Special Bulletin

from the Office of the Chief Medical Officer of Health



Date: March 31, 2021

To: Nova Scotia Health Care Providers (including 811/911)

Topic: Update regarding use of AstraZeneca COVID-19 vaccine; Adverse Events Following Immunization (AEFI)

Reporting Requirements

The National Advisory Committee on Immunization (NACI), has recommended an immediate pause in the use of AstraZeneca COVID-19 vaccine in all individuals under 55 years of age at this time, while investigations regarding a safety signal are ongoing. This pause is based on evidence of rare instances of vaccine-induced prothrombotic immune thrombocytopenia (VIPIT) following AstraZeneca COVID-19 vaccination reported in Europe, with associated high case fatality and related sequelae. To date, such adverse events have not been reported in Canada. Adults 55 years of age and older may still be offered the AstraZeneca COVID-19 vaccine with informed consent, given the increased risk of hospitalization and death due to COVID-19 disease in this population and since VIPIT appears to be a rarer event in that age group. Currently, in Nova Scotia, individuals 60 to 64 years of age are being offered the AstraZeneca COVID-19 vaccine.

Health Canada has issued a label change and guidance on the AstraZeneca COVID-19 vaccine and has issued additional terms and conditions requiring AstraZeneca manufacturers to conduct a detailed assessment of the benefits and risk of the vaccine by age and sex in the Canadian context. This, along with further international evidence, will be used to determine any additional regulatory actions necessary.

It is imperative that healthcare providers counsel their patients prior to receipt of vaccines. In particular, patients need to be aware to seek immediate medical attention for symptoms of thromboembolism and/or thrombocytopenia between days 4 and 20 following receipt of AstraZeneca COVID-19 vaccine. Individuals should be advised that if they experience any of the following symptoms, they need to call 911 or seek medical assistance right away, ensuring they mention they have received the vaccine. Symptoms to be vigilant for include:

- shortness of breath,
- chest pain,
- leg swelling,
- persistent abdominal pain,
- neurological symptoms including sudden onset of severe or persistent worsening headaches or blurred vision,
- skin bruising (other than at the site of vaccination) or petechiae.

Healthcare professionals should be aware of VIPIT including how to diagnose and treat the condition (see <u>Ontario Science Table guidelines</u>). Guidance from Thrombosis Canada is forthcoming but in the interim, the Ontario management is appropriate.



Under the Nova Scotia Health Protection Act and the Regulations under the Act, an Adverse Event Following Immunization (AEFI) is notifiable and must be reported to the Medical Officer of Health, through the local Public Health office in accordance with the details outlined on the poster titled <u>It's the Law: Reporting of Adverse Events Following Immunization</u>.

An AEFI is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of a vaccine. An adverse event of special interest (AESI) is a specific adverse event that has been identified by international health authorities to be monitored as part of COVID-19 vaccine safety surveillance. The conditions have been included because they have been associated with COVID-19 disease or there is a theoretical/proven association with vaccines in general or a vaccine platform. Further information regarding AESIs is available via the Brighton Collaboration. The Brighton Collaboration AESI list may be found here: https://brightoncollaboration.us/wp-content/uploads/2021/01/COVID-19-updated-AESI-list.pdf. Examples of AESIs include but are not limited to thrombocytopenia, acute cardiovascular injury, coagulation disorders, acute kidney or liver injury, acute pancreatitis, and rhabdomyolysis. These events must also be reported to public health by providers. Providers reporting an AEFI to public health can obtain the AEFI form and the User Guide from the Public Health Agency of Canada. working days. Other adverse events must be reported within five working days.

