



BC Centre for Disease Control
Provincial Health Services Authority

March 29, 2021

Dear Doctor,

RE: Updated Recommendations for AstraZeneca and COVISHIELD Vaccines

Today a change has been announced in the use of COVISHIELD and AstraZeneca COVID-19 vaccines. Due to evolving research and evidence coming from Europe related to safety concerns with use of these vaccines, the national and subsequent provincial precautionary direction is to **immediately pause use of both AstraZeneca products in people under 55 years of age**. As a contingency measure and to proceed with the COVID-19 vaccination strategy, those who are eligible for COVID-19 vaccination will be offered alternate mRNA vaccines.

Safety Signal Identified

Vaccines go through rigorous clinical trials before approval, and through post-marketing surveillance after approval for use. When safety surveillance detects a signal, an investigation is initiated. **At this time, a safety signal has been identified in Europe following the use of the AstraZeneca vaccines in those under 55 years of age:**

Several European countries have reported rare cases of blood clots associated with a syndrome named “Vaccine-Induced Prothrombotic Immune Thrombocytopenia” (VIPIT) in patients who had received the COVISHIELD/AstraZeneca vaccine in the previous 4 to 16 days. Affected patients to date are primarily under 55 years of age.

While these reported adverse events have occurred primarily in women, investigations are ongoing as it is possible that more women received the COVISHIELD/AstraZeneca vaccine making it difficult to assess risk based on sex. To date, no instances of VIPIT have been reported in Canada. Canada is participating in reporting any adverse events following immunization, including VIPIT.

Regulatory Agency Action in Canada, Europe, and UK

Health Canada has updated the Warning and Precautions Section (Section 7) of both [product monographs](#) with information about these findings. The European Medicines Agency and the UK Medicines and Healthcare Products Regulatory Agency have advised that the benefit of use of the vaccine continue to outweigh the risks but have advised health care providers and the public about these events and their diagnosis and management. Some countries have modified their immunization programs accordingly.

Canada's National Advisory Committee on Immunization (NACI) Recommendation

While the safety signal is investigated, NACI is [recommending an immediate pause on the use of the COVISHIELD/AstraZeneca vaccines in those aged <55](#) in Canada. Adults 55 and older may be offered these vaccines, given the [increased risk of hospitalization and death due to COVID-19](#) in this population and since VIPIT reports have been even rarer in that age group.

Recommendation for Physicians Whose Patients Received COVISHIELD/AstraZeneca Vaccine

Individuals receiving the COVISHIELD/AstraZeneca vaccine should be reassured that adverse events are very rare, and COVID-19 infections can lead to significant complications, including a range of clotting disorders.

Those who have been vaccinated with either product in the last 20 days, and anyone vaccinated with either product vaccine going forward, should monitor for symptoms and seek immediate medical attention in the very unlikely event that they develop:

<ul style="list-style-type: none">• prolonged headache beginning 4 or more days after vaccination• blurred vision• difficulty speaking• seizure• difficulty moving parts of the body• shortness of breath	<ul style="list-style-type: none">• chest pain• new severe swelling, pain or colour change of an arm or a leg• persistent abdominal pain• abnormal bruising, reddish or purple spots or blood blisters under the skin• bleeding beyond site of vaccination
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It is important to note that the outcome of VIPIT can be serious, but it can be treated if diagnosed early. In addition to timely diagnosis and management, clinicians who identify vaccine recipients with VIPIT should promptly report such cases to the [adverse events following immunization system](#) in BC.

Treatment of VIPIT

The Ontario Science Table COVID-19 Advisory has issued [diagnostic and treatment guidelines](#), and these are applicable should any suspect cases be identified in BC. Treatment precautions and recommendations for VIPIT include **no** heparin, **no** platelet transfusions, and use of direct oral anti-Xa inhibitors for anticoagulation (e.g., rivaroxaban, apixaban, edoxaban) as well as intravenous immunoglobulin, all under the guidance of a hematologist.

Informed Consent and Additional Documentation Being Updated

An addendum document to the Health File used to support informed consent for [COVID-19 vaccine](#) is being prepared to provide information about this event for those aged 55 years and older who will continue to receive this vaccine. The aftercare form and other information will also be updated to provide advice about signs and symptoms warranting medical attention for those who have or will receive this vaccine.

Continue to Advocate for Patients to Receive COVID-19 Vaccination

Canada can adapt the offer of the AstraZeneca vaccines because we have other vaccine options available while the investigation into this safety signal is completed. COVID-19 continues to circulate in our communities and to pose a significant threat, and protection via immunization is the most effective prevention.

Please continue to encourage your patients to receive any of the recommended COVID-19 vaccines available to them. For those over 55, AstraZeneca and COVSHIELD vaccines continue to be recommended as a safe and effective prevention measure against COVID-19.