

## 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, including Israel, the United States (U.S.) and Europe. These cases are rare and most reported cases to date have followed vaccination with an mRNA vaccine (Pfizer-BioNTech/Comirnaty and Moderna/Spikevax) and 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.

### Summary of current evidence of myocarditis and/or pericarditis following COVID-19 immunization:

- Overall, incidence rates of myocarditis and/or pericarditis following a COVID vaccination remain low.
- 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.
- Vaccine safety surveillance data in Canada and the US suggest relatively higher rates of myocarditis and/or pericarditis reported after Moderna vaccination compared to Pfizer-BioNTech vaccination, in particular following the second dose. Additional analyses are ongoing.
- The benefit of immunization still far outweighs the risks of COVID-19 vaccination, including in adolescents and young adults. The risk of cardiac complications, including myocarditis, has been shown to be substantially increased following COVID-19 infection, and it is higher following infection than after vaccination.
- 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.
- 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 Canada

There have been a relatively small number of reports of myocarditis and/or pericarditis following COVID-19 immunization in Canada. Up to and including September 24 2021, there were 812 cases of myocarditis and/or pericarditis with reports submitted to the Public Health Agency of Canada (PHAC) and Health Canada from over 56 million administered doses of COVID-19 vaccines. Of the 812 myocarditis and /or pericarditis cases:

- 466 cases received Pfizer-BioNTech COVID-19 vaccine
- 321 cases received Moderna vaccine
- 21 cases received COVISHIELD/AstraZeneca vaccines
- the vaccine name of four were 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 risks of myocarditis and/or pericarditis following vaccination.
- On August 27, the [National Advisory Committee on Immunization \(NACI\)](#) released updated advice also noting higher rate of cases of myocarditis and/or pericarditis has been reported after the administration of the Moderna vaccine compared to the Pfizer-BioNTech vaccine, although verification of this potential difference is ongoing. In considering the rare risks and known benefits of COVID-19 vaccines, NACI continues to recommend vaccination with either mRNA COVID-19 vaccines for people 12 years of age and over, given the proven benefits of the vaccines in preventing severe illness and death.
- On September 29, out of an abundance of caution, Ontario issued a preferential recommendation of the use of Pfizer-BioNTech vaccine for individuals aged 18-24 years old on the current available analysis from Ontario's AEFI surveillance system.
  - From their data, [Ontario's reporting rate](#) in males aged 18-24 years following the Pfizer vaccine as second dose was 37.4 per million doses and was 263.2 per million following the Moderna vaccine as second dose.
- Current data from Alberta's AEFI surveillance system does not support the need for a similar shift, and at this time younger Albertans can get either the Pfizer vaccine or the Moderna vaccine with informed consent.
- On October 1, the Council of Chief Medical Officers of Health issued [a joint statement](#) considering these 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. Based on national surveillance data, cases of myocarditis and/or pericarditis experience relatively mild illness and recover quickly. While cases occur more frequently after receiving the Moderna vaccine, some studies also suggest that Moderna vaccines prompt a stronger immune response, providing a level of higher protection and its effects wane more slowly compared to Pfizer-BioNTech COVID-19 vaccine. All eligible individuals are encouraged to get fully vaccinated.

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.

### Situation in Alberta

In Alberta, as of September 23, there have been 24 confirmed cases of myocarditis after COVID-19 immunization out of over 6 million doses of vaccine administered; two additional cases are currently under investigation. Of the confirmed cases, one case followed a first dose of AstraZeneca, 16 cases followed after immunization with Pfizer (2 cases after first dose, 14 cases after second dose) and 7 cases followed immunization with Moderna (2 cases after first dose, 5 cases after second dose). The majority of these 24 cases have had mild illness, responded well to symptomatic treatment (anti-inflammatory medication) and rest, and had their symptoms improved quickly within days. 22 of the 24 confirmed cases were males, and 17 of these cases were between the ages of 15 and 29.

Based on current Alberta AEFI data, all ages and both sexes combined, the rate of myocarditis after second dose of the Pfizer vaccine is 6.6 per million, while the rate after second dose of Moderna is 8.3 per million. Although the rate following the Moderna vaccination is slightly higher, occurrence of myocarditis is still very rare.

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 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 rare risk of myocarditis and/or pericarditis following immunization, as well as the significant benefits that COVID-19 vaccines provide. Those receiving a Moderna vaccine should be informed of the potentially higher but still rare risk of myocarditis and pericarditis with the Moderna COVID-19 vaccine. Adolescents 12 to 17 years of age should also be informed that data on myocarditis and pericarditis following Moderna COVID-19 vaccine is very limited in their age group because the vaccine was only recently authorized for 12-17 years of age.
  - 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 4 for more information.

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

### 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.
- Data 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. Israel recently included children 12+ in their booster immunization program and preliminary data indicates that fewer than 10 cases of heart inflammation have been identified following a third dose out of over 3 million booster doses administered. They are also reporting that the third dose currently has the lowest side effect rate overall.
- 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's (UK) Joint Committee of Vaccination and Immunisation (JCVI) also reviewed data from the UK, US and Canada and agreed that while there is increasingly robust evidence of an association between vaccination with mRNA COVID-19 vaccines and myocarditis, this is a very rare adverse event. Their assessment noted that until longer-term data on potential adverse reactions is available, only first doses to individuals' ages 15-17 is recommended unless they are deemed high-risk; then a full two-dose series is recommended.

### 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-CDCl). 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/>.

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