

Communiqué to health practitioners

Reports of Myocarditis/pericarditis after COVID-19 vaccination (June 3, 2021)



Background

In May 2021, <u>international reports</u>¹ of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following vaccination with COVID-19 mRNA vaccines emerged, including from Israel and the <u>United States</u>².

Available information indicates that:

- Cases were more commonly reported after the second dose
- Symptom onset was typically within several days after vaccination
- Cases were mainly adolescents and young adults
- Cases were more often males compared to females
- Cases experienced mild illness, responded well to conservative treatment and rest, and their symptoms improved quickly.

Follow-up on these cases is ongoing. **No clear association has been established between myocarditis/pericarditis and mRNA vaccines**, and to date, no regulatory action has been taken in Canada or internationally.

Situation in Canada

As part of ongoing COVID-19 vaccine safety efforts, the Public Health Agency of Canada (PHAC) and Health Canada are closely monitoring myocarditis/pericarditis in passive and active Canadian safety surveillance systems, including the <u>Canadian Adverse Events Following Immunization Surveillance System (CAEFISS)</u>³, the <u>Canada Vigilance Program</u> (CV)⁴, the <u>Canadian National Vaccine Safety Network (CANVAS)</u>⁵ and the <u>Canadian Immunization Monitoring Program ACTive (IMPACT)</u>⁶.

In Canada, there have been a small number of reports of <u>pericarditis or myocarditis</u>⁷, following vaccination with a COVID-19 mRNA vaccine, however it is important to note that adverse events occurring after vaccination are **not** necessarily related to the vaccine. Based on the few reports received in Canada, we are **not** currently seeing higher rates than would be expected in the general population. The Canadian <u>weekly online adverse events report</u>⁸ provides updates on the latest numbers.

Diagnosis and reporting

Myocarditis and pericarditis both involve inflammation of the heart in response to an infection or some other trigger. Symptoms can include shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm.

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. They should consider doing an electrocardiogram (ECG), troponins, and an echocardiogram, in consultation with a cardiologist. It would also be important to rule out other potential causes of myocarditis and pericarditis, as such, consultation with infectious disease and/or rheumatology is recommended, to assist in this evaluation, particularly for acute COVID-19 infection (e.g., PCR testing), prior SARS-CoV-2

infection (e.g., detection of SARS-CoV-2 nucleocapsid antibodies), and other viral etiologies (e.g., enterovirus PCR and comprehensive respiratory viral pathogen testing).

All cases of myocarditis or pericarditis following vaccination should be reported to the <u>local health authority</u>⁹. Health Canada, PHAC, and the provincial and territorial health authorities will continue to closely monitor reports of myocarditis and/or pericarditis. Health Canada is also working closely with the manufacturers and international regulators to review information as it becomes available and will take appropriate action as needed. More information will be shared as it becomes available.

The benefits of the mRNA vaccines continue to outweigh their risks in the <u>authorized</u> populations, as there are clear benefits of mRNA vaccines in reducing deaths and hospitalizations due to COVID-19 infections.

References and links

- COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety (GACVS) reviews cases of mild myocarditis reported with COVID-19 mRNA vaccines. https://www.who.int/news/item/26-05-2021-gacvs-myocarditis-reported-with-covid-19-mrna-vaccines
- 2. Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html
- 3. Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html
- 4. Canada Vigilance Program. https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/canada-vigilance-program.html
- 5. Canadian National Vaccine Safety Network (CANVAS). https://cirnetwork.ca/network/national-ambulatory-network/
- 6. Canadian Immunization Monitoring Program ACTive (IMPACT). https://www.cps.ca/impact
- 7. Brighton Collaboration Myocarditis Decision Tree. https://brightoncollaboration.us/wp-content/uploads/2021/05/Myocarditis-decision-tree_brief-format_DRAFT_24May2021.pdf
- 8. Reported side effects following COVID-19 vaccination in Canada. https://health-infobase.canada.ca/covid-19/vaccine-safety/
- 9. Reporting Adverse Events Following Immunization (AEFI) in Canada. https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html