: Health Canada is the Federal regulator that reviews and approves drugs, vaccines (biologics), and medical devices for use in Canada based on effectiveness and safety data. The National Advisory Committee on Immunization (NACI) is a group of external health experts that advise the government on the safe and effective use of vaccines, including the COVID-19 vaccines.

Timeline of changes to AstraZeneca vaccine guidance

- **February 26, 2021:** [Health Canada approved the AstraZeneca vaccine](#) for use in adults aged 18 and older
- **March 1, 2021:** NACI recommended that the AstraZeneca vaccine not be used in people aged 65 and older due to limited data from the clinical trials for this age group
- **March 16, 2021:** [NACI recommendations](#) were expanded to include the 65 and older age group as eligible for the AstraZeneca vaccination, based on review of real-world effectiveness and safety
- **March 29, 2021:** [NACI recommendations](#) were updated to indicate that the AstraZeneca vaccine not be used in people aged 55 years of age and younger while VIPIT is investigated
- **April 19, 2021:** the [Government of Ontario made an announcement](#) that people 40 and older are now eligible for the AstraZeneca vaccine, due to real-world evidence from Europe and the United Kingdom and the need to vaccinate younger people in hotspots

Age recommendations may continue to change based on emerging real-world evidence and clinical studies that inform the safe and effective use of the AstraZeneca vaccine, and the risk of SARS-CoV-2 infection in these age groups. Based on current evidence, the benefits continue to outweigh the risks for the AstraZeneca vaccine.

Refer to [CEP: AstraZeneca Safety](#) for more information about the changing guidance around the AstraZeneca vaccine and the roles of Health Canada and NACI.

Additional Resources:

To learn more about clinical trial details, contraindications and vaccine ingredients, refer to:

- [CEP: Oxford-AstraZeneca viral vector vaccine](#)
- [CEP: Vaccines at a glance](#)

To learn more about safety information, including information on VIPIT, refer to:

- [CEP: AstraZeneca safety](#)

For a patient-friendly resource, refer to:

- [AstraZeneca - Johnson & Johnson Patient Info Sheet](#)