

## Alberta COVID-19 Immunization Program Update

### Safety Information on AstraZeneca Vaccine Risk of Thrombosis with Thrombocytopenia

Dear Health Practitioners,

Alberta Health would like to take this opportunity to update you on the AstraZeneca/COVISHIELD vaccine.

#### Key Messages

As health practitioners, many of you may be asked questions about recent reports regarding the risk of thrombosis after AstraZeneca vaccine. The following key messages may assist in communicating with your patients or clients, other health care workers, and community partners.

- The AstraZeneca/COVISHIELD vaccine is not associated with an increased overall risk of blood clotting disorders. However, there have been very rare cases of unusual blood clots accompanied by low levels of blood platelets after immunization.
- The reported cases were almost all in women under 55 years of age.
- Because COVID-19 can also cause very serious illness including a higher risk of blood clotting, the benefits of the vaccine in preventing disease must be weighed against this rare risk.
- Anyone exhibiting the following symptoms after receiving the AstraZeneca/COVISHIELD vaccine should seek immediate medical assistance and inform their health practitioner that they have received the vaccine:
  - Breathlessness
  - Pain in the chest or stomach
  - Swelling or coldness in an arm or leg
  - Severe or worsening headache or blurred vision
  - Persistent bleeding
  - Multiple small bruises, reddish or purplish spots or blood blisters under the skin

#### European safety signal details:

- A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely in the European Union (EU) and the United Kingdom (UK) following vaccination with Oxford AstraZeneca vaccine. This includes severe cases presenting as venous thrombosis, including unusual sites such as mesenteric vein or cerebral vein/cerebral venous sinus thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia mostly occurring within 14 days of immunization.
- The European regulator reviewed 7 cases of blood clots in multiple blood vessels (disseminated intravascular coagulation [DIC]) and 18 cases of cerebral venous sinus thrombosis (CVST) that were reported in approximately 20 million people who received the AstraZeneca/COVISHIELD vaccine in the EU and UK. The majority of reports involved women under 55, although some of this may reflect increased use of the vaccine in such individuals due to targeted vaccine campaigns in different jurisdictions.
- The Paul-Ehrlich-Institut in Germany reported the incidence of the rare form of thrombosis (primarily cerebral venous thrombosis) associated with thrombocytopenia to be approximately one case per 100,000 vaccinations of AstraZeneca.
- It is challenging to ascertain the baseline incidence rate of this rare form of thrombotic events; however, assessments done in Europe to date showed the number of reported events exceeds that expected, particularly in those under 55. A causal link with the vaccine is not proven, but is possible and deserves further analysis.
- Health Canada has a robust monitoring system in place for vaccines. In Canada, the provinces are currently administering the COVISHIELD version of the AstraZeneca vaccine and Health Canada has not received any reports of these very rare events to date.

## Regulatory assessment:

- The UK and European regulators (European Medicines Agency, Medicines and Healthcare Products Regulatory Agency) considers that the benefit-risk balance of the AstraZeneca vaccine remains positive, and there is no association with thromboembolic disorders overall.
- Health Canada concurs with this assessment and confirmed on March 18 that the benefits of the AstraZeneca/COVISHIELD vaccine in protecting Canadians from COVID-19 continue to outweigh the risks and encourages Canadians to get immunized with any of the COVID-19 vaccines that are authorized in Canada.
- Health Canada has updated the [product monograph](#) (page 23) and has issued [guidance](#) on March 24, and continues to work closely with European regulators, scientific experts and the manufacturer to monitor this situation and to review all evidence as it becomes available.
  - Health Canada is aware that researchers in Europe have indicated that they have identified a possible cause for these very rare events observed in AstraZeneca COVID-19 vaccine recipients; however, little information is available about this emerging research.
  - As of March 24, approximately 54,000 doses of AstraZeneca/COVISHIELD vaccine have been administered in Alberta. These doses have primarily been given to Albertans 60-64 years of age, and First Nations and Métis people ages 40-49. There have been no reported cases of thrombosis or thrombocytopenia after receipt of the AstraZeneca/COVISHIELD vaccine in Alberta.
- Health Canada and the Government of Alberta will continue to monitor the scientific evidence, and will adjust recommendations as needed.

## Implications for clinicians – response if adverse event suspected:

- Health practitioners are urged to be alert for possible cases of thromboembolism, DIC or CVST occurring in immunized individuals who have received the AstraZeneca/COVISHIELD vaccine.
- Patients or clients may not be aware of this information. Health practitioners should inform their patients/clients to seek immediate medical attention for symptoms of thromboembolism and especially signs of thrombocytopenia and cerebral blood clots such as easy bruising or bleeding or severe headaches particularly beyond 3 days after immunization.
- Treatment for this condition requires specialized medical attention, and an urgent hematology consult should be initiated if this condition is suspected.
- If this condition is identified post-immunization, it should be reported by completing and submitting the [AEFI report form](#). If unable to complete the form, call 1-855-444-2324 (1-855-444-CDCI). More information is available at: <https://www.albertahealthservices.ca/info/Page16187.aspx>.

## Implications for clinicians – prevention and counseling:

- Individuals eligible for AstraZeneca vaccine will be informed of what is currently known about this risk before they receive their vaccine.
- If clinicians are asked about this risk by patients prior to receiving a vaccine, patients should be informed of what is known about the rare but serious nature of this health event, as well as the risks of COVID-19 infection in order to help them make an informed decision.