Adverse Events Following Immunization (AEFI) with COVID-19 Vaccines in Nova Scotia

December 16, 2020 to June 30, 2022

This Report in Context

- This is the first quarterly AEFI with COVID-19 vaccine report and includes new AEFI reported between April 1, 2022 and June 30, 2022
- Nova Scotia has administered 2,369,773 doses of COVID-19 vaccine since the start of the COVID-19 immunization program (December 16, 2020) and 107,587 doses in the last quarter.
- There have been 750 Adverse Events Following Immunization (AEFI). There was a net loss of 2 AEFI this report. Although 35 were newly reported this last quarter, 37 were removed due to ineligibility following review.
- The majority of AEFI in Nova Scotia (82.0%) were non-serious; 18.0% were serious
- The rate of AEFI reported in Nova Scotia is low (31.6 per 100k doses administered) and decreased slightly over this quarter. The rate of serious AEFI reported is also low (5.7 per 100k doses administered) and remained stable over this quarter.
- In comparison, the rate of AEFI reports in Canada, to date are:
  - 45 non-serious events per 100k doses administered
  - 11 serious adverse events per 100k doses administered.[i]
- AEFI are reported more often in females than males
- AEFI are reported most often in those aged 30-64 years and least often in those aged 5-17 years.

Overall Summary of Adverse Events Following Immunization

Between December 16, 2020 and June 30, 2022 Nova Scotia has administered 2,368,773 doses of COVID-19 vaccine and has received a total 750 reports of adverse events following immunization.

Table 1: Number and rate of AEFI reported following immunization for COVID-19, December 16, 2020 to June 30, 2022

	Number	Per 100k Doses Administered
Total AEFIs	750	31.6
Non-Serious AEFIs	615	26.0
Serious AEFIs	135	5.7

Table 2: Number and rate of AEFI reported following immunization for COVID-19, by vaccine product, December 16, 2020 to June 30, 2022

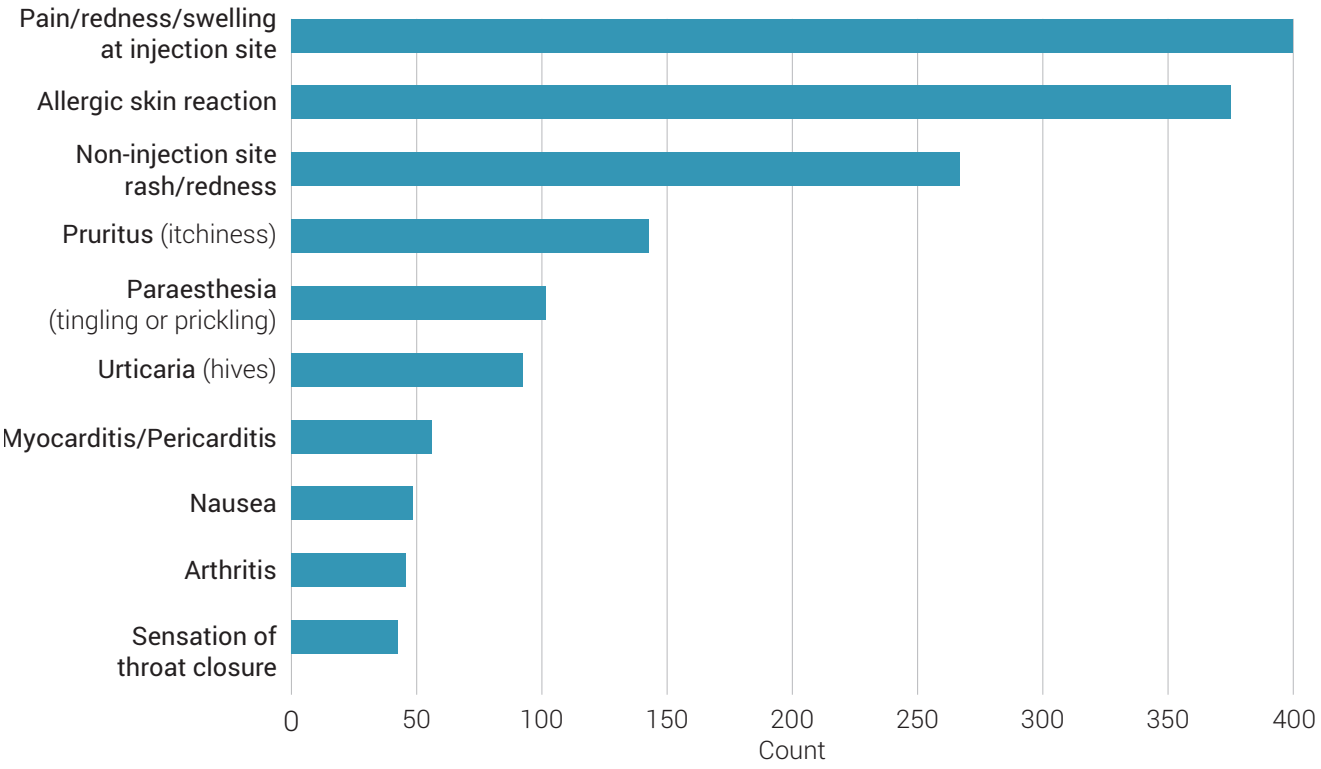
	Pfizer	Moderna	COVISHIELD/ AZ	Unknown/ Other	Total
Total number of AEFI reported	445	244	57	4	750
Number of Non-Serious AEFI	376	185	51	3	615
Number of Serious AEFI	69	59	6	1	135
Total number of doses administered	1596666	706052	62251	4812	2369773
Total AEFI reported per 100,000 doses	27.9	34.6	91.6	83.1	31.6
Serious AEFI reported per 100,000 doses	4.3	8.4	9.6	20.8	5.7

Table 3: Number and rate of AEFI reported following immunization for COVID-19, by age group and sex, December 16, 2020 to June 30, 2022

Age Group	Female		Male		Total	
	N	Rate per 100,000 doses	N	Rate per 100,000 doses	N	Rate per 100,000 doses
5-17*	18	19.8	12	12.7	30	16.2
18-29	58	35.8	38	24.8	96	30.4
30-49	181	59.4	51	18.7	232	40.2
50-64	157	52.3	53	19.4	210	36.6
65-79	90	31.8	54	21.0	144	26.7
80+	25	23.8	13	17.7	38	21.3
Total	529	42.4	221	19.7	750	31.6

*4 AEFI report in children 5-11 years of age

Figure 1: Number of the ten most frequently reported adverse events following immunization for COVID-19, December 16, 2020 to June 30, 2022



*An AEFI report may contain multiple adverse events. The total adverse event-specific counts may not equal the total number of AEFI reports. This does not include AEFIs classified in the composite "Other" category.

Serious Adverse Events Following Immunization Summary

An event is serious if it occurs within a specified time period after vaccination and it results in hospitalization, is life threatening, or results in death.[ii] These reports do not imply a causal relationship between the vaccine and the adverse event. As more Nova Scotians are vaccinated, a greater number of adverse events that are incidental to vaccination will be reported.

Between December 16, 2020 and June 30, 2022, there have been a total 135 Serious Adverse Events Following Immunization reported in Nova Scotia.

121 of these adverse event reports required hospitalization

2 of these adverse event reports resulted in permanent disability

There were 11 reports of death within 30 days of vaccination. Reports of death are events temporally associated with vaccine that have not been clearly attributed to other causes. A preliminary review of these events indicated that none were clearly attributable to the vaccine.

Adverse Events of Special Interest Following Immunization

There are three adverse events of special interest (AESI) following immunization which are being actively monitored in Canada as safety signals. Nova Scotia has reported 65 cases of adverse events of interest.

Myocarditis/Pericarditis

- 57 cases
- Cases ranged from 18 to 86 years of age
- 63.2% (n=39) cases among adolescents/young adults under 30 years of age
- 86% (n=49) occurred after dose 2; one case occurred after dose 3; two after dose 4
- 74% (n=42) required hospitalization
- 90% (n=57) occurred within 7 days of vaccination
- 68% (n=39) occurred after vaccination with Moderna; 31% (n=32) occurred after vaccination with Pfizer

Guillain-Barre Syndrome

- 5 cases have occurred in total;
  - 2 cases occurred after Moderna vaccination (both after dose 1)
  - 2 cases occurred after Pfizer vaccination (1 after dose 1; 1 after dose 2)
  - 1 case occurred after COVISHIELD/AstraZeneca vaccine (after dose 1)

Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)

- 2 cases have occurred in total
  - 2 cases occurred after vaccination with COVISHIELD/AstraZeneca

DATA NOTES

Data Sources:

Nova Scotia data: Panorama and CanImmunize

Definitions

Adverse Events Following Immunization (AEFI): A serious or non-serious reaction experienced by a patient following immunization.

The numbers included in the report reflect the number of AEFIs with a status of "Review complete", "Review complete, follow-up required" or "Follow-up complete" AND a Public Health Agency of Canada report date entered into Panorama

Serious AEFI: An adverse event following immunization that has resulted in at least one of the following:

- hospitalization or prolongation of existing hospitalization
- permanent disability
- death

Non-Serious AEFI: An adverse event following immunization that has resulted in at least one of the following:

- a reaction that did not require hospitalization or prolongation of existing hospitalization
- a reaction that did not result in permanent disability
- a reaction that did not result in death

Adverse Events of Special Interest (AESI): Adverse Events of Special Interest are reactions that are of special interest because they are monitored at a national and international level.

Safety Signal: When an Adverse Event Following Immunization occurs at greater than expected frequency for a specific vaccine type or within a specific population group

[i] https://health-infobase.canada.ca/covid-19/vaccine-safety/

[ii] https://health-infobase.canada.ca/covid-19/vaccine-safety/