https://www.alberta.ca/coronavirus-info-for-albertans.aspx

November 23, 2021

Alberta COVID-19 Immunization Program Update

Dear colleagues,

I would like to update you with some important information about the COVID-19 Immunization Program.

As of November 23, 2021, Alberta is recommending that Pfizer-BioNTech (Comirnaty) COVID-19 vaccine be offered as the preferred choice of mRNA COVID-19 vaccine for Albertans 12 to 29 years of age to start and/or complete their primary series (including immunocompromised individuals who are eligible for a third dose as their primary series).

- The preferential recommendation is based on a higher rate of myocarditis and/or pericarditis following immunization with Moderna (Spikevax) COVID-19 vaccine relative to Pfizer-BioNTech (Comirnaty) COVID-19 vaccine in those aged 12 to 29 years, particularly among males. It should be noted that the risk is still considered rare.
- This recommendation is supported by the Alberta Advisory Committee on Immunization (AACI), based on their review of all currently available evidence including the most up-to-date Alberta data.
- People 12 to 29 years old can still take the Moderna (Spikevax) COVID-19 vaccine, if they so choose, with informed consent.

More information on these changes is included below.

Thank you for your ongoing efforts to support the COVID-19 Immunization Program.

Yours sincerely,

Deena Hinshaw, BSc, MD, MPH, CCFP, FRCP Chief Medical Officer of Health

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Recommendation for ages 12-29 years:

Pfizer-BioNTech (Comirnaty) COVID-19 vaccine should be offered as the preferred choice of COVID-19 vaccine to Albertans 12 to 29 years of age to start and/or complete their primary series (including immunocompromised individuals who are eligible for a third dose as their primary series).

Overview

- A small number of cases of myocarditis and pericarditis following COVID-19 vaccination have been reported in Canada and internationally, including Israel, the United States (US) and Europe.
- Incidence rates of myocarditis and/or pericarditis following COVID-19 immunization remain low. These cases are rare and most reported cases to date have followed immunization with an mRNA COVID-19 vaccine: Pfizer-BioNTech (Comirnaty) or Moderna (Spikevax) vaccine.
- Current evidence suggests there is a likely causal association between myocarditis and the mRNA COVID-19 vaccines: Pfizer-BioNTech (Comirnaty) and Moderna (Spikevax) vaccine.
- Cases were more frequent: in adolescents and younger adults under 30 years of age than older individuals; and in males than females and following the second dose of COVID-19 vaccine. Vaccine safety surveillance data in Canada, the US and Europe suggest relatively higher rates of myocarditis and/or pericarditis reported after Moderna vaccination than Pfizer-BioNTech vaccination, although the overall risk is small.
- Symptoms usually started within 4 to 7 days after vaccination. Most cases had mild illness, responded well to conservative therapy and rest, and their symptoms improved quickly.
- As of November 12, 2021, there were 1,241 cases of myocarditis and/or pericarditis reported to the Public Health Agency of Canada (PHAC) and Health Canada from over 59 million COVID-19 vaccine doses administered. Of these 1,241 cases:
 - 775 cases received Pfizer-BioNTech (Comirnaty) COVID-19 vaccine,
 - 439 cases received Moderna (Spikevax) COVID-19 vaccine,
 - 24 cases received COVISHIELD/AstraZeneca (Vaxzevria) COVID-19 vaccine, and
 - 3 cases where the vaccine name was unspecified.
- Note that the above numbers are case counts, not incidence rates. The majority of COVID-19 vaccine doses administered in Canada to date have been Pfizer-BioNTech (Comirnaty) vaccine, so that denominator would need to be considered. There are many potential causes of myocarditis and pericarditis, including COVID-19 and other viral infections.
- In Alberta, as of November 15, 2021, there have been 72 confirmed cases of myocarditis after COVID-19 vaccination out of over 6 million vaccine doses administered. Of these 72 cases, there were 8 females and 64 males, with the majority of cases affecting ages 12-29. The majority of cases had mild illness, responded well to symptomatic treatment (antiinflammatory medication) and rest, and their symptoms improved quickly within days.

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• The benefits of COVID-19 vaccination still outweigh the risks, including in adolescents and young adults. The risk of cardiac complications, like myocarditis, substantially increases following COVID-19 infection, and it is higher following infection than after vaccination.

Current evidence

- On October 27, the World Health Organization (WHO) Global Advisory Committee on Vaccine Safety (GACVS) COVID-19 subcommittee, after reviewing preliminary data from a Nordic study and from Australia, Canada, Israel, and the US, concluded that evidence suggests a likely causal association between myocarditis and mRNA COVID-19 vaccines.
 - In the US, the Advisory Committee on Immunization Practices (ACIP) reviewed evidence and also determined that while there is a likely association between mRNA COVID-19 vaccines and rare cases of heart inflammation in adolescents and young adults, the benefits of vaccination still clearly outweigh the risks.
 - Current data from Israel suggest a likely association of myocarditis and/or pericarditis with mRNA COVID-19 vaccines in adolescents and young adults, specifically following a second dose of Pfizer-BioTNech (Comirnaty) COVID-19 vaccine, which is the primary COVID-19 vaccine used in Israel.
 - The United Kingdom's (UK) Joint Committee of Vaccination and Immunisation (JCVI) reviewed data from the UK, US and Canada and agreed that while there is increasingly robust evidence of an association between mRNA COVID-19 vaccines and myocarditis, this is a very rare adverse event.
 - A <u>French study</u> of individuals aged 12 to 50 years who were hospitalized for myocarditis and/or pericarditis found cases of myocarditis were over 80% lower with Pfizer-BioNTech (Comirnaty) COVID-19 vaccine than Moderna (Spikevax) COVID-19 vaccine.
- On June 30, Health Canada updated the product monographs for both Moderna (Spikevax) and Pfizer-BioNTech (Comirnaty) COVID-19 vaccines to include information on the risks of myocarditis and/or pericarditis following immunization.
- On October 1, 2021, the Council of Chief Medical Officers of Health issued a joint statement considering the rare events of myocarditis and/or pericarditis occurring after immunization with mRNA COVID-19 vaccines, noting that risks of developing these conditions are greater following COVID-19 infection than following immunization.
 - While cases occur more frequently after receiving the Moderna (Spikevax) vaccine, some studies also suggest that the Moderna (Spikevax) vaccine prompts a stronger immune response, providing a level of higher protection that wanes more slowly than the Pfizer-BioNTech (Comirnaty) vaccine.
 - The joint statement also reaffirms NACI's statement that in considering the rare risks and known benefits of COVID-19 vaccines, vaccination with either mRNA COVID-19 vaccines for people 12 years of age and over, should continue, given the proven benefits of the vaccines in preventing severe illness and death.

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- It is unknown if people with a history of previous myocarditis, pericarditis or post-COVID inflammatory syndrome are at higher risk of vaccine-associated myocarditis and/or pericarditis.
- It is unclear if people who developed myocarditis and/or pericarditis after a first dose of an mRNA COVID-19 vaccine may be at increased risk of further adverse cardiac effects following a second dose of the vaccine. See the <u>Clinical Investigation and Diagnosis</u> section in this document for more information.
- For additional information regarding additional doses for immunocompromised individuals, please see <u>here.</u>

Clinical Investigation and Diagnosis

Healthcare providers should consider myocarditis and pericarditis in evaluation of acute chest pain or pressure, arrhythmias, shortness of breath or other clinically compatible symptoms after COVID-19 vaccination, and consider testing including electrocardiogram (ECG), serial troponin levels, echocardiogram and consultation with a cardiologist.

It is important to rule out other potential causes of myocarditis and pericarditis. Consultation with infectious disease and/or rheumatology could assist in this evaluation, particularly for acute or prior COVID-19 infection and other viral etiologies (e.g., enterovirus PCR and comprehensive respiratory viral pathogen testing).

Clinical considerations related to COVID-19 vaccines

Individuals who experienced myocarditis and/or pericarditis after a first dose of an mRNA COVID-19 vaccine should discuss decisions around the second dose, including timing, with their clinician.

The current NACI recommendation is that individuals who experienced myocarditis and/or pericarditis after a first dose of an mRNA COVID-19 vaccine should defer a second dose until more data is available. However, a second dose can be considered in specific circumstances (e.g., individuals with a high risk of severe disease, increased community transmission and high personal risk of infection) after discussion with their clinician.

When providing consultation about second doses to individuals, clinicians may refer to this <u>CDC document</u>, which lists factors that may be taken into consideration.

Generally, deferral of COVID-19 immunization is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA vaccines who are no longer followed clinically for cardiac issues. If these individuals have questions or concerns about their prior history of myocarditis or pericarditis and immunization, it is recommended that individuals consult with their clinician. However, consultation with a clinician is not required to receive COVID-19 vaccines.

There is emerging evidence that indicates a potential reduction of myocarditis risk with a longer interval between first and second doses of mRNA COVID-19 vaccine. In alignment with the <u>NACI recommendations</u> for optimal interval, Alberta is now recommending a dosing interval of 8 weeks between the first and second dose of any mRNA vaccine series for all age groups, including a mixed series.

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Reporting

As with other adverse events following immunization (AEFI), health care professionals in Alberta must submit any reports of myocarditis or pericarditis following a COVID-19 vaccine to Alberta Health Services AEFI team. The <u>AEFI report form</u> can be completed and submitted or, if unable to complete the form, call 1-855-444-2324 (1-855-444-CDCI). AEFIs must be reported within three (3) days of the health practitioner determining or being informed that a patient has had an AEFI that has not yet been reported.

Members of the public are also able to report an adverse event following immunization by calling Health Link at 811 or by contacting their health care provider. National data on all AEFIs are published by Health Canada at https://health-infobase.canada.ca/covid-19/vaccine-safety/.

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