

ENHANCED EPIDEMIOLOGICAL SUMMARY

Myocarditis and Pericarditis Following Vaccination with COVID-19 mRNA Vaccines in Ontario: December 13, 2020 to August 7, 2021

Purpose

This report summarizes reports of myocarditis/pericarditis that have been reported as adverse events following immunization (AEFIs) in Ontario following the receipt of a COVID-19 mRNA vaccine. Data on Ontario-specific reporting rates of myocarditis/pericarditis following COVID-19 mRNA vaccines are presented.

AEFIs reported in the Public Health Case and Contact Management Solution (CCM) as of August 7, 2021 are included in this report. Vaccine doses administered up to and including August 7, 2021 were extracted from the COVaxON application to calculate reporting rates (see technical notes for details on data sources). For a summary of all COVID-19 AEFIs and more details on Ontario's vaccine safety surveillance system, please see [Public Health Ontario's COVID-19 AEFI weekly summary](#).¹

Background

There have been international reports, including from the United States and Israel, of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) associated with COVID-19 mRNA vaccines (Pfizer-BioNTech and Moderna vaccines).^{2,3} Information to date indicates that these events occur more commonly after the second dose, within the week following vaccination (typically within 4-5 days), mainly in adolescents/young adults and more often in males than females.^{3,4} Early evidence from the Vaccine Safety Datalink (VSD), a collaborative project between the Centers for Disease Control and Prevention (CDC) and nine health care organizations in the United States, suggested that there may be mRNA vaccine product-specific differences in the rates of myocarditis and/or pericarditis in individuals aged 12-39 years, although the differences were not statistically significant.⁴

In early June 2021, Public Health Ontario (PHO) issued an Enhanced Surveillance Directive (ESD), requiring Public Health Units (PHU) to prioritize follow-up for any reports of myocarditis or pericarditis following any COVID-19 mRNA vaccine and notify PHO on the same day of PHU notification of the report. In addition to the start of enhanced surveillance, there were many other COVID-19 vaccine program changes that began in June 2021 including: an acceleration of second dose administration that was facilitated by increased Moderna vaccine supply, the increased use of mixed product schedules, an increase in the number of young adults and adolescents immunized, and a transition from a longer interval between first and second dose to shorter intervals such as those outlined in the vaccine product monographs (i.e., 21 or 28 days). These are important contextual factors for the interpretation of the data presented in this summary.

Highlights

- Since the start of the COVID-19 immunization program in Ontario, there have been 314 reports of myocarditis or pericarditis following receipt of COVID-19 mRNA vaccines in Ontario.
- Of those, 204 reports of myocarditis/pericarditis met the Brighton Collaboration case definition levels of diagnostic certainty 1, 2 or 3 for myocarditis or pericarditis and are subsequently included in the remainder of the analysis.^{5,6}
 - Among the 204 reports, 79.9% occurred in males and 69.6% occurred following second dose.
- The reporting rate of myocarditis/pericarditis was higher following the second dose of mRNA vaccine than after the first dose, particularly for those receiving the Moderna vaccine as the second dose of the series (regardless of the product received for the first dose).
 - The reporting rate for the Pfizer-BioNTech vaccine was 6.4 per million doses administered following first dose and 8.7 per million doses administered following second dose, for all age groups and genders combined.
 - The reporting rate for the Moderna vaccine was 6.6 per million doses administered following first dose and 28.2 per million doses administered following second dose, for all age groups and genders combined.
- The highest reporting rate of myocarditis/pericarditis was observed in males aged 18-24 years following second dose.
 - The reporting rate in this group following the Pfizer-BioNTech vaccine as second dose was 37.4 per million doses and was 263.2 per million following the Moderna vaccine as second dose.
- Similar patterns in reporting rates were observed when the analysis was restricted to individuals who received their first dose on or after June 1st, 2021, to account for enhanced awareness and surveillance of myocarditis/pericarditis that began in June and a number of other programmatic factors that occurred at that time.
- Myocarditis/pericarditis following COVID-19 mRNA vaccines remains a rare AEFI (defined by the Canadian Immunization Guide as occurring at frequency of 0.01% to less than 0.1%), even among the age groups where the highest rates of this event have been observed.⁷
- COVID-19 vaccines continue to be recommended and are highly effective at preventing symptomatic infection and severe outcomes from COVID-19 disease, which is also associated with a risk of myocarditis.

Summary of Findings

Characteristics of myocarditis/pericarditis reports following COVID-19 mRNA vaccines

- Among all reports of myocarditis/pericarditis received as of August 7, 2021, 204 reports of myocarditis/pericarditis following COVID-19 mRNA vaccines met the Brighton Collaboration case definition levels of diagnostic certainty 1, 2 or 3 ([Table 1](#)).
 - 79.9% occurred in males
 - 69.6% occurred following second dose
 - The median time from vaccine administration to symptom onset was two days for those reports with known time to onset (n=191). Of those, 79.1 % occurred within 7 days of vaccine administration ([Figure 3](#)).

Reporting rates of myocarditis/pericarditis following COVID-19 mRNA vaccines

- The reporting rate of myocarditis/pericarditis was higher following the second dose than after the first dose for both the Pfizer-BioNTech and Moderna vaccines ([Tables 2a and 2b](#)).
 - The overall reporting rate of myocarditis or pericarditis following the Pfizer-BioNTech vaccine was 8.7 per million following second dose, compared to 6.4 per million doses following first dose.
 - For the Moderna vaccine, the overall reporting rate was 28.2 per million following second dose and 6.6 per million following first dose.
 - The trend of higher reporting rates following second dose was most pronounced in the younger age groups.
- The reporting rate of myocarditis/pericarditis was highest for individuals aged 18-24 years following second dose of the Moderna vaccine ([Figure 4, Tables 2a and 2b](#)).
 - The reporting rate of myocarditis/pericarditis for males aged 18-24 years following second dose of the Moderna vaccine was seven times higher than males in the same age group following second dose of the Pfizer-BioNTech vaccine (263.2 versus 37.4 reports per million doses administered, respectively).
 - This difference in the reporting rates persisted when the analysis was restricted to those AEFIs reported in individuals who received their first dose on or after June 1, 2021 (to control for the period of enhanced surveillance). However, the magnitude of the difference between the two products was reduced ([Tables 3](#)).
- The number of reported events of myocarditis/pericarditis began to increase in early June of 2021. This period of time coincided with increased vaccine supply (particularly of Moderna), administration of second doses, program expansion to younger age groups, and release of the ESD ([Figures 1 and 2](#)).

- Further details on vaccine roll-out over time, including by age, sex, dose number, and product can be found in [PHO's COVID-19 Vaccine Uptake and Program Impact in Ontario report](#).⁸
- The ESD was activated on June 4, 2021, and increasing clinician and public awareness of myocarditis/pericarditis as a possible rare AEFI began prior to this date. We used June 1, 2021 as a cut off to examine potential increases in reporting rates due to increase in detection and/or stimulated reporting following heightened awareness of this issue and the ESD ([Tables 3a and 3b](#)).
- When restricting only to those AEFIs reported in individuals who received their first dose on or after June 1, 2021, the overall rates of myocarditis and pericarditis followed a similar pattern as for the full surveillance period ([Tables 2 and 3](#)).
 - A difference in reporting rates between products continued to be observed for the group with the highest reporting rate of myocarditis/pericarditis, males aged 18-24 years following the second dose (198.6 versus 35.5 reports per million doses administered, for Moderna and Pfizer-BioNTech vaccines respectively).
 - Owing to a smaller number of AEFIs in the restricted analysis, many strata include zero or small numbers of events, which should be interpreted with caution.

Table 1. Characteristics of myocarditis/pericarditis reports following COVID-19 mRNA vaccines: Ontario, December 13, 2020 to August 7, 2021

	After dose 1	After dose 2	Total
Total number of reports	62	142	204
Median age, years (range)	26 (12 – 78)	23 (12 – 81)	24 (12 – 81)
Age group (years)			
12-17	12 (19.4%)	19 (13.4%)	31 (15.2%)
18-24	16 (25.8%)	59 (41.5%)	75 (36.8%)
25-39	17 (27.4%)	37 (26.1%)	54 (26.5%)
40+	17 (27.4%)	27 (19.0%)	44 (21.6%)
Gender			
Male (%)	44 (71.0%)	119 (83.8%)	163 (79.9%)
Female (%)	18 (29.0%)	23 (16.2%)	41 (20.1%)
Median time to onset, days (range)*	7 (0 – 37)	2 (0 – 23)	2 (0 – 37)
Vaccine product			
Pfizer-BioNTech	49 (79.0%)	51 (35.9%)	100 (49.0%)
Moderna	13 (21.0%)	91 (64.1%)	104 (51.0%)
Clinical diagnosis			
Myocarditis	20 (32.3%)	52 (36.6%)	72 (35.3%)
Pericarditis	27 (43.5%)	31 (21.8%)	58 (28.4%)
Myopericarditis**	15 (24.2%)	59 (41.5%)	74 (36.3%)
Severity			
Emergency department visit	62 (100.0%)	140 (98.6%)	202 (99.0%)
In-patient hospitalization***	37 (59.7%)	109 (76.8%)	146 (71.6%)
ICU admission	2 (3.2%)	1 (0.7%)	3 (1.5%)
Fatal	0 (0.0%)	0 (0.0%)	0 (0.0%)

Notes:

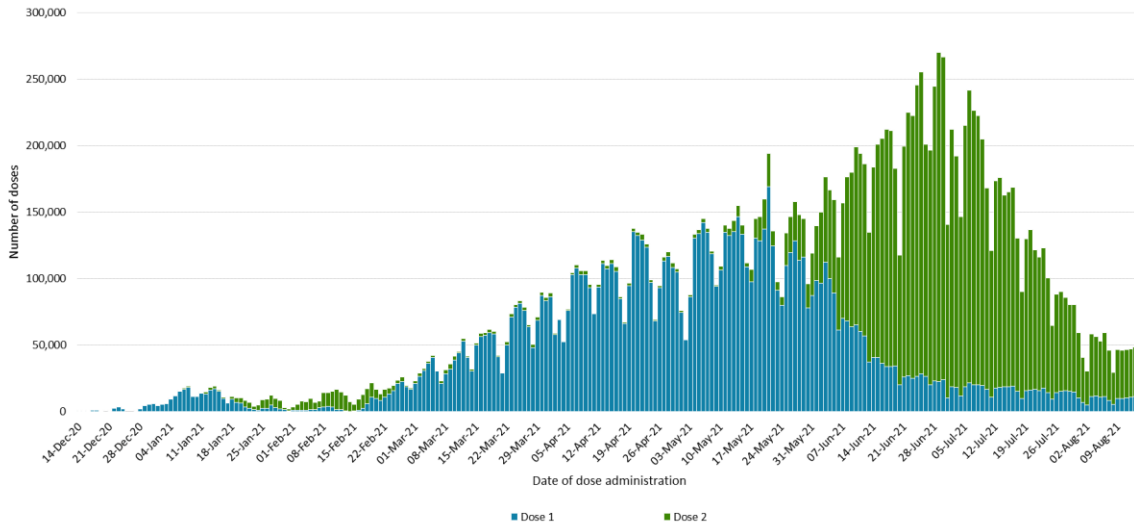
*13 reports with unknown time to onset were excluded from this calculation.

**Includes “myocarditis/pericarditis” (n=2), myopericarditis (n=63), perimyocarditis (n=8) and pleuropericarditis (n=1).

***The proportion of individuals hospitalized was 86.1%, 31.0%, and 89.2% for myocarditis, pericarditis, and myopericarditis respectively.

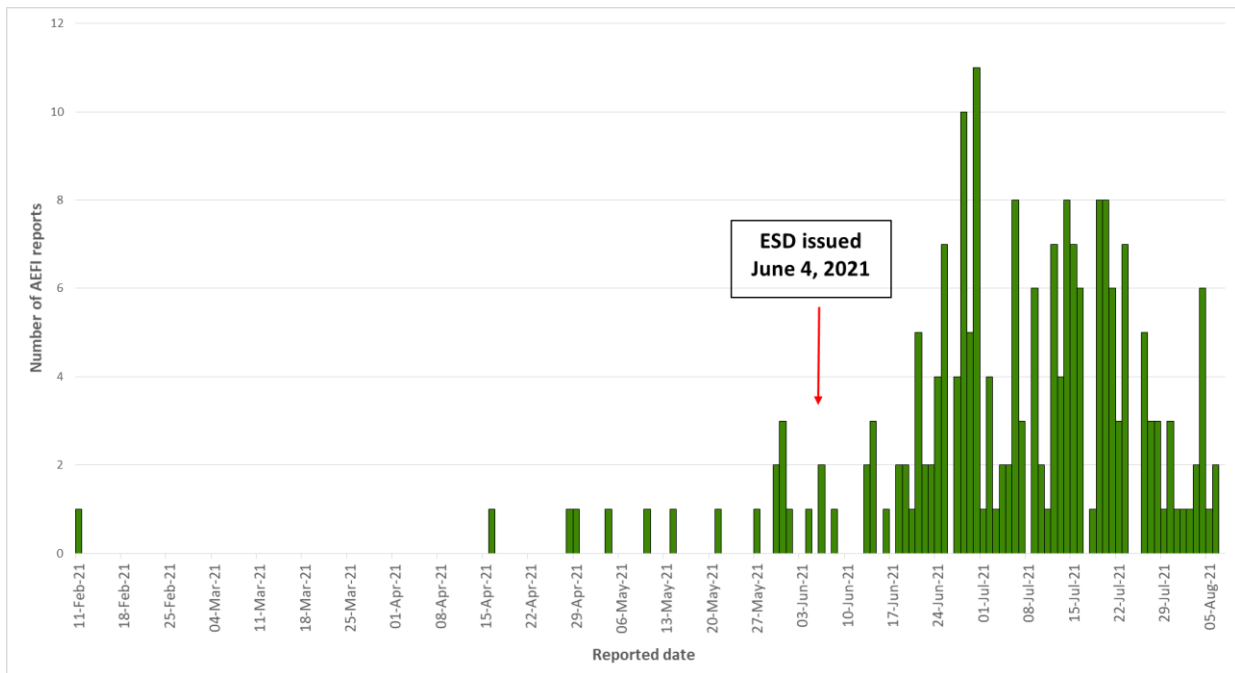
Data source: CCM

Figure 1. Number of COVID-19 vaccine doses administered in Ontario by dose number



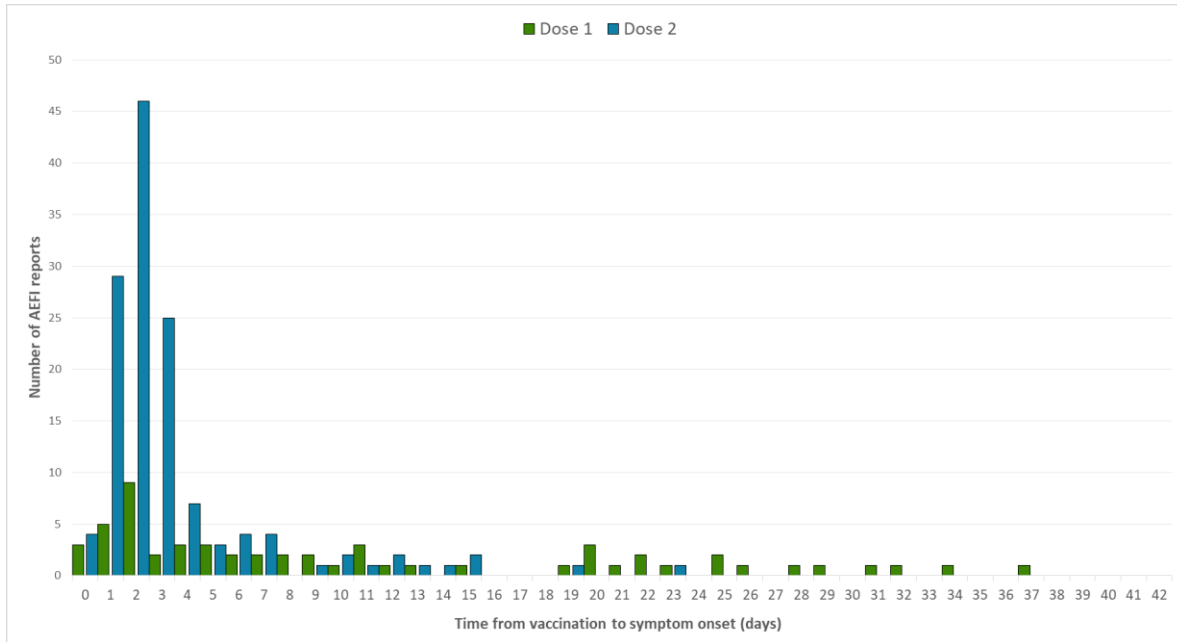
Data source: COVaxON

Figure 2. Myocarditis/pericarditis reports following any dose of COVID-19 mRNA vaccine by reported date: Ontario, December 13, 2020 to August 7, 2021



Data source: CCM

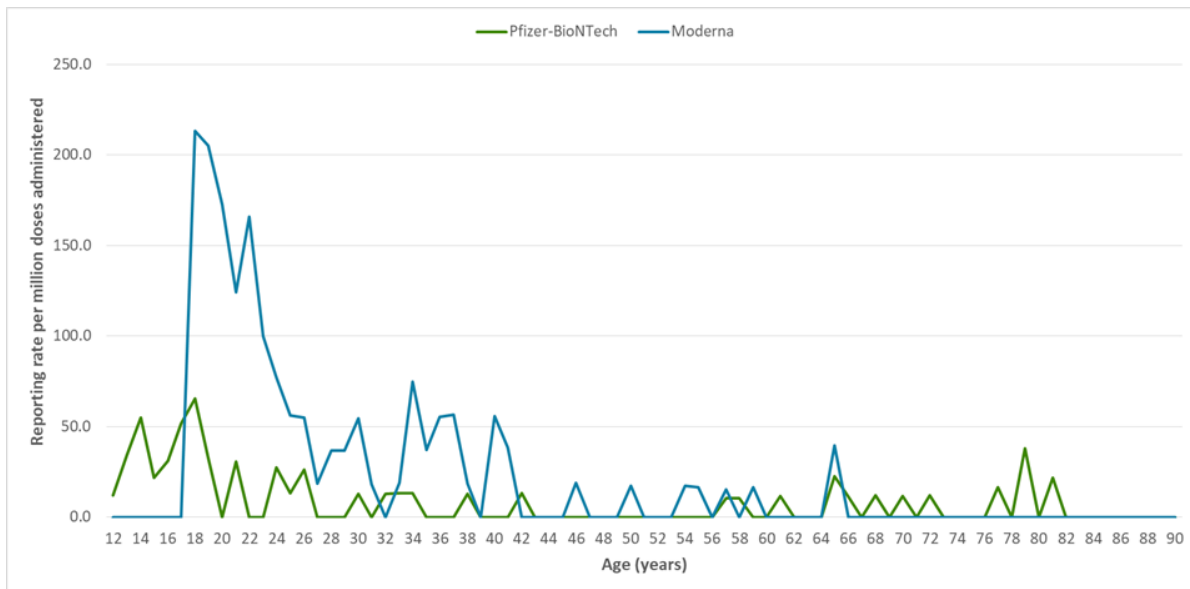
Figure 3. Myocarditis/pericarditis reports following COVID-19 mRNA vaccines by dose number and time to symptom onset: Ontario, December 13, 2020 to August 7, 2021



Notes: Excludes 13 reports with unknown time to onset.

Data source: CCM

Figure 4. Reporting rate of myocarditis/pericarditis per million doses administered by age and mRNA product following administration of second dose: Ontario, December 13, 2020 to August 7, 2021



Notes: No reports were received in individuals over the age of 90 years. There are no reports in individuals aged 12-17 years following the receipt of Moderna vaccine, as the age indication for this vaccine over the period captured in this analysis was for those 18 years of age and older.

Data source: CCM, COVaxON

Table 2a. Crude reporting rate of myocarditis/pericarditis per million doses administered following Pfizer-BioNTech vaccines by dose number, age, and gender: Ontario, December 13, 2020 to August 7, 2021 (n=100)

Age group (years)	All gender: All doses	All gender: Dose 1	All gender: Dose 2	Females: All doses	Females: Dose 1	Females: Dose 2	Males: All doses	Males: Dose 1	Males: Dose 2
12-17	24.5	16.7	34.7	4.8	2.8	7.3	44.0	30.4	62.1
18-24	19.8	18.6	21.6	11.1	13.1	8.1	29.2	24.5	37.4
25-39	6.9	6.8	7.0	3.9	3.3	4.9	10.2	10.6	9.5
40+	3.1	2.5	3.8	1.8	1.2	2.5	4.6	3.9	5.4
Total	7.4	6.4	8.7	3.3	3.0	3.8	12.1	10.3	14.6

Notes: Includes all reports, including reports with missing time to onset (i.e., no restriction on time to onset applied). Data used to calculate the reporting rates are available in [Appendix A1](#).

Data source: CCM, COVaxON

Table 2b. Crude reporting rate of myocarditis/pericarditis per million doses administered following Moderna vaccines by dose number, age, and gender: Ontario, December 13, 2020 to August 7, 2021 (n=104)

Age group (years)	All gender: All doses	All gender: Dose 1	All gender: Dose 2	Females: All doses	Females: Dose 1	Females: Dose 2	Males: All doses	Males: Dose 1	Males: Dose 2
12-17	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
18-24	89.2	8.3	148.0	21.9	8.9	30.8	152.6	7.8	263.2
25-39	24.9	9.0	35.8	9.3	7.7	10.3	39.2	10.2	59.4
40+	5.9	5.2	6.2	3.0	5.0	1.9	8.9	5.4	10.8
Total	20.0	6.6	28.2	6.6	6.2	6.8	33.5	7.1	49.6

Notes: Includes all reports, including reports with missing time to onset (i.e., no restriction on time to onset applied). Data used to calculate the reporting rates are available in [Appendix A2](#).

Data source: CCM, COVaxON

Table 3a. Crude reporting rate of myocarditis/pericarditis per million doses administered following Pfizer-BioNTech vaccines by dose number, age, and gender among individuals who initiated their vaccination in the enhanced surveillance period: Ontario, June 1, 2021 to August 7, 2021 (n=30)

Age group (years)	All gender: All doses	All gender: Dose 1	All gender: Dose 2	Females: All doses	Females: Dose 1	Females: Dose 2	Males: All doses	Males: Dose 1	Males: Dose 2
12-17	20.8	15.2	29.3	2.7	4.5	0.0	38.4	25.5	57.9
18-24	23.3	16.9	37.5	25.5	18.7	39.9	21.6	15.5	35.5
25-39	7.4	10.9	0.0	0.0	0.0	0.0	14.3	20.9	0.0
40+	1.6	2.4	0.0	0.0	0.0	0.0	3.2	4.7	0.0
Total	12.4	10.7	15.6	4.3	4.0	4.9	20.1	17.1	26.0

Notes: Includes all reports, including reports with missing time to onset (i.e., no restriction on time to onset applied). Data used to calculate the reporting rates are available in [Appendix B1](#).

Data source: CCM, COVaxON

Table 3b. Crude reporting rate of myocarditis/pericarditis per million doses administered following Moderna vaccines by dose number, age, and gender among individuals who initiated their vaccination in the enhanced surveillance period: Ontario, June 1, 2021 to August 7, 2021 (n=24)

Age group (years)	All gender: All doses	All gender: Dose 1	All gender: Dose 2	Females: All doses	Females: Dose 1	Females: Dose 2	Males: All doses	Males: Dose 1	Males: Dose 2
12-17	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
18-24	68.7	11.6	134.9	28.8	0.0	59.6	100.0	20.1	198.6
25-39	27.4	11.7	44.6	0.0	0.0	0.0	49.8	20.8	82.6
40+	12.4	21.7	0.0	6.7	11.9	0.0	17.2	30.0	0.0
Total	29.5	15.8	45.9	8.2	5.1	11.7	47.1	24.4	75.2

Notes: Includes all reports, including reports with missing time to onset (i.e., no restriction on time to onset applied). Data used to calculate the reporting rates are available in [Appendix B2](#).

Data source: CCM, COVaxON

Technical Notes

Data Sources

- The data for this report were based on:
 - AEFI information from the Public Health Case and Contact Management Solution (CCM) extracted on **August 9, 2021 at approximately 9:00 a.m.**
 - Doses administered data from Ontario Ministry of Health's COVaxON application extracted on **August 9 at approximately 7:00 a.m.** Methodology used to calculate the number of doses administered is documented in [PHO's COVID-19 Vaccine Uptake in Ontario report](#).⁸

Data Caveats

- Data presented in this report only represent AEFIs reported to public health units and recorded in CCM. As a result, all counts will be subject to varying degrees of underreporting or stimulated reporting due to a variety of factors.
- CCM and COVaxON are dynamic reporting systems which allow ongoing updates to data previous entered. As a result, data extracted from CCM and COVaxON represent a snapshot at the time of data extraction and may differ from previous or subsequent reports.

Methods

- AEFI reports from CCM where the Disposition was reported as ENTERED IN ERROR, DOES NOT MEET DEFINITION or DUPLICATE – DO NOT USE, or any variation on these values have been excluded. AEFI reports from CCM where the Status was reported as MERGED-OBSOLETE have also been excluded.
- Reports of myocarditis/pericarditis were identified through keyword search on all AEFI reports following receipt of COVID-19 vaccines in Ontario in CCM for 'myocarditis' or 'pericarditis'. In addition, all AEFI reports with event reported as 'COVID-19 AESI: cardiovascular injury' and 'COVID-19 AESI: myocarditis/pericarditis' have been reviewed.
- All identified reports of myocarditis or pericarditis were assessed using the Brighton Collaboration case definitions for myocarditis or pericarditis, as appropriate. This score is not a measure of severity but rather reflects the level of diagnostic certainty, with level 1 being the most highly specific for the condition.^{5,6}
- Reports of myocarditis or pericarditis included in this report are those that have a:
 - Diagnosis of myocarditis and meeting Brighton Collaboration level of diagnostic certainty 1 to 3 for myocarditis⁵ OR
 - Diagnosis of pericarditis and meeting the Brighton Collaboration level of diagnostic certainty 1 to 3 for pericarditis⁶ OR
 - Diagnosis of myopericarditis or perimyocarditis and meeting either the Brighton Collaboration levels 1 to 3 for myocarditis or pericarditis^{5,6}
- Reporting rates of myocarditis or pericarditis were calculated per million doses of COVID-19 mRNA vaccine doses administered by age group, gender, dose number, and product type. All

reports, including reports with missing time to onset (i.e., no restriction on time to onset applied, were included in the calculation of reporting rates.

- The calculation of reporting rates were repeated by restricting both the numerator and denominator to individuals who initiated their vaccination series on or after June 1, 2021, in order to account for any increase in AEFI reporting following the increased awareness resulting from media reports and the provincial ESD for myocarditis/pericarditis that began in June 2021.

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Appendix A

Table A1. Number of myocarditis/pericarditis reports and doses administered following the Pfizer-BioNTech vaccine by dose number, age, and gender: Ontario, December 13, 2020 to August 7, 2021

Gender	Age group	Dose Number	Number of reports	Doses administered
Female	12-17	1	1	352,913
Female	12-17	2	2	273,262
Female	18-24	1	5	382,256
Female	18-24	2	2	246,351
Female	25-39	1	3	907,289
Female	25-39	2	3	617,687
Female	40+	1	3	2,415,760
Female	40+	2	5	2,017,978
Male	12-17	1	11	362,110
Male	12-17	2	17	273,582
Male	18-24	1	9	367,869
Male	18-24	2	8	214,024
Male	25-39	1	9	848,652
Male	25-39	2	5	527,118
Male	40+	1	8	2,028,924
Male	40+	2	9	1,659,236

Data source: CCM, COVaxON

Table A2. Number of myocarditis/pericarditis reports and doses administered following the Moderna vaccine by dose number, age and gender: Ontario, December 13, 2020 to August 7, 2021

Gender	Age group	Dose Number	Number of reports	Doses administered
Female	12-17	1	0	934
Female	12-17	2	0	2,110
Female	18-24	1	1	111,826
Female	18-24	2	5	162,588
Female	25-39	1	2	260,341
Female	25-39	2	4	387,242
Female	40+	1	3	601,728
Female	40+	2	2	1,057,824
Male	12-17	1	0	800
Male	12-17	2	0	2,001
Male	18-24	1	1	127,760
Male	18-24	2	44	167,198
Male	25-39	1	3	293,616
Male	25-39	2	25	421,158
Male	40+	1	3	560,280
Male	40+	2	11	1,020,857

Data source: CCM, COVaxON

Appendix B

Table B1. Number of myocarditis/pericarditis reports and doses administered following the Pfizer-BioNTech vaccine by dose number, age and gender among individuals who initiated their vaccination in the enhanced surveillance period: Ontario, June 1, 2021 to August 7, 2021

Gender	Age group	Dose Number	Number of reports	Doses administered
Female	12-17	1	1	223,492
Female	12-17	2	0	151,113
Female	18-24	1	2	106,971
Female	18-24	2	2	50,115
Female	25-39	1	0	218,897
Female	25-39	2	0	104,932
Female	40+	1	0	208,862
Female	40+	2	0	101,889
Male	12-17	1	6	235,673
Male	12-17	2	9	155,441
Male	18-24	1	2	128,905
Male	18-24	2	2	56,353
Male	25-39	1	5	239,660
Male	25-39	2	0	109,194
Male	40+	1	1	214,424
Male	40+	2	0	101,798

Data source: CCM, COVaxON

Table B2. Number of myocarditis/pericarditis reports and doses administered following the Moderna vaccine by dose number, age and gender among individuals who initiated their vaccination in the enhanced surveillance period: Ontario, June 1, 2021 to August 7, 2021

Gender	Age group	Dose Number	Number of reports	Doses administered
Female	12-17	1	0	111
Female	12-17	2	0	433
Female	18-24	1	0	35,985
Female	18-24	2	2	33,545
Female	25-39	1	0	75,194
Female	25-39	2	0	71,767
Female	40+	1	1	83,869
Female	40+	2	0	64,547
Male	12-17	1	0	111
Male	12-17	2	0	459
Male	18-24	1	1	49,732
Male	18-24	2	8	40,291
Male	25-39	1	2	95,990
Male	25-39	2	7	84,782
Male	40+	1	3	100,103
Male	40+	2	0	74,042

Data source: CCM, COVaxON

Citation

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines in Ontario: December 13, 2020 to August 7, 2021. Toronto, ON: Queen's Printer for Ontario; 2021.

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