Adverse Events Following Immunization (AEFIs) with COVID-19 Vaccines in Nova Scotia (JAN 01, 2022, to DEC 31, 2022):

January 31, 2023

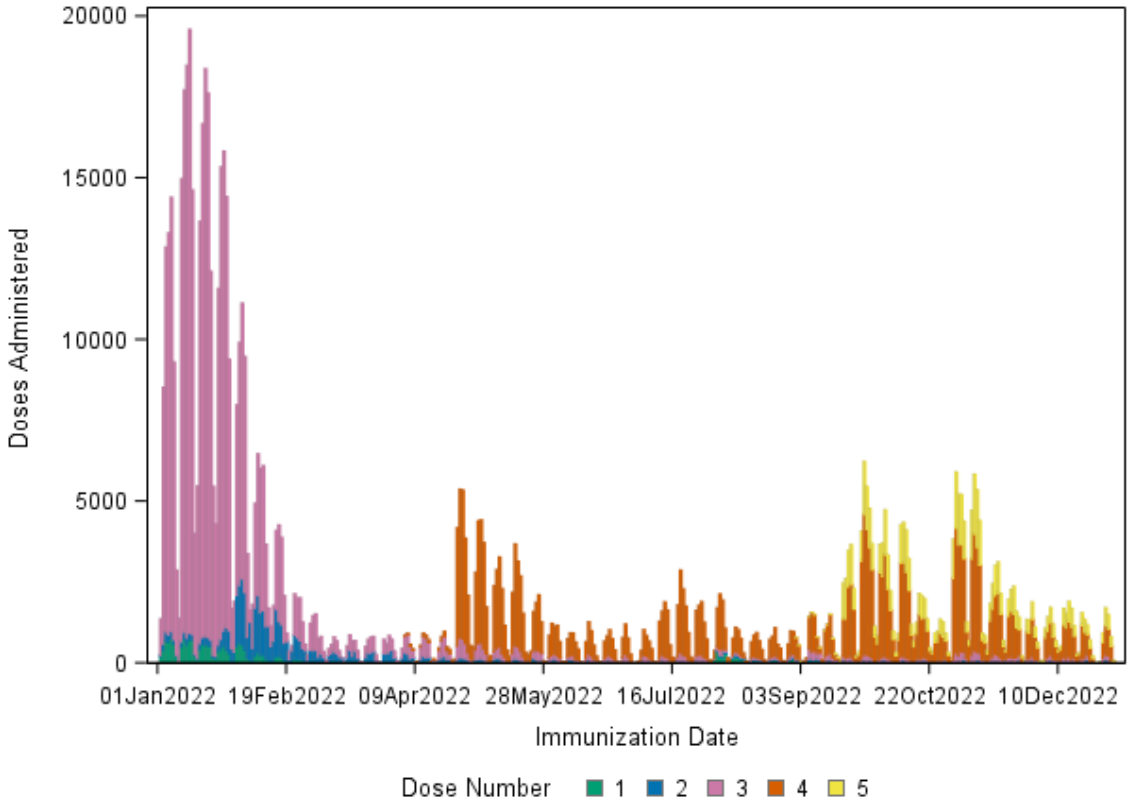
Public Health Branch
Nova Scotia Department of Health and Wellness

Highlights:

- In 2022, a total of 807,927 doses of COVID-19 vaccine were administered, with the vast majority being 3rd, 4th, and 5th doses.
- A total of 62 AEFIs were reported to the province (52 non-serious AEFIs, 10 serious AEFIs).
- AEFIs were most commonly reported following the third dose in the immunization series (10.1 per 100k 3rd doses administered vs 7.7 across all doses administered).
- AEFIs were reported more often in females (9.0 per 100k doses) than in males (6.2 per 100k doses). Serious AEFIs were more reported more often in males (1.6 per 100k) than in females (0.9 per 100k)
- Pain and redness at the injection site was the most commonly reported AEFI (21.6% of all AEFIs). Seizures were the most commonly reported serious AEFI (33% of all serious AEFIs)
- There were 6 adverse events of special interest following immunization reported in the 2022 calendar year: 5 were cases of myocarditis/pericarditis; and 1 was a case of thrombocytopenia.
- A total of eight hospitalizations and one death were reported.

Doses Administered

Figure 1. COVID-19 vaccine doses administered by dose number in the current reporting period (01JAN2022 to 31DEC2022) (N = 807927)



Adverse Events Following Immunization (AEFI)

Table 1. Adverse events following immunization with any COVID-19 vaccine (01JAN2022 to 31DEC2022) by dose number and severity

	Reaction Severity					
	Non-Serious		Serious		Total	
Dose Number	N	Per 100k Doses	N	Per 100k Doses	N	Per 100k Doses
1	2	7.1	0	0.0	2	7.1
2	1	2.0	2	4.0	3	6.0
3	38	9.1	4	1.0	42	10.1
4	10	3.9	4	1.6	14	5.5
5	1	1.7	0	0.0	1	1.7
Total	52	6.4	10	1.2	62	7.7

Notes:
- Dose number represents the total lifetime doses.

Table 2. Number and rate of adverse events following immunization with any COVID-19 vaccine (01JAN2022 to 31DEC2022) by age, sex and reaction severity

	All AEFIs						Serious AEFIs					
	Males		Females		Total		Males		Females		Total	
Age Group	N	Per 100k Doses	N	Per 100k Doses	N	Per 100k Doses	N	Per 100k Doses	N	Per 100k Doses	N	Per 100k Doses
6 mo-11 years	2	8.0	1	4.2	3	6.1	1	4.0	0	0.0	1	2.0
12-19 years	3	20.9	1	6.7	4	13.7	0	0.0	0	0.0	0	0.0
20-39 years	1	1.8	7	10.1	8	6.4	80	0.0	0	0.0	0	0.0
40-59 years	9	9.4	17	15.3	26	12.6	264	4.2	0	0.0	4	1.9
60-79 years	6	4.0	9	5.4	15	4.8	0	0.0	3	1.8	3	1.0
80+ years	2	5.9	4	8.5	6	7.4	1	3.0	1	2.1	2	2.5
Total	**23**	**6.2**	**39**	**9.0**	**62**	**7.7**	**6**	**1.6**	**4**	**0.9**	**10**	**1.2**

Table 3. Number and rate of adverse events following immunization with any COVID-19 vaccine (01JAN2022 to 31DEC2022) by brand and severity

	Doses Administered	All AEFIs		Serious AEFIs	
Product	N	N	Per 100k Doses	N	Per 100k Doses
Other (total)	**358**	**0**	**0.0**	**0**	**0.0**
AstraZeneca	65	0	0.0	0	0.0
Janssen	293	0	0.0	0	0.0
Moderna (total)	**329664**	**27**	**8.2**	**4**	**1.2**
Moderna (original)	220950	24	10.9	4	1.8
Moderna (low-dose)	6044	0	0.0	0	0.0
Moderna (bivalent)	102670	3	2.9	0	0.0
Pfizer (total)	**463138**	**29**	**6.3**	**5**	**1.1**
Pfizer (original)	329435	27	8.2	5	1.5
Pfizer (infant)	373	0	0.0	0	0.0
Pfizer (pediatric)	47083	2	4.2	0	0.0
Pfizer (bivalent)	86247	0	0.0	0	0.0

Table 4. Adverse events following immunization with any COVID-19 vaccine (01JAN2022 to 31DEC2022) by reaction type and severity

	Reaction Severity		
	Non-Serious	Serious	Total
Reaction Type			
Allergic	14	0	14
Local	7	0	7
Neurological	4	2	6
Other	27	8	35

Notes:

- Pfizer doses are categorized as pediatric (5-11 years) and infant (6 months to 4 years).
- AEFI without a known brand name are not listed in **Table** 3; however, they are captured in other tables and figures throughout this report.
- Many adverse events do not fall into one of the major types of reactions (allergic, local, or neurological) and are captured as “other”. A more detailed description of the most common adverse events can be found in **Figures 2a/b**

Figure 2a. Ten most common non-serious AEFIs (01JAN2022 to 31DEC2022) [N = 52]

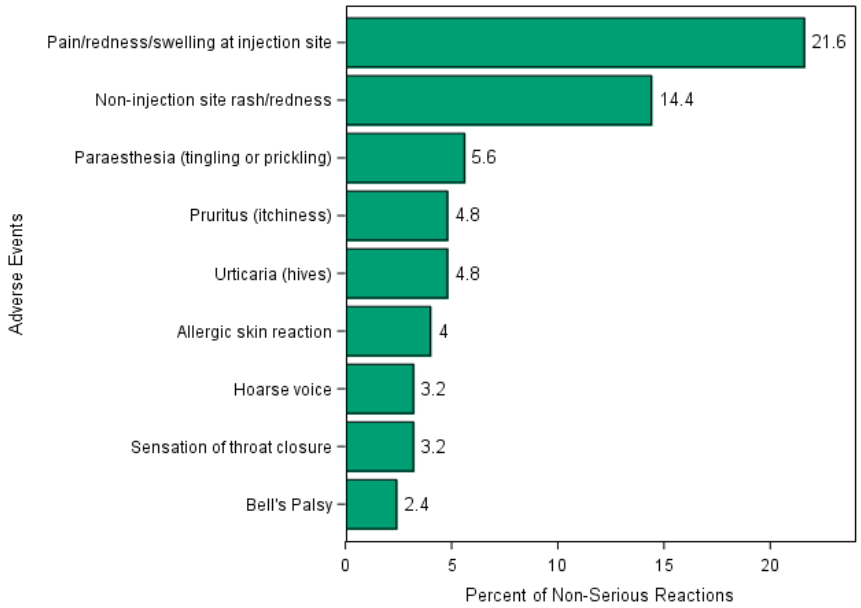
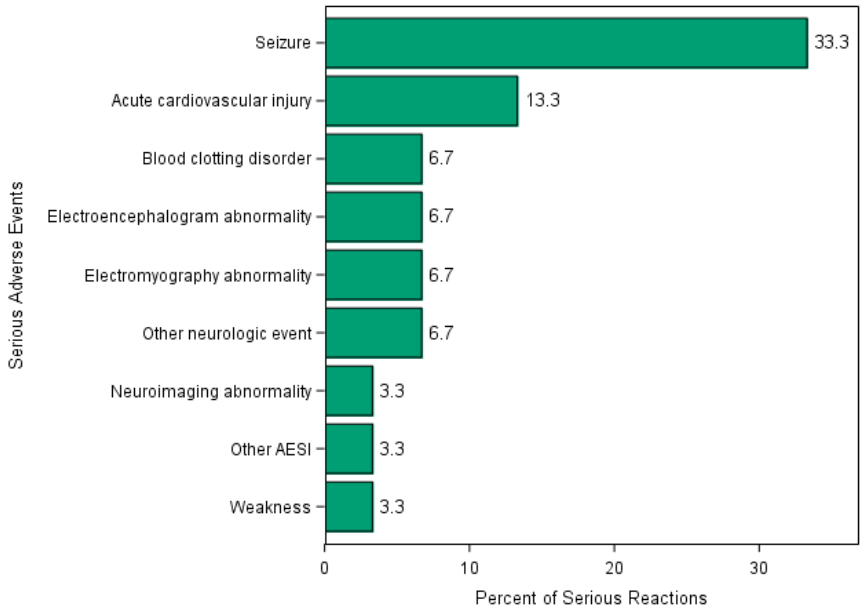


Figure 2b. Ten serious AEFIs (01JAN2022 to 31DEC2022) [N = 10]



Notes:

- Each adverse event can generate multiple described reactions. As such, the frequencies will not sum to, or be proportional to, the number of reported AEFIs
- A category of AEFIs labeled “other serious or unexpected event” are not shown but are relatively frequent (8% of all reactions). These primarily include recurring conditions (e.g., gout, cancer, etc).

Adverse Events of Special Interest (AESI)

There are three adverse events of special interest (AESI) following COVID-19 immunization which are being actively monitored in Canada as safety signals. Nova Scotia received 6 reports of AESIs.

Table 5. Adverse events of special interest following immunization (AESI) with any COVID-19 vaccine (01JAN2022 to 31DEC2022)

AESI	N	Median Age	Age Range
Myocarditis/Pericarditis	5	48	19 - 86
Thrombocytopenia	1	70	N/A
Guillain-Barre Syndrome	0	N/A	N/A

Serious Adverse Events Following Immunization

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.[i] 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.

Table 6 summarizes the serious adverse events following immunization. Between January 1, 2022 and December 31, 2022, there were 10 Serious Adverse Events Following Immunization reported in Nova Scotia.

8 of these adverse event reports required hospitalization.

1 of these adverse event reports resulted in permanent disability.

There was 1 report 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.

Table 6. Outcomes of adverse events of following immunization with any COVID-19 vaccine (01JAN2022 to 31DEC2022)

Outcome	N	Median Age	Age Range
Hospitalizations	8	49	7 - 86
Permanent Disability/Incapacity	1	78	N/A
Deaths	1	80	N/A

Data Sources and Notes:

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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/