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AT A GLANCE

Myocarditis and Pericarditis Following COVID-19 mRNA Vaccines

2nd revision – October 1, 2021

Background

In May 2021, international reports 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 United States.[1-2] Information to date indicates that these events occur: mainly in adolescents and young adults, more often in males than females, more commonly after the second dose, and typically within several days after vaccination. Most cases appear to be mild and respond well to conservative treatment (e.g. non-steroidal anti-inflammatory drugs) and rest.

All countries using mRNA vaccines in young adults and adolescents are continuing to recommend their use, but are following the evolving evidence on this topic very closely as further information is collected.

Situation in Canada, Ontario, and Internationally

Surveillance of myocarditis/pericarditis following COVID-19 vaccination from passive and active vaccine safety surveillance systems in Canada demonstrates a higher number of cases in younger people (i.e., less than 40 years of age) than would normally be expected in the general population. Weekly updates on national vaccine safety data can be found on the Public Health Agency of Canada's (PHAC) website.[3] Health Canada recently updated the product monographs for both Moderna Spikevax® and Pfizer-BioNTech Comirnaty® COVID-19 vaccines to include information about these risks.[4] Health Canada and PHAC continue to monitor reports of myocarditis/pericarditis and the evolving information regarding the association with mRNA vaccines.

Public Health Ontario's (PHO) enhanced epidemiological summary of myocarditis/pericarditis following COVID-19 mRNA vaccines in Ontario from December 13, 2020 to August 7, 2021 similarly found that the highest reporting rate of myocarditis/pericarditis was observed in males aged 18-24 years following the second dose of mRNA vaccines.[5] Additionally, the reporting rate of myocarditis/pericarditis was higher for those receiving the Moderna Spikevax® as the second dose of the series (regardless of the product received for the first dose).[5] For males aged 18-24 years old, the reporting rate for second dose Moderna Spikevax® was 263.2 per million doses compared to 37.4 per million doses in this group with Pfizer-BioNTech Comirnaty® second dose.[5]

In the United States, analysis from the Vaccine Safety Datalink (VSD) has shown an elevated rate ratio of confirmed myocarditis/pericarditis cases among 12 to 39 year olds, after both Pfizer-BioNTech Comirnaty® and Moderna Spikevax® COVID-19 vaccines, during days 0-21 and especially, days 0-7 following vaccination, most notably after the second dose (adjusted rate ratio, 23.84, 95% confidence interval, 8.49 to 83.64).[6] In Israel, Pfizer-BioNTech Comirnaty® was found to be associated with an

excess myocarditis risk of 1 to 5 events per 100,000 persons (risk ratio, 3.24; 95% confidence interval, 1.55 to 12.44).[7]

Reporting of myocarditis and pericarditis in Ontario

Health care professionals in Ontario should submit any reports of myocarditis/pericarditis following COVID-19 vaccines to their local public health unit using the Ontario AEFI reporting form.[8-9] PHO is monitoring adverse events following immunization (AEFI) as part of COVID-19 vaccine safety surveillance[10] including events of myocarditis/pericarditis following COVID-19 mRNA vaccines in Ontario.

Clinical considerations, including recommendations for clinicians, are available from the Canadian Cardiovascular Society, Hospital for Sick Children, the Canadian Journal of Cardiology, and the Centres for Disease Control and Prevention (CDC).[11-14] The National Advisory Committee on Immunization (NACI) recommends that as a precautionary measure, individuals who experienced myocarditis/pericarditis after a first dose of an mRNA COVID-19 vaccine should wait to receive a second dose until more information is available[15] which is also supported by a recent article published in the Canadian Journal of Cardiology.[13]

NACI recommends informed consent for mRNA COVID-19 vaccines should include a discussion about the rare risk of myocarditis/pericarditis following immunization, and that individuals should seek immediate medical attention should symptoms develop.[16] Post-market preliminary safety data reported by the US VSD, as well as Canadian post-market passive and active surveillance data suggest relatively higher rates of myocarditis/pericarditis reported after Moderna Spikevax® compared to Pfizer-BioNTech Comirnaty®, although verification of this potential difference is ongoing. NACI also notes that provinces and territories may decide to continue using only Pfizer-BioNTech Comirnaty® for adolescents given more experience with this product in this age group and the possibility of a lower rate of myocarditis and/or pericarditis with Pfizer-BioNTech Comirnaty®.[16] On September 29, 2021, out of an abundance of caution, Ontario issued a preferential recommendation for the use of Pfizer-BioNTech Comirnaty® vaccine for individuals 18-24 years of age, and the continued use of Pfizer-BioNTech for individuals 12-17 years of age, based on an analysis of data from Ontario's AEFI surveillance system.[17]

PHO will continue to monitor for reported events of myocarditis/pericarditis following COVID-19 vaccination in partnership with the Ontario Ministry of Health and federal/provincial/territorial vaccine safety networks, and will provide timely updates as more information becomes available.

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Citation

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