

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 6, there have been two reported cases of myocarditis after COVID-19 vaccination although causality has not been established. One case followed a first dose of AstraZeneca and the other followed a second dose of Pfizer.

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 2, 2021, there were 105 cases of myocarditis and/or pericarditis with reports submitted to the Public Health Agency of Canada (PHAC) and Health Canada from over 38,217,511 million administered doses of COVID-19 vaccines. Of the 105 myocarditis and /or pericarditis cases:

- 70 cases received Pfizer-BioNTech COVID-19 vaccine
- 26 cases received Moderna vaccine
- 8 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. In fact, so far the observed number of cases associated with vaccines in Canada is less than the number that would be expected based on background rates alone.

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 that there is a possible link between mRNA vaccines and very rare cases of myocarditis and pericarditis, reiterated that the benefits of COVID-19 vaccines 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 [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

1. Advisory Committee on Immunization Practices. ACIP Presentation Slides: June 23-25, 2021 Meeting. Centres for Disease Control and Prevention; 2021. Available from: <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-06.html>
2. Advisory Committee on Immunization Practices. Statement Following CDC ACIP Meeting from Nation's Leading Doctors, Nurses, Pharmacists and Public Health Leaders on Benefits of Vaccination. U.S. Department of Health & Human Services; 2021. Available from: <https://www.hhs.gov/about/news/2021/06/23/statement-following-cdc-acip-meeting-nations-leading-doctors-nurses-public-health-leaders-benefits-vaccination.html>
3. BioNTech Manufacturing GmbH. Pfizer-BioNTech COVID-19 Vaccine Product Monograph. June 30, 2021. Available from: <https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf>
4. Centres for Disease Control and Prevention. Clinical considerations: myocarditis and pericarditis after receipt of mRNA COVID-19 vaccines among adolescents and young adults. Atlanta, GA: Centers for Disease Control and Prevention; 2021 Available from: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>
5. Centres for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States (People with a history of myocarditis or pericarditis). Atlanta, GA: Centers for Disease Control and Prevention; 2021 Available from: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#underlying-conditions>
6. European Medicines Agency. Comirnaty and Spikevax: possible link to very rare cases of myocarditis and pericarditis. Amsterdam, NL; 2021. Available from: <https://www.ema.europa.eu/en/news/comirnaty-spikevax-possible-link-very-rare-cases-myocarditis-pericarditis>
7. Government of Canada. An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI): Recommendations on the use of COVID-19 Vaccines. Public Health Agency of Canada; 2021. Available from: <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html>
8. Government of Israel. Surveillance of myocarditis (inflammation of the heart muscle) cases between December 2020 and May 2021. Jerusalem: Government of Israel; 2021 Available from: <https://www.gov.il/en/departments/news/01062021-03>
9. Moderna TX, Inc. Moderna COVID-19 Vaccine Product Monograph. June 30, 2021. Available from: <https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf>
10. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Myocarditis and Pericarditis Following COVID19 mRNA Vaccines. Toronto, ON: Queen's Printer for Ontario; 2021. Available from: <https://www.publichealthontario.ca/-/media/documents/ncov/vaccines/2021/06/covid-19-mrna-vaccines-myocarditis-pericarditis.pdf?la=en>
11. Public Health Agency of Canada. Reported side effects following COVID-19 vaccination in Canada [Internet]. Ottawa, ON: Government of Canada; 2021. Available from: <https://health-infobase.canada.ca/covid-19/vaccine-safety/>