

## FOCUS ON

# (ARCHIVED) Myocarditis and Pericarditis after COVID-19 mRNA Vaccines

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### ARCHIVED DOCUMENT

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## Introduction

This document is intended for health care providers and public health partners. It provides an overview of what is currently known about events of myocarditis and pericarditis following mRNA COVID-19 vaccines. This document will be updated as new information becomes available.

## Key Messages

- Cases of myocarditis/pericarditis following immunization with mRNA COVID-19 vaccines have been reported in Ontario, Canada, and internationally. Reported cases have occurred more frequently in males under the age of 30 years, more commonly following their second dose, usually within one week of vaccination, and have been mild with a quick recovery.
- Post-marketing safety data reported in Ontario, Canada and the the United States (US) suggests higher rates of myocarditis/pericarditis reported after Moderna Spikevax COVID-19 vaccine as compared to Pfizer-BioNTech Comirnaty COVID-19 vaccine, particularly among adolescent males.
- Although early on in the roll-out of the pediatric COVID-19 vaccination, there have been very few reports of myocarditis/pericarditis in Ontario, Canada, and internationally following the administration of pediatric Pfizer-BioNTech Comirnaty, in children 5 -11 years of age. Similar to older age groups, there is a male predominance with most cases occurring after dose 2 in the 5-11 year olds. However, reporting rates of myocarditis/pericarditis for males ages 5-11-years are substantially lower than for males ages 12–15 and 16–17-years.
- In order to further minimize the rare risk of adolescents and young adults experiencing myocarditis/pericarditis after receiving a mRNA COVID-19 vaccine, the National Advisory Committee on Immunization (NACI) issued a preferential recommendation for the use of Pfizer-

BioNTech Comirnaty mRNA COVID-19 vaccine (30 mcg) product in adolescents and young adults 12 to 29 years of age, on December 3, 2021.

- The Ontario Ministry of Health (MOH) also preferentially recommends the use of Pfizer-BioNTech COVID-19 vaccine for individuals under 30 years old, in alignment with NACI and based on the the observed increase in the number of reports of myocarditis/pericarditis following vaccination with Moderna relative to Pfizer-BioNTech in the 12-29 year old age group in Ontario.
- The benefits of vaccination continue to outweigh the risks of COVID-19 illness and vaccination is highly recommended for all eligible individuals, including children and youth.

## Background

In May 2021, international reports of myocarditis/pericarditis following vaccination with COVID-19 mRNA vaccines emerged from the United States<sup>1,2</sup> and Israel.<sup>3</sup> Preliminary reports, which have been confirmed with additional investigation (outlined below) indicated that these cases occurred mainly in adolescents and young adults, more often in males than females, more commonly after the second dose, and typically within one week after vaccination.<sup>1,2,4</sup> Most cases appeared to be mild and responded well to conservative treatment (e.g., non-steroidal anti-inflammatory drugs) and rest. While no myocarditis/pericarditis events were initially observed with Pfizer-BioNTech Comirnaty<sup>5</sup> including among 12 to 15 year old adolescents<sup>6</sup>, and Moderna Spikevax<sup>7</sup> clinical trials, these trials were not adequately powered to detect rare adverse events following immunization. Since these original reports, multiple immunization advisory groups and vaccine regulatory committees have met to discuss this vaccine signal and to provide recommendations. To date, all countries offering COVID-19 vaccination in young adults and adolescents continue to recommend their use.

## Overview of Myocarditis and Pericarditis

Myocarditis is defined as inflammation of the heart muscle and pericarditis is defined as inflammation of the lining outside the heart. Symptoms of both can include shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm.<sup>1,2,4</sup> Other non-cardiac symptoms can include fatigue, gastrointestinal symptoms (nausea, vomiting, abdominal pain), dizziness or syncope, edema (swelling of the lower legs), or cough.<sup>4</sup>

The list of possible causes or triggers for myocarditis/pericarditis is broad and includes both infectious (i.e., recent viral, bacterial, fungal, tuberculosis, parasitic infection),<sup>8</sup> and non-infectious triggers (i.e., auto-immune, connective tissue disease, metabolic (e.g., renal), malignancy, trauma, toxins, drug-induced).<sup>4,9</sup> Smallpox vaccination is the only vaccine that has ever been conclusively linked to myocarditis based on a significantly higher relative risk.<sup>10</sup>

Myocarditis<sup>11,12</sup> and pericarditis<sup>13</sup> have also been associated with recent Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection. In two case studies and one cohort study, competitive athletes infected with SARS-CoV-2 had cardiac magnetic resonance (cMR) findings consistent with myocarditis (1.4%, 2.3%, 15%, respectively).<sup>14-16</sup> A large nationwide Israeli study demonstrated that SARS-CoV-2 infection was associated with a substantially increased risk of myocarditis (risk ratio, 18.28; 95% CI, 3.95-25.12; risk difference, 11.0 events per 100,000 persons; 95% CI, 5.6-15.8) and of additional serious adverse events, including pericarditis.<sup>17</sup> Subsequent analysis demonstrated that the risk of myocarditis and pericarditis after SARS-CoV-2 infection increased in both males and females under and over the age of 40 years. Specifically, in young male adolescents and adults ages 16-39 years old, there was an excess of 11.54 events of myocarditis per 100,000 persons (95% CI, 2.48-22.55).<sup>18</sup>

## Early Reports of Myocarditis and Pericarditis Following COVID-19 Vaccination

In April 2021, an Israeli news release reported 62 cases of myocarditis out of approximately five million doses of Pfizer-BioNTech Comirnaty vaccine administered.<sup>19</sup> Of these cases, 56 occurred after dose 2, with most occurring in men younger than 30 years of age.

In April 2021, 23 cases of symptomatic acute myocarditis presented within four days following COVID-19 mRNA vaccination (seven with Pfizer-BioNTech Comirnaty, sixteen with Moderna Spikevax) were reported by the US Department of Defence in healthy military members; twenty of which occurred after the second dose.<sup>20</sup>

## Clinical Description of Events

Numerous published studies of myocarditis following COVID-19 mRNA vaccinations (Pfizer-BioNTech Comirnaty, Moderna Spikevax) have demonstrated that these events typically present as chest pain, fever or shortness of breath in adolescent and young adult males, within two to seven days after their second dose.<sup>21-30</sup> Cases are typically mild with no reported deaths. In cases requiring hospitalization, the majority were of short durations, in non-ICU settings.<sup>21-30</sup> Generally, these individuals recovered quickly with resolution of their symptoms within a couple of weeks of discharge, and typically with conservative treatment of non-steroidal anti-inflammatories (NSAIDs) and rest.<sup>28,29,31,32</sup> Troponin levels were elevated with abnormal echocardiogram and/or cMR.<sup>22-32</sup>

## Epidemiology of Myocarditis/Pericarditis after a primary series of COVID-19 vaccines

### Reporting Rate of Myocarditis/Pericarditis Internationally

- A published meta-analysis of studies from four international databases from January 1, 1947 until October 15, 2021 reported on the incidence of myocarditis/pericarditis following COVID-19 vaccination compared to non-COVID-19 vaccination.<sup>33</sup> In the general population, there was no significant difference in the incidence of myocarditis/pericarditis between COVID-19 vaccines (mRNA and non-mRNA vaccines) (19.3 per million vaccine doses, 95%-CI, 10.9-34.3) and non-COVID-19 vaccines (51.4 per million vaccine doses, 95%-CI, 9.8-269.5). For COVID-19 vaccines, the incidence of myocarditis/pericarditis was significantly higher among males, individuals less than 30 years of age, those who had received mRNA vaccines, and among persons who had received a second dose of COVID-19 vaccination.<sup>33</sup>
- An unpublished Nordic study found men under the age of 30 in Finland, Sweden, Norway, and Denmark who had received Moderna Spikevax COVID-19 vaccine had a slightly higher risk than others of developing myocarditis. Based on this data, as of October 7, 2021, Finland, Sweden and Denmark have paused the use of Moderna COVID-19 vaccine for younger males.<sup>34</sup> This was substantiated by a population-based cohort study from Denmark that subsequently found that vaccination with Moderna Spikevax COVID-19 vaccine was associated with a significantly increased rate of myocarditis or myopericarditis, especially among individuals aged 12-39 years (adjusted hazard ratio 5.24 (95% CI, 2.47-11.12); absolute rate 5.7 (3.3-9.3) per 100 000 individuals aged 12-39 years within 28 days of vaccination).<sup>35</sup>

## Reporting Rate of Myocarditis/Pericarditis in the United States

- The Vaccine Adverse Event Reporting System (VAERS) is a passive vaccine safety surveillance system in the US.
  - In the most updated analyses of data from VAERS (through January 13, 2022) found that reporting rates of myocarditis following dose 2 of Moderna Spikevax COVID-19 vaccination, from 0 to 7 days after vaccination, was highest among males 18-24 years old (40.0 cases per million doses administered) followed by males 25-29 years old (18.3 cases per million doses administered).<sup>36</sup> In males, reporting rates of myocarditis were consistently higher after dose 2 than dose 1. Reporting rates after dose 1 (18-39 year olds) and dose 2 (18-49 year olds) consistently exceeded background rates of myocarditis. The estimated background rate of myocarditis in the US regardless of vaccination status is 0.2 to 2.2 per million person 8-day risk period.<sup>36</sup>
  - A published descriptive study of reports of myocarditis to VAERS following mRNA-based COVID-19 vaccine administration between December 2020 and August 2021 in individuals older than 12 years of age in the US also found that the rates of myocarditis were highest after the second vaccination dose in adolescent males aged 12 to 15 years (70.7 per million doses of the Pfizer-BioNTech Comirnaty vaccine) and in adolescent males aged 16 to 17 years (105.9 per million doses of the Pfizer-BioNTech Comirnaty vaccine).<sup>37</sup>
  - Data on adverse events following immunization (AEFIs) in children and adolescents, as of December 19, 2021 Among 12-15 year olds for 18,707,169 administered doses of Pfizer-BioNTech Comirnaty vaccine, there were 265 verified cases of myocarditis; 90% of these occurred in males.<sup>38</sup> Among 8,674,378 administered doses of the pediatric Pfizer-BioNTech Comirnaty vaccine to 5-11 year olds, there were 12 verified cases of myocarditis; 67% of these occurred in males.<sup>38</sup> The reporting rates of myocarditis among males following a second dose of mRNA vaccine was more than ten times lower in those 5 to 11 as compared to those 12-15 and 16-17 years of age, although it did exceed the background incidence in all age groups.<sup>38</sup> For males, reporting rates (per 1 million administered doses) exceeded background incidence especially following dose 2 (ages 5–11 (4.3), 12–15 (45.7), and 16–17 (70.2) years).<sup>38</sup>
- The Vaccine Safety Datalink (VSD) is an active surveillance system in the US that uses a rapid cycle analysis (RCA), to examine the observed number of adverse events compared with the expected number of events.
  - Using data from VSD, Klein et al. assessed the safety of the mRNA COVID-19 vaccines (Pfizer-BioNTech Comirnaty and Moderna Spikevax) from one to twenty-one days after dose 1 or 2 over a six month period from December 2020 through June 2021.<sup>39</sup> Among individuals aged 12 to 39 years, the incidence of myocarditis/pericarditis per 1,000,000 person-years and adjusted relative risk (aRR) during the risk versus comparison intervals was 321 versus 35 (aRR 9.83; 95%CI, 3.35-35.77) during days 0 to 7 after vaccination after either dose 1 or 2. This corresponded to a statistically additional 6.3 cases per million doses ( $p < 0.001$ , 95%CI, 4.9-6.8) after either dose 1 or dose 2.<sup>39</sup> The aRR estimates were higher for both Pfizer-BioNTech Comirnaty and Moderna Spikevax vaccines, with significant clustering within the first five days of mRNA vaccination and the risk being highest after dose two.<sup>39</sup>

- Up to January 15, 2022, confirmed cases of myocarditis and pericarditis in the 0–7-day risk interval were compared with outcome events in vaccinated comparators on the same calendar days for mRNA COVID-19 vaccination for adults aged 18–39.<sup>36</sup> Moderna Spikevax COVID-19 vaccination is associated with increased risk of myocarditis and pericarditis in persons ages 18–39 years.<sup>36</sup> The increased risk was observed after both dose 1 and dose 2; the risk is higher following dose 2 of Moderna Spikevax. There was a statistically significant 61.8 excess cases per million doses administered to males following dose 2 of Moderna.<sup>36</sup>
- For the period up until December 24, 2021, validated cases of myocarditis/pericarditis, among 12–17-year olds in the 0-7 day risk interval after Pfizer-BioNTech Comirnaty were compared with outcome events in vaccinated comparators on the same calendar days.<sup>40</sup> Among 12–17-year-olds, the rate ratio for myocarditis/pericarditis was elevated during after Dose 2. After dose 2, there were significantly excess of 70.2 cases per million doses administered (adjusted rate ratio 46.18).<sup>40</sup>
- For 5-11 year olds, two potential cases of myocarditis/pericarditis were identified in a 21 day risk window following administration of a total of 431,485 doses of the pediatric formulation of the Pfizer-BioNTech Comirnaty, as of December 25, 2021.<sup>40</sup> A chart review verified one 11-year-old as having acute pericarditis 19 days after dose 2.

### Reporting Rate of Myocarditis/Pericarditis in Israel

- Analysis of observational data of adverse events following mRNA vaccination from the largest health care organization in Israel compared matched individuals forty-two days after being vaccinated with two doses of Pfizer-BioNTech to unvaccinated individuals. Vaccination was most strongly associated with an elevated risk of myocarditis (risk ratio, 3.24; 95% CI, 1.55-12.44; risk difference, 2.7 events per 100,000 persons; 95% CI, 1.0-4.6).<sup>17</sup>
- The risk of myocarditis increased by a factor of three after vaccination, which translated to approximately 3 excess events per 100,000 persons (95% CI, 1 to 5 excess events per 100,000 persons).<sup>17</sup> Among the persons with myocarditis in the vaccinated group, the median age was 25 years and 90.9% were male.
- Further analysis of adverse events following mRNA vaccination stratified by age and sex, found that among males between 16 and 39 years old, there was an excess of 8.62 events of myocarditis per 100,000 persons (95% CI, 2.82-14.35) with a risk ratio of 4.95 (95% CI, 1.61-16.57).<sup>18</sup> In comparison, the excess risk for the same group following SARS CoV-2 infection was 11.54 events of myocarditis per 100,000 persons (95% CI, 2.48-22.55). Similarly, there was an increased risk of pericarditis following mRNA vaccines in young males aged 16-39 years (risk ratio, 2.67; 95% CI, 1.03-9.26; risk difference, 5.28 events per 100,000 persons; 95% CI, 0.17-10.33).<sup>18</sup>

### Reporting Rate of Myocarditis/Pericarditis in Canada

- Up to and including March 4, 2022, there were 1,886 reports of myocarditis/pericarditis to the Public Health Agency of Canada and Health Canada.<sup>41</sup> Of these reported cases, 1,192 occurred following a Pfizer-BioNTech Comirnaty COVID-19 vaccine for a reporting rate of 2.18 events per 100,000 administered doses. There were 656 events following the Moderna Spikevax COVID-19 vaccine for a reporting rate of 2.88 per 100,000 administered doses.<sup>41</sup>

- For all ages and sexes combined, the reporting rate of cases of myocarditis/pericarditis following vaccination with Moderna Spikevax COVID-19 vaccine is higher than that of Pfizer-BioNTech Comirnaty COVID-19 vaccine.<sup>41</sup> confirmed that there is a product-specific difference observed in Canada between the two mRNA vaccines and the risk for myocarditis and/or pericarditis.<sup>42</sup> In 18-29 year-old males who received a second dose of mRNA COVID-19 vaccine, the attributable risk of myocarditis and/or pericarditis was found to be 6.37 (95% CI, 4.20-6.69; p = 0.007) times higher among Moderna Spikevax COVID-19 vaccine recipients as compared to Pfizer-BioNTech COVID-19 vaccine recipients.<sup>42</sup> In the same age group, modelling estimated that the risk of myocarditis and/or pericarditis was 4.73 (95% CI, 3.19-7.20; p <0.001) times higher after Moderna Spikevax compared to Pfizer-BioNTech Comirnaty vaccination.<sup>42</sup>

## Reporting Rate of Myocarditis/Pericarditis in Ontario

- Using a broad definition of myocarditis and pericarditis from the 10th revision of the International Classification of Diseases, baseline data in Ontario was obtained from the Institute for Clinical Evaluative Sciences (ICES) for the period of 2015-2020.<sup>43</sup> The average annual incidence of myocarditis/pericarditis per 100,000 individuals for the following age groups was: 12-19 years (16.0; 95% confidence Interval [CI], 15.1-16.9), 20-29 years (27.3; 95% CI, 26.4-28.2), 30-39 years (27.7; 95% CI, 26.7, 28.7), and 40-49 years (28.6; 95% CI, 27.7-29.7). For Ontarians 80 years of age and older, the average annual incidence of myocarditis/pericarditis (broad definition) was 78.1 per 100,000 individuals (95% CI, 75.3-81.0). Incidence was consistently higher in males than females for each of the above age groups. (Kwong J, ICES, personal communication email, 2021 Aug 5).<sup>43</sup>
- Passively reported events of myocarditis/pericarditis following COVID-19 vaccine in Ontario are higher than expected in the general population based on trends in background rates for these types of events.<sup>44</sup> Additional information on these events and other COVID-19 reported AEFIs can be found in Public Health Ontario's [weekly AEFI summary](#).<sup>44</sup>
  - As of March 6, 2022, there have been 708 reports of myocarditis/pericarditis following receipt of COVID-19 mRNA vaccines in Ontario for an overall crude reporting rate of 24.3 per million doses of mRNA vaccines administered. Of these, 190 (26.8%) were diagnosed with myocarditis and 333 (47.0%) were diagnosed with pericarditis.<sup>44</sup> The remaining 183 (26.1%) were diagnosed with perimyocarditis (n=37), myopericarditis (n=137) and myocarditis/pericarditis (n=11).<sup>44</sup>
  - The highest reporting rates were observed in younger age groups (12-17 and 18-24 years) and among males. The highest reporting rate was observed for males aged 18-24 years of age following dose 2, at 199.2 events per million doses administered.<sup>44</sup>
  - Among children 5-11 years old, there has only been 1 report of myocarditis/pericarditis in a female following a first dose of the pediatric Pfizer-BioNTech Comirnaty COVID-19 vaccine. The crude reporting rate for two doses of the pediatric Pfizer-BioNTech Comirnaty COVID-19 vaccine for both sexes is 1.0 per million doses administered.<sup>44</sup>
- Public Health Ontario has produced an [Enhanced Epidemiological Summary](#) of myocarditis/pericarditis following vaccination with COVID-19 mRNA vaccines in Ontario from December 13, 2020 to November 21, 2021.<sup>45</sup>

- The reporting rate of myocarditis/pericarditis was higher following the second dose than after the first dose for both the Pfizer-BioNTech Comirnaty and Moderna Spikevax COVID-19 vaccines.<sup>45</sup>
- The reporting rate of myocarditis/pericarditis was highest for individuals aged 18-24 years, followed by individuals aged 25-29 years following Moderna Spikevax COVID-19 vaccine as the second dose.<sup>45</sup>
- The reporting rate of myocarditis/pericarditis for males aged 18-24 years following Moderna Spikevax COVID-19 vaccine as the second dose was approximately 4.6 times higher than the reporting rate of males in the same age group following Pfizer-BioNTech Comirnaty COVID-19 vaccine as the second dose.<sup>45</sup>
- Buchan et al. examined the epidemiology of myocarditis and pericarditis following mRNA COVID-19 vaccines in Ontario by vaccine product, schedule, and interval in a pre-print using the provincial passive vaccine safety surveillance database.<sup>46</sup> The highest reporting rate of myocarditis/pericarditis was observed in males aged 18-24 years following Moderna Spikevax COVID-19 vaccine as the second dose.<sup>46</sup> Overall, reporting rates were higher when the inter-dose interval was shorter (i.e.,  $\leq 30$  days) for both mRNA vaccine products, Pfizer-BioNTech Comirnaty and Moderna Spikevax. Among individuals who received Moderna Spikevax COVID-19 vaccine for the second dose, rates were higher for those who had a heterologous as opposed to homologous vaccine schedule.<sup>46</sup>

## Epidemiology of Myocarditis/Pericarditis after a booster dose of COVID-19 vaccines

- For a mRNA booster dose, preliminary data from the US and Israel suggests that the rate of myocarditis following a Pfizer-BioNTech Comirnaty (30 mcg) booster dose may fall between the rates observed after dose 1 and the rates observed after dose 2.<sup>47</sup> However, preliminary data from the UK suggests that myocarditis was higher post-vaccine dose 3 compared to post-vaccine dose 2 of a a Pfizer-BioNTech Comirnaty (30 mcg) COVID vaccine.<sup>47</sup>

## Summary of Immunization Advisory Group Recommendations on COVID-19 Vaccine Use

### WHO Global Advisory Committee on Vaccine Safety (GACVS)

- As of July 9, 2021, after reviewing published guidance from countries including the US (VAERS), GACVS concluded that current evidence suggests a likely causal association between myocarditis and the mRNA vaccines.<sup>48</sup> However, GACVS deemed that the benefits of mRNA COVID-19 vaccines outweigh the risks in reducing hospitalizations and deaths due to COVID-19 infections.<sup>48</sup>

- In October 2021, GACVS reviewed data from Australia, Canada, Israel, and the US and found that some, but not all, data suggest a higher incidence of myocarditis after a second dose of the COVID-19 vaccine from Moderna Spikevax COVID-19 vaccine than Pfizer-BioNTech Comirnaty COVID-19 vaccine in young males, although the overall risk is small.<sup>49</sup> It was also noted that myocarditis can occur following SARS-CoV-2 infection and that mRNA vaccines have a clear benefit in preventing hospitalisation and death from COVID-19.<sup>49</sup>

### **Centers for Disease Control and Prevention (CDC)**

- Following a benefit-risk assessment for myocarditis/pericarditis after vaccination with mRNA COVID-19 vaccines, the ACIP determined that the benefits of using mRNA COVID-19 vaccines clearly outweigh the risks of myocarditis/pericarditis.<sup>36,38</sup> For this reason, the CDC continues to recommend COVID-19 vaccination for everyone 12 years of age and older given the greater risk of other serious complications related to COVID-19, such as hospitalization, multisystem inflammatory syndrome in children (MIS-C), or death.<sup>1,50</sup>
- It is recommended that any individuals with a history of myocarditis/pericarditis after a dose of an mRNA COVID-19 vaccine should generally avoid a subsequent dose of any COVID-19 vaccine.<sup>50</sup>

### **The National Advisory Committee on Immunization (NACI)**

- In order to further minimize the rare risk of adolescents and young adults experiencing myocarditis and/or pericarditis after receiving a COVID-19 mRNA vaccine, NACI recommends that Pfizer-BioNTech Comirnaty mRNA vaccine (30 mcg) is preferred in adolescents and young adults 12 to 29 years of age to start or complete a primary vaccine series<sup>47</sup> and for booster doses in 18 to 29 year olds.<sup>51</sup> For adolescents 12 to 17 years of age receiving an mRNA COVID-19 vaccine primary series, NACI recommends that the second dose of mRNA vaccine should be provided 8 weeks after the first dose as a longer interval between doses is associated with potentially a lower risk of myocarditis or pericarditis.<sup>47</sup>
- NACI recommends that “In most circumstances, and as a precautionary measure until more information is available, further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine.”<sup>52</sup> NACI also recommends that “Those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations, can be revaccinated once they are symptom free and at least 90 days has passed since vaccination.” For any individual with confirmed myocarditis and/or pericarditis who chooses to receive another dose of vaccine after discussing the risks and benefits with their healthcare provider, NACI recommends that they should be offered the Pfizer-BioNTech Comirnaty (30 mcg) vaccine due to the lower reported rate of myocarditis/pericarditis following the Pfizer-BioNTech Comirnaty vaccine compared to the Moderna Spikevax (100 mcg) vaccine.<sup>52</sup> Informed consent should include a discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt of additional doses of Pfizer-BioNTech Comirnaty COVID-19 vaccine in individuals with a history of confirmed myocarditis.

## Ontario Ministry of Health (MOH)

- Ontario issued a preferential recommendation for the use of Pfizer-BioNTech Comirnaty COVID-19 vaccine for individuals under 30 years of age<sup>53</sup> based on: (1) on analysis of data from Ontario's passive adverse events following immunization (AEFI) surveillance system<sup>44,45</sup> which demonstrated an increased reports of myocarditis/pericarditis following vaccination with Moderna Spikevax COVID-19 vaccine relative to Pfizer-BioNTech Comirnaty COVID-19 vaccine in the 12-29 year old age group; and (2) [NACI's](#) recommendations<sup>47</sup> for the preferential use of the Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg) over the use of the Moderna Spikevax COVID-19 vaccine (100 mcg) in order to minimize the rare risk of adolescents and young adults experiencing myocarditis and/or pericarditis after receiving a COVID-19 mRNA vaccine.<sup>53</sup>

## Clinical Practice Guidance Recommendations

- If an individual develops symptoms including chest pain, shortness of breath, or palpitations following receipt of an mRNA vaccine, in light of the post-market safety surveillance reports of myocarditis/pericarditis in the days following immunization, they are advised to seek immediate medical attention.<sup>1,2,50,54,55</sup>
- All suspected cases of post-vaccine myocarditis/pericarditis should be evaluated by a physician including consultation with a cardiologist as indicated, who may consider doing an electrocardiogram (ECG), troponins, or an echocardiogram.<sup>1,4,54,55</sup>
- It is important to evaluate for other potential causes of myocarditis/pericarditis in consultation with speciality services (e.g., infectious disease, rheumatology, cardiology), to assist in this evaluation, particularly for acute COVID-19 infection (e.g., PCR testing), prior SARS-CoV-2 infection, and other viral etiologies (e.g., enterovirus PCR and comprehensive respiratory viral pathogen testing).<sup>1</sup>
- In Ontario, clinical guidance of the evaluation and management of events of myocarditis/pericarditis following mRNA vaccines in children and adults has been developed by the [Hospital for Sick Children](#), the [Canadian Paediatric Society](#) and the [Canadian Journal of Cardiology](#).<sup>4,54,55</sup>

## Surveillance and Reporting Requirements

- Health care professionals in Ontario should submit any reports of myocarditis/pericarditis following COVID-19 vaccines to their [local public health unit](#)<sup>56</sup> using the [Ontario AEFI reporting form](#)<sup>57</sup>. The [Brighton Collaboration](#) has issued [case definitions](#) for myocarditis/pericarditis<sup>58,59</sup>, which have been summarized in the [Ontario Adverse Events of Special Interest \(AESIs\) for COVID-19 Vaccines Surveillance](#) document<sup>60</sup>.
- As part of ongoing COVID-19 vaccine safety surveillance, the Public Health Agency of Canada (PHAC) and Health Canada are closely monitoring myocarditis/pericarditis in passive and active Canadian vaccine safety surveillance systems, including the [Canadian Adverse Events Following Immunization Surveillance System \(CAEFISS\)](#)<sup>61</sup>, the [Canada Vigilance Program \(CV\)](#)<sup>62</sup>, the [Canadian National Vaccine Safety Network \(CANVAS\)](#)<sup>63</sup> and the [Canadian Immunization Monitoring Program Active \(IMPACT\)](#).<sup>64</sup>

## Conclusions and Implications for Clinical Practice

- NACI continues to strongly recommend that a complete series with an mRNA vaccine should be offered to all eligible individuals without contraindications, including those five years of age and older. However, there is a recommendation by NACI that adolescents and young adults 12 to 29 years of age preferentially receive Pfizer-BioNTech Comirnaty to minimize the rare risk of myocarditis/pericarditis following COVID-19 mRNA vaccination.
- The benefits of COVID-19 mRNA vaccines continue to outweigh the risks of COVID-19 illness in the authorized populations as mRNA vaccines are effective in reducing COVID-19 infections including severe disease such as multisystem inflammatory syndrome in children (MIS-C), hospitalizations, and deaths.
- The risk of myocarditis is higher following infection with SARS-CoV-2, than following mRNA vaccination.
- The Ontario [MOH](#) also preferentially recommends the use of Pfizer-BioNTech Comirnaty COVID-19 vaccine for individuals 12-29 years of age.
- As a precautionary measure, [NACI](#) recommends:
  - In specific circumstances, further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine until more information is available, depending on an individual risk-benefit assessment.
  - Those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations, can be revaccinated once they are symptom free and at least 90 days has passed since vaccination.
  - For any individual with confirmed myocarditis and/or pericarditis who chooses to receive another dose of vaccine after discussing the risks and benefits with their healthcare provider, they should be offered the Pfizer-BioNTech Comirnaty (30 mcg) vaccine due to the lower reported rate of myocarditis/pericarditis following the Pfizer-BioNTech Comirnaty vaccine compared to the Moderna Spikevax (100 mcg) vaccine.
  - Informed consent should include a discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt of additional doses of Pfizer-BioNTech Comirnaty.
- Clinicians and vaccine-recipients need to maintain ongoing vigilance for the clinical syndrome of myocarditis/pericarditis following COVID-19 vaccination. All patients presenting with symptoms suggestive of myocarditis/pericarditis in the days following COVID-19 mRNA vaccination should be [rapidly assessed](#) in-person by a physician or nurse practitioner.
- Public Health Ontario ([PHO](#)) will continue to monitor for reported events of myocarditis/pericarditis following COVID-19 vaccination in partnership with the Ontario MOH and federal/provincial/territorial vaccine safety networks, and will provide [timely updates](#) as more information becomes available.

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