Myocarditis and/or Pericarditis following COVID-19 Vaccines

A small number of cases of myocarditis (inflammation of the heart muscle) and/or pericarditis (inflammation of the lining around the heart) following immunization with COVID-19 vaccines have been reported in Canada and internationally. These cases are very rare and most reported cases to date have followed vaccination with an mRNA vaccine (Pfizer-BioNTech and Moderna) and were resolved with symptomatic therapy within days.

As part of ongoing COVID-19 vaccine safety efforts, Alberta Health is monitoring cases of myocarditis and/or pericarditis following COVID-19 vaccine, including any long-term sequelae. This includes monitoring cases in the AEFI (adverse events following immunization) surveillance system, as well as domestic and international evidence.

Alberta recommendations:
- All Albertans age 12+ are recommended to receive COVID-19 vaccine as the benefits of the COVID-19 vaccines continue to outweigh their potential risks.
- Given what we know about myocarditis and/or pericarditis following immunization with COVID-19 vaccines at this time, Alberta Health also advises people receiving an mRNA vaccine be:
  - informed of the very rare risk of myocarditis and/or pericarditis following immunization, as well as the significant benefits that COVID-19 vaccines provide.
  - advised to seek medical care, and inform healthcare providers about their recent COVID-19 immunization, if they develop symptoms compatible with myocarditis and/or pericarditis, which may include chest pain or pressure, shortness of breath, or the feeling of a rapid or abnormal heart rhythm.
- Alberta Health recommends that individuals who experienced myocarditis and/or pericarditis after a first dose of an mRNA vaccine should discuss decisions around the second dose, including timing, with their clinician. In general, they are advised to defer receiving a second dose until more data is available. However, a second dose can be considered in specific circumstances. See the Clinical Considerations section on page 3 for more information.

Summary of current evidence
Most of the current information for myocarditis and/or pericarditis following COVID-19 immunization comes from cases reported in Israel and the US:
- Cases happen more frequently following the second dose of an mRNA vaccine (Pfizer-BioNTech or Moderna COVID-19 vaccine)
- Cases were reported more often in adolescents and younger adults under 30 years of age than older individuals, and more often in males than females.
- Usually, symptoms started within one week after vaccination (4-7 days).
- Most cases had mild illness, responded well to usual medical treatment and rest, and their symptoms improved quickly. No long-term data is available yet.
- The benefit of immunization still far outweighs the risks of COVID-19 vaccination, including in adolescents and young adults – for example, in young adults who are infected with COVID-19, myocarditis has been reported about 100 times more often than has been reported after a vaccine.
- 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.
There is currently insufficient evidence around any change to the risk of myocarditis and/or pericarditis after the second dose related to the interval length between first and second doses of vaccines, as most cases have been reported from jurisdictions using conventional short interval dosing.

There is currently no data on myocarditis and/or pericarditis following a mixed vaccine schedule (e.g. first dose with Pfizer and second with Moderna).

**Situation in Alberta**

In Alberta, as of July 21, there have been six reported cases of myocarditis after COVID-19 immunization, two of which have been confirmed, although causality has not been established. Four of the six cases followed a second dose of Pfizer, one case followed a first dose of Pfizer and one case followed a first dose of AstraZeneca. Five of the six reported cases were males between the ages of 15 and 22.

The Alberta Advisory Committee on Immunization reviewed all available evidence on June 25, 2021 and concluded that the COVID-19 immunization program for adolescents and young adults should continue with no changes, as the benefits far outweigh the risks.

Alberta Health will continue to review evidence as it becomes available, provide information to the public and take appropriate action if needed.

**Situation in Canada**

There have been a small number of reports of myocarditis and/or pericarditis following COVID-19 immunization in Canada. Up to and including July 9, 2021, there were 163 cases of myocarditis and/or pericarditis with reports submitted to the Public Health Agency of Canada (PHAC) and Health Canada from over 41,526,682 million administered doses of COVID-19 vaccines. Of the 163 myocarditis and/or pericarditis cases:

- 111 cases received Pfizer-BioNTech COVID-19 vaccine
- 40 cases received Moderna vaccine
- 11 cases received COVISHIELD/AstraZeneca vaccines
- the vaccine name of one was unspecified

It should be noted that the majority of vaccine doses administered in Canada to date have been with Pfizer-BioNTech vaccine, so the numbers above are influenced by that denominator. It should also be remembered that myocarditis and pericarditis are not uncommon, and there are many potential causes including COVID-19 infection and other viral infections.

On June 30, Health Canada updated the product monographs for both Moderna and Pfizer COVID-19 vaccines to include information around these risks. Health Canada and PHAC continue to monitor the evolving information regarding the association between myocarditis and/or pericarditis and mRNA vaccines, particularly as more adolescents and young adults are vaccinated and more second doses are given.

On July 2, the National Advisory Committee on Immunization (NACI) updated their overall guidance document on the use of COVID-19 vaccines to include a section on myocarditis and pericarditis and continues to strongly recommend that a complete series with an mRNA vaccine should be offered to all eligible individuals without contraindications, including those 12 years of age and older.

**Other jurisdictions**

- In the US, the Advisory Committee on Immunization Practices (ACIP) reviewed current evidence and determined that while there’s a likely association between the mRNA COVID-19 vaccines and rare cases of heart inflammation in adolescents and young adults, the benefits of vaccination for everyone age 12 and older still clearly outweigh the risks.
- Preliminary findings from Israel also suggest a likely association of myocarditis with mRNA vaccination in adolescents and young adults; however, due to the increasing prevalence of the variant strains, Israel has also recommended that the risks of myocarditis are minor compared to those of COVID-19.
Europe’s safety advisory body has completed its assessment of worldwide reports of myocarditis and/or pericarditis. It concluded there is a possible link between mRNA vaccines and very rare cases of myocarditis and pericarditis, reiterated that the benefits of COVID-19 vaccine continue to outweigh their risks, and recommended listing myocarditis and/or pericarditis as new side effects in vaccine product monographs.

The United Kingdom (UK) is not seeing the same trends as those reported from Israel and the US, possibly because, similar to Canada, second doses in younger people have not yet been given in large numbers in the UK and AstraZeneca vaccine was used widely for the full series in the UK.

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 vaccination and consider testing including electrocardiogram (ECG), serial troponin levels, an echocardiogram and consultation with a cardiologist.

It is also 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
Albertans who have a history of previous myocarditis, pericarditis or post-COVID inflammatory syndrome are advised to consult with their clinician before COVID-19 vaccination.

Individuals who experienced myocarditis and/or pericarditis after a first dose of an mRNA 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, the clinician can refer to this Centre for Disease Control and Prevention (CDC) document, which lists factors that may be taken into consideration.

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 AEFI report form 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 contacting Health Link at 811 or by contacting their health provider. National data on all AEFIs are published by Health Canada at https://health-infobase.canada.ca/covid-19/vaccine-safety/.
References


