

655 West 12th Avenue Vancouver, BC V5Z 4R4 Communicable Diseases & Immunization Service

www.bccdc.ca www.immunizebc.ca Tel 604.707.2548 Fax 604.707.2515

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Dear Doctor:

## Re: Myocarditis/ pericarditis in association with receipt of mRNA COVID-19 vaccine

In late May 2021, the World Health Organization vaccine safety committee noted that myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines are events of special interest for continued evaluation.<sup>1</sup>

A small number of case series have emerged from Israel and the United States.<sup>2,3,4</sup> The US Centres for Disease Control and Prevention provided recommendations for clinicians<sup>5</sup> and on June 10<sup>th</sup> presented safety assessments to the Food and Drugs Administration in readiness of review of emergency use authorization of the Moderna mRNA vaccine in adolescents.<sup>6</sup>

Available information indicates that:

- Symptom onset was usually within a few days after vaccination
- Cases were mainly male adolescents and young adults after the second dose; in the US data the median age of cases following 2<sup>nd</sup> dose was 24 years
- Most cases experienced mild illness, responded well to conservative treatment and rest, and their symptoms improved quickly.

In the US data analyses, the observed cases exceeded the expected number of cases (based on background rates of myocarditis) following the 2<sup>nd</sup> dose in the age group 16-24 years. The estimated rate of myocarditis was about 16 cases per million 2<sup>nd</sup> doses (35 per million in 16-17 year olds; 21 per million in 18-24 year olds). While 9% of doses were administered in the 12-24 year age group, this group accounted for 53% of myocarditis reports following the 2<sup>nd</sup> dose.<sup>7</sup>

To date, no regulatory action has been taken in Canada or internationally. Additional discussion including a benefit risk assessment are scheduled for review at the US Advisory Committee on Immunization Practices on June 18th.

## Situation in Canada and BC

As part of ongoing COVID-19 vaccine safety efforts, BC Centre for Disease Control (BCCDC) along with local medical health officers, 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 Canadian Adverse Events Following Immunization Surveillance System (CAEFISS)<sup>8</sup>, the Canada Vigilance Program<sup>9</sup>, the Canadian National Vaccine Safety Network (CANVAS)<sup>10</sup> and the Canadian Immunization Monitoring Program ACTive (IMPACT).<sup>11</sup>





In BC and elsewhere in Canada, there have been a small number of reports of pericarditis or myocarditis following vaccination with a COVID-19 mRNA vaccine. In Canada and BC to date, higher rates than would be expected have not yet been observed. The weekly Canadian<sup>12</sup> and BC<sup>13</sup> adverse events following COVID-19 vaccine reports provide updates on the latest numbers.

## Diagnosis and reporting

Myocarditis and pericarditis 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, documented arrhythmia, shortness of breath or other clinically compatible symptoms after vaccination. They should consider doing an electrocardiogram (ECG) and measuring, troponins, BNP (brain natriuretic peptide), and C-reactive protein (CRP) when available. If these markers are consistent with myocardial involvement and an acute coronary syndrome is not high on the differential, testing for acute COVID-19 infection (e.g., PCR testing), prior SARS-CoV-2 infection (e.g., detection of SARS-CoV-2 spike and nucleocapsid antibodies), and other viral etiologies (e.g., respiratory viruses associated with myocarditis) are recommended in consultation with the BCCDC Medical Microbiologist (telephone 604-661-7033). It should be noted that troponins, BNP and CRP are non-specific biomarkers and may be elevated in a number of non-cardiac medical conditions. If concern for myocarditis or pericarditis persists, an echocardiogram can be undertaken in consultation with cardiology at BC Children's (telephone 604-875-2161), or an adult cardiology care provider as appropriate. While the gold standard(s) for diagnosing myocarditis is cardiac MRI, PET or endomyocardial biopsy, these will typically not be necessary in an otherwise well adolescent or young adult. Consultation can be sought with infectious disease and/or rheumatology if other etiologies are being considered.

All cases of myocarditis or pericarditis following vaccination should be reported to the local health authority. BCCDC and other Canadian public 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 including in adolescent populations. Parents, teens and young adults should be reassured that these events are rare and typically associated with mild illness and full recovery. There are clear benefits of mRNA vaccines in reducing infection and transmission as well as hospitalizations and deaths due to COVID-19 infections.





2021. https://doi.org/10.1016/j.vaccine.2021.05.087

https://journals.lww.com/pidj/Abstract/9000/Transient Cardiac Injury in Adolescents Receiving.95800.aspx

https://www.aappublications.org/news/2021/06/10/covid-vaccine-myocarditis-rates-061021

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<sup>&</sup>lt;sup>1</sup> 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

<sup>&</sup>lt;sup>2</sup> Mouch SA, Roguin A, Hellou E, Ishai A et al. Myocarditis following COVID-19 mRNA vaccination. Vaccine. 2021 May 28:S0264-410X(21)00682-4. doi: 10.1016/j.vaccine.2021.05.087. Epub ahead of print. PMID: 34092429.

<sup>&</sup>lt;sup>3</sup> Snapiri O, Rosenberg D, Chen MD, Shirman N, et al. Transient Cardiac Injury in Adolescents Receiving the BNT162b2 mRNA COVID-19 Vaccine. Pediatr Infect Dis J. 2021 June 2. doi: 10.1097/INF.0000000000003235. Online ahead of print.

<sup>&</sup>lt;sup>4</sup> Marshall M, Ferguson ID, Lewis P, Jaggi P, et al. Symptomatic Acute Myocarditis in Seven Adolescents Following Pfizer-BioNTech COVID-19 Vaccination. Pediatrics. 2021 Jun 4:e2021052478. doi: 10.1542/peds.2021-052478. Epub ahead of print. PMID: 34088762. https://pubmed.ncbi.nlm.nih.gov/34088762/

<sup>&</sup>lt;sup>5</sup> Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

<sup>&</sup>lt;sup>6</sup> COVID-19 vaccine safety updates. Vaccines and Related Biological Product Avisory Committee. June 10 2021. Presnetation by Dr. Tom Shimabukuro. Vaccine Safety Team. CDC COVID-19 Vaccine Task Force. https://www.fda.gov/media/150054/download

<sup>&</sup>lt;sup>7</sup> Melissa Jenco. American Academy of Pediatrics News. CDC confirms 226 cases of myocarditis after COVID-19 vaccination in people 30 and under. June 10 2021.

<sup>&</sup>lt;sup>8</sup> 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

<sup>&</sup>lt;sup>9</sup> Canada Vigilance Program. <a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/canada-vigilance-program.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/canada-vigilance-program.html</a>

<sup>&</sup>lt;sup>10</sup> Canadian National Vaccine Safety Network (CANVAS).

https://cirnetwork.ca/network/national-ambulatory-network/

<sup>&</sup>lt;sup>11</sup> Canadian Immunization Monitoring Program ACTive (IMPACT). <a href="https://www.cps.ca/impact">https://www.cps.ca/impact</a>
<sup>12</sup> Reported side effects following COVID-19 vaccination in Canada. <a href="https://health-page-14">https://health-page-14</a>

infobase.canada.ca/covid-19/vaccine-safety/

<sup>&</sup>lt;sup>13</sup> BC Centre for Disease Control. BC's weekly report on adverse events. BC Report: AEFI with COVID-19 vaccines. <a href="http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/monitoring-vaccine-uptake-safety-and-effectiveness">http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/monitoring-vaccine-uptake-safety-and-effectiveness</a>

<sup>&</sup>lt;sup>14</sup> BC Centre for Disease Control. Report of Adverse Event Following Immunization with COVID-19 Vaccine. http://www.bccdc.ca/resource-