Public Health Agency of Canada | Agence de la santé publique du Canada

Canada

Background rates

CONFIDENTIAL

Public Health Agency of Canada
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Methodology

- Includes all acute hospital (DAD)[1] and emergency department (NACRS)[2] records with an admission diagnosis of the condition of interest between 2015-2019.
- Excludes records:
  - where the condition was flagged as a questionable diagnosis.
  - which occurred within 365 days of a previous event.
    - 30 days for the seizure background rates
  - which occurred on the same episode as another record.
  - where the individual left the emergency department without being seen (registered and/or triaged and then left).
- Rates calculated using Statistics Canada's population estimates as of July.[3]
- Confidence intervals calculated using the Poisson exact method to account for rare events.

1. CIHI Discharge Abstract Database, Canadian Institute for Health Information, fiscal years 2013-2019
2. CIHI National Ambulatory Care Reporting System, Canadian Institute for Health Information, fiscal years 2013-2019
3. Statistics Canada, Centre for Demography

Limitations and considerations

- The reporting coverage to NACRS varies by province/territory and time. Therefore, the background rates may underreport the rate in Canada excluding Quebec.
- Quebec data is excluded as their data is not included in DAD and NACRS.
- Emergency department data (NACRS) is not provided for the following provinces/territories: New Brunswick, Newfoundland and Labrador, Northwest Territories, and Nunavut
- As we do not have access to physician billing records, conditions investigated must have been serious enough to warrant a hospital or emergency department visit. Therefore, this may underreport the true rate.
- As we rely on ICD-10-CA codes to identify each condition, there may be misclassification of the outcome.
- We did not have follow up time for each individual in the denominator resulting in limitations when interpreting the results.
- **Information shared within this publication must not be used for identifying individuals.**

Comparing background rates to observed reporting rates

- CAUTION: as we did not have follow up time for each individual, rates are presented as "rate per 100,000 persons".

- In order to compare the background rates to the observed reporting rates, the at-risk period needs to be accounted for (e.g. We may only expect cases of bell's palsy to be reported to CAEFISS if they occurred within 90 days of vaccination).
  - If we ASSUME that, when calculating the background rate, each individual contributed a full year of follow up time, the rates in this document can be interpreted as "rate per 100,000 person-years"

- FORMULA: background rate adjusting for the at-risk period of the AEFI

$$Background\ rate\ per\ 100{,}000\ person\ years * \left(\frac{At\ risk\ period}{365.2425}\right) = Background\ rate\ per\ 100{,}000\ persons\ \boldsymbol{in\ at\ risk\ period}$$

- Example 1: Background rate for bell's palsy for all ages and sexes combined after adjusting for an at-risk period of 90 days

$$23.15 * \left(\frac{90}{365.2425}\right) = 5.7\ per\ 100{,}000\ persons\ in\ 90\ days$$

- Example 2: Background rate for ischemic stroke for males ages 65+ after adjusting for an at-risk period of 21 days

$$747.73 * \left(\frac{21}{365.2425}\right) = 42.99\ per\ 100{,}000\ persons\ in\ 21\ days$$

Abdominal thrombosis

Definitions

Definition	ICD-10-CA codes
Abdominal thrombosis[1]	I81, I82.0, I82.2, I82.3, I82.8, I82.9.

[1]Definition developed in consultation with medical team within the Public Health Agency of Canada

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
Abdominal thrombosis	10.12 (9.75 - 10.5)	11.13 (10.74 - 11.53)	11.88 (11.48 - 12.29)	13.46 (13.04 - 13.89)	14.46 (14.03 - 14.91)	12.24 (12.06 - 12.43)

Rate per 100,000 persons

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Abdominal thrombosis background rate by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	12.24 (12.06 - 12.43)	13.31 (13.05 - 13.59)	11.19 (10.94 - 11.43)
0-4	5.94 (5.4 - 6.52)	6.86 (6.05 - 7.74)	4.99 (4.29 - 5.76)
5-11	0.91 (0.74 - 1.1)	0.99 (0.75 - 1.29)	0.82 (0.6 - 1.1)
12-17	2.03 (1.75 - 2.34)	1.97 (1.6 - 2.41)	2.09 (1.69 - 2.55)
18-29	4.2 (3.94 - 4.47)	3.81 (3.46 - 4.17)	4.62 (4.23 - 5.04)
30-39	7.51 (7.13 - 7.9)	6.66 (6.16 - 7.2)	8.33 (7.77 - 8.92)
40-49	11.08 (10.61 - 11.57)	11.19 (10.52 - 11.9)	10.98 (10.32 - 11.67)
50-59	16.53 (15.98 - 17.1)	18.8 (17.97 - 19.66)	14.29 (13.57 - 15.04)
60-69	24.29 (23.55 - 25.05)	29.31 (28.14 - 30.52)	19.53 (18.6 - 20.49)
70+	30.14 (29.28 - 31.01)	36.48 (35.07 - 37.94)	25.05 (24.01 - 26.13)

Rate per 100,000 persons

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Acute disseminated encephalomyelitis (ADEM)

Definitions

Definition	ICD-10-CA codes
ADEM[1]	G04.0

[1]Sturkenboom, M., Willame, C., Duran, C., Engelen, R., & Belbachir, L. ACCESS: Background rates of AESI to monitor vaccine safety- definition Acute disseminated encephalomyelitis (1.0). Zenodo; 2021. https://doi.org/10.5281/zenodo.5109555

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
ADEM	0.16 (0.12 - 0.21)	0.18 (0.13 - 0.23)	0.20 (0.15 - 0.26)	0.18 (0.14 - 0.24)	0.17 (0.13 - 0.23)	0.18 (0.16 - 0.20)

Rate per 100,000 persons

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ADEM background rate by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	0.18 (0.16 - 0.20)	0.21 (0.17 - 0.24)	0.15 (0.12 - 0.18)
0-4	0.68 (0.51 - 0.90)	0.96 (0.68 - 1.33)	0.38 (0.21 - 0.64)
5-11	0.38 (0.28 - 0.52)	0.49 (0.32 - 0.71)	0.28 (0.16 - 0.46)
12-17	0.27 (0.17 - 0.39)	0.19 (0.09 - 0.35)	0.35 (0.20 - 0.57)
18-29	0.14 (0.10 - 0.20)	0.14 (0.08 - 0.23)	0.14 (0.08 - 0.23)
30-39	0.08 (0.04 - 0.13)	0.07 (0.03 - 0.15)	0.08 (0.04 - 0.16)
40-49	0.10 (0.06 - 0.16)	0.13 (0.07 - 0.23)	0.07 (0.03 - 0.15)
50-59	0.11 (0.07 - 0.17)	0.12 (0.06 - 0.21)	0.11 (0.05 - 0.19)
60-69	0.18 (0.12 - 0.25)	0.20 (0.11 - 0.32)	0.15 (0.08 - 0.26)
70+	0.10 (0.05 - 0.16)	0.10 (0.04 - 0.21)	0.09 (0.04 - 0.18)

Rate per 100,000 persons

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Acute kidney injury (AKI)

Definitions

Definition	ICD-10-CA codes
AKI 1[1]	N17.9
AKI 2[1]	N17.x
AKI 3[2]	N10, N12, N13.3, N13.6, N16.0, N17.0, N17.2, N17.9, S37.00x

[1]Definition developed in consultation with medical team within the Public Health Agency of Canada
[2]MEDSAFE. Adverse events following immunisation with COVID-19 vaccines: Safety Report #43 – 30 April 2022. (2022, May 11). Retrieved August 24, 2022, from https://www.medsafe.govt.nz/COVID-19/safety-report-43.asp#death

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
AKI 1	281.54 (279.56 - 283.52)	307.2 (305.15 - 309.26)	327.16 (325.05 - 329.28)	355.66 (353.48 - 357.85)	374.77 (372.55 - 377)	329.92 (328.97 - 330.86)
AKI 2	288.36 (286.35 - 290.37)	314.37 (312.29 - 316.46)	334.93 (332.8 - 337.07)	363.36 (361.16 - 365.57)	381.9 (379.66 - 384.15)	337.24 (336.28 - 338.2)
AKI 3	395.14 (392.79 - 397.49)	421.08 (418.67 - 423.5)	442.83 (440.38 - 445.29)	472.23 (469.72 - 474.76)	488.52 (485.98 - 491.06)	444.62 (443.52 - 445.72)

Rate per 100,000 persons

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AKI 1 – background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	329.92 (328.97 - 330.86)	363.61 (362.2 - 365.03)	296.75 (295.49 - 298.02)
0-4	14.99 (14.12 - 15.89)	16.53 (15.27 - 17.87)	13.37 (12.21 - 14.61)
5-11	7.92 (7.4 - 8.47)	8.22 (7.48 - 9.01)	7.61 (6.89 - 8.39)
12-17	13.6 (12.87 - 14.37)	13.1 (12.1 - 14.17)	14.12 (13.05 - 15.25)
18-29	34.82 (34.07 - 35.6)	41.24 (40.09 - 42.41)	27.93 (26.95 - 28.93)
30-39	59.54 (58.45 - 60.63)	73.67 (71.97 - 75.4)	45.5 (44.17 - 46.86)
40-49	105.26 (103.79 - 106.74)	127.3 (125 - 129.63)	83.78 (81.94 - 85.64)
50-59	219.17 (217.15 - 221.21)	263.87 (260.72 - 267.04)	174.97 (172.42 - 177.54)
60-69	504.08 (500.67 - 507.52)	611.64 (606.26 - 617.07)	401.97 (397.71 - 406.25)
70+	1903.31 (1896.45 - 1910.18)	2219.1 (2208.01 - 2230.23)	1650.38 (1641.82 - 1658.97)

Rate per 100,000 persons

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AKI 2 – background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	337.24 (336.28 - 338.2)	372.31 (370.88 - 373.74)	302.72 (301.45 - 304)
0-4	16.06 (15.16 - 16.99)	17.73 (16.42 - 19.11)	14.3 (13.1 - 15.58)
5-11	8.26 (7.73 - 8.82)	8.54 (7.79 - 9.34)	7.96 (7.23 - 8.76)
12-17	14.41 (13.65 - 15.2)	13.85 (12.82 - 14.94)	14.99 (13.89 - 16.15)
18-29	36.55 (35.77 - 37.34)	43.28 (42.1 - 44.48)	29.32 (28.32 - 30.34)
30-39	62.1 (61 - 63.22)	76.81 (75.07 - 78.57)	47.5 (46.14 - 48.89)
40-49	109.26 (107.76 - 110.77)	132.19 (129.85 - 134.56)	86.91 (85.04 - 88.82)
50-59	226.18 (224.13 - 228.25)	272.33 (269.13 - 275.55)	180.56 (177.97 - 183.17)
60-69	517.53 (514.08 - 521.01)	628.72 (623.26 - 634.22)	411.97 (407.67 - 416.31)
70+	1934.55 (1927.65 - 1941.48)	2259.1 (2247.91 - 2270.33)	1674.62 (1665.99 - 1683.27)

Rate per 100,000 persons

AKI 3 – background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	337.24 (336.28 - 338.2)	372.31 (370.88 - 373.74)	302.72 (301.45 - 304)
0-4	16.06 (15.16 - 16.99)	17.73 (16.42 - 19.11)	14.3 (13.1 - 15.58)
5-11	8.26 (7.73 - 8.82)	8.54 (7.79 - 9.34)	7.96 (7.23 - 8.76)
12-17	14.41 (13.65 - 15.2)	13.85 (12.82 - 14.94)	14.99 (13.89 - 16.15)
18-29	36.55 (35.77 - 37.34)	43.28 (42.1 - 44.48)	29.32 (28.32 - 30.34)
30-39	62.1 (61 - 63.22)	76.81 (75.07 - 78.57)	47.5 (46.14 - 48.89)
40-49	109.26 (107.76 - 110.77)	132.19 (129.85 - 134.56)	86.91 (85.04 - 88.82)
50-59	226.18 (224.13 - 228.25)	272.33 (269.13 - 275.55)	180.56 (177.97 - 183.17)
60-69	517.53 (514.08 - 521.01)	628.72 (623.26 - 634.22)	411.97 (407.67 - 416.31)
70+	1934.55 (1927.65 - 1941.48)	2259.1 (2247.91 - 2270.33)	1674.62 (1665.99 - 1683.27)

Rate per 100,000 persons

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Appendicitis

Definition

Definition	ICD-10-CA codes
Appendicitis[1]	K35.2, K35.3, K35.8, K36, K37

Definition	CCI procedural codes
Appendicitis[1]	1.NV.89.^^, 1.NV.52.^^

[1]Definition developed in consultation with medical team within the Public Health Agency of Canada

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
Appendicitis	119.99 (118.70 –121.29)	121.68 (120.39 – 122.98)	122.32 (121.04 – 123.62)	123.83 (122.55 – 125.13)	125.21 (123.92 –126.50)	122.64 (122.07 –123.22)

Rate per 100,000 person

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Appendicitis background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	122.64 (122.07 – 123.22)	123.73 (122.91 – 124.56)	121.56 (120.75 – 122.37)
0-4	26.07 (24.93 – 27.26)	30.16 (28.45 – 31.95)	21.78 (20.29 – 23.35)
5-11	140.90 (138.69 – 143.15)	166.38 (163.00 – 169.80)	114.40 (111.55 – 117.30)
12-17	197.40 (194.58 – 200.26)	212.86 (208.75 – 217.02)	181.20 (177.33 – 185.13)
18-29	167.76 (166.09 – 169.44)	165.83 (163.52 – 168.16)	169.81 (167.39 – 172.25)
30-39	146.64 (144.94 – 148.35)	146.27 (143.87 – 148.71)	146.96 (144.56 – 149.38)
40-49	120.48 (118.90 – 122.06)	117.02 (114.82 – 119.26)	123.83 (121.59 – 126.10)
50-59	106.35 (104.94 – 107.77)	93.98 (92.11 – 95.88)	118.56 (116.47 – 120.68)
60-69	91.77 (90.31 – 93.24)	84.32 (82.33 – 86.35)	98.83 (96.73 – 100.97)
70+	71.29 (69.97 – 72.63)	73.97 (71.95 – 76.02)	69.14 (67.40 – 70.92)

Rate per 100,000 person

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Bell's Palsy (BP)

Definition

Definition	ICD-10-CA codes
Bell's palsy (BP)[1,2,3,4]	G51.0

[1]Black S, Eskola J, Siegrist CA, et al. Importance of background rates of disease in assessment of vaccine safety during mass immunisation with pandemic H1N1 influenza vaccines. Lancet. 2009;374(9707):2115-2122. doi:10.1016/S0140-6736(09)61877-8

[2]Li X, Ostropolets A, Makadia R, et al. Characterizing the incidence of adverse events of special interest for COVID-19 vaccines across eight countries: a multinational network cohort study. medRxiv. 2021; Published 2021 Apr 17. doi:10.1101/2021.03.25.21254315

[3]Klein NP, Lewis N, Goddard K, et al. Surveillance for Adverse Events After COVID-19 mRNA Vaccination. JAMA. 2021;326(14):1390-1399. doi:10.1001/jama.2021.15072

[4]Nasreen S, Calzavara A, Buchan SA, et al. Background incidence rates of adverse events of special interest related to COVID-19 vaccines in Ontario, Canada, 2015 to 2020, to inform COVID-19 vaccine safety surveillance. Vaccine. 2022;40(24):3305-3312. doi:10.1016/j.vaccine.2022.04.065

Notes:
Background rates may be underestimated as individuals may not be diagnosed in the hospital or ED.

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
BP	22.18 (21.63 - 22.75)	22.38 (21.83 - 22.94)	23.29 (22.73 - 23.86)	23.72 (23.16 - 24.29)	24.12 (23.56 - 24.69)	23.15 (22.9 - 23.41)

Rate per 100,000 persons

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BP background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	23.15 (22.9 - 23.41)	24.27 (23.91 - 24.64)	22.04 (21.7 - 22.39)
0-4	4.97 (4.48 - 5.5)	4.69 (4.03 - 5.43)	5.26 (4.54 - 6.06)
5-11	6.27 (5.81 - 6.76)	5.57 (4.97 - 6.23)	6.99 (6.3 - 7.74)
12-17	12.03 (11.34 - 12.75)	11.59 (10.65 - 12.59)	12.49 (11.49 - 13.55)
18-29	16.76 (16.24 - 17.3)	14.81 (14.13 - 15.52)	18.86 (18.06 - 19.69)
30-39	23.85 (23.17 - 24.55)	23.84 (22.88 - 24.84)	23.85 (22.89 - 24.84)
40-49	27.46 (26.71 - 28.22)	31.04 (29.91 - 32.2)	23.95 (22.97 - 24.95)
50-59	31.1 (30.34 - 31.88)	34.84 (33.71 - 36.01)	27.4 (26.4 - 28.43)
60-69	32.29 (31.43 - 33.17)	36.33 (35.03 - 37.67)	28.46 (27.34 - 29.62)
70+	33.71 (32.8 - 34.63)	37.29 (35.87 - 38.76)	30.82 (29.66 - 32.02)

Rate per 100,000 persons

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Giant Cell Arteritis (GCA)

Definition

Definition	ICD-10-CA codes
Giant Cell Arteritis[1,2]	**M31.5, M31.6, I77.6**

[1]Barra L, Pope J, Pequeno P, Saxena F, Bell M, Haaland D, et al. Incidence and prevalence of giant cell arteritis in Ontario, Canada [Internet]. Rheumatology. 6 Apr 2022; 59(11): 3250-3258. Available from: https://doi.org/10.1093/rheumatology/keaa095.

[2]Aggar W, Deviley J, Borgert A, and Rasmussen C. Increased incidence of giant cell arteritis after introduction of a live varicella zoster virus vaccine [Internet]. Open Forum Infectious Diseases. 28 Dec 2020; 8(2). Available from: https://doi.org/10.1093/ofid/ofaa647.

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
GCA	5.36 (5.09 – 5.64)	5.59 (5.32 – 5.88)	5.53 (5.26 – 5.81)	5.74 (5.47 – 6.02)	5.90 (5.62 – 6.19)	5.63 (5.51 – 5.75)

Rate per 100,000 persons

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GCA background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	5.63 (5.51 – 5.75)	4.66 (4.51 – 4.83)	6.58 (6.39 – 6.77)
0-11	0.51 (0.41 – 0.62)	0.59 (0.44 – 0.76)	0.42 (0.30 – 0.58)
12-17	1.09 (0.89 – 1.33)	0.71 (0.49 – 0.99)	1.50 (1.17 – 1.90)
18-29	1.69 (1.53 – 1.87)	1.45 (1.24 – 1.69)	1.95 (1.70 – 2.22)
30-39	2.38 (2.17 – 2.61)	1.96 (1.69 – 2.26)	2.80 (2.48 – 3.15)
40-49	3.61 (3.34 – 3.89)	3.27 (2.91 – 3.66)	3.94 (3.55 – 4.37)
50-59	5.45 (5.13 – 5.78)	4.70 (4.28 – 5.14)	6.19 (5.72 – 6.69)
60-69	9.93 (9.45 – 10.42)	9.20 (8.55 – 9.89)	10.62 (9.94 – 11.33)
70+	22.39 (21.66 – 23.15)	18.80 (17.79 – 19.85)	25.27 (24.22 – 26.36)

Rate per 100,000 persons

Granulomatosis with polyangiitis (GPA)

Definition

Definition	ICD-10-CA codes
Granulomatosis with polyangiitis[1]	**M31.3**

[1]Definition developed in consultation with medical team within the Public Health Agency of Canada

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
GPA	1.06 (0.95 – 1.19)	0.96 (0.85 – 1.08)	0.89 (0.78 – 1.01)	0.99 (0.88 – 1.11)	0.83 (0.73 – 0.94)	0.95 (0.90 – 1.00)

Rate per 100,000 persons

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GPA background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	0.95 (0.90 – 1.00)	0.92 (0.85 – 0.99)	0.97 (0.90 – 1.05)
<18	0.15 (0.11 – 0.20)	0.11 (0.06 – 0.17)	0.19 (0.12 – 0.28)
18-29	0.43 (0.35 – 0.52)	0.32 (0.23 – 0.44)	0.54 (0.41 – 0.70)
30-39	0.55 (0.45 – 0.67)	0.42 (0.30 – 0.58)	0.68 (0.52 – 0.86)
40-49	0.84 (0.72 – 0.99)	0.79 (0.62 – 1.00)	0.89 (0.71 – 1.10)
50-59	1.17 (1.02 – 1.32)	1.15 (0.95 – 1.38)	1.18 (0.98 – 1.41)
60-69	1.96 (1.76 – 2.19)	2.25 (1.93 – 2.60)	1.70 (1.43 – 2.00)
70+	2.38 (2.14 – 2.64)	2.59 (2.22 – 3.00)	2.21 (1.91 – 2.55)

Rate per 100,000 persons

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Guillain-Barre syndrome (GBS)

Definition

Definition	ICD-10-CA codes
Gullain-Barré Syndrome (GBS)[1,2,3,4,5,6]	G61.0

[1]Black S, Eskola J, Siegrist CA, et al. Importance of background rates of disease in assessment of vaccine safety during mass immunisation with pandemic H1N1 influenza vaccines. Lancet. 2009;374(9707):2115-2122. doi:10.1016/S0140-6736(09)61877-8
[2]Salinas JL, Major CG, Pastula DM, et al. Incidence and clinical characteristics of Guillain-Barré syndrome before the introduction of Zika virus in Puerto Rico. J Neurol Sci. 2017;377:102-106. doi:10.1016/j.jns.2017.04.006
[3]Li X, Ostropolets A, Makadia R, et al. Characterizing the incidence of adverse events of special interest for COVID-19 vaccines across eight countries: a multinational network cohort study. medRxiv. 2021; Published 2021 Apr 17. doi:10.1101/2021.03.25.21254315
[4]Sturkenboom, MCJM, Willame, C, Engelen, R, et al. ACCESS: Background Rates of AESI to Monitor Vaccine Safety- GBS Definition. Zenodo; 2021. doi:10.5281/zenodo.5109436
[5]Klein NP, Lewis N, Goddard K, et al. Surveillance for Adverse Events After COVID-19 mRNA Vaccination. JAMA. 2021;326(14):1390-1399. doi:10.1001/jama.2021.15072
[6]Nasreen S, Calzavara A, Buchan SA, et al. Background incidence rates of adverse events of special interest related to COVID-19 vaccines in Ontario, Canada, 2015 to 2020, to inform COVID-19 vaccine safety surveillance. Vaccine. 2022;40(24):3305-3312. doi:10.1016/j.vaccine.2022.04.065

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
GBS	1.77 (1.62 - 1.93)	1.97 (1.8 - 2.14)	1.97 (1.81 - 2.14)	1.91 (1.75 - 2.08)	1.84 (1.69 - 2)	1.89 (1.82 - 1.96)

Rate per 100,000 persons

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GBS background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	1.89 (1.82 - 1.96)	2.22 (2.11 - 2.33)	1.57 (1.48 - 1.66)
0-4	0.79 (0.6 - 1.02)	0.96 (0.68 - 1.33)	0.6 (0.38 - 0.91)
5-11	0.53 (0.4 - 0.69)	0.63 (0.44 - 0.88)	0.43 (0.27 - 0.65)
12-17	0.74 (0.58 - 0.94)	0.96 (0.7 - 1.27)	0.52 (0.33 - 0.78)
18-29	1.05 (0.92 - 1.19)	1.03 (0.86 - 1.23)	1.06 (0.88 - 1.27)
30-39	1.56 (1.39 - 1.74)	1.9 (1.64 - 2.2)	1.21 (1 - 1.45)
40-49	1.67 (1.49 - 1.86)	2.04 (1.75 - 2.35)	1.3 (1.08 - 1.56)
50-59	2.4 (2.19 - 2.62)	2.58 (2.28 - 2.92)	2.21 (1.93 - 2.52)
60-69	3.49 (3.21 - 3.79)	4.23 (3.79 - 4.7)	2.79 (2.45 - 3.17)
70+	3.64 (3.34 - 3.95)	4.93 (4.42 - 5.49)	2.6 (2.27 - 2.96)

Rate per 100,000 persons

Idiopathic Inflammatory Myopathy

Definitions

Definition	ICD-10-CA codes
Idiopathic inflammatory myopathy	**M60.1x, M60.8x, M60.9x, M33.0, M33.1, M33.2, M33.9, G72.0, G72.4, G72.8, G72.9**

[1]Definition developed in consultation with medical team within the Public Health Agency of Canada

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
Idiopathic inflammatory myopathy	6.59 (6.29 – 6.90)	9.53 (9.17 – 9.90)	7.65 (7.34 – 7.98)	9.10 (8.76 – 9.46)	9.38 (9.03 – 9.74)	8.46 (8.31 – 8.62)

Rate per 100,000 persons

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Idiopathic Inflammatory myopathy background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	8.46 (8.31 – 8.62)	9.64 (9.41 – 9.87)	7.31 (7.11 – 7.51)
0-4	14.44 (13.59 – 15.33)	19.34 (17.98 – 20.79)	9.29 (8.32 – 10.33)
5-11	23.43 (22.53 – 24.35)	32.62 (31.13 – 34.15)	13.87 (12.89 – 14.91)
12-17	4.34 (3.92 – 4.78)	4.53 (3.95 – 5.17)	4.13 (3.57 – 4.76)
18-29	3.51 (3.27 – 3.76)	3.39 (3.06 – 3.73)	3.64 (3.29 – 4.01)
30-39	4.65 (4.35 – 4.97)	5.10 (4.66 – 5.57)	4.21 (3.81 – 4.63)
40-49	5.67 (5.34 – 6.03)	5.91 (5.42 – 6.43)	5.44 (4.98 – 5.93)
50-59	6.38 (6.03 - 6.73)	6.08 (5.61 - 6.58)	6.67 (6.18 - 7.19)
60-69	9.37 (8.91 - 9.85)	9.56 (8.90 - 10.26)	9.19 (8.56 - 9.86)
70+	14.81 (14.21 - 15.42)	16.73 (15.78 - 17.72)	13.27 (12.51 - 14.06)

Rate per 100,000 persons

IgA Vasculitis (Henoch-Schonlein)

Definitions

Definition	ICD-10-CA codes
IgA vasculitis[1]	**D69.0**

[1]Nossent J, Raymond W, Keen H, Inderjeeth C, and Preen D. Hospitalisation rates and characteristics for adult and childhood immunoglobulin A vasculitis in western Australia [Internet]. Internal Medicine Journal. 24 Jul 2018; 49(4): 475-481. Available from: https://doi.org/10.1111/imj.14065.

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
IgA vasculitis	2.48 (2.30 – 2.67)	2.77 (2.58 – 2.97)	2.85 (2.65 – 3.05)	2.48 (2.30 – 2.67)	2.51 (2.33 – 2.70)	2.62 (2.53 – 2.70)

Rate per 100,000 persons

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IgA Vasculitis background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	2.62 (2.53 – 2.70)	2.83 (2.71 – 2.96)	2.41 (2.30 – 2.53)
00-04	13.12 (12.31 – 13.96)	13.87 (12.72 – 15.10)	12.33 (11.21 – 13.52)
05-11	15.60 (14.87 – 16.36)	16.51 (15.46 – 17.61)	14.66 (13.65 – 15.72)
12-17	2.83 (2.50 – 3.19)	2.89 (2.43 – 3.41)	2.76 (2.30 – 3.29)
18-29	0.78 (0.67 – 0.91)	0.76 (0.61 – 0.93)	0.81 (0.65 – 1.00)
30-39	0.50 (0.41 – 0.61)	0.58 (0.44 – 0.75)	0.42 (0.30 – 0.57)
40-49	0.56 (0.46 – 0.68)	0.56 (0.41 – 0.78)	0.57 (0.43 – 0.75)
50-59	0.62 (0.51 – 0.73)	0.76 (0.60 – 0.95)	0.48 (0.35 – 0.63)
60-69	0.53 (0.43 – 0.65)	0.55 (0.40 – 0.73)	0.52 (0.38 – 0.70)
70+	1.00 (0.85 – 1.17)	1.11 (0.88 – 1.39)	0.92 (0.72 – 1.14)

Rate per 100,000 persons

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Immune thrombocytopenia (ITP)

Definitions

Definition	ICD-10-CA codes
Immune thrombocytopenia (ITP)[1,2,3,4,5,6]	**D69.3x**

[1]Heden KE, Jensen AØ, Farkas DK, Nørgaard M. Validity of a procedure to identify patients with chronic idiopathic thrombocytopenic purpura in the Danish National Registry of Patients. Clin Epidemiol. 2009;1:7-10. Published 2009 Aug 9. doi:10.2147/clep.s4832

[2]Moulis G, Palmaro A, Montastruc JL, et al. Epidemiology of incident immune thrombocytopenia: a nationwide population-based study in France. Blood. 2014; 124(22):3308-3315. doi: https://doi.org/10.1182/blood-2014-05-578336.

[3]Weycker D, Hanau A, Hatfield M, et al. Primary immune thrombocytopenia in US clinical practice: incidence and healthcare burden in first 12 months following diagnosis. J Med Econ. 2020;23(2):184-192. doi:10.1080/13696998.2019.1669329

[4]Nasreen S, Calzavara AJ, Sundaram ME, et al. Background incidence rates of hospitalisations and emergency department visits for thromboembolic and coagulation disorders in Ontario, Canada for COVID-19 vaccine safety assessment: a population-based retrospective observational study. BMJ Open. 2021;11(12):e052019. Published 2021 Dec 17. doi:10.1136/bmjopen-2021-052019

[5]Klein NP, Lewis N, Goddard K, et al. Surveillance for Adverse Events After COVID-19 mRNA Vaccination. JAMA. 2021;326(14):1390-1399. doi:10.1001/jama.2021.15072

[6]Nasreen S, Calzavara A, Buchan SA, et al. Background incidence rates of adverse events of special interest related to COVID-19 vaccines in Ontario, Canada, 2015 to 2020, to inform COVID-19 vaccine safety surveillance. Vaccine. 2022;40(24):3305-3312. doi:10.1016/j.vaccine.2022.04.065

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
ITP	6.03 (5.74 - 6.32)	6.3 (6.01 - 6.6)	5.92 (5.64 - 6.21)	5.76 (5.48 - 6.04)	5.56 (5.3 - 5.84)	5.91 (5.78 - 6.04)

Rate per 100,000 persons

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ITP background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	5.91 (5.78 - 6.04)	5.71 (5.53 - 5.89)	6.11 (5.93 - 6.29)
0-4	9.96 (9.26 - 10.71)	11.65 (10.6 - 12.79)	8.19 (7.29 - 9.17)
5-11	5.04 (4.63 - 5.48)	5.25 (4.67 - 5.89)	4.82 (4.25 - 5.45)
12-17	3.47 (3.11 - 3.87)	3.07 (2.6 - 3.61)	3.89 (3.34 - 4.51)
18-29	3.22 (2.99 - 3.46)	2.38 (2.11 - 2.67)	4.13 (3.76 - 4.52)
30-39	3.8 (3.53 - 4.08)	2.4 (2.1 - 2.73)	5.18 (4.74 - 5.65)
40-49	3.58 (3.32 - 3.87)	3.02 (2.67 - 3.39)	4.14 (3.74 - 4.57)
50-59	4.55 (4.26 - 4.85)	4.31 (3.92 - 4.74)	4.78 (4.37 - 5.23)
60-69	6.93 (6.53 - 7.34)	7.4 (6.82 - 8.02)	6.47 (5.94 - 7.04)
70+	16.15 (15.53 - 16.8)	18.63 (17.62 - 19.67)	14.17 (13.39 - 14.99)

Rate per 100,000 persons

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Intracranial venous thrombosis (IVT)

Definitions

Definition	ICD-10-CA codes
Intracranial venous thrombosis (IVT)[1]	**I63.6, I67.6, O22.50x, O87.30x.**

[1]Definition developed in consultation with medical team within the Public Health Agency of Canada

Notes:
As ICD-10-CA codes are limited, it was not possible to develop a specific CVST definition. I67.6 includes a combination of CVST conditions as well as broader IVT conditions. If this background rate is used to investigate CVST, the background rate may be overestimated.

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
IVT	0.58 (0.49 - 0.68)	0.52 (0.44 - 0.61)	0.59 (0.51 - 0.69)	0.55 (0.47 - 0.64)	0.65 (0.56 - 0.75)	0.58 (0.54 - 0.62)

Rate per 100,000 persons

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IVT background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	0.58 (0.54 - 0.62)	0.48 (0.43 - 0.53)	0.68 (0.62 - 0.74)
0-11	0.3 (0.23 - 0.4)	0.37 (0.26 - 0.52)	0.23 (0.14 - 0.36)
12-17	0.31 (0.21 - 0.44)	0.42 (0.25 - 0.64)	0.2 (0.09 - 0.37)
18-29	0.6 (0.51 - 0.71)	0.24 (0.16 - 0.35)	0.99 (0.81 - 1.19)
30-39	0.76 (0.64 - 0.9)	0.44 (0.32 - 0.6)	1.08 (0.88 - 1.3)
40-49	0.55 (0.45 - 0.67)	0.41 (0.29 - 0.57)	0.69 (0.53 - 0.88)
50-59	0.53 (0.43 - 0.64)	0.57 (0.43 - 0.74)	0.49 (0.36 - 0.64)
60-69	0.55 (0.44 - 0.67)	0.58 (0.43 - 0.78)	0.52 (0.38 - 0.7)
70+	0.92 (0.78 - 1.08)	0.93 (0.71 - 1.18)	0.92 (0.72 - 1.14)

Rate per 100,000 persons

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Ischemic stroke

Definitions

Definition	ICD-10-CA codes
Ischemic stroke	**G45.8, G45.9, I63.x**

[1]Shimabukuro TT. mRNA COVID-19 bivalent booster vaccine safety update. 2023; Available at: https://stacks.cdc.gov/view/cdc/127294. Accessed January 8, 2024.

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
Ischemic stroke	151.81 (150.36 - 153.28)	154.45 (152.99 - 155.91)	154.6 (153.15 - 156.05)	156.94 (155.49 - 158.4)	157.25 (155.81 - 158.7)	155.05 (154.4 - 155.7)

Rate per 100,000 persons

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Ischemic stroke background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	155.05 (154.4 - 155.7)	161.6 (160.66 - 162.54)	148.59 (147.7 - 149.49)
0-17	2.1 (1.94 - 2.28)	2.26 (2.02 - 2.52)	1.94 (1.71 - 2.19)
18-29	5.2 (4.91 - 5.5)	4.44 (4.07 - 4.84)	6.01 (5.56 - 6.48)
30-39	15.29 (14.74 - 15.85)	15.35 (14.58 - 16.15)	15.23 (14.46 - 16.02)
40-49	47.94 (46.95 - 48.94)	55 (53.49 - 56.54)	41.05 (39.77 - 42.36)
50-59	119.1 (117.61 - 120.61)	147.56 (145.21 - 149.94)	90.97 (89.14 - 92.83)
60-64	214.48 (211.47 - 217.52)	270.66 (265.83 - 275.56)	160.57 (156.93 - 164.27)
65+	701.18 (697.77 - 704.61)	747.73 (742.53 - 752.97)	661.88 (657.38 - 666.4)

Rate per 100,000 persons

Kawasaki Disease (KD)

Definitions

Definition	ICD-10-CA codes
Kawasaki Disease[1]	M30.3

[1]Williams C, Sathe N, Krishnaswami S, and McPheeters M. A systematic review of validated methods for identifying Kawasaki disease using administrative or claims data. Vaccine [Internet]. 26 Mar 2013; 31(10):K28-K33. Available from: https://doi.org/10.1016/j.vaccine.2013.03.078.

[2]Kamidani S, Panagiotakopoulos L, Licata C, Daley M, Wih K, Zerbo O, et al. Kawasaki disease following the 13-valent pneumococcal conjugate vaccine and rotavirus vaccines [Internet]. Pediatrics. 6 Dec 2022;150(6): 1-9. Available from: https://doi.org/10.1542/peds.2022-058789.

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
Kawasaki Disease	1.72 (1.57 – 1.88)	1.73 (1.58 – 1.89)	1.91 (1.75 – 2.08)	1.96 (1.81 – 2.13)	1.76 (1.61 – 1.92)	1.82 (1.75 – 1.89)

Rate per 100,000 persons

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Kawasaki Disease background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	1.82 (1.75 – 1.89)	2.17 (2.06 – 2.28)	1.48 (1.39 – 1.57)
0-4	21.61 (20.57 – 22.69)	24.66 (23.12 – 26.29)	18.41 (17.04 – 19.85)
5-11	6.28 (5.82 – 6.77)	7.44 (6.74 – 8.20)	5.07 (4.48 – 5.71)
12-17	0.72 (0.56 – 0.92)	1.08 (0.81 – 1.42)	0.35 (0.20 – 0.57)
18-29	0.13 (0.09 – 0.19)	0.18 (0.11 – 0.27)	0.09 (0.04 – 0.17)
30-39	0.09 (0.05 – 0.15)	0.08 (0.04 – 0.16)	0.10 (0.05 – 0.19)
40+	0.21 (0.18 – 0.25)	0.23 (0.18 – 0.29)	0.20 (0.16 – 0.25)

Rate per 100,000 persons

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Postmenopausal bleeding

Definitions

Definition	ICD-10-CA codes
Postmenopausal bleeding[1]	**N95.0**

[1]Definition developed in consultation with medical team within the Public Health Agency of Canada and the background rates working group

Note:
Background rate may be underestimated as individuals may not be diagnosed in the hospital or ED setting.

Background rates – Canada excluding Quebec (Females 55+)

Definition	2015	2016	2017	2018	2019	2015 – 2019
Postmenopausal bleeding	45.33 (43.32 - 47.42)	44.77 (42.8 - 46.81)	47.4 (45.4 - 49.47)	46.35 (44.4 - 48.36)	46.35 (44.42 - 48.33)	46.06 (45.18 - 46.96)

Rate per 100,000 persons

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Postmenopausal bleeding background rates by age – Canada excluding Quebec, 2015-2019

Age group	Females
40+	36.55 (35.93 - 37.17)
40-44	1.8 (1.44 - 2.23)
45-49	12.49 (11.5 - 13.53)
50-54	49.1 (47.2 - 51.05)
55+	46.06 (45.18 - 46.96)
55-59	56.72 (54.69 - 58.82)
60-64	48.15 (46.16 - 50.19)
65-69	46.32 (44.21 - 48.51)
70+	38.45 (37.15 - 39.78)

Rate per 100,000 persons

Parts of this material are based on data and information compiled and provided by CIHI. However, the analyses, conclusions, opinions and statements expressed herein are those of the author, and not necessarily those of CIHI.

Pulmonary Embolism (PE)

Definitions

Definition	ICD-10-CA codes
Pulmonary embolism (PE)[1]	**I26.x, O88.20x**

[1]Nasreen S, Calzavara AJ, Sundaram ME, et al. Background incidence rates of hospitalisations and emergency department visits for thromboembolic and coagulation disorders in Ontario, Canada for COVID-19 vaccine safety assessment: a population-based retrospective observational study. BMJ Open. 2021;11(12):e052019. Published 2021 Dec 17. doi:10.1136/bmjopen-2021-052019

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
PE	57.92 (57.02 - 58.83)	62.27 (61.35 - 63.21)	63.39 (62.47 - 64.33)	64.21 (63.28 - 65.14)	66.26 (65.33 - 67.2)	62.86 (62.45 - 63.28)

Rate per 100,000 persons

Parts of this material are based on data and information compiled and provided by CIHI. However, the analyses, conclusions, opinions and statements expressed herein are those of the author, and not necessarily those of CIHI.

PE background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	62.86 (62.45 - 63.28)	60.46 (59.89 - 61.04)	65.22 (64.63 - 65.82)
0-11	0.24 (0.18 - 0.33)	0.32 (0.22 - 0.46)	0.17 (0.09 - 0.27)
12-17	2.98 (2.64 - 3.34)	1.43 (1.11 - 1.81)	4.59 (3.99 - 5.25)
18-29	18.07 (17.53 - 18.63)	10.78 (10.2 - 11.38)	25.87 (24.94 - 26.84)
30-39	30.95 (30.17 - 31.75)	23.77 (22.81 - 24.76)	38.07 (36.86 - 39.32)
40-49	45.76 (44.79 - 46.74)	44.56 (43.2 - 45.95)	46.93 (45.55 - 48.33)
50-59	69.52 (68.38 - 70.67)	78.62 (76.9 - 80.36)	60.53 (59.04 - 62.05)
60-69	120.6 (118.93 - 122.28)	130.64 (128.16 - 133.16)	111.07 (108.84 - 113.33)
70+	229.61 (227.23 - 232.01)	232.78 (229.19 - 236.4)	227.06 (223.89 - 230.26)

Rate per 100,000 persons

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Seizures

Definitions

Definition	ICD-10-CA codes
Febrile seizure[1]	R56.0, R56.01, R56.02, R56.09
Other seizure[1]	G40.6, G40.7, G41.x

[1]Definition developed in consultation with medical team within the Public Health Agency of Canada

Background rates – Canada excluding Quebec

Definition	Age Group	2015	2016	2017	2018	2019	2015 – 2019
Febrile seizure	0-4	395.19 (385.15 - 405.43)	473.44 (462.49 - 484.58)	412.38 (402.17 - 422.78)	441.49 (430.92 - 452.25)	429.92 (419.48 - 440.55)	430.55 (425.86 - 435.28)
Other seizure	0-17	27.56 (26.19 – 28.99)	29.28 (27.87 – 30.74)	28.91 (27.52 – 30.36)	29.64 (28.23 – 31.11)	30.36 (28.94 – 31.84)	29.16 (28.53 - 29.80)

Rate per 100,000 persons

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Seizure background rates by age and sex – Canada excluding Quebec, 2015-2019

Febrile seizure

Age group	All sexes	Males	Females
0-4	430.55 (425.86 - 435.28)	470.82 (463.98 - 477.74)	388.21 (381.84 - 394.65)

Rate per 100,000 persons

Parts of this material are based on data and information compiled and provided by CIHI. However, the analyses, conclusions, opinions and statements expressed herein are those of the author, and not necessarily those of CIHI.

Other seizure

Age group	All sexes	Males	Females
0-17	29.16 (28.53 - 29.80)	30.48 (29.58 - 31.4)	27.78 (26.90 - 28.68)
0-4	50.02 (48.43 - 51.65)	49.95 (47.74 - 52.24)	50.10 (47.83 - 52.45)
5-11	21.42 (20.56 - 22.31)	23.25 (22.00 - 24.55)	19.52 (18.35 - 20.74)
12-17	21.54 (20.61 - 22.50)	23.32 (21.98 - 24.73)	19.67 (18.41 - 20.99)

Rate per 100,000 persons

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Single Organ Cutaneous Vasculitis (SOCV)

Definitions

Definition	ICD-10-CA codes
Single Organ Cutaneous Vasculitis[1]	**D69.0, M31.0, L95.8, L95.9**

[1]Definition developed in consultation with medical team within the Public Health Agency of Canada

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
SOCV	4.55 (4.30 – 4.81)	4.61 (4.36 – 4.87)	4.76 (4.51 – 5.02)	4.42 (4.18 – 4.67)	4.58 (4.34 – 4.83)	4.58 (4.47 – 4.70)

Rate per 100,000 persons

Parts of this material are based on data and information compiled and provided by CIHI. However, the analyses, conclusions, opinions and statements expressed herein are those of the author, and not necessarily those of CIHI.

SOCV background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	4.58 (4.47 – 4.70)	4.70 (4.54 – 4.86)	4.47 (4.32 – 4.63)
0-4	13.65 (12.83 – 14.51)	14.63 (13.44 – 15.89)	12.63 (11.50 – 13.84)
05-11	15.90 (15.16 – 16.67)	16.70 (15.65 – 17.81)	15.07 (14.05 – 16.15)
12-17	3.27 (2.92 – 3.66)	3.18 (2.69 – 3.72)	3.37 (2.86 – 3.95)
18-29	2.04 (1.86 – 2.23)	1.86 (1.63 – 2.13)	2.23 (1.96 – 2.52)
30-39	1.77 (1.59 – 1.96)	1.75 (1.50 – 2.03)	1.79 (1.53 – 2.07)
40-49	2.34 (2.13 – 2.57)	2.24 (1.95 – 2.57)	2.44 (2.13 – 2.78)
50-59	3.21 (2.97 – 3.47)	3.16 (2.83 – 3.53)	3.26 (2.92 – 3.63)
60-69	3.62 (3.33 – 3.92)	3.72 (3.31 – 4.17)	3.52 (3.13 – 3.94)
70+	5.86 (5.49 – 6.26)	6.24 (5.66 – 6.85)	5.56 (5.08 – 6.08)

Rate per 100,000 persons

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Thrombosis and thrombocytopenia syndrome (TTS)

Definitions

Definition	ICD-10-CA codes
Thrombosis and thrombocytopenia syndrome (TTS)[1] **Diagnosis of thrombosis and thrombocytopenia on the same episode of care**	**Thrombosis codes: I26.x, O88.20x, I80.1, I80.2, I80.3, I80.8, I80.9, O22.30x, O87.10x, I63.x, I64, H34.1, I67.6, O22.50x, O87.30x, K55.0, I81, I82.2, I82.3, I82.8, I82.9, I21.x, I22.x, I51.3** **Thrombocytopenia codes:D69.3x, D69.4, D69.5, D69.6, D82.0, M31.1, D65, O45.01x, O46.01x**

[1]Definition developed in consultation with medical team within the Public Health Agency of Canada and the background rates working group

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
TTS	2.59 (2.4 - 2.79)	3.11 (2.91 - 3.33)	3.19 (2.99 - 3.41)	3.28 (3.07 - 3.49)	3.16 (2.96 - 3.37)	3.07 (2.98 - 3.16)

Rate per 100,000 persons

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TTS background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	3.07 (2.98 - 3.16)	3.55 (3.41 - 3.69)	2.6 (2.48 - 2.72)
0-11	0.24 (0.18 - 0.33)	0.27 (0.17 - 0.39)	0.22 (0.14 - 0.34)
12-17	0.23 (0.15 - 0.35)	0.17 (0.07 - 0.33)	0.3 (0.17 - 0.51)
18-29	0.62 (0.52 - 0.73)	0.49 (0.37 - 0.63)	0.77 (0.61 - 0.95)
30-39	1.13 (0.99 - 1.29)	1 (0.81 - 1.22)	1.26 (1.05 - 1.51)
40-49	1.57 (1.39 - 1.76)	1.62 (1.37 - 1.9)	1.52 (1.28 - 1.79)
50-59	3.38 (3.13 - 3.64)	4.07 (3.68 - 4.48)	2.7 (2.39 - 3.03)
60-69	6.08 (5.71 - 6.47)	7.47 (6.88 - 8.09)	4.77 (4.31 - 5.26)
70+	12.35 (11.8 - 12.91)	16.4 (15.46 - 17.38)	9.11 (8.48 - 9.77)

Rate per 100,000 persons

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Transverse Myelitis (TM)

Definitions

Definition	ICD-10-CA codes
Transverse myelitis[1,2,3,4]	**G37.3**

[1]Li X, Ostropolets A, Makadia R, et al. Characterizing the incidence of adverse events of special interest for COVID-19 vaccines across eight countries: a multinational network cohort study. medRxiv. 2021; Published 2021 Apr 17. doi:10.1101/2021.03.25.21254315
[2]Sturkenboom, MCJM, Belbachir, L, Souverein, P, Martín-Pérez, M, García-Poza, P, Durán, C. Access-background Rate of Adverse Events-definition –transverse Myelitis. Zenodo; 2021. doi:10.5281/zenodo.5237332
[3]Klein NP, Lewis N, Goddard K, et al. Surveillance for Adverse Events After COVID-19 mRNA Vaccination. JAMA. 2021;326(14):1390-1399. doi:10.1001/jama.2021.15072
[4]Nasreen S, Calzavara A, Buchan SA, et al. Background incidence rates of adverse events of special interest related to COVID-19 vaccines in Ontario, Canada, 2015 to 2020, to inform COVID-19 vaccine safety surveillance. Vaccine. 2022;40(24):3305-3312. doi:10.1016/j.vaccine.2022.04.065

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
Transverse myelitis	0.73 (0.64 - 0.84)	0.87 (0.77 - 0.99)	0.85 (0.75 - 0.96)	0.86 (0.76 - 0.98)	0.85 (0.75 - 0.97)	0.83 (0.79 - 0.88)

Rate per 100,000 persons

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Transverse myelitis background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	All sexes	Males	Females
All ages	0.83 (0.79 - 0.88)	0.69 (0.63 - 0.76)	0.97 (0.9 - 1.05)
0-4	0.37 (0.25 - 0.54)	0.44 (0.26 - 0.71)	0.3 (0.15 - 0.54)
5-11	0.4 (0.29 - 0.54)	0.45 (0.29 - 0.66)	0.36 (0.21 - 0.55)
12-17	0.53 (0.39 - 0.7)	0.42 (0.25 - 0.64)	0.65 (0.44 - 0.93)
18-29	0.62 (0.52 - 0.73)	0.37 (0.27 - 0.5)	0.88 (0.72 - 1.08)
30-39	0.92 (0.79 - 1.06)	0.78 (0.61 - 0.97)	1.06 (0.86 - 1.28)
40-49	1.06 (0.92 - 1.22)	0.74 (0.57 - 0.94)	1.38 (1.15 - 1.64)
50-59	0.95 (0.82 - 1.1)	0.76 (0.6 - 0.95)	1.15 (0.95 - 1.37)
60-69	1.07 (0.92 - 1.24)	1.03 (0.82 - 1.28)	1.11 (0.89 - 1.35)
70+	1.08 (0.92 - 1.26)	1.13 (0.89 - 1.41)	1.04 (0.84 - 1.28)

Rate per 100,000 persons

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Background Rates Working Group Members

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Health Canada

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Background Rates for COVID-19 AEFIs May 2021

Background Rates

Overview

The rollout of COVID-19 vaccines will be one of the largest and most complex mass health interventions in history. Multiple potential COVID-19 vaccines are currently under development, some of which are based on new technologies and the long term safety of COVID-19 vaccines are unknown. While Canada's rigorous regulatory system ensures that vaccines are safe, effective and of high quality before they are approved, no health product is completely risk-free.

Post-licensure surveillance of a vaccine after its introduction to the market is critical since clinical trials are conducted in controlled settings, which differ greatly from the real world setting. For instance, clinical trials rarely include individuals with underlying health conditions or pregnant women, may not detect rare or very rare reactions, or reactions with delayed onset and typically, long term safety data is not available. Finally, public confidence in vaccine safety and efficacy is pivotal to the success of the roll out. With the introduction of several new COVID-19 vaccines, there is a need for PHAC to be able to quickly detect any emerging post-market vaccine safety issues following immunization.

Adverse Events Following Immunization (AEFI)

With the rapid development and implementation of various COVID-19 vaccines, PHAC must be able to quickly detect and respond to adverse events following immunization (AEFIs). Additionally PHAC must be prepared to address adverse events of special interest (AESIs) as well as other safety issues that may arise (such as events that may cause public concern, counterfeit vaccines, etc.). This is even more critical due to the fact that the virus itself is new and much is still unknown regarding the disease.

Typically the following criteria is used to prioritize which AEFIs should be focused on:

- Serious AEFIs in vaccinated patients that result in death, are life-threatening, require inpatient hospitalization or prolongation of existing hospitalization, result in persistent or significant disability/incapacity, or result in a congenital anomaly or birth defect or is a
medically important event or reaction;

- Occurrence of events with an unexpected high rate or unusual severity;

- Signals generated as a result of individual or clustered cases;

- Significant events of unexplained cause, occurring up to 1 year after COVID-19

vaccination
(and that are not listed in the product information); or

- Events causing significant parental, family or community concerns.

Background Rates

Background rates are a critical component of the assessment of possible vaccine safety concerns and assist in determining whether the event is associated with the vaccine[i]. In particular, knowledge of background rates assists with the assessment as to whether events temporally associated with a vaccine are due to chance or if they reflect a real (causally) increase in risk of AEFIs [ii]. Background rates can be used to estimate the expected number of cases of an event, i.e. the number that would occur naturally over a period of time in a population in absence of COVID-19 vaccination and to compare this estimate with the observed number of cases reported in vaccinated individuals [iii].

Objectives:

PHAC is developing the methodology for calculating background rates for the adverse events of special interest that have been identified for COVID-19. This methodology can then be employed by provinces and territories that would like to compare their background rates to the national rates.

1. Establish national case definitions and algorithms for all adverse events following immunization of special interest (AESIs) including source of data (See Table 1) in addition to any other adverse events following immunization (AEFI) which may be of interest.
2. Develop standard methodology to be used by when calculating background rates.
    a. Define population
    b. Time period
    c. Calculation for rates and confidence intervals
    d. Stratification

Challenges:

1. There are many different case definitions for the various conditions/diseases of interest. Need to define definitions that will be suitable in the Canadian context while enabling comparisons internationally.
2. PHAC does not have access to the individual provincial and territorial health administrative databases and therefore do not have access to:
    a. Physician billing data (rates may be underestimated for certain conditions)
    b. Denominators for the calculation of the rates (PHAC will use Statistics Canada's population estimates)
    c. Unable to link databases in order to establish cohorts for follow up or calculating Person Years

   d. DAD and NACRS do not include Quebec data for most years
3. CIHI data processing
   a. Identify transfer of patients between hospitals and determine how to handle these cases
4. How to handle separate episodes in the same individual for certain conditions (i.e. anaphylaxis)

Table I: Adverse Events of Special Interest (AESIs)

Body system/classification	AESI
Auto-immune diseases	Guillain-Barré Syndrome (GBS)
	Acute disseminated encephalomyelitis (ADEM)
	Thrombocytopenia
	Heart Failure
	Stress cardiomyopathy
	Coronary artery disease
	Arrhythmia
	Myocarditis
Circulatory system, coagulation disorders	Thromboembolism
	Haemorrhage
	Single organ cutaneous vasculitis
Hepato-gastrointestinal and renal system	Acute liver injury
	Acute kidney injury
Nerves and central nervous system	Generalized convulsion
	Meningoencephalitis
	Transverse myelitis
Respiratory system	Acute respiratory distress syndrome
Other system	Multisystem inflammatory syndrome in children
	Enhanced disease following immunization
	Sudden Death
	Gestational Diabetes

Pregnancy outcome - maternal	Pre-eclampsia
	Maternal death
Pregnancy outcome - neonates	Fetal growth restriction
	Spontaneous abortions
	Stillbirth
	Preterm birth
	Major congenital anomalies
	Microcephaly
	Neonatal death
	Termination Of Pregnancy for Fetal Anomaly (TOPFA)
	Induced abortions

Data

Data from CIHI's discharge abstract database and emergency department visits will be used to calculate the background rates. Due to the fact that we do not have access to the provincial and territorial health administrative databases to calculate the denominator, Statistics Canada's population estimates will be used.

Discharge abstract database (DAD)

The Discharge Abstract Database (DAD) captures administrative, clinical and demographic information on hospital discharges (including deaths, sign-outs and transfers). Some provinces and territories also use the DAD to capture day surgery. Data is received directly from acute care facilities or from their respective health/regional authority or ministry/department of health. Facilities in all provinces and territories except Quebec are required to report. Data from Quebec is submitted to CIHI directly by the ministère de la Santé et des Services sociaux du Québec however it is not included in DAD. As a result, all results will exclude Quebec.

National Ambulatory Care Reporting System (NACRS)

The National Ambulatory Care Reporting System (NACRS) contains data on hospital-based and community-based ambulatory care: day surgery, outpatient and community-based clinics and emergency departments. Client visit data is collected at the time of service in participating facilities. Data collection methods may vary by facility. CIHI does not mandate data submission to NACRS. We will restrict our analysis to emergency department records within NACRS.

Methods:

Study period: 2015-2019

Base population: Statistics Canada's yearly population estimates as of July 1st, by age, sex and province.

Denominator: For each year, assume each individual included in Statistic Canada's yearly population estimates by age, sex and province contributes data during the whole year (i.e 1 person year)

Numerator (AESI): Event count for each AEFI for each year using date of admission in DAD and registration date in NACRS.

- Events will be identified using ICD-10-CA codes.

Exclusions:

- Those with an unknown health card number (healthcard_num="000000000000").
- Event flagged as a questionable diagnosis.
- Event occurs within x days of previous event.

  - In most cases x is set to 365 days but there may be exceptions (e.g. for anaphylaxis, exclude events which occur within 72 hours of another event).
- Event which occurs on the same episode of care as another event
  - Episode of care: records (DAD or NACRS) where an individual is admitted less than 7 hours after a previous discharge or where the individual was admitted within 7-12 hours of a previous discharge and one of the institutions codes the transfer. The records are then linked as the same episode of care and not two separate occurrences of the same event.
- Event where individual left the emergency department without being seen (registered and/or triaged and then left).
- Events with unknown or other sex

Result:

- Rates will be calculated using the total number of events in a calendar year divided by the Statistics Canada population estimates for that year.
- Rates will be calculated for Canada excluding Quebec, as well as rates by Canada excluding Quebec by 10-year age and sex when possible
  - Age groups: 0-19, 20-29, 30-39, 40-49, 50-59, 60-69, 70-79, 80+
  - Sex: Male, Female (Cannot include a category for other sex as we have no denominator)
- An overall rate for all years (2015-2019) combined will also be calculated by taking the sum of the number of events over all years and dividing it by the sum of the population estimates over all years.
- Confidence intervals for crude rates will be calculating using the Poisson exact method.

Limitations/Assumptions

- The reporting coverage to NACRS varies by province/territory and time. Therefore, the background rates may underreport the rate in Canada excluding Quebec.
- As we do not have access to physician billing records, conditions investigated must have been serious enough to warrant a hospital or emergency department visits. Therefore, this may underreport the true rates.
- As we rely on ICD-10-CA codes to identify each condition, there may be misclassification of the outcome.
- Assume Canadian population (excluding Quebec) as of July 1st had a full year of follow up.
- Assume background rate accurately represents the definition used to classify observed cases.

List of background rates with completed ICD-10-CA definitions:

- Anaphylaxis (3 definitions)
- Bell's Palsy

- Arrhythmias (Narrow/broad)
- GBS
- Transverse myelitis (Narrow/broad)
- ADEM (Narrow/broad)
- Myocarditis/Pericarditis (Narrow/broad)
- Myocarditis (Narrow/broad)
- Pulmonary embolism
- Deep vein thrombosis
- Stroke (Broad, subarachnoid haemorrhage, intracerebral haemorrhage, ischemic stroke)
- Intracranial venous thrombosis
- Idiopathic thrombocytopenia (Narrow/broad)
- Disseminated intravascular coagulation
- Abdominal thrombosis
- Myocardial infarction
- Thrombosis only (excluding records when a thrombocytopenia occurred within the same episode of care)
- Thrombocytopenia only (excluding records when a thrombosis occurred within the same episode of care)
- Thrombosis and thrombocytopenia (TTS)

Note: AEFIs highlighted in red need to be confirmed with background rates working group

List of completed background rates

- Anaphylaxis (3 definitions)
- Bell's Palsy
- GBS
- Transverse myelitis (Narrow/broad)
- Myocarditis/Pericarditis (Narrow/broad)
- Myocarditis (Narrow/broad)
- Pulmonary embolism
- Deep vein thrombosis
- Stroke (Broad, subarachnoid haemorrhage, intracerebral haemorrhage, ischemic stroke)
- Intracranial venous thrombosis
- Idiopathic thrombocytopenia (Narrow/broad)
- Disseminated intravascular coagulation
- Thrombosis only (excluding records when a thrombocytopenia occurred within the same episode of care)
- Thrombocytopenia only (excluding records when a thrombosis occurred within the same episode of care)
- Thrombosis and thrombocytopenia (TTS)

Observed versus expected[iv]

Objective: Determine if the number of AEFI we are seeing post vaccination exceeds what we would expect to see given the number of events which occur in the general population.

Number of observed: Total number of observed cases of the AEFI of interested in CAEFISS (and CV if possible) according to medical case review or MedDRA codes. Note, record date cases observed up until. This date will be used to determine the person time at risk used in the number of expected calculation.

- 95% confidence intervals for number of observed will be calculated using the Poisson exact method.

Number of expected: Calculated for each vaccine type using the age and sex specific background rates (BGR), number of doses administered, proportion of vaccines administered by age and sex, and the at risk period.

$$Expected = \sum_{s=1}^{N} [BGR]_s * [PT] * [Proportion]_s$$

s: 10-year age and sex specific stratum.

BGR: Age and sex specific background rate for Canada excluding Quebec.

PT: Vaccine specific total person time.

- Calculated using doses administered from vaccine coverage using data from all P/Ts, Canadian Armed Forces, and Correctional Services Canada and the at risk period for each AEFI.
    - Time at risk is unique to the AEFI being studied (e.g. 30 days following immunization for TTS). Medical advisors will need to be consulted for each AEFI.
    - New doses administered each week used to account for the at risk time available for each dose administered.
        - E.g. if observed data as of May 2nd, and new doses administered as of April 24th, then the new doses administered as of April 24th would contribute 9 days to the person time at risk (May 2 – April 24).

Proportion: For each vaccine, the proportion of doses administered to each 10-year age and sex group (sum of proportions should equal 1 for each vaccine).

- Use the most recent available data from vaccine coverage.

Limitations/Assumptions

- Assume no dose response.

- Assume age/sex distribution in doses administered has remained constant over time (unlikely).
- All cases presenting the event of interest after immunization are reported (less likely for non-severe cases).
- The at risk time period is shorter than the average time window between dose 1 and dose 2.
- The at risk time period is correctly measured.

References

[i] Black S, Eskola J, Siegrist CA, Halsey N, MacDonald N, Law B, Miller E, Andrews N, Stowe J, Salmon D, Vannice K, Izurieta HS, Akhtar A, Gold M, Oselka G, Zuber P, Pfeifer D, Vellozzi C. Importance of background rates of disease in assessment of vaccine safety during mass immunisation with pandemic H1N1 influenza vaccines. Lancet. 2009 Dec 19;374(9707):2115-2122. doi: 10.1016/S0140-6736(09)61877-8. Epub 2009 Oct 31. Erratum in: Lancet. 2010 Jan 30;375(9712):376. PMID: 19880172; PMCID: PMC2861912.

[ii] Rasmussen Thomas A, Jørgensen Martin R S, Bjerrum Stephanie, Jensen-Fangel Søren, Støvring Henrik, Østergaard Lars et al. Use of population based background rates of disease to assess vaccine safety in childhood and mass immunisation in Denmark: nationwide population based cohort study BMJ 2012; 345 :e5823

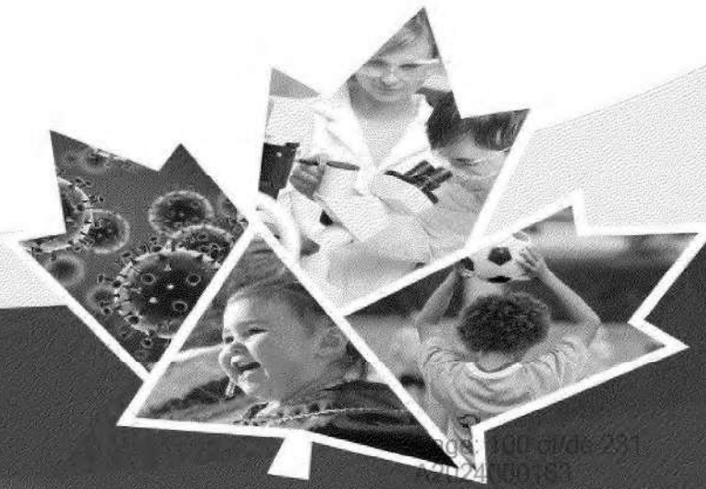
[iii] European Medicines Agency, ACCESS background incidence rates of AESIs, User Guide.

[iv] Mahaux O, Bauchau V, Van Holle L. Pharmacoepidemiological considerations in observed-to-expected analyses for vaccines. Pharmacoepidemiology and drug safety. 2016; 25:215-222. doi: 10.1002/pds.3918.

Canada

Submission of reports of death following receipt of COVID-19 vaccine to PHAC

For discussion



PROTECTING AND EMPOWERING CANADIANS
TO IMPROVE THEIR HEALTH

Background

- Post-market vaccine safety monitoring is an essential part of immunization program.
  - Allows us to identify potential signals of concern regarding vaccines (especially when new to the market) or specific lots of vaccines where there may have been a quality issue.
  - Important for maintaining confidence in immunization programs.
- Canada has a well-established vaccine surveillance system that is a collaboration between provinces and territories (PTs), the Public Health Agency of Canada (PHAC), Health Canada (HC, the Regulator), and vaccine manufacturers.
  - Weekly web reporting of adverse events following immunization with COVID-19 vaccine provides timely and transparent information.
- COVID-19 vaccines are new products that merit close monitoring for any unexpected events or outcomes.

Reporting death as an adverse event following immunization

- Given that we are prioritizing older adults who may have multiple chronic conditions, unrelated deaths and health events in the time after COVID-19 vaccination are expected.
- It can be challenging to differentiate events due to natural causes from events related to the vaccine.

All-cause mortality in Canada by age group, 2019 (Statistics Canada Vital Statistics)

Age at time of death	Number of deaths	Age-specific mortality rate per 100,000 population
All ages	284,082	756.5
65 to 69 years	22,649	1,080.8
70 to 74 years	29,170	1,709.7
75 to 79 years	32,476	2,790.0
80 to 84 years	38,721	4,913.8
85 to 89 years	45,423	8,875.6
90 years and over	61,115	18,842.6

Guidance on death reporting from elsewhere

- WHO COVID-19 Vaccines: Safety Surveillance Manual:
  - Calls for the development of robust surveillance systems that are: "…capable of identifying both known adverse events following immunization (AEFIs) seen in clinical trials as well as new events, including potential rare serious adverse reactions in all age groups, particularly adults…"
  - As such, the WHO recommends that systems are sensitive enough to pick up any adverse events temporally associated with the COVID-19 vaccine, regardless of causality.
  - Indicates that "All countries should define specific protocols for investigating deaths following COVID-19 vaccination… Individuals who die following COVID-19 vaccination, including those with any related diagnosis that is an AESI, should be included in the protocol for investigating deaths following COVID-19 vaccination."
- WHO Global Manual on Surveillance of Adverse Events Following Immunization:
  - Suggests reporting all deaths within 30 days of immunization
- European Medicines Agency Guideline on Good Pharmacovigilance Practices (GVP):
  - Notes "a report of sudden death would usually need to be considered as a case of suspected adverse reaction and the valid (case report) should be submitted."
  - Also acknowledges that "It should be appreciated that this may be a rather imprecise criterion and prioritising all case (reports) with reported death may result in many false positive signals. Hence it is considered that further methodological research may be required in this area."

Current practice in Canada:

- Variability between P/Ts in criteria used to determine which cases of death to submit to CAEFISS
  - Some will report all deaths reported within 30 days
  - Some will review cases first and exclude deaths where there is a known alternate cause of death

Recent interest in deaths in frail elderly following Pfizer-Biotech vaccine

- Norway flagged a potential signal of deaths following vaccine in the frail elderly
- Upon further review by WHO Global Advisory Committee on Vaccine Safety:
  - Reports do not suggest any unexpected or untoward increase in fatalities in frail, elderly individuals or any unusual characteristics of adverse events following administration of BNT162b2.
  - In line with the expected, all-cause mortality rates and causes of death in the sub-population of frail, elderly individuals.
  - Available information does not confirm a contributory role for the vaccine in the reported fatal events.
  - Recommends that countries should continue to monitor the safety of vaccines, and promote routine after-care following immunization, consistent with good immunization practices for any vaccine and that data on suspected adverse events should be collected and reviewed continuously - nationally, regionally, and globally - as the COVID-19 vaccines are rolled out, world-wide.

Considerations for reporting of deaths

- Complete reporting of deaths and other serious adverse events enables post-marketing surveillance programs to:
  - ensure that any safety or efficacy issues not found in clinical trials can be identified and mitigated
  - enable PHAC to flag if observed counts exceed the expected based on the estimated background rates
- News about the cases of deaths that are not included in the national AEFI updates can create public mistrust in our data publication (PHAC has already received requests for data on death reports)
- Reports of death following immunization can have a negative impact on vaccination programs.
- Investigation of deaths and transparency can help build public confidence.
  - Provides public reassurance that we are looking into deaths and they are consistent with underlying causes.
- Consider communications around reports of death: reports are not unexpected and most of these deaths will likely not be associated with the vaccine.

Recommendations

- **Reporting cases of death to CAEFISS:** VSS recommends that P/Ts notify PHAC and report all deaths that occur within 30 days of vaccination, regardless of cause.
  - Please include details available on cause of death.
  - Please report deaths occurring beyond 30 days after immunization if a potential link to the vaccine is suspected.
- **Combining death reports in CAEFISS and Canada Vigilance:** PHAC and Health Canada will work together to consolidate reports as much as possible to avoid duplicate counts.
- **Including deaths in internal and external reports:** Wording will be needed to provide context that deaths are expected in the period following immunization and not necessarily related to vaccination.
  - For example: "PHAC and Health Canada, like other countries, have received reports of deaths in the 30 days following immunization with COVID-19 vaccines. X reports of deaths in the time following immunization have been received and are under review. Due to the population of elderly Canadians with chronic conditions who are currently receiving COVID-19 vaccines, reports of death are expected and do not mean that the death is related to the vaccine."

Thank you

Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, February 4, 2021 from 1:30 – 2:30 PM EST
Record of Decisions (RoD)

Agenda Item	Description	Lead	Further Actions or Completed
5. Roundtable **▪ Reporting deaths following vaccination** - What is each PT doing? - Do PTs report all deaths following vaccine, or only those ones they determine to be casually related? - Which PTs are currently reporting AEFIs publically?	a) PHAC asked jurisdictions to provide their responses on how they report deaths following vaccination and if AEFIs are reported publically. The responses from each jurisdiction is listed below: **AB** ▪ AB is only reporting deaths that are within 30 days of immunization and do not have a clear cause of death. ▪ Developing a dashboard for public reporting **BC** ▪ Only report deaths with no other clear cause within 30 days ▪ Not publically reporting AEFIs but may in the future **MB** ▪ MB reports deaths that occur within 30 days of vaccination ▪ The antecedent AEFI or medical condition that led to the demise itself is reportable. If no antecedent AEFI is identified, the death itself is the AEFI and should be reported as such if occurred within 30 days. **NB**	All	**ACTION:** a) No action b) No action

Agenda Item	Description	Lead	Further Actions or Completed
	▪ Agrees with MB; reports deaths if AEFI meets criteria and results in death (even if no causality) ▪ Will confirm that this is the case for COVID ▪ Not currently reporting AEFIs publically but developing a dashboard **NL** ▪ N/A **NS** ▪ NS does not report an AEFI death to PHAC until a full investigation has been completed. ▪ Any death of a vaccine recipient temporally linked (within one month) to immunization, where no other clear cause of death can be established must be reported to the province. Also, fetal deaths that occur following immunization of a pregnant woman and deaths in infants diagnosed as Sudden Infant Death Syndrome when the investigation has concluded. ▪ NS only reports AEFI numbers annually within their Annual Notifiable Diseased Reports which are available on their public website **NU** ▪ Report all deaths within 30 days ▪ Not publically reporting AEFIs **NWT** ▪ Following PHACs preference and reporting all deaths within 30 days ▪ Not publically reporting AEFIs **ON** ▪ ON only includes reports of deaths that meet their provincial surveillance definition for a confirmed case which does not include those death that have been attributed to another		

Agenda Item	Description	Lead	Further Actions or Completed
	cause of death through a formal process and they do not include reports of deaths that are currently under review/investigation. ▪ No formal causality review committee ▪ They do have a public report (weekly summary on website) **QC** ▪ Deaths are reported where there is clearly no other cause that can explain the issue ▪ Reports will be publically available as of February 11, 2021 **PEI** ▪ PEI Investigates all deaths and only report those determined causally related ▪ Not publically reporting AEFIs **SK** ▪ Reporting all deaths within 30 days ▪ Not publically reporting AEFIs **YT** ▪ Report deaths causally related ▪ Not publically reporting AEFIs		

Vaccine Surveillance Reference Group

[redacted]

Covid-19 Immunity Task Force

January 28th, 2021

Rationale for Creating the VSRG

Why create a VSRG?
Need to track vaccine effectiveness and safety in Canada
Need to study populations and address issues not included in Phase III vaccine trials

How was it established?
Under **PHAC** mandate in cooperation with the **COVID-19 Immunity Task Force** (CITF), the **Canadian Immunization Research** Network (CIRN) and the **National Advisory Committee on Immunizations** (NACI). CITF secretariat will provide support.

VSRG Mandate

Reporting to the President of the Public Health Agency of Canada (PHAC), the VSRG will **advance support for** accelerated and effective implementation of **vaccine surveillance plans across Canada** in coordination with existing federal, provincial and territorial institutions and **with attention to all priority groups including Indigenous persons**, to monitor the safety and effectiveness of COVID-19 vaccines.

VSRG Inventory of Current Vaccine Studies

The following information is being collected at the Federal, Provincial and Territorial level as well as CITF and other funding organizations including CIHR:

- Organization details
- Focus on safety or effectiveness
- Name of the initiative
- Lead name
- Lead contact information
- Focus of the initiative
- Population
- Geographic area
- Key knowledge gaps

Coordination with Provincial CMOs is needed to ensure inventory is complete and non-redundant

Coordination with Provinces and Territories

- The COVID-19 Immunity Task Force (CITF) will support the VSRG and utilize its existing institutional resources and networks to monitor vaccine rollout and facilitate harmonizing of data collection and rapid sharing of results.
- Need an effective communication mechanism with provinces, to inform on studies contemplated or funded
  - To ensure studies fit provincial and national priorities
  - Avoid duplication of efforts
  - Ensure all sources of funding for a project are considered

- [redacted]
- https://www.covid19immunitytaskforce.ca/request-for-applications/

Priorities Addressed by the VSRG

Priority population groups:

- Individuals of colour/ racialized communities
- Indigenous communities
- Individuals of lower socioeconomic status
- Individuals with active co-morbidities
- Individuals with primary or secondary immune defects
- Individuals with cancer including those receiving treatments for their malignancies
- Individuals with autoimmunity including those receiving treatments that may alter their immune response
- Individuals who are pregnant or breastfeeding.
- Shared Living Facilites
- Adolescents and children.

NACI Research Priorities:

- Efficacy, effectiveness, immunogenicity and safety of COVID-19 vaccines across specific population groups, including those with previous SARS-CoV-2 infection
- Durability of immune responses against SARS-CoV-2 including antibodies and cell-mediated responses
- Single dose versus two-dose series of COVID-19 vaccine
- Anaphylactic reaction or serious adverse events following immunization
- Cross-protection from exposure to human seasonal coronaviruses
- Negative interactions between COVID-19 vaccination and other medications
- The effectiveness of COVID-19 vaccination in interrupting transmission

Request for Expressions of Interest (RFEOI)

Call out to the Canadian research community to apply for funding to assess the safety and effectiveness of current and future SARS-CoV-2 vaccines deployed in Canada

Information gathered will help public health decision-makers understand the response to vaccination in priority populations and/or address specific issues that were insufficiently addressed in pre-licensure Phase 3 studies.

Proposals are expected to:

- Demonstrate active engagement of relevant public health partners and networks
- Consider a range of relevant independent variables that determine individual, household, racial, age, SES and/or workplace risks or protective factors;
- Be innovative, interdisciplinary and provide relevant timely information to inform public health decisions
- Be carried out within a 12-18-month time frame
- Be prepared to share anonymized aggregate data with the CITF
- If the study includes measures of COVID-19 immunity (serological, cellular) it is highly recommended that teams network with existing funded CITF studies.

Review and Funding Process

1

VSRG will review proposals for vaccine safety/effectiveness studies emerging from the two Working Groups and make recommendations for support of proposals to the CITF Executive Committee (EC).

2

The CITF EC will function as an arm's-length audit/finance committee to ensure that due diligence has been done both scientifically and from a value-for-money perspective.

3

The CITF EC will then recommend studies for approval by Public Health Agency of Canada (PHAC) for financing.

Federal Programs in Inventory

- Health Canada
- Canadian Immunization Network (CIRN)
  - Special Immunization Clinic Network
  - Canadian National Vaccine Safety Network (CANVAS)
  - Serious Outcomes Surveillance
  - Provincial Collaborative Network
- National Advisory Committee on Immunization (NACI)
- Public Health Agency of Canada (PHAC)
  - Canadian Immunization Monitoring Program ACTive (IMPACT)
  - COVID-19 Vaccine Effectiveness Coordination
- Canadian Adverse Events Following Immunization Surveillance System (CAEFISS)
  - Canadian AEFI Surveillance System
  - Expert AEFI review committee

Vaccine Vigilance Working Group (VVWG) Teleconference

Friday, March 12, 2021 from 2:30 – 3:30 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] BC: [redacted] MB: [redacted] NB: [redacted] NL: [redacted]
[redacted] NS [redacted] NU: [redacted] ON: (MOH) [redacted] (PHO): [redacted]
[redacted] SK: [redacted]

Liaison Members in Attendance:
BRDD: [redacted] DND: [redacted] MHPD: [redacted]

Observers/Presenters in Attendance:
[redacted] (Federal Co-Chair), [redacted]

Regrets:
NT: [redacted] PE: [redacted] QC: [redacted] YT: [redacted] CANVAS: [redacted] CSC [redacted] FNIHB: [redacted] IMPACT: [redacted] RCMP: [redacted]

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction	a) [redacted] provided a brief summary of the high cases of anaphylaxis following the Pfizer COVID -19 vaccine. • On March 11, 2021, PHAC received a notification from British Columbia. The notification was about a high number of anaphylaxis events with the Pfizer-BioNTech COVID-19 Vaccine lot **number EP6017**. British Columbia reached out to PHAC.	[redacted]	**ACTION:** a) No action
2. Summary from BC	a) [redacted] provided a summary of what they have seen in BC from LOT # EP6017.	[redacted] BC)	**ACTION:** a) No action

Agenda Item	Description	Lead	Further Actions or Completed
	• British Columbia (BC) recorded18 AEFI reports for events managed as anaphylaxis with lot number EP6017 (Pfizer vaccine). • A total of 45,000 doses of lot number EP6017 were shipped to BC on February 17, 2021, for a rate of 40 anaphylaxis events per 100,000 doses distributed in BC (or 33% of all anaphylaxis events in BC with the Pfizer-BioNTech COVID-19 Vaccine) • Of the 18 AEFI reports for anaphylaxis events, 10 anaphylaxis events were classified as the Brighton Collaboration level 1, 2 or 3 (or a rate of 22 per 100,000 doses distributed in British Columbia). • Two individuals were hospitalized (1 admitted for too much adrenaline, 1 is recovering). • There were also 13 other allergic events reported from the same LOT number and that is about 12% of all of BC's allergic events of the Pfizer vaccine in BC. • The reports were received from all Health Regions in BC. There were 15 AEFI reports in females and 3 AEFI reports in males, with age ranging from 23 to 68 years old. Nine of the 18 AEFI reports have reported history of allergic reactions. • Higher rates of anaphylaxis in British Columbia were observed compared to what has been observed nationally for anaphylaxis.		
3. Summary of data in CAEFISS	a) [redacted] provided a summary of data in CAEFISS • This analysis only includes the cases that met the Brighton Criteria, level 1 to 3. • Other allergic reactions are excluded from this and this only includes cases we have reviewed. There are still 10 cases outstanding. • To date, the overall rate of anaphylaxis is equal between Moderna and Pfizer.	[redacted]	**ACTION:** a) No action

Agenda Item	Description	Lead	Further Actions or Completed
	• In terms of the lot numbers, when the anaphylaxis cases were broken down, the reports varied. Some lot numbers do not have any reports of anaphylaxis and some do. It is not necessarily the lot that BC has flagged that has the most anaphylaxis cases. • Overall, our rate is 15.1 per million doses distributed • Background rates were updated a couple of weeks ago and additional codes needed to be added therefore, the background rates are much higher now. The rate is now 212 per million which is quite high.		
4. Distribution of LOT across Canada	a) [redacted] provided a summary of the Lot distribution in Canada. • Nine PTs received the lot in question (EP6017) • 40% of the doses received were in Ontario followed by 22% in British Columbia and about 17% in Quebec. • All other provinces reported few or no anaphylaxis cases with this lot • One PT inquired if this was a new lot and it was noted that this particular lot was shipped on February 15, 2021. • Another PT inquired if BC tends to have a higher rate of anaphylaxis reporting and is this a trend. According to PHAC data, the rate was not, the highest reported in the country but mid range. BC noted that they are the third highest for reporting. This is a higher reporting rate than they would get for the flu season as a comparison. BC usually sees less than one per 100,000 reports. They are seeing higher rates than what they have seen from other vaccines within BC where they can compare out in an adult population. • A PT inquired if this lot went to other countries or to Canada only. Health Canada noted that they did do	[redacted]	**ACTION:** a) Health Canada will reach out to the manufacturer to find out where else this lot has been distributed to internationally.

Agenda Item	Description	Lead	Further Actions or Completed
	a search and they could not find where else this LOT was sent to. The lot Canada received came from Panama. Health Canada will reach out to the manufacturer to find out where else this lot has been distributed to internationally. • The lot number EP6017 has been fully distributed and used up in British Columbia		
5. Summary from Canada Vigilance and Health Canada	a) Canada Vigilance and Health Canada provided a brief summary • In a search of the Canada Vigilance Program on March 12, 2021 (up to and including March 11, 2021), seven foreign and no domestic spontaneous reports with the Pfizer-BioNTech COVID-19 Vaccine lot number EP6017 were retrieved. The seven foreign reports were serious and originated from a physician in Panama. One patient was female (unknown gender in 6 patients, unknown age in all patients). All the reports described pruritic rash on the abdomen, back, arms and ears (not on the face) within 30 minutes after vaccination. The patients' medical history and concomitant medications were not reported. The outcome is reported as unknown in all reports. • The MAHs, Pfizer Canada ULC and BioNTech Manufacturing GmbH, did not report adverse reactions in association with lot number EP6017 in the Summary Monthly Safety Reports covering the reporting period of December 1, 2020 to January 31, 2021.	[redacted] (Health Canada)	**ACTION:** **a)** Health Canada
6. Roundtable	a) A summary of anaphylaxis events with the Pfizer-BioNTech COVID-19 vaccine lot number E and territories:	ALL	**ACTION:** a) It was recommended that PHAC could start reviewing cases

Agenda Item	Description	Lead	Further Actions or Completed
	Alberta: 1 anaphylaxis and 1 allergic reaction **Manitoba:** 2 other allergic reactions **Ontario:** 3 anaphylaxis **Quebec:** 0 anaphylaxis **New Brunswick:** 1 anaphylaxis **Nova Scotia:** 0 anaphylaxis **Newfoundland and Labrador:** no doses received **Prince-Edward-Island:** no representative on the call **Saskatchewan:** 1 anaphylaxis **Territories:** no doses received		before a full medical review commences. b) **Next Steps for BC:** A review of the reports will need to be done more closely. More education may need to be provided to immunizers about anaphylaxis and recognizing anaphylaxis. c) PHAC will do a follow up looking more in depth in the CAEFISS database and PHAC will do more investigation and this will be shared with BC. It will then be shared with VVWG at the next meeting on March 18, 2021.

Anaphylaxis Cases Submitted to CAEFISS (as of March 11, 2021)

	Submitted to CAEFISS, reviewed, meets BC 1,2,3 (N)	Doses distributed	Rate (count/doses distributed)*1M
Anaphylaxis (as indicated on AEFI form)			
Total (Pfizer)	34	2,251,470	15.1
Total (Moderna)	10	688,300	14.5
LOT (Pfizer only)			
EK4175	2	30,225	66.2
EL0140	4	39,000	102.6
EJ1686	0	57,525	0.0
EK4241	12	212,550	56.5
EK4245	5	137,475	36.4
EL0203	4	219,375	18.2
EL1404	0	106,665	0.0
EL1406	4	187,395	21.3
EN1194	0	95,940	0.0
EP6017	3	245,700	12.2
EP6775	0	475,020	0.0
ER1742	0	444,600	0.0
No lot	0	0	0.0
TOTAL	**34**	**2,251,470**	**15.1**

Background Rates:

Definition 1: Anaphylaxis due to vaccination or other serum and not otherwise classified

ICD-10-CA codes: T78.2, T80.5

All ages: Rate (per 1,000,000 persons) and confidence interval

2015	2016	2017	2018	2019	2015-2019
171.7 (166.9 – 176.7)	185.1 (180.1 – 190.2)	196.7 (191.5 – 201.9)	210.4 (205.1 – 215.8)	212.4 (207.1 – 217.7)	195.5 (193.2 – 197.9)

Definition 2: All codes related to anaphylaxis

ICD-10-CA codes: T78.0x, T78.2, T80.5, T88.6

All ages: Rate (per 1,000,000 persons) and confidence interval

2015	2016	2017	2018	2019	2015-2019
378.8 (371.6 – 386.2)	417.8 (410.3 – 425.5)	449.7 (441.9 – 457.6)	468.2 (460.3 – 476.2)	488.5 (480.5 – 496.6)	441.4 (437.9 – 444.8)

From: [redacted] (PHAC/ASPC) on behalf of Vaccine Vigilance (PHAC/ASPC)

Sent: 2021-03-19 8:32 AM

To: [redacted]

[redacted]

Subject: Diagnoses following COVISHIELD for close monitoring and extra vigilance

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Dear VVWG Member,

As discussed on yesterday's call, below are the list of potential AESIs that we are asking you to look out for and to please notify us by email as soon as possible if you receive a case report or are given a heads-up about a case with one of these diagnoses following vaccination with any of the COVID vaccines, with particular attention to the events following COVISHIELD. We are casting a somewhat wide for case finding at this time:

1-) Thrombotic events. This would include:

- Pulmonary embolism
- Venous thromboembolism (VT) e.g., deep vein thrombosis, phlebitis, thrombophlebitis
- Stroke (if it would be possible to confirm if it was an embolic or hemorrhagic stroke, that would be valuable)
- Limb ischemia

2-) Hemorrhagic disease or bleeding disorders

3-) Thrombocytopenia

4-) Other coagulation or blood disorders:

- Disseminated intravascular coagulation (DIC)
- Hemolytic uremic syndrome (HUS)
- Complement disorder

Thank you for your assistance in keeping an eye out for any potential signals.

All the best,

[redacted]
Medical Advisor / Médecin conseil
Centre for Immunization and Respiratory Infectious Diseases/ Centre de l'immunisation et des maladies respiratoires infectieuses
Public Health Agency of Canada / Agence de la santé publique du Canada
Please note my new phone number / Veuillez noter mes nouvelles coordonnés: [redacted]

Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, March 18, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] BC: [redacted] MB: [redacted] NB: [redacted] NS: [redacted]
[redacted] NT: [redacted] NU: [redacted] ON: (PHO) [redacted] PE: [redacted]
QC: [redacted] SK: [redacted] YT: [redacted]

Liaison Members in Attendance:
BRDD: [redacted] CSC: [redacted] DND: [redacted] IMPACT: [redacted] MHPD: [redacted]

Observers/Presenters in Attendance:
[redacted] (Federal Co-Chair) [redacted]

Regrets:
CANVAS: [redacted] FNIHB: [redacted] RCMP: [redacted]

ACTION ITEMS

1. **Action Item Updates**
   - i) **Weekly On-line COVID AEFI Report**
     - PHAC will report back to VVWG next week about the local reactions associated with technique of vaccine.
   - ii) **CANVAS Update**
     - There were no questions sent to the VVWG inbox regarding the CANVAS update.
   - iii) **Rehearsal of Concept**
     - Jurisdictions provided a summary of what strategies, activities, and capacity increases are being planned /used within provinces and territories and if they require support from PHAC and what type of support they may need.

Agenda Item	Description	Lead	Further Actions or Completed
1. **Introduction, roll call, agenda, minutes from last meeting**	a) Agenda was approved with no additional items. b) RoD was reviewed. Amendments can be	[redacted]	**ACTION:** a) No action

Agenda Item	Description	Lead	Further Actions or Completed
a) Review and approval of agenda b) Review of March 11, 2021 RoD	provided to [redacted] by end of day on March 19, 2021.		b) Members can provide changes or updates to the RoD to [redacted] by end of day on March 19, 2021 to approve and finalize the RoD from March 11, 2021.
2. Weekly On-line COVID AEFI Report	a) [redacted] provided a brief summary of the Weekly on-line COVID AEFI Report. It will be posted on March 19, 2021. • MB inquired if PHAC could show how the rates compare to other vaccines such as, the reporting rate we are getting for COVID. How that rate compares to other vaccines, and is it more reactogenic than other vaccines in general, maybe other vaccines, specifically flu as one example. • PHAC noted that it could be added into the results shared with VVWG.	[redacted]	**ACTION:** a) PHAC will start including this in our presentation to VVWG.
3. CAEFISS Analysis - Bells Palsy - Anaphylaxis	a) [redacted] provided a brief summary of the CAEFISS Weekly Report. The data provided is up to March 12, 2021. The results of the analysis of Bells Palsy were also provided • Only one of the 26 Bells Palsy reports was classified as serious. • NB inquired if PHAC is reporting on medically important AEFI and are they included in the serious one. If not, is PHAC planning to report the number of AEFIs that are classified as medically important? - [redacted] noted that medically important would be included in part of the serious category. Medically important is mainly reported with Health Canada and PHAC does not have any in CAEFISS that are	[redacted]	**ACTION:** a) Health Canada will send out the definition of **medically important event** to VVWG and the criteria that is used to classify their AEFIs as medically important events. b) PHAC will send out the definition of **serious medically important** to VVWG. c) The Pfizer LOT EP6017 that was in question from BC last week was not noted on the report. PHAC will look into this and add this to the report next week

Agenda Item	Description	Lead	Further Actions or Completed
	classified as medically important. They are classified as serious or non-serious based on the severity score. • BC inquired about what are the criteria for the medical reviews and what the criteria would be for Causality Assessment. BC asked what the differences are. - [redacted] noted that they are both the same. All serious events and all of the adverse events of special interest for COVID vaccine undergo causality assessment. - [redacted] noted that there are two levels of causality assessment. The first level is the one that the medical reviewers do as part of their medical review. This is done for all the serious cases they review. The second level refers to ongoing plans to develop a Causality Committee and for these it would be specific cases where there is a concern with the medical review (an unusual case). • BC inquired about medically important events. Bells Palsy would not be considered as a serious event however, the one event that was reported as serious was because the person was hospitalized and this is how it met the criteria of important. - Health Canada will provide VVWG with the definition of medically important events and the criteria that is used to classify their AEFIs as medically important events.		

Agenda Item	Description	Lead	Further Actions or Completed
	b) [redacted] provided the results of the analysis of anaphylaxis. There have been no changes in trends since the previous update. • All of these have undergone medical review. There are 65 cases or less that are pending review. • A PT inquired, is the medical case review the process by which you do the levelling or do you have an automated system for doing it? - [redacted] noted that we do it as part of the Brighton Collaboration levels of certainty we do that as part of our medical case review and have two reviewers check it against each other to ensure there are no errors. • The LOT EP6017 from Pfizer in question from last week was not noted in the report. PHAC will look into this for next week's report.		
4. CANVAS Update	a) [redacted] was unable to attend the meeting. The CANVAS update will be moved to next week's meeting.	[redacted]	**ACTION:** a) This will be moved to next week's agenda.
5. AstraZeneca hold in EU - Update on current situation - AEFIs of concern	a) [redacted] provided a summary of the AstraZeneca hold in EU. • The EU held a press conference today and revealed that the benefits of the AstraZeneca COVID-19 vaccine continue to outweigh the risks for use. • Health Canada will issue a similar statement as the EU press conference to say that the benefits of AstraZeneca COVID-19 vaccine continue to outweigh the risks for use in Canada and encourages Canadians to get immunized with any of the recommended COVID-19 vaccines that are authorized in Canada.	[redacted] (HC) / [redacted] (PHAC)	**ACTION:** a) Health Canada will provide a list of other countries that have been approved to use COVISHIELD and will summarize and provide to VVWG.

Agenda Item	Description	Lead	Further Actions or Completed
	b) [redacted] provided a summary of AEFIs of concern. • The events of concern that were reported out of Europe were not just from a thrombotic event where there is a blood clot that is detected. This tended to present as blood clots with thrombocytopenia as well as frequently bleeding. These were somewhat unusual and often quite severe events that they were reporting. PHAC has been monitoring the reports that have been coming in through CAEFISS. PHAC currently does not have anything from COVIDSHIELD reported yet through CAEFISS. Canada Vigilance has received a small number at this time. • PHAC has done a review and to date the following reports have been made: 6 strokes (4 - Pfizer, 1 - Moderna, 1 - COVISHIELD), 2 Pulmonary embolism (2 - Pfizer). To date, nothing has been reported on embolism or other factors such as, bleeding, strokes and pulmonary embolism, thrombocytopenia. At this time, there is nothing to be concerned about at this time but PHAC will continue to monitor this. • ON inquired if the product monographs will be changed to make reference to specific counselling about the risk of these events especially for people under 50 looking at the way the EMA position was worded and making note of observed events being greater than expected in that population under 50. - Health Canada noted it will be changed but they are waiting for details on what		

Agenda Item	Description	Lead	Further Actions or Completed
	AstraZeneca will end up filing. It should not be too long for this to take place. • BC inquired what their understanding might be around the biological mechanisms for a causal association. - HC noted that there is a discussion that is taking place about potential changes to the coagulation pathway but there is no data available at this point. The EMA presented a number of theoretical biological mechanisms but nothing that had any data.		
6. Advisory Committee on Causality Assessment (ACCA) re-establishment	a) [redacted] introduced [redacted] who is new to the VSS team and will be working on re-establishing the Advisory Committee on Causality Assessment (ACCA). • [redacted] will be working on the causality assessment. She will be contacting jurisdictions to discuss this matter further.	[redacted]	**ACTION:** a) No action
7. Rehearsal of Concept	a) [redacted] provided a brief summary of the Rehearsal of Concept. • There was a Rehearsal of Concept that was conducted fairly recently that was to stage how we were all going to be prepared for phase 2, which is the significant increase in the availability of vaccines in Canada to be rolled out (anticipated high increase in AEFI reports).	[redacted]	**ACTION:** a) No action
8. Roundtable - Expected increase in AEFI reporting with phase 2 vaccine roll-out: What strategies, activities and capacity increases are being planned/used within P/Ts?	a) Jurisdictions were asked to provide a summary of what strategies, activities, and capacity increases are being planned /used within provinces and territories. Also, is there some support needed that PHAC could provide to help in this preparation for the additional surge and whether that support is in terms of human	ALL	**ACTION:** a) Jurisdictions can provide their summary to the VVWG email account. A reminder email will be sent out.

Agenda Item	Description	Lead	Further Actions or Completed
- Use of COVISHIELD (Astra Zeneca) vaccine in Canada: Any initial observations from vaccination sites and at provincial level re AEFIs? - Collection of AEFIs of concern	resources (i.e. public health officers supporting vaccine safety) or financial to help prepare for the surge. • Four provinces, BC, MB, ON, and SK provided their summaries. The remaining jurisdictions will provide their summaries via email to the VVWG email inbox. ➢ Please see Appendix A for the summary from each jurisdictions.		
9. Confirm Next Call	a) Next call: March 25, 2021 (1:30 – 3:00 EDT)	[redacted]	**ACTION:** a) No action

Jurisdiction	Update on Thrombotic events	Experience with COVISHIELD vaccinations	What are jurisdictions doing to raise awareness of need to ask about vaccine history for people presenting with thrombotic events in ERs and clinicians?
AB	• AB has experienced a couple of thrombotic events that have been stroke like events from the Pfizer vaccine but nothing from Moderna and COVISHIELD • Two AEFIs have been reported but as non-serious (allergic type reactions)	• AB has had a good experience so far and it has been well received. • 2 AEFIs have been reported related to COVISHIELD both allergic type reactions	• AB is not sure what the plan is but they are looking into it (in progress) • AB is actively thinking of strategies to promote messaging to clinicians around thrombotic events and asking about vaccination history
BC	• No thrombotic events have been reported	• Have been administering COVISHIELD for 1.5 weeks • No AEFIs reports for COVISHIELD	• Lots of disccusions taking place in BC around messaging to clinicians but no communication has been issued yet
MB	• No thrombotic events have been reported	• 3 AEFIS have been reported from COVISHIELD that are non-serious and no thrombotic events	• Have disseminated usual guidelines (eg NACI statements, label changes) and have discussed the issue at existing governance tables that include public health and clinicians. Will be using these forums on a continuous basis to provide ongoing updates and emphasizing AESIs to watch out for.
NB	•	•	•
NL	•	•	•
NS	• No thrombotic events have been reported	• NS just began using the COVISHIELD on March 20, 2020 • Not seeing any thrombotic events. One case was just submitted to CAEFISS on March 25, 2021	• NS will get back to PHAC regarding communication with clinicians.
NT	• No thrombotic events have been reported	• COVISHIELD is not being used in NT.	• NT is working on their messaging. • Have not issued any info to clinicians; is interested in learning from other jurisdictions on what they're doing
NU	• No thrombotic events have been reported	• COVISHIELD is not being used in NU.	• NU is working on their messaging.
ON	• 3 thrombotic events have been reported and all from Moderna	• 15 non-serious events related to COVISHIELD	• Guidance will be issued soon for clinicians and have sent communique to public health units to look out for these AEFIs

Jurisdiction	Update on Thrombotic events	Experience with COVISHIELD vaccinations	What are jurisdictions doing to raise awareness of need to ask about vaccine history for people presenting with thrombotic events in ERs and clinicians?
QC	• Over 1 million doses have been administered (majority have been from Pfizer) - 21 anaphylaxis have been reported - 5 deaths but they are not associated with the vaccine	• Over 110,000 doses of the COVISHIELD have been administered. - 2 anaphylaxis cases have been reported to date - 2-3 other events that are under investigation have been reported but no signals have been seen so far.	•
SK	• No thrombotic events have been reported	• SK have been administering COVISHIELD for a while with a low refusal rate. The vaccine has been well received. SK updated their patient information sheets regarding thrombotic events • Will bring forward the issue of emphazing vigilance for thrombolytic events • No thrombolytic events associated with COVISHIELD reported so far	• SK will consult with MHOs to see how they want to address vaccine history
YK	• No thrombotic events have been reported	• COVISHIELD is not being used in YK.	• YK is working on their messaging, in progress. • YK have not issued any info to clinicians

Public Health Agency of Canada | Agence de la santé publique du Canada

Canada

Background rates

[redacted]

Public Health Agency of Canada

Background rates working group

April 9, 2021

PROTECTING AND EMPOWERING CANADIANS
TO IMPROVE THEIR HEALTH

Methodology

- Included all acute hospital (DAD)[1] and emergency department (NACRS)[2] records with an admission diagnosis of the condition of interest between 2015-2019.
- Excluded records:
  - where the condition was flagged as a questionable diagnosis.
  - which occurred within 365 days of a previous event.
  - which occurred on the same episode as another record.
  - where the individual left the emergency department without being seen (registered and/or triaged and then left).
  - with unknown or other sex.
- Rates calculated using Statistics Canada's population estimates as of July.[3]
- Confidence intervals calculated using the exact method to account for rare events.

1. CIHI Discharge Abstract Database, Canadian Institute for Health Information, fiscal years 2013-2019
2. CIHI National Ambulatory Care Reporting System, Canadian Institute for Health Information, fiscal years 2013-2019
3. Statistics Canada, Centre for Demography

Coagulation Disorders

Definitions

Definition	ICD-10-CA codes
Pulmonary embolism (PE)	I26.x, O88.20x
Deep vein thrombosis (DVT)	I80.1-I80.3, I80.8, I80.9, O22.30x, O87.10x
Stroke	I60.x, I61.x, I62.x, I63.x, I64, H34.1
Intracranial venous thrombosis (IVT)	G08.x, I63.6, I67.6, O22.50x, O87.30x
Idiopathic thrombocytopenia	D69.3x
Disseminated intravascular coagulation (DIC)	D65, O45.01x, O46.01x

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
PE	57.92 (57.02 - 58.83)	62.27 (61.35 - 63.2)	63.39 (62.46 - 64.32)	64.21 (63.28 - 65.14)	66.21 (65.28 - 67.15)	62.85 (62.44 - 63.26)
DVT	80.46 (79.4 - 81.52)	80.89 (79.84 - 81.95)	79.91 (78.87 - 80.96)	78.81 (77.79 - 79.85)	77.13 (76.13 - 78.15)	79.42 (78.95 - 79.88)
Stroke	154.48 (153.01 - 155.95)	155.98 (154.52 - 157.46)	156.13 (154.68 - 157.6)	158.16 (156.71 - 159.63)	158.3 (156.86 - 159.76)	156.64 (155.99 - 157.29)
IVT	1.39 (1.25 - 1.53)	1.46 (1.32 - 1.61)	1.52 (1.38 - 1.67)	1.3 (1.17 - 1.44)	1.59 (1.45 - 1.74)	1.45 (1.39 - 1.52)
Idiopathic thrombocytopenia	6.03 (5.74 - 6.32)	6.3 (6.01 - 6.6)	5.92 (5.64 - 6.21)	5.76 (5.48 - 6.04)	5.56 (5.29 - 5.84)	5.91 (5.78 - 6.04)
DIC	1.46 (1.32 - 1.61)	1.47 (1.33 - 1.62)	1.49 (1.35 - 1.64)	1.47 (1.34 - 1.62)	1.5 (1.36 - 1.65)	1.48 (1.41 - 1.54)

Rate per 100,000 persons

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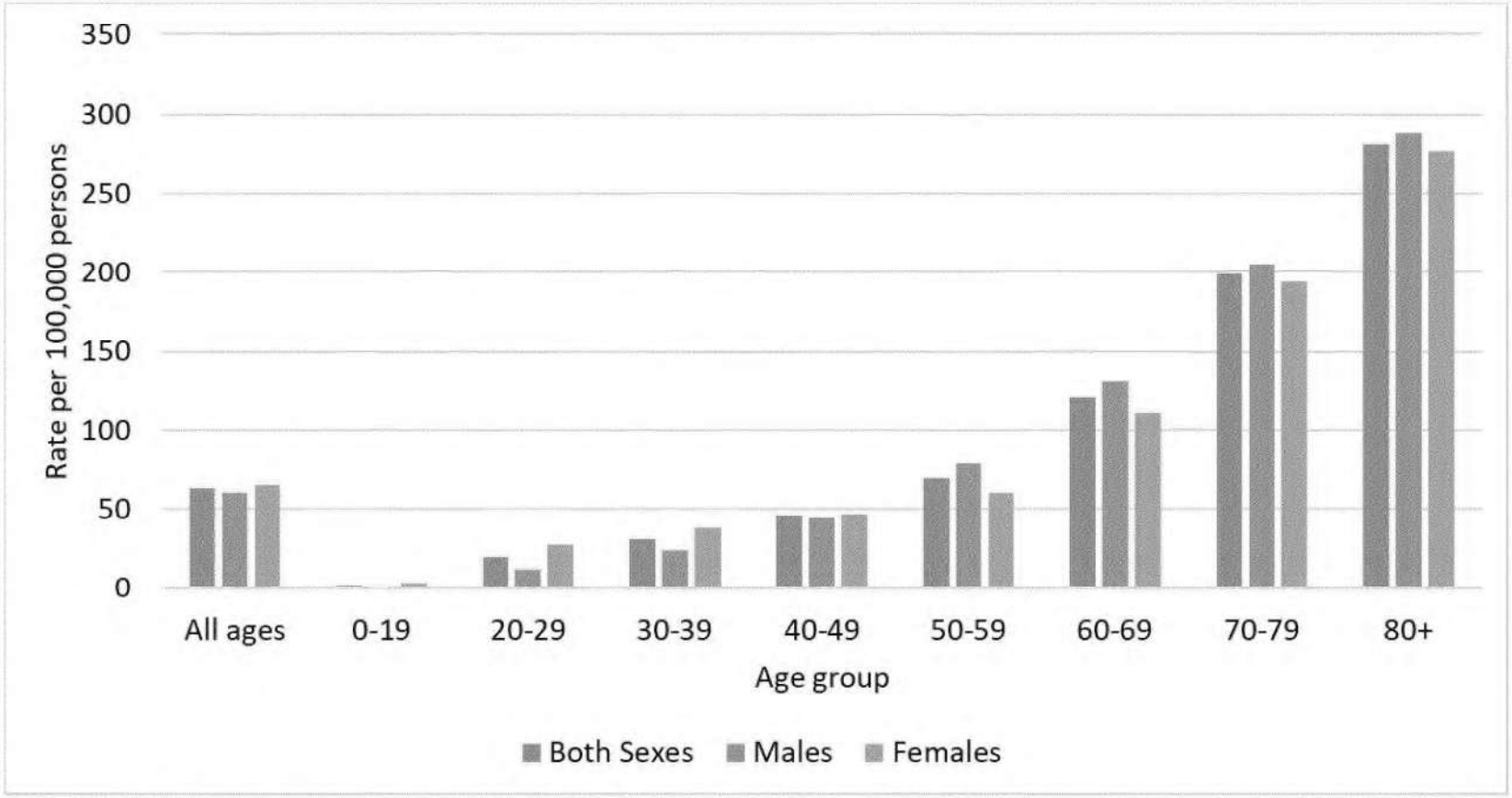
PE background rates by age and sex – Canada excluding Quebec 2015 – 2019

Age group	Both sexes	Males	Females
All ages	62.85 (62.44 - 63.26)	60.45 (59.87 - 61.02)	65.21 (64.62 - 65.81)
0-19	2.2 (2.04 - 2.37)	1.12 (0.96 - 1.29)	3.34 (3.06 - 3.64)
20-29	19.47 (18.85 - 20.1)	11.95 (11.28 - 12.64)	27.53 (26.48 - 28.61)
30-39	30.95 (30.17 - 31.74)	23.76 (22.8 - 24.75)	38.07 (36.86 - 39.32)
40-49	45.75 (44.78 - 46.73)	44.54 (43.18 - 45.92)	46.93 (45.55 - 48.33)
50-59	69.52 (68.38 - 70.67)	78.62 (76.91 - 80.36)	60.52 (59.03 - 62.05)
60-69	120.57 (118.91 - 122.26)	130.61 (128.13 - 133.13)	111.05 (108.82 - 113.31)
70-79	198.89 (196.09 - 201.72)	204.89 (200.76 - 209.08)	193.53 (189.73 - 197.38)
80+	280.52 (276.25 - 284.85)	287.42 (280.58 - 294.38)	275.94 (270.47 - 281.49)

Rate per 100,000 persons

Rate of PE by age and sex – Canada excluding Quebec, 2015 – 2019



Rate per 100,000 persons

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DVT background rates by age and sex – Canada excluding Quebec 2015 – 2019

Age group	Both sexes	Males	Females
All ages	79.42 (78.95 - 79.88)	78.58 (77.93 - 79.24)	80.24 (79.58 - 80.9)
0-19	4.03 (3.81 - 4.25)	3.45 (3.17 - 3.75)	4.63 (4.3 - 4.99)
20-29	27.23 (26.5 - 27.97)	20.7 (19.82 - 21.61)	34.22 (33.05 - 35.42)
30-39	51.71 (50.71 - 52.74)	43.7 (42.39 - 45.04)	59.66 (58.13 - 61.21)
40-49	75.55 (74.31 - 76.81)	75.23 (73.47 - 77.02)	75.87 (74.12 - 77.64)
50-59	98.85 (97.49 - 100.22)	112.78 (110.72 - 114.86)	85.08 (83.31 - 86.88)
60-69	138.4 (136.62 - 140.21)	155.93 (153.21 - 158.68)	121.77 (119.44 - 124.14)
70-79	209.07 (206.21 - 211.97)	217.66 (213.4 - 221.97)	201.4 (197.53 - 205.33)
80+	311.68 (307.17 - 316.24)	313.6 (306.46 - 320.87)	310.4 (304.6 - 316.28)

Rate per 100,000 persons

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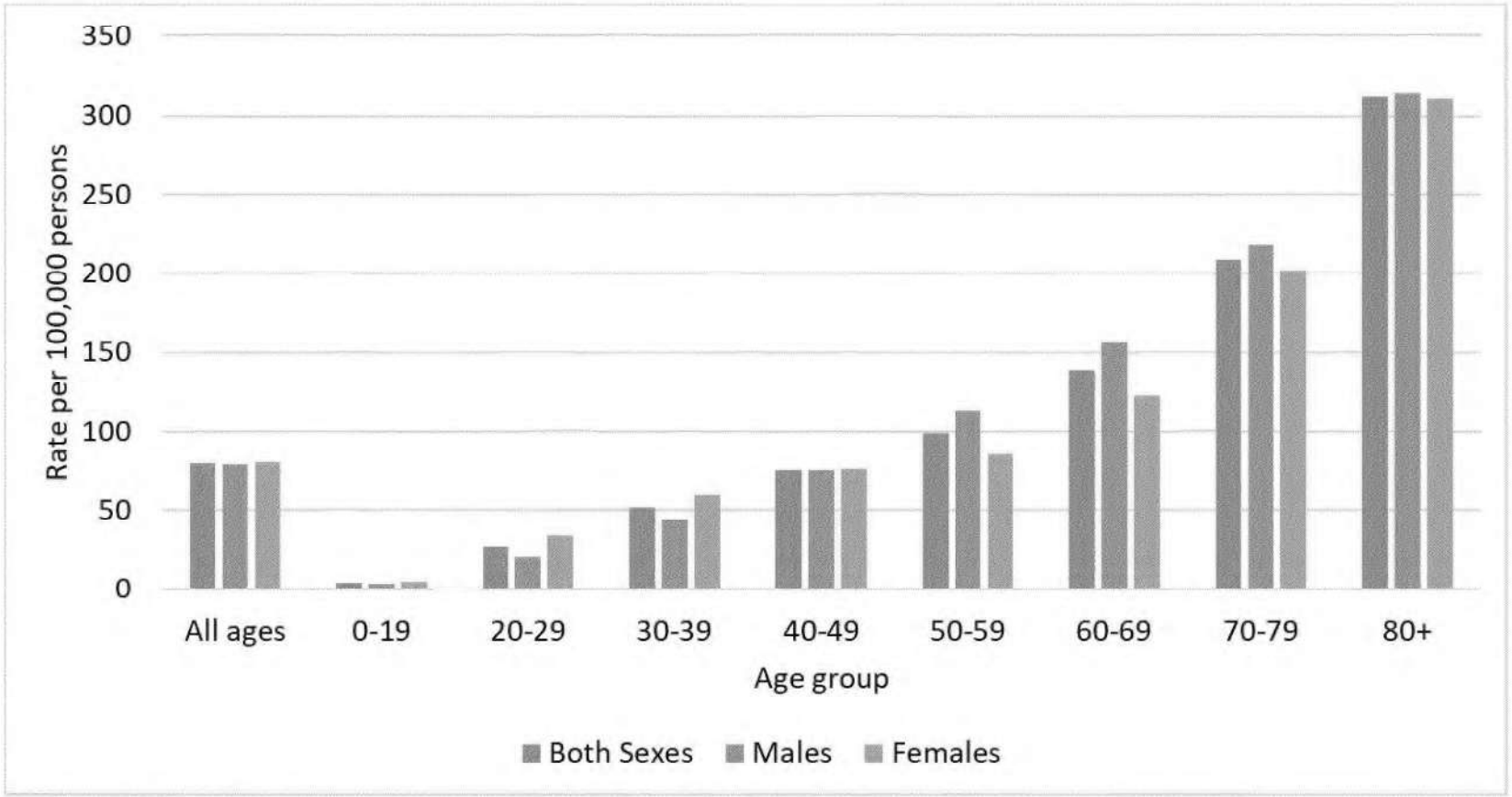
Rate of DVT by age and sex – Canada excluding Quebec, 2015 – 2019



Rate per 100,000 persons

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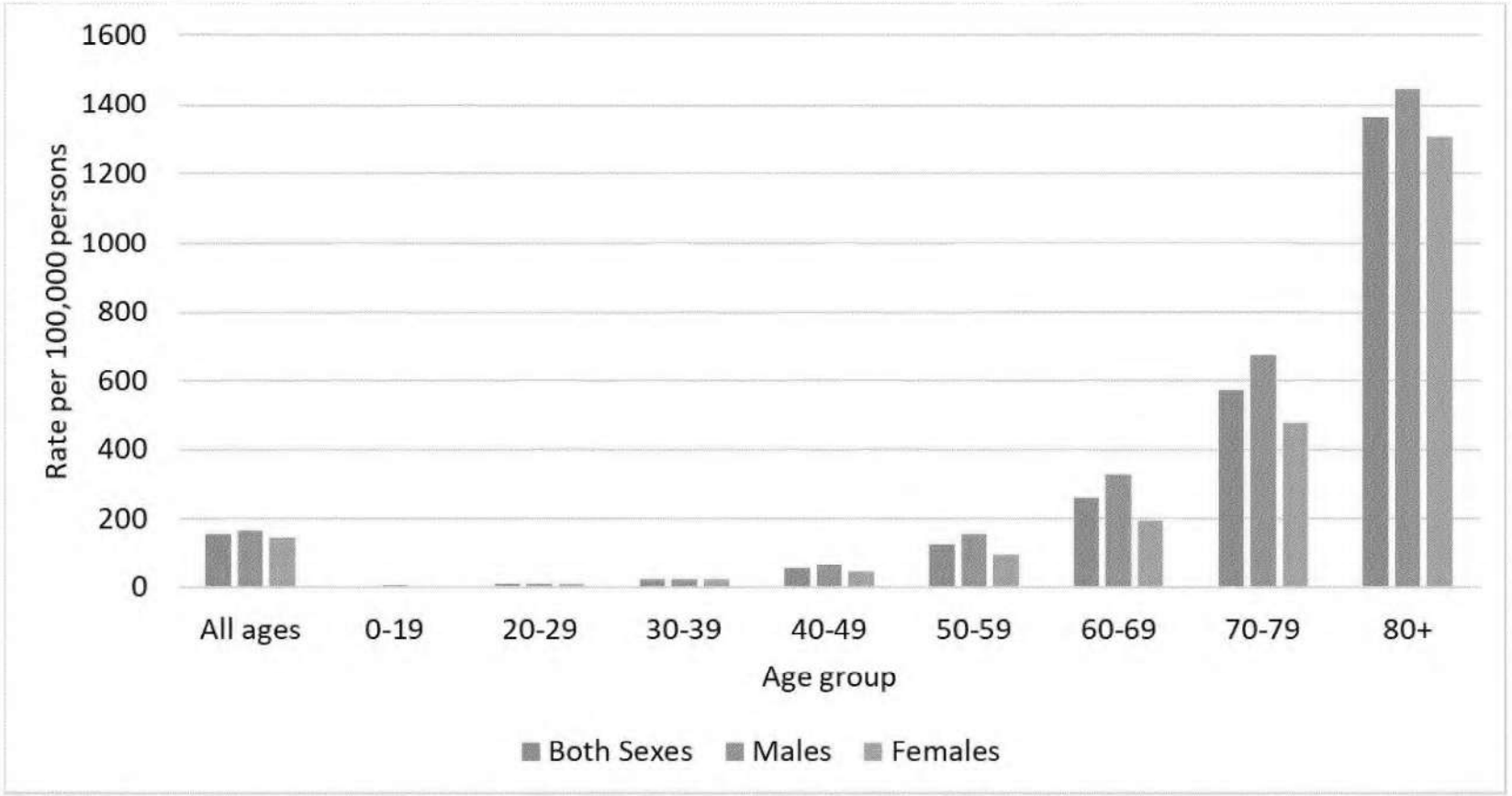
Stroke background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	Both sexes	Males	Females
All ages	156.64 (155.99 - 157.29)	166.66 (165.71 - 167.62)	146.78 (145.89 - 147.67)
0-19	4.4 (4.17 - 4.63)	4.99 (4.65 - 5.34)	3.78 (3.48 - 4.1)
20-29	9.76 (9.32 - 10.21)	9.65 (9.05 - 10.28)	9.87 (9.24 - 10.53)
30-39	21.59 (20.94 - 22.25)	22.45 (21.51 - 23.41)	20.74 (19.85 - 21.67)
40-49	54.85 (53.79 - 55.93)	63.37 (61.76 - 65.02)	46.55 (45.19 - 47.95)
50-59	126.95 (125.41 - 128.5)	156.71 (154.29 - 159.16)	97.54 (95.64 - 99.47)
60-69	259.58 (257.13 - 262.05)	329.08 (325.13 - 333.07)	193.62 (190.67 - 196.6)
70-79	570.02 (565.27 - 574.79)	674.79 (667.28 - 682.36)	476.36 (470.4 - 482.38)
80+	1361.91 (1352.46 - 1371.4)	1446.02 (1430.64 - 1461.54)	1306 (1294.07 - 1318.01)

Rate per 100,000 persons

Rate of stroke by age and sex – Canada excluding Quebec, 2015 – 2019



Rate per 100,000 persons

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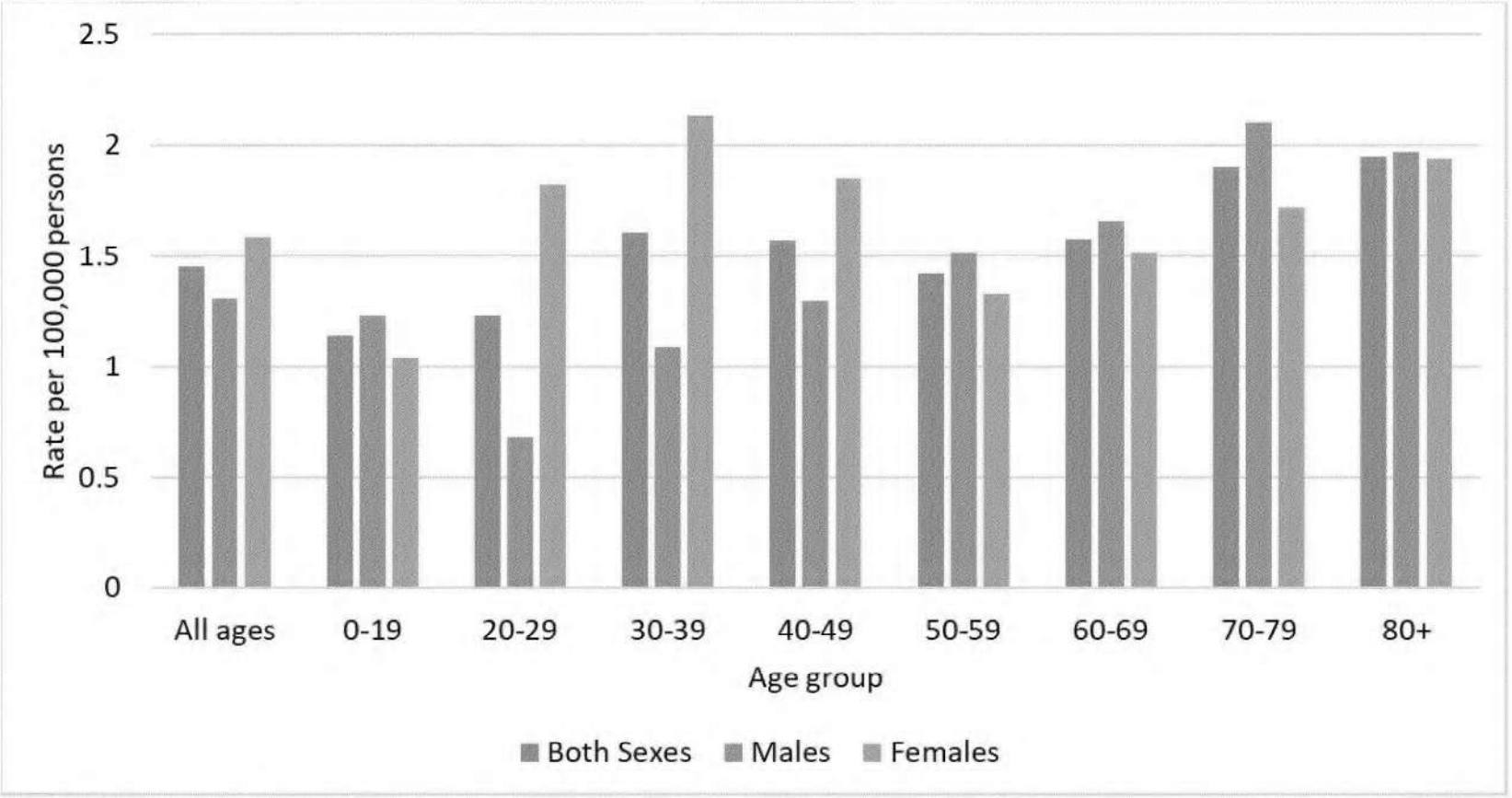
IVT background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	Both sexes	Males	Females
All ages	1.45 (1.39 - 1.52)	1.31 (1.23 - 1.4)	1.59 (1.5 - 1.68)
0-19	1.14 (1.02 - 1.26)	1.23 (1.06 - 1.41)	1.04 (0.88 - 1.21)
20-29	1.23 (1.08 - 1.39)	0.68 (0.52 - 0.86)	1.82 (1.56 - 2.11)
30-39	1.61 (1.44 - 1.8)	1.09 (0.89 - 1.32)	2.13 (1.85 - 2.44)
40-49	1.57 (1.4 - 1.76)	1.3 (1.07 - 1.55)	1.85 (1.58 - 2.14)
50-59	1.42 (1.26 - 1.59)	1.51 (1.28 - 1.77)	1.33 (1.12 - 1.57)
60-69	1.58 (1.4 - 1.79)	1.66 (1.39 - 1.97)	1.51 (1.26 - 1.79)
70-79	1.9 (1.63 - 2.19)	2.1 (1.7 - 2.56)	1.72 (1.38 - 2.12)
80+	1.95 (1.61 - 2.34)	1.97 (1.44 - 2.63)	1.94 (1.5 - 2.45)

Rate per 100,000 persons

Rate of IVT by age and sex – Canada excluding Quebec, 2015 – 2019



Rate per 100,000 persons

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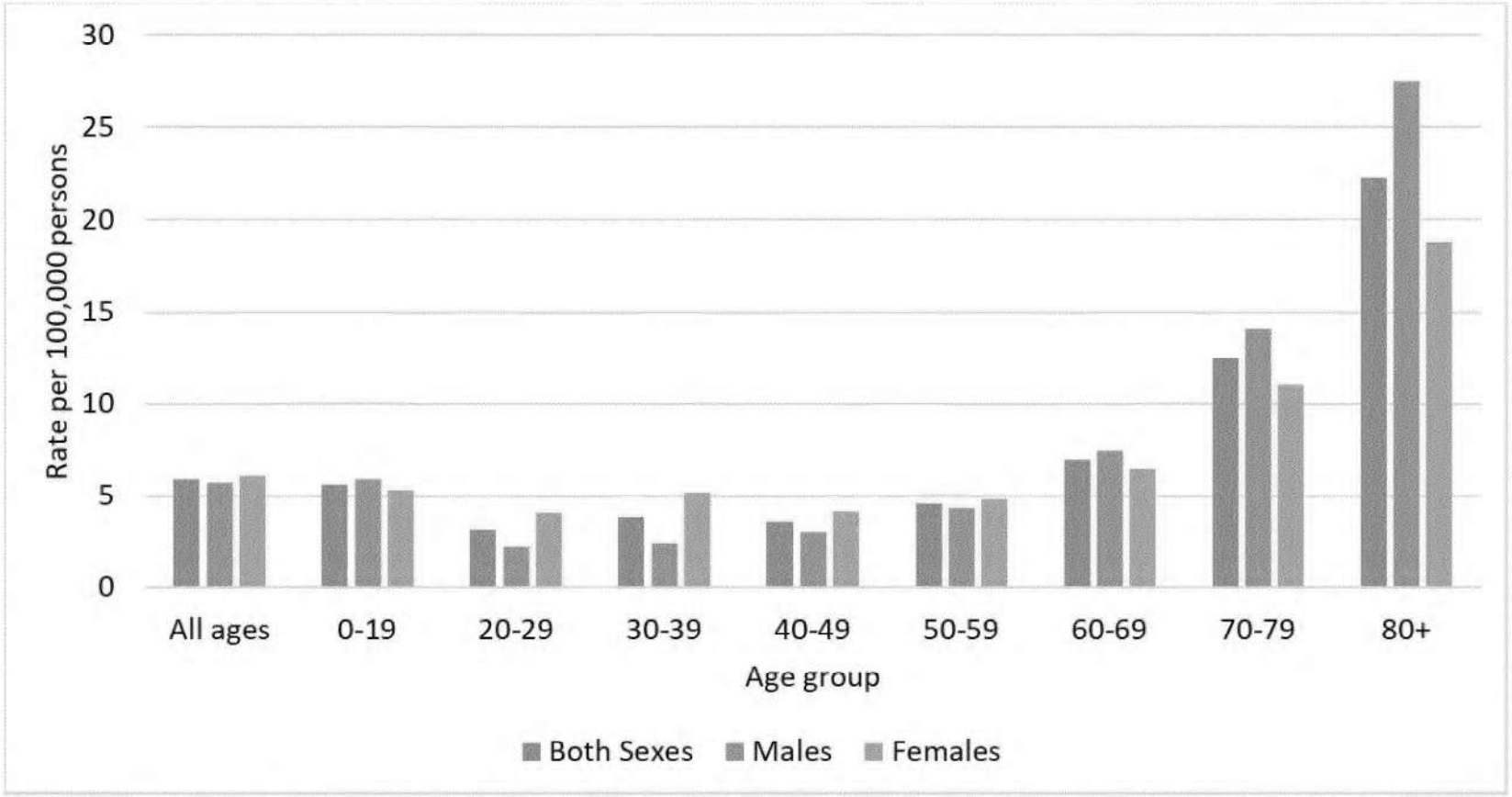
Idiopathic thrombocytopenia background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	Both sexes	Males	Females
All ages	5.91 (5.78 - 6.04)	5.71 (5.53 - 5.89)	6.11 (5.93 - 6.29)
0-19	5.59 (5.33 - 5.86)	5.87 (5.5 - 6.26)	5.3 (4.94 - 5.68)
20-29	3.14 (2.9 - 3.4)	2.26 (1.98 - 2.58)	4.08 (3.68 - 4.51)
30-39	3.8 (3.53 - 4.08)	2.4 (2.1 - 2.73)	5.18 (4.74 - 5.65)
40-49	3.58 (3.32 - 3.87)	3.02 (2.67 - 3.39)	4.14 (3.74 - 4.57)
50-59	4.55 (4.26 - 4.85)	4.31 (3.92 - 4.74)	4.78 (4.37 - 5.23)
60-69	6.93 (6.53 - 7.34)	7.41 (6.82 - 8.02)	6.47 (5.94 - 7.04)
70-79	12.46 (11.76 - 13.18)	14.08 (13.01 - 15.21)	11 (10.11 - 11.95)
80+	22.27 (21.08 - 23.52)	27.51 (25.42 - 29.72)	18.79 (17.39 - 20.28)

Rate per 100,000 persons

Rate of idiopathic thrombocytopenia by age and sex – Canada excluding Quebec, 2015 – 2019



Rate per 100,000 persons

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DIC background rates by age and sex – Canada excluding Quebec, 2015-2019

Age group	Both sexes	Males	Females
All ages	1.48 (1.41 - 1.54)	1.46 (1.37 - 1.55)	1.49 (1.4 - 1.58)
0-19	0.49 (0.42 - 0.58)	0.45 (0.35 - 0.57)	0.54 (0.43 - 0.67)
20-29	0.85 (0.73 - 0.99)	0.63 (0.48 - 0.8)	1.1 (0.9 - 1.33)
30-39	1.12 (0.98 - 1.28)	0.83 (0.66 - 1.03)	1.42 (1.19 - 1.67)
40-49	1.08 (0.94 - 1.24)	1.01 (0.82 - 1.24)	1.15 (0.94 - 1.38)
50-59	1.73 (1.56 - 1.92)	1.86 (1.6 - 2.14)	1.61 (1.38 - 1.88)
60-69	2.45 (2.22 - 2.7)	2.6 (2.26 - 2.98)	2.31 (2 - 2.65)
70-79	3.46 (3.1 - 3.85)	4.18 (3.6 - 4.81)	2.81 (2.37 - 3.31)
80+	4.35 (3.83 - 4.91)	5.44 (4.54 - 6.47)	3.62 (3.01 - 4.3)

Rate per 100,000 persons

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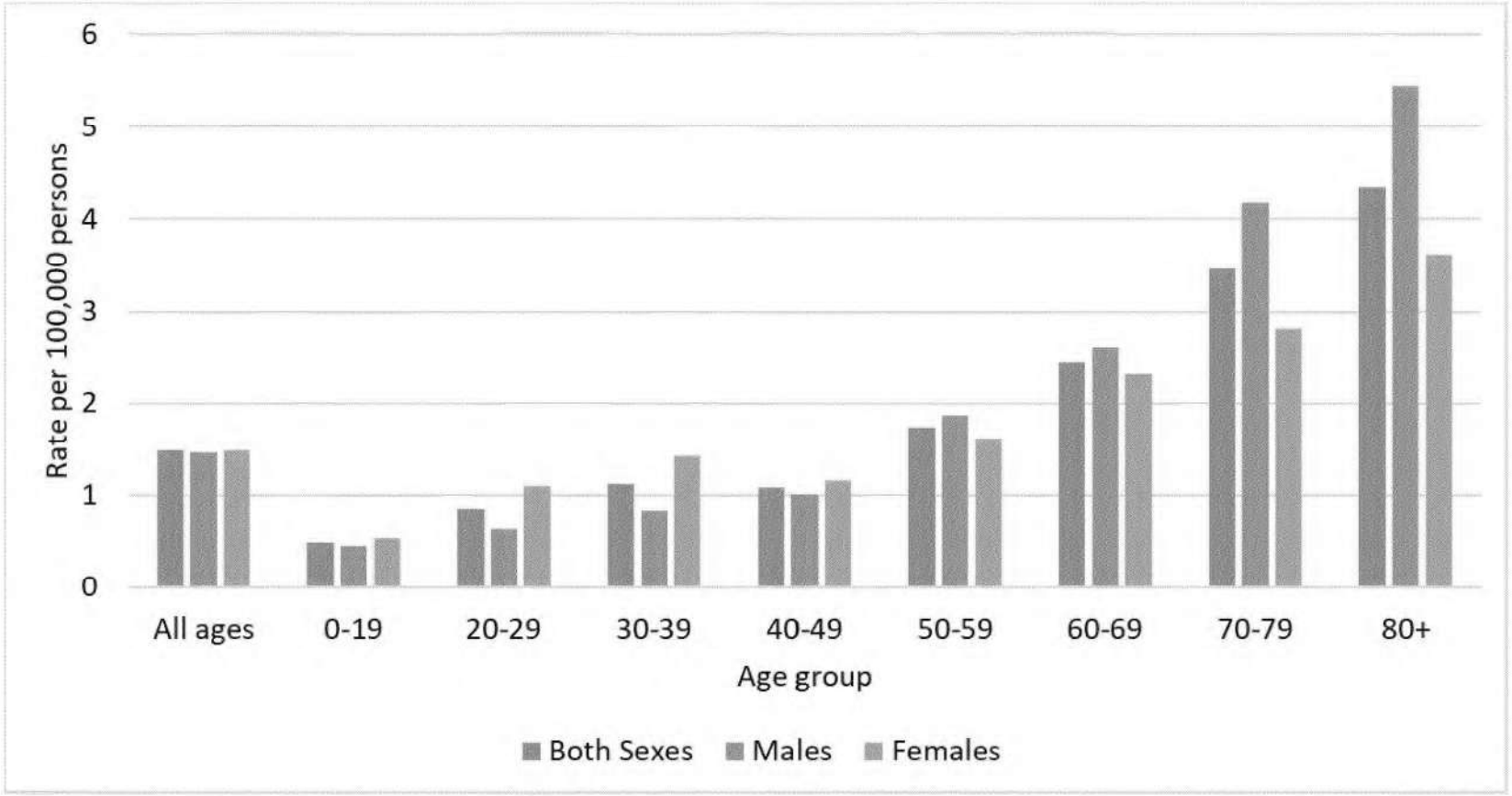
Rate of DIC by age and sex – Canada excluding Quebec, 2015 – 2019



Limitations

- The reporting coverage to NACRS varies by province/territory and time. Therefore, the background rates may underreport the rate in Canada excluding Quebec.
- Quebec data is excluded as their data is not included in DAD and NACRS.
- As we do not have access to physician billing records, conditions investigated must have been serious enough to warrant a hospital or emergency department visit. Therefore, this may underreport the true rate.
- As we rely on ICD-10-CA codes to identify each condition, there may be misclassification of the outcome.

Background Rates Working Group Members

PHAC

[redacted]

[redacted]

Manitoba Health

[redacted]

Government of Alberta

[redacted]

University of Toronto

[redacted]

Health Canada

[redacted]

BC Centre for Disease Control

[redacted]

Contact: [redacted]@canada.ca

Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, April 1, 2021 from 1:30 – 3:00 PM EST

Record of Decisions (RoD)

Members in Attendance:

AB: [redacted] (Provincial Co-Chair), BC [redacted] MB [redacted] NB: [redacted] NS: [redacted] NT: [redacted]
NU: [redacted] ON: (MOH) [redacted] (PHO): [redacted] QC [redacted]
[redacted] SK: [redacted] YT: [redacted]

Liaison Members in Attendance:

BRDD: [redacted] IMPACT [redacted] MHPD [redacted]

Observers/Presenters in Attendance:

[redacted] (Federal Co-Chair) [redacted]
[redacted] CANVAS: [redacted]

Regrets:

NL [redacted] PE: [redacted] CSC: [redacted] DND: [redacted] FNIHB [redacted] RCMP [redacted]

ACTION ITEMS

1. **Action Item Updates**

i) **CAEFISS Analysis**

- PHAC provided the most frequently reported AESIs to VVWG on March 25, 2021.
- PHAC sent out an email on March 26, 2021 to VVWG to provide a report on the confidence intervals for serious and non-serious AEFI following COVID-19 vaccination

ii) AstaZeneca hold in EU

[redacted] will present at next week's VVWG meeting the results of the active surveillance system.

- Health Canada will be sending out questions to VVWG to understand how this is being treated in each jurisdiction and whether the reports that you are collecting and those that are being provided to PHAC would identify the specific version of the vaccine. (Patient information card or second dose card was produced that allows the identification of AstraZeneca versus COVISHIELD)

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of RoDs from March 12, March 18 and March 25, 2021	a) Agenda was approved with no additional items. b) RoDs were reviewed. Amendments can be provided to [redacted] by end of day on April 6, 2021.	[redacted]	**ACTION:** a) No action b) Members can provide changes or updates to the RoDs to [redacted] by end of day on April 6, 2021 to approve and finalize the RoDs from March 12, 18 and 25, 2021. Members were reminded to provide their responses to the following surveys: 1) Preparedness and resources needed to get ready for the influx in AEFIs; and 2) Experience with AstraZeneca. Members who did provide information need to confirm if their information is correct.
2. Weekly On-line COVID AEFI Report	a [redacted] provided a brief summary of the Weekly on-line COVID AEFI Report. The update and the embargoed report will be posted by the end of day on April 1, 2021.	[redacted]	**ACTION:** a) The COVID AEFI report will be sent out at the end of the day on April 1, 2021 to the VVWG members.
3. CAEFISS Analysis	a) [redacted] provided a brief summary of the CAEFISS Weekly Report. The data provided is up to March 26, 2021. The data presented today includes all AEFIs that were submitted to CAEFISS including those reports that have not been completed or assessed. • One lot number in Moderna (Lot # 300042460) that seem to have a higher rate of AESIs compared to all other lot numbers in Moderna. PHAC will have a look at this this because it had one of the fewer number of doses distributed 168,600 doses distributed. • BC inquired about the definition of life threatening and thought it was every anaphylaxis report but the numbers are different between what is being reported as anaphylaxis and what is being considered as life	[redacted]	**ACTION:** a) PHAC will examine Moderna Lot # 300042460 as this lot has a higher rate of AESIs compared to other lot numbers with Moderna. b) [redacted] will clarify for BC the anaphylaxis and the life threatening rates that have been reported. This will be provided next week. c) PHAC will provide the top 3, 5 or 10 lot numbers of each vaccine (COVISHIELD,

Agenda Item	Description	Lead	Further Actions or Completed
	threatening. In addition, BC noted that the total serious does not include all the anaphylaxis cases, which they thought were all life threatening. - [redacted] noted that it could be the coding that has been done in CAEFISS. PHAC is currently going through a QA in CAEFISS to ensure that all anaphylaxis is recorded as life threatening. • AB inquired if it would be possible for PHAC to look at the top 10 lot numbers for each of Moderna, Pfizer, and COVISHIELD and present a table of the top 3, 5 or 10 lot numbers of each vaccine that that we are seeing the most AEFIs with. PHAC has agreed to provide this at next week's meeting.		Moderna, and Pfizer) that we are seeing the most AEFIs.
4. CANVAS Update	a) [redacted] provided an update on the CANVAS weekly report. The CANVAS weekly report presentation was shared with VVWG members. • BC inquired about comparison to control group rates. - [redacted] noted that yes, they are collecting controls. They are still working on merging. She is hoping that they will have control data for VVWG next week. b) [redacted] provided a presentation on Coagulation rates report. • It was noted that there is a higher rate among women than men and independent of the vaccine that they are getting. • Dose 2 data is limited • [redacted] inquired if they get the details to be able to split out what the coagulation problem is. - [redacted] noted that no, they cannot.	[redacted]	**ACTION:** a) [redacted] will share the CANVAS weekly report to VVWG Secretariat weekly to circulate to the members.
5. AstraZeneca Update - NACI Statement - Health Canada Statement - International Updates	a) [redacted] provided a summary of the NACI statement that was released this week. • On March 29, 2021, NACI released a rapid response recommending that AstraZeneca should not be used in adults under 55 years of age while the safety signal of	[redacted]	**ACTION:** a) PHAC has shared the link the to NACI statement with VVVWG: NACI rapid response: https://www.canada.ca/en/public-

Agenda Item	Description	Lead	Further Actions or Completed
	Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) following vaccination with AstraZeneca COVID-19 vaccine is investigated further. • The rationale of this decision was based on the data that they currently have which is incomplete at this stage and NACI is currently monitoring on what is forthcoming. • The current data showed that in younger adults that complications from COVID-19 or the risk of dying is quite low but an adverse event that occurred in Europe following the receipt of the AstraZeneca vaccine, the cases identified have been primarily women under the age of 55 although some cases in men have also been reported. The rate of fatality was approximately 40%. The risk benefit balance was not in favour of younger adults therefore, NACI recommended that AstraZeneca should only be administered to adults 55 and older. • NACI is closely monitoring the information that is coming from Europe and other countries, and based on the evidence, NACI will update the recommendation if needed. • EMA released a statement on March 31, 2021 that they have not changed their recommendation regarding the use of AstraZeneca. They are going to release different recommendation during the preliminary meeting that will be held from April 6-9, 2021. b) [redacted] provided a summary of the Health Canada Statement that was released this week. • As of last week, HC put forward labelling updates for the product monograph for COVISHIELD, and AstraZeneca • A public advisory was done from March 11 and March 18, 2021		health/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-recommended-use-astrazeneca-covid-19-vaccine-younger-adults.html b) HC has shared the EMA preliminary assessment link with VWG: https://www.ema.europa.eu/en/news/astrazeneca-covid-19-vaccine-review-very-rare-cases-unusual-blood-clots-continues

Agenda Item	Description	Lead	Further Actions or Completed
	• HC requested the updated Risk Management Plan which contains undescribed post marketing activities • HC also requested additional cumulative assessment of the adverse events for the company to assess and summarize. HC also imposed terms and conditions. • HC will be observing the EMA meeting taking place from April 6-9, 2021. • EMA released their new statement about their assessment to date. This is available on their website.		
6. Thrombolic events in CAEFISS - CAEFISS case definition updates - BC/SPECA definition and algorithm	a) [redacted] provided a presentation on CAEFISS case definitions – Thrombosis and Thrombocytopenia cases. [redacted] will share a copy of her power point presentation after the meeting. b) [redacted] provided a presentation on Brighton Collaboration/SPECA definition and algorithm. • A word document will be provided and posted on CNPHI soon. • [redacted] from PHAC inquired about when this document will be finalized. - [redacted] noted that it would be another 4-6 weeks before this is finalized. Currently, the draft is being shared and it can be used. • MB inquired about level 4 and level 5. - MB will send the question in detail to the VVWG email inbox and [redacted] will provide a response via email due to time constraints at the meeting.	[redacted]	**ACTION:** a) [redacted] will share a copy of her power point presentation to VVWG members after the meeting. b) MB will send their detailed question to the VVWG inbox and [redacted] will respond via email.
7. Background Rates Update - Thrombolic events	a) [redacted] provided a presentation on the Background rates. The power point presentation will be shared with VVWG after the meeting. • [redacted] inquired if they would be able to do a breakout by age group. - [redacted] noted that yes they do plan to do a breakout by age group and sex. Once they are ready, they do plan to put them on CNPHI. They plan to add potential	[redacted]	**ACTION:** a) The Background rates power point presentation will be shared with the VVWG members after the meeting.

Agenda Item	Description	Lead	Further Actions or Completed
	subgroups, for stroke, and a broader definition for thrombocytopenia. They are going to update the anaphylaxis rates with the current methodology, bells palsy, GBS, etc. • [redacted] from IMPACT inquired if PHAC would be able to get background rates from 2020. Some of the events have been seen as complications of COVID-19. Are you able to get background rates for cerebral venous since thrombosis? Also, interesting to look by sex. - Yes, PHAC is able to get the 2020 data but it might not be fully complete as the provinces can continue to update their data. PHAC has not been able to work on this yet, as it can take some time but it can be done. - [redacted] will add cerebral venous to their list. She will take it back to the working group and the working group will work on a definition and then add it to the background rates.		
8. Roundtable - Update on AZ use in PTs - Updates on thrombotic cases in PTs - Response to survey on preparedness and needs	a) This item was deferred to the next week's VVWG call.	ALL	**ACTION:** a) The roundtable items will be discussed at next week's VVWG meeting.
9. Confirm Next Call	a) Next call: April 8, 2021 (1:30 – 3:00 EDT)	[redacted]	**ACTION:** a) No action

Yome, Julie (PHAC/ASPC)

From: [redacted] on behalf of Vaccine Vigilance (PHAC/ASPC) <phac.vaccine.vigilance.aspc@canada.ca>
Sent: 2021-04-12 12:59 PM
To: [redacted]
Subject: Excel worksheets for cumulative counts and rates for COVID-19 AEFIs/AESIs
Attachments: Cumulative_AEFI_table_04_08.xlsx

Follow Up Flag: Follow up
Flag Status: Flagged

Good afternoon VVWG members,

As mentioned at Thursdays VVWG meeting, please find attached the excel worksheets for cumulative counts and rates for COVID-19 AEFIs/AESIs. As the list of AESIs is quite extensive, we have only included the specific AESIs that had at least 1 report.

Please note: The data provided in these worksheets includes all AEFIs/AESIs submitted to CAEFISS, including those reports that have not been completed or assessed yet.

TAB 1 - Counts Tab Summary:

- 'Local reactions at or near the vaccination site' (n=3,410) make up roughly a third of all AEFIs reported followed by 'Other allergic events' (n=1,007) and 'Anesthesia/paraesthesia' (n=385).
- 'Local reaction at or near the vaccination site' accounts for 53% of all AEFIs following vaccination with Moderna and 13% following vaccination with Pfizer.

TAB 2 - Rates with overall heat map Summary:

- The top 3 overall total AEFI rates are:
  - Moderna Lot #300042460: 1124.48/100,000 doses distributed (95% CI [1073.88 -1175.08 per 100,000 doses distributed])
  - Moderna Lot #300042698: 821.10/100,000 doses distributed (95% CI [778.22 -863.97 per 100,000 doses distributed])
  - Pfizer-BioNTech Lot# EK4175: 701.41/100,000 doses distributed (95% CI [606.99-795.82 per 100,000 doses distributed])
- The top 3 serious AEFI rates are:
  - Pfizer-BioNTech Lot# EK4175: 16.54/100,000 doses distributed (95% CI [6.66 -17.05 per 100,000 doses distributed])
  - Moderna Lot #300042460: 11.86/100,000 doses distributed (95% CI [4.32 -13.16 per 100,000 doses distributed])
  - Moderna Lot #300042698: 8.74/100,000 doses distributed (95% CI [2.04 -31.04 per 100,000 doses distributed])

TAB 3 – Rates with heat map by AEFI/AESI Summary:

- Highest rates for selected AESIs/seriousness
  - Local reaction at or near the vaccination site - Moderna Lot #300042460: 605.22/100,000 doses distributed (95% CI [568.09 -641.34 per 100,000 doses distributed])
  - Anaphylaxis – Pfizer-BioNTech Lot# EL0140: 10.61/100,000 doses distributed (95% CI [2.12 -19.10 per 100,000 doses distributed])
  - Bell's palsy - Pfizer-BioNTech Lot #EK4175: 9.93/100,000 doses distributed (95% CI [0 -21.16 per 100,000 doses distributed])
  - Anaesthesia/paraesthesia - Pfizer-BioNTech Lot #EK4175: 49.63/100,000 doses distributed (95% CI [24.51 -74.74 per 100,000 doses distributed])
  - Death - Moderna Lot #300042698: 2.91/100,000 doses distributed (95% CI [0.36 -5.47 per 100,000 doses distributed])
  - Hospitalization/prolongation of hospitalization - Pfizer-BioNTech Lot #EK4175: 9.93/100,000 doses distributed (95% CI [0 -21.16 per 100,000 doses distributed])

Kind regards,
VVWG Secretariat
Phac.vaccine.vigilance.aspc@canada.ca

COVID-19 AEFI counts in CAEFISS - Includes all submitted AEFIs
(Cumulative up to and including Friday April 2, 2021)
National Summary

Vaccine	Lot Number	Doses distributed	Local reaction at or near vaccination site	Other allergic event	Anaphylaxis	ORS	Seizures	GBS	Bell's palsy	Encephalopathy/encephalitis/myelitis/transverse myelitis	Anaesthesia/Paraesthesia	Acute Cerebellar Ataxia	Other neurological diagnosis	Thrombocytopenia	Maternal and fetal outcomes	Cardiac arrhythmias	Myocarditis	Haemorrhage	Acute kidney injury	Anosmia, Ageusia	Chilblain - like lesions	Adenopathy/lymphadenopathy	Vomiting and/or diarrhea	Arthritis/Arthralgia	Death	Hospitalization or prolongation	Total Non-serious	Total Serious	Total AEFIs
MODERNA																													
	300042460	168700	1021	95	15	0	4	0	4	0	30	0	24	1	1	4	0	1	0	3	0	29	24	11	4	8	1877	20	1897
	300042698	171600	825	80	10	1	3	0	7	1	16	0	20	1	0	1	0	0	0	0	0	27	18	9	5	4	1394	15	1409
	300042722	180000	333	58	6	1	0	0	3	1	12	0	8	0	0	0	0	0	0	0	0	6	16	5	1	3	670	4	674
	3000489	168000	165	17	3	0	2	0	0	0	9	0	2	2	0	0	0	0	0	0	0	10	3	1	0	1	343	1	344
	3001176	466800	45	12	3	0	0	0	0	0	1	0	3	0	0	0	0	0	0	0	0	1	3	0	0	0	136	0	136
	UNKNOWN		89	15	1	1	0	0	2	0	4	0	3	0	0	0	0	0	0	0	0	6	5	0	1	1	192	2	194
MODERNA Total		**1155100**	**2478**	**277**	**38**	**3**	**9**	**0**	**16**	**2**	**72**	**0**	**60**	**4**	**1**	**5**	**0**	**1**	**0**	**3**	**0**	**79**	**69**	**26**	**11**	**17**	**4612**	**42**	**4654**
COVISHIELD																													
	4120Z003	200000	19	14	5	0	1	0	0	0	8	0	5	0	0	1	0	0	0	0	0	2	0	2	1	1	164	2	166
	4120Z029	300500	5	4	0	0	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	38	0	38
	UNKNOWN		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	3	0	3
COVISHIELD Total		**500500**	**24**	**18**	**5**	**0**	**2**	**0**	**0**	**0**	**9**	**0**	**5**	**0**	**0**	**2**	**0**	**0**	**0**	**0**	**0**	**3**	**1**	**2**	**1**	**1**	**205**	**2**	**207**
ASTRAZENECA																													
	UNKNOWN		**0**	0	0	0	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	0	0	1	0	**1**
ATRAZENECA Total			**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**
PFIZER-BIONTECH																													
	EJ1686	57525	13	16	1	2	0	0	0	0	6	0	1	0	0	0	0	0	0	0	0	5	4	2	0	0	145	0	145
	EK4175	30225	32	23	2	0	0	0	3	0	15	0	7	0	0	0	0	0	0	0	0	2	1	2	0	3	207	5	212
	EK4241	337350	195	149	19	2	1	0	9	3	59	0	34	1	1	1	0	0	0	2	0	31	36	21	1	3	1315	19	1334
	EK4245	137475	110	63	8	0	0	0	5	0	28	0	24	0	1	0	1	0	0	1	1	17	18	13	1	3	637	9	646
	EL0140	56550	20	10	6	0	1	0	0	0	6	0	5	0	0	0	0	0	0	0	0	10	5	1	0	0	153	4	157
	EL0203	219375	132	91	18	1	3	1	6	1	41	0	17	1	2	0	0	1	0	3	0	20	29	12	1	4	926	12	938
	EL1404	106665	30	11	4	0	0	0	1	0	2	0	3	0	0	0	0	0	0	0	0	11	7	3	0	0	166	1	167
	EL1406	187395	105	52	15	0	1	0	1	1	28	0	18	0	0	0	0	0	0	0	0	25	18	7	1	0	636	6	642
	EN1194	95940	7	8	4	0	0	0	2	0	2	1	2	0	1	0	0	0	0	0	0	4	4	0	1	1	80	2	82
	EN1196	305370	2	1	1	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	21	0	21
	EN1198	237510	0	1	3	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	1	0	0	0	29	0	29
	EP6017	245700	61	58	23	0	2	0	3	0	24	0	19	0	1	0	0	0	0	0	0	8	12	8	1	6	585	19	604
	EP6775	475020	62	99	22	1	4	0	4	0	39	1	33	0	0	3	1	0	0	1	0	8	24	3	1	4	806	5	811
	ER1742	1096290	50	75	28	1	0	0	1	0	35	0	12	0	0	1	1	0	0	1	0	2	11	5	2	1	610	3	613
	UNKNOWN		89	55	5	0	1	0	0	0	17	0	9	0	0	1	1	0	1	0	0	26	16	5	1	3	567	4	571
PFIZER-BIONTECH Total		**3588390**	**908**	**712**	**159**	**7**	**14**	**1**	**35**	**5**	**303**	**2**	**187**	**2**	**6**	**6**	**4**	**1**	**1**	**8**	**1**	**169**	**186**	**82**	**10**	**28**	**6883**	**89**	**6972**
Grand Total		5243990	**3410**	**1007**	**202**	**10**	**25**	**1**	**51**	**7**	**385**	**2**	**252**	**6**	**7**	**13**	**4**	**2**	**1**	**11**	**1**	**251**	**256**	**110**	**22**	**46**	**11701**	**133**	**11834**

COVID-19 AEFI counts in CAEFIS		0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
(Cumulative up to and including		0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
National Summary		0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0		0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Vaccine	Lot Number	Doses distributed	Local reaction at or near vaccination site	Other allergic event	Anaphylaxis	ORS	Seizures	GBS	Bell's palsy	Encephalopathy/encephalitis/myelitis/Transverse myelitis	Anaesthesia/Paraesthesia	Acute Cerebellar Ataxia	Other neurological diagnosis	Thromocytopenia	Maternal and fetal outcomes	Cardiac arrhythmias	Myocarditis	Haemorrhage	Acute kidney injury	Anosmia, Ageusia	Chilblain - like lesions	Adenopathy/lymphadenopathy	Vomiting and/or diarrhea	Arthritis/Arthralgia	Death	Hospitalization or prolongation	Total Non-serious	Total Serious	Total AEFIs
MODERNA																															
	300042460	168700	605.22	56.31	8.89	0.00	2.37	0.00	2.37	0.00	17.78	0.00	14.23	0.59	0.59	2.37	0.00	0.59	0.00	1.78	0.00	17.19	14.23	6.52	2.37	4.74	1112.63	11.86	1124.48
	300042698	171600	480.77	46.62	5.83	0.58	1.75	0.00	4.08	0.58	9.32	0.00	11.66	0.58	0.00	0.58	0.00	0.00	0.00	0.00	0.00	15.73	10.49	5.24	2.91	2.33	812.35	8.74	821.10
	300042722	180000	185.00	32.22	3.33	0.56	0.00	0.00	1.67	0.56	6.67	0.00	4.44	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	3.33	8.89	2.78	0.56	1.67	372.22	2.22	374.44
	3000489	168000	98.21	10.12	1.79	0.00	1.19	0.00	0.00	0.00	5.36	0.00	1.19	1.19	0.00	0.00	0.00	0.00	0.00	0.00	0.00	5.95	1.79	0.60	0.00	0.60	204.17	0.60	204.76
	3001176	466800	9.64	2.57	0.64	0.00	0.00	0.00	0.00	0.00	0.21	0.00	0.64	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.21	0.64	0.00	0.00	0.00	29.13	0.00	29.13
	UNKNOWN																														
MODERNA Total		1155100	214.53	23.98	3.29	0.26	0.78	0.00	1.39	0.17	6.23	0.00	5.19	0.35	0.09	0.43	0.00	0.09	0.00	0.26	0.00	6.84	5.97	2.25	0.95	1.47	399.27	3.64	402.91
COVISHIELD																															
	4120Z003	300500	6.32	4.66	1.66	0.00	0.33	0.00	0.00	0.00	2.66	0.00	1.66	0.00	0.00	0.33	0.00	0.00	0.00	0.00	0.00	0.67	0.00	0.67	0.33	0.33	54.58	0.67	55.24
	4120Z029	200000	2.50	2.00	0.00	0.00	0.50	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.50	0.00	0.00	0.00	0.00	0.00	0.00	0.50	0.00	0.00	0.00	19.00	0.00	19.00
	UNKNOWN																														
COVISHIELD Total		500500	4.80	3.60	1.00	0.00	0.40	0.00	0.00	0.00	1.80	0.00	1.00	0.00	0.00	0.40	0.00	0.00	0.00	0.00	0.00	0.60	0.20	0.40	0.20	0.20	40.96	0.40	41.36
PFIZER-BIONTECH																															
	EJ1686	57525	22.60	27.81	1.74	3.48	0.00	0.00	0.00	0.00	10.43	0.00	1.74	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	8.69	6.95	3.48	0.00	0.00	252.06	0.00	252.06
	EK4175	30225	105.87	76.10	6.62	0.00	0.00	0.00	9.93	0.00	49.63	0.00	23.16	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	6.62	3.31	6.62	0.00	9.93	684.86	16.54	701.41
	EK4241	337350	57.80	44.17	5.63	0.59	0.30	0.00	2.67	0.89	17.49	0.00	10.08	0.30	0.30	0.30	0.00	0.00	0.00	0.59	0.00	9.19	10.67	6.22	0.30	0.89	389.80	5.63	395.44
	EK4245	137475	80.01	45.83	5.82	0.00	0.00	0.00	3.64	0.00	20.37	0.00	17.46	0.00	0.73	0.00	0.73	0.00	0.00	0.73	0.73	12.37	13.09	9.46	0.73	2.18	463.36	6.55	469.90
	EL0140	56550	35.37	17.68	10.61	0.00	1.77	0.00	0.00	0.00	10.61	0.00	8.84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	17.68	8.84	1.77	0.00	0.00	270.56	7.07	277.63
	EL0203	219375	60.17	41.48	8.21	0.46	1.37	0.46	2.74	0.46	18.69	0.00	7.75	0.46	0.91	0.00	0.00	0.46	0.00	1.37	0.00	9.12	13.22	5.47	0.46	1.82	422.11	5.47	427.58
	EL1404	106665	28.13	10.31	3.75	0.00	0.00	0.00	0.94	0.00	1.88	0.00	2.81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	10.31	6.56	2.81	0.00	0.00	155.63	0.94	156.56
	EL1406	187395	56.03	27.75	8.00	0.00	0.53	0.00	0.53	0.53	14.94	0.00	9.61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	13.34	9.61	3.74	0.53	0.00	339.39	3.20	342.59
	EN1194	95940	7.30	8.34	4.17	0.00	0.00	0.00	2.08	0.00	2.08	1.04	2.08	0.00	1.04	0.00	0.00	0.00	0.00	0.00	0.00	4.17	4.17	0.00	1.04	1.04	83.39	2.08	85.47
	EN1196	305370	0.65	0.33	0.33	0.00	0.33	0.00	0.00	0.00	0.33	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	6.88	0.00	6.88
	EN1198	237510	0.00	0.42	1.26	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.26	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.42	0.00	0.00	0.00	12.21	0.00	12.21
	EP6017	245700	24.83	23.61	9.36	0.00	0.81	0.00	1.22	0.00	9.77	0.00	7.73	0.00	0.41	0.00	0.00	0.00	0.00	0.00	0.00	3.26	4.88	3.26	0.41	2.44	238.10	7.73	245.83
	EP6775	475020	13.05	20.84	4.63	0.21	0.84	0.00	0.84	0.00	8.21	0.21	6.95	0.00	0.00	0.63	0.21	0.00	0.00	0.21	0.00	1.68	5.05	0.63	0.21	0.84	169.68	1.05	170.73
	ER1742	1096290	4.56	6.84	2.55	0.09	0.00	0.00	0.09	0.00	3.19	0.00	1.09	0.00	0.00	0.09	0.09	0.00	0.00	0.09	0.00	0.18	1.00	0.46	0.18	0.09	55.64	0.27	55.92
	UNKNOWN																														
PFIZER-BIONTECH Total		3588390	25.30	19.84	4.43	0.20	0.39	0.03	0.98	0.14	8.44	0.06	5.21	0.06	0.17	0.17	0.11	0.03	0.03	0.22	0.03	4.71	5.18	2.29	0.28	0.78	191.81	2.48	194.29
Grand Total		5243990	65.03	19.20	3.85	0.19	0.48	0.02	0.97	0.13	7.34	0.04	4.81	0.11	0.13	0.25	0.08	0.04	0.02	0.21	0.02	4.79	4.88	2.10	0.42	0.88	223.13	2.54	225.67

COVID-19 AEFI counts in CAEFIS		0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
(Cumulative up to and including		0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
National Summary		0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0		0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Vaccine	Lot Number	Doses distributed	Local reaction at or near vaccination site	Other allergic event	Anaphylaxis	GBS	Seizures	GBS	Bell's palsy	Encephalopathy/encephalitis/myelitis/Transverse myelitis	Anaesthesia/Paraesthesia	Acute Cerebellar Ataxia	Other neruological diagnosis	Thrombocytopenia	Maternal and fetal outcomes	Cardiac arrhythmias	Myocarditis	Haemorrhage	Acute kidney injury	Anosmia, Ageusia	Chilblain - like lesions	Adenopathy/lymphadenopathy	Vomiting and/or diarrhea	Arhtritis/Arthralgia	Death	Hospitalization or prolongation	Total Non-serious	Total Serious	Total AEFIs
MODERNA																														
	300042460	168700	605.22	56.31	8.89	0.00	2.37	0.00	2.37	0.00	17.78	0.00	14.23	0.59	0.59	2.37	0.00	0.59	0.00	1.78	0.00	17.19	14.23	6.52	2.37	4.74	1112.63	11.86	1124.48
	300042698	171600	480.77	46.62	5.83	0.58	1.75	0.00	4.08	0.58	9.32	0.00	11.66	0.58	0.00	0.58	0.00	0.00	0.00	0.00	0.00	15.73	10.49	5.24	2.91	2.33	812.35	8.74	821.10
	300042722	180000	185.00	32.22	3.33	0.56	0.00	0.00	1.67	0.56	6.67	0.00	4.44	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	3.33	8.89	2.78	0.56	1.67	372.22	2.22	374.44
	3000489	168000	98.21	10.12	1.79	0.00	1.19	0.00	0.00	0.00	5.36	0.00	1.19	1.19	0.00	0.00	0.00	0.00	0.00	0.00	0.00	5.95	1.79	0.60	0.00	0.60	204.17	0.60	204.76
	3001176	466800	9.64	2.57	0.64	0.00	0.00	0.00	0.00	0.00	0.21	0.00	0.64	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.21	0.64	0.00	0.00	0.00	29.13	0.00	29.13
	UNKNOWN																													
MODERNA Total		1155100	214.53	23.98	3.29	0.26	0.78	0.00	1.39	0.17	6.23	0.00	5.19	0.35	0.09	0.43	0.00	0.09	0.00	0.26	0.00	6.84	5.97	2.25	0.95	1.47	399.27	3.64	402.91
COVISHIELD																														
	4120Z003	300500	6.32	4.66	1.66	0.00	0.33	0.00	0.00	0.00	2.66	0.00	1.66	0.00	0.00	0.33	0.00	0.00	0.00	0.00	0.00	0.67	0.00	0.67	0.33	0.33	54.58	0.67	55.24
	41207029	200000	2.50	2.00	0.00	0.00	0.50	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.50	0.00	0.00	0.00	0.00	0.00	0.00	0.50	0.00	0.00	0.00	19.00	0.00	19.00
	UNKNOWN																													
COVISHIELD Total		500500	4.80	3.60	1.00	0.00	0.40	0.00	0.00	0.00	1.80	0.00	1.00	0.00	0.00	0.40	0.00	0.00	0.00	0.00	0.00	0.60	0.20	0.40	0.20	0.20	40.96	0.40	41.36
PFIZER-BIONTECH																														
	EJ1686	57525	22.60	27.81	1.74	3.48	0.00	0.00	0.00	0.00	10.43	0.00	1.74	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	8.69	6.95	3.48	0.00	0.00	252.06	0.00	252.06
	EK4175	30225	105.87	76.10	6.62	0.00	0.00	0.00	9.93	0.00	49.63	0.00	23.16	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	6.62	3.31	6.62	0.00	9.93	684.86	16.54	701.41
	EK4241	337350	57.80	44.17	5.63	0.59	0.30	0.00	2.67	0.89	17.49	0.00	10.08	0.30	0.30	0.30	0.00	0.00	0.00	0.59	0.00	9.19	10.67	6.22	0.30	0.89	389.80	5.63	395.44
	EK4245	137475	80.01	45.83	5.82	0.00	0.00	0.00	3.64	0.00	20.37	0.00	17.46	0.00	0.73	0.00	0.73	0.00	0.00	0.73	0.73	12.37	13.09	9.46	0.73	2.18	463.36	6.55	469.90
	EL0140	56550	35.37	17.68	10.61	0.00	1.77	0.00	0.00	0.00	10.61	0.00	8.84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	17.68	8.84	1.77	0.00	0.00	270.56	7.07	277.63
	EL0203	219375	60.17	41.48	8.21	0.46	1.37	0.46	2.74	0.46	18.69	0.00	7.75	0.46	0.91	0.00	0.00	0.46	0.00	1.37	0.00	9.12	13.22	5.47	0.46	1.82	422.11	5.47	427.58
	EL1404	106665	28.13	10.31	3.75	0.00	0.00	0.00	0.94	0.00	1.88	0.00	2.81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	10.31	6.56	2.81	0.00	0.00	155.63	0.94	156.56
	EL1406	187395	56.03	27.75	8.00	0.00	0.53	0.00	0.53	0.53	14.94	0.00	9.61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	13.34	9.61	3.74	0.53	0.00	339.39	3.20	342.59
	EN1194	95940	7.30	8.34	4.17	0.00	0.00	0.00	2.08	0.00	2.08	1.04	2.08	0.00	1.04	0.00	0.00	0.00	0.00	0.00	0.00	4.17	4.17	0.00	1.04	1.04	83.39	2.08	85.47
	EN1196	305370	0.65	0.33	0.33	0.00	0.33	0.00	0.00	0.00	0.33	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	6.88	0.00	6.88
	EN1198	237510	0.00	0.42	1.26	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.26	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.42	0.00	0.00	0.00	12.21	0.00	12.21
	EP6017	245700	24.83	23.61	9.36	0.00	0.81	0.00	1.22	0.00	9.77	0.00	7.73	0.00	0.41	0.00	0.00	0.00	0.00	0.00	0.00	3.26	4.88	3.26	0.41	2.44	238.10	7.73	245.83
	EP6775	475020	13.05	20.84	4.63	0.21	0.84	0.00	0.84	0.00	8.21	0.21	6.95	0.00	0.00	0.63	0.21	0.00	0.00	0.21	0.00	1.68	5.05	0.63	0.21	0.84	169.68	1.05	170.73
	ER1742	1096290	4.56	6.84	2.55	0.09	0.00	0.00	0.09	0.00	3.19	0.00	1.09	0.00	0.00	0.09	0.09	0.00	0.00	0.09	0.00	0.18	1.00	0.46	0.18	0.09	55.64	0.27	55.92
	UNKNOWN																													
PFIZER BIONTECH Total		3588390	25.30	19.84	4.43	0.20	0.39	0.03	0.98	0.14	8.44	0.06	5.21	0.06	0.17	0.17	0.11	0.03	0.03	0.22	0.03	4.71	5.18	2.29	0.28	0.78	191.81	2.48	194.29
Grand Total		5243990	65.03	19.20	3.85	0.19	0.48	0.02	0.97	0.13	7.34	0.04	4.81	0.11	0.13	0.25	0.08	0.04	0.02	0.21	0.02	4.79	4.88	2.10	0.42	0.88	223.13	2.54	225.67

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Canada

Thrombocytopenia Thrombosis Syndrome (TTS) – Interim Case Finding Definition for Passive Surveillance

COVID-19 Vaccine Surveillance

Vaccine Safety

April 22, 2021

PROTECTING AND EMPOWERING CANADIANS TO IMPROVE THEIR HEALTH

Brighton Collaboration Draft Case Definition for Thrombocytopenia with Thrombosis Syndrome (TTS) - UPDATES

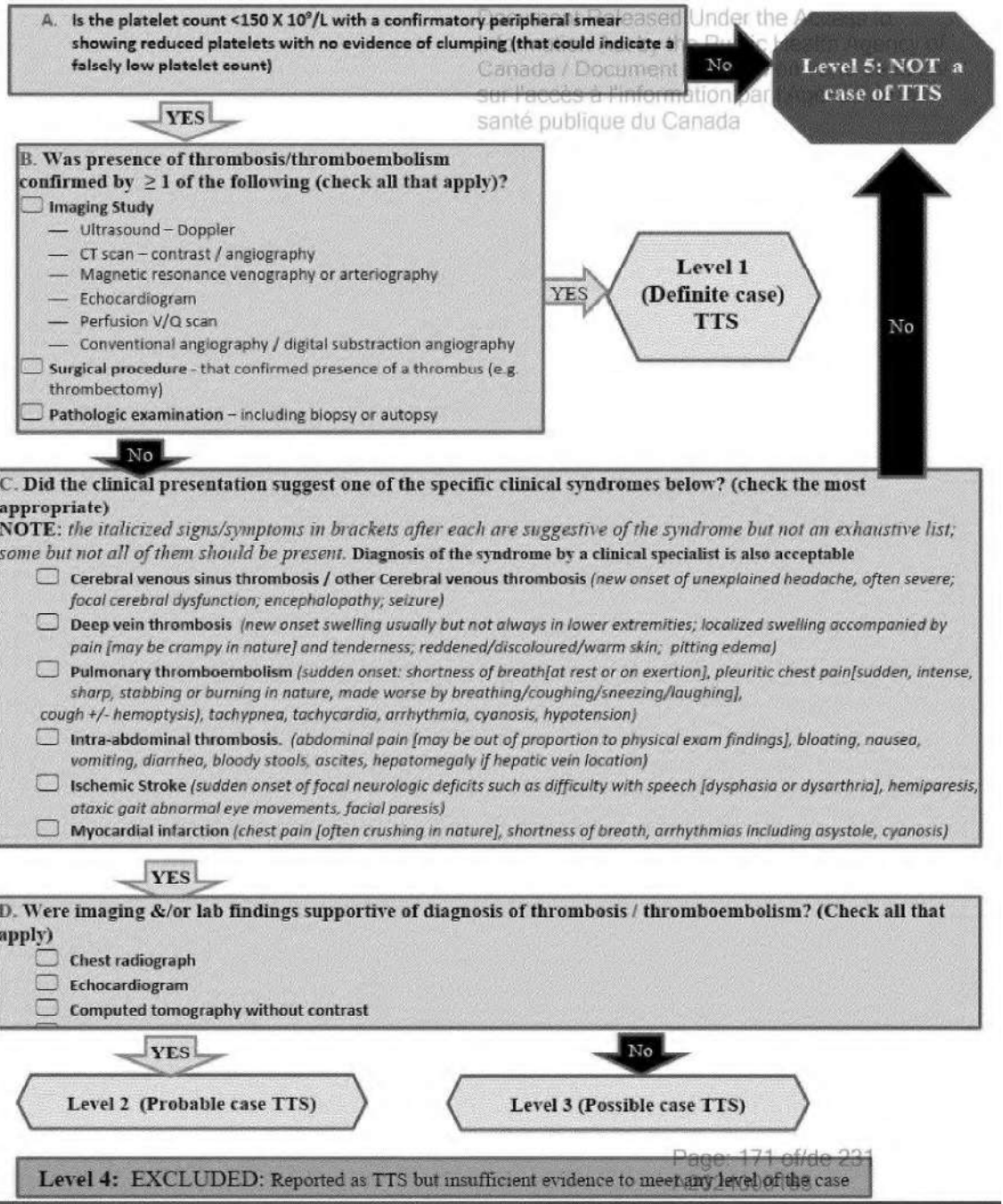
Thrombocytopenia component:

- Now includes a confirmatory peripheral smear
- Adds qualifier: "No known **recent** exposure to heparin"

Thrombosis/thromboembolism component:

- No change to level 1 (definite case):
  - Imagine studies, surgical procedure, and/or pathologic examination can confirm the presence of thrombosis/thromboembolism
- New probable and possible definitions:
  - PROBABLE: (Level 2) specific clinical syndromes with supportive imaging or laboratory evidence for CVST, DVT, PE, intra-abdominal thrombosis, ischemic stoke, myocardial infarction
  - POSSIBLE: (Level 3) specific clinical syndromes but no supportive lab findings

- Anti-PF4 confirmatory functional testing is not mentioned in explanatory section



Question 1: Should we extend the timing of timing of onset of symptom from within 28 days to 6 weeks?

- 3 cases in the EMA report occurred after 30 days (max 37 days)
- 28 days aligns with UK expert hematology panel recommendation
- Other jurisdictions in Canada, internationally?

Question 2: Should anti-PF4 status be a subtype of a confirmed TTS case definition?

- May encourage appropriate hematology consults, heightening awareness consistently across Canada
- Enables analyses of both anti-PF4 positive and negative cases
  - Allows capture and investigation of cases that are anti-PF4 negative (esp. those with CVST and other rare clots)
    - Enables the investigation of other mechanisms (e.g., those implicated in natural infection)
    - Negative anti-PF4 cases of thrombocytopenia with rare thrombosis - detected in higher than expected numbers in Europe
- Would the absence of a requirement for positive anti-PF4 status anticipated to have consequences on the identification and treatment of these cases?

Proposed Options for Thrombocytopenia with Thrombosis Syndrome (TTS) Case Definition – Definitive case options

Thrombocytopenia

- Plt<150^9 with no evidence of clumping on peripheral smear
- No known exposure to heparin prior to symptom onset or any other underlying condition or explanation for the condition
- Within 42 days of vaccination

AND

OPTION 1 Definitive Case

Level 1 TTS, as per Brighton Collaboration

(Thrombosis/thromboembolism confirmed by imaging, procedure, or pathology)

OPTION 2 Definitive Case

Level 1 TTS, as per Brighton Collaboration (as above)

Recommendation to classify subtype based on functional assays that detect platelet-activating properties of HIT antibodies (as indicated by a hematologist

A) anti-PF4 positive

B) anti-PF4 negative

C) anti-PF4 unknown

Question 2: Should PF4 status be a subtype of a confirmed TTS case definition? (continued)

- If anti-PF4 status is a subtype of a confirmed definition, there are additional options for accompanying probable and possible definitions (see slides 8 and 10)
- If anti-PF4 status is a requirement for a confirmed definition
  - This would limit analyses and miss cases that have thrombocytopenia with thrombosis who are anti-PF4 negative
  - Confirmed cases: testing would require the functional assay that detects platelet-activating properties of HIT antibodies (currently only conducted out of McMaster)
  - Probable cases: thrombocytopenia with thrombosis, with unknown anti-PF4 status, initial HIT screen negative (EIA test for IgG-specific antibodies against the PF4/heparin complexes)
  - Possible cases: could include thrombocytopenia alone or with unconfirmed thrombus but evidence suggestive of a hypercoagulable state

Question 3: Should possible and probable case definitions be based on Brighton Collaboration levels of certainty of thrombosis or thromboembolism, or do other criteria take precedence in the Canadian context?

- Equity - LMIC who may have limited/no access to confirmatory testing
  - P/T health care systems generally well-resourced
  - Patients with thrombocytopenia with thrombosis require care at centres with these diagnostic capabilities
  - Rural and remote locations: is patient transfer reasonably expected, from a surveillance perspective?
- Alignment would facilitate participation in common study protocol and assessment tools
- The Brighton Collaboration level 2 and 3 may serve a purpose in Canada to enable quick reporting of the AEFI while awaiting results for confirmatory investigations

Question 4: Should a possible case definition include thrombocytopenia with or without signs of thrombosis, but with signs of a prothrombotic state?

- This was considered and ruled out by Brighton Collaboration
- Anti-PF4 positive case after AstraZeneca vaccination recently detected in someone without signs of thrombosis, but with thrombocytopenia
  - Early detection of a prothrombotic state, before actual formation of a significant thrombus
- Evidence could include high D-Dimers, shortened PT/PTT
- Clinical care guideline from Ontario (VIPIT/VITT) recommends that without evidence of a clot, unlikely to be anti-PF4 positive
- Isolated thrombocytopenia post-vaccination is rare with COVID-19 vaccination in Canada, based on CAEFISS data to date
  - Testing all cases of thrombosis/thromboembolism is not recommended, given capacity restraints
- Majority of arguments in the EMA report support the surveillance of thrombocytopenia alone and thrombosis alone using the TTS case definition
- Benefits of inclusion when thrombosis alone and thrombocytopenia alone already are reportable as AESIs?
  - Inclusion may encourage more consistent reporting of these cases and encourage a higher degree of clinical suspicion, possibly resulting in earlier identification and appropriate treatment of cases

Question 5:

- What case definitions have already been developed in your jurisdiction?

Summary: Questions for VVWG members

1. Should we extend the timing of timing of onset of symptom from within 28 days to 6 weeks?
2. **Should anti-PF4 status be a subtype of a confirmed TTS case definition?**
3. Should possible and probable case definitions be based on Brighton Collaboration levels of certainty of thrombosis or thromboembolism, or do other criteria take precedence in the Canadian context?
4. Should a possible case definition additionally include thrombocytopenia with or without signs of thrombosis?
5. **What case definitions have already been developed in your jurisdiction?**
6. Any other comments or suggestions?

Feedback due by: Monday April 26, COB

Table: Cases of thromboses and thrombocytopenia, by vaccine type, reported to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) as of April 19, 2021 and Canada Vigilance Database for COVID-19 Vaccines as of April 18, 2021.

	Pfizer/ BioNTech			Moderna			COVISHIELD/AstraZenca			Total cases
	# cases	Rate per 100,000 doses administered (CI)*	Age range	# cases	Rate per 100,000 doses administered (CI)*	Age range	# cases	Rate per 100,000 doses administered (CI)*	Age range	
Thrombosis only	24	0.33 (0.19-0.54)	27-90	7	0.38 (0.12-0.88)	27-93	18	1.63 (0.85-2.80)	25-91	**50**
Thrombocytopenia only	2	0.03 (0-0.12)	86-90	3	0.16 (0.02-0.56)	51-88	0	NA	NA	**5**
Thrombosis with Thrombocytopenia (TTS)	0	NA	NA	1	0.05 (0-0.37)	84-85	4	0.36 (0.07-1.07)	34-72	**5**
+ anti-PF4 TTS	0	NA	NA	0	NA	NA	3	0.27 (0.04-0.93)**	34-72	**3**
Total	**26**	**NA**	**27-90**	**11**	**NA**	**27-93**	**24**	**NA**	**25-91**	**60**
Total Doses Administered (as of April 17, 2021)		7,183,048			1,843,805			1,106,753		10,136,388

*CI (confidence interval); confidence intervals calculated using 95% Poisson exact confidence intervals using the Bonferonni correction
**Bonferonni correction not applied

Note:

- *One thrombosis only case had an unknown vaccine*
- *Four thrombocytopenia only cases previously reported have been excluded because they are not confirmed*
- *There are 2, 782 doses administered that do not have an assigned vaccine manufacturer*
- *It is often not possible to determine whether an adverse reaction reported to Health Canada is a result of using a specific health product. Other factors contributing to the reaction could be a person's health conditions or other health products they are using at the same time.*
- *Adverse reaction reports are suspected associations and reflect the opinion or observation of the individual reporter. The data do not reflect any Health Canada assessment of association between the health product and the reaction(s).*
- *Please consult the following link for additional caveats on the interpretation of suspected adverse reaction data collected by the Canada Vigilance Program.*

Case management - Ontario VIPIT

- Hematology consult as per usual referral pattern (generally, tertiary care centre on call)
- Do not use platelets or heparin
- If suspicion of VITT, the hematologist will call McMaster referral centre and arrange for further testing
- McMaster has limited capacity for functional assays (4 tests per day) and individual consultations

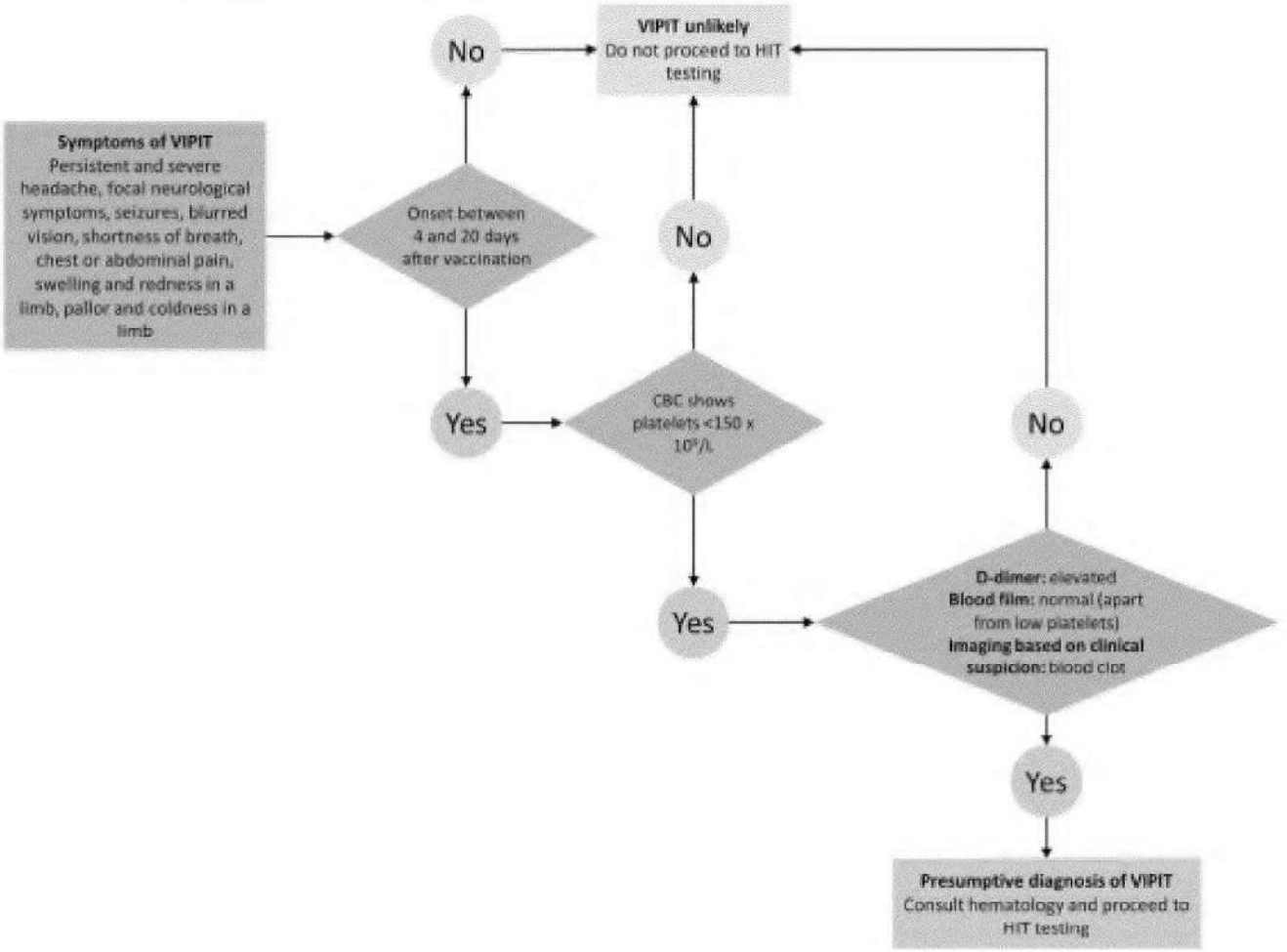


Figure 1. Decision Tree for Diagnosing and Ruling Out VIPIT

EMA report finding

- There were more CVST cases without thrombocytopenia than expected

Table 8 – Observed to expected analysis for CVST, CVST with thrombocytopenia, and CVST without thrombocytopenia

	CVST	CVST with thrombocytopenia	CVST without thrombocytopenia
Age group	**OE 14d with 95% c.i.**	**OE 14d with 95% c.i.**	**OE 14d with 95% c.i.**
18-29	**33.61 (10.83 - 78.44)**	**6.72 (0.09 - 37.40)**	**26.89 (7.23 - 68.84)**
30-49	**9.38 (5.46 - 15.02)**	**6.07 (3.03 - 10.86)**	**3.31 (1.21 - 7.20)**
50-59	**14.55 (7.26 - 26.04)**	**6.62 (2.13 - 15.44)**	**7.94 (2.90 - 17.28)**
60-69	1.11 (0.01 - 6.16)	1.11 (0.01 - 6.16)	0.00 (0.00 - 4.06)
70-79	0.00 (0.00 - 6.89)	0.00 (0.00 - 6.89)	0.00 (0.00 - 6.89)
80+	0.00 (0.00 - 14.83)	0.00 (0.00 - 14.83)	0.00 (0.00 - 14.83)
Total	**7.73 (5.35 - 10.80)**	**4.09 (2.42 - 6.47)**	**3.64 (2.08 - 5.91)**

Key data elements to report into CAEFISS for TTS cases

Investigations	History

Thrombocytopenia
❑ Platelet count
❑ Peripheral smear (r/o clumping)
 	
Thrombosis
❑ Imaging, surgery, or pathologic examination for confirmation or support for diagnosis of clinical syndromes
 	
If available:
❑ HIT IgG (EIA)
❑ Confirmatory functional anti-PF4 assay
❑ Investigations ruling in/out current AND prior COVID-19 infection
	❑ Time of onset:
	  ❑ In relation to vaccination
	  ❑ Thrombocytopenia versus thrombosis
	❑ Course (duration, re-occurrence, interventions, final outcome)
	❑ Past medical history– risk factors for coagulation disorders (including family history)
	❑ Medications

- Further details may be requested upon medical review of CAEFISS report

COVID-19 AEFI counts in CAEFISS - Includes all submitted AEFIs
(Cumulative up to and including Friday April 9, 2021)
National Summary

Vaccine	Lot Number	Doses distributed		Local reaction at or near vaccination site	Other allergic event	Anaphylaxis	ORS	Seizures	GBS	Bell's palsy	Encephalopathy/encephalitis/myelitis/Transverse myelitis	Anaesthesia/Paraesthesia	Coagulation and bleeding diastheses/Embolism/Platelet disorders	Acute Cerebellar Ataxia	Other neurological diagnosis	Thrombocytopenia	Maternal and fetal outcomes	Cardiac arrhythmias	Myocarditis	Haemorrhage	Acute kidney injury	Anosmia, Ageusia	Chilblain - like lesions	Adenopathy/lymphadenopathy	Vomiting and/or diarrhea	Arthritis/Arthralgia	Death	Hospitalization or prolongation	Total Non-serious	Total Serious	Total AEFIs
MODERNA																														
	300042460		168700	1045	97	15	0	4	0	4	0	30	2	0	24	0	1	4	0	1	0	3	0	30	26	11	4	8	1909	20	1929
	300042698		171600	826	82	10	1	3	0	7	1	16	3	0	20	0	0	1	0	0	0	0	0	28	18	10	5	4	1405	15	1420
	300042722		180000	343	65	6	1	0	0	3	1	13	0	0	9	0	0	0	0	0	0	0	0	7	16	5	1	3	707	4	711
	3000489		168000	213	27	3	0	2	0	0	0	8	3	0	2	0	0	0	0	0	0	0	0	10	6	1	0	1	414	1	415
	3001176		466800	79	27	5	0	1	0	0	0	9	0	0	4	0	0	0	0	0	0	0	0	2	11	0	0	1	278	1	279
	3001530		147500	0	1	1	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	17	0	17
	3001414		108000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2
	UNKNOWN			96	18	1	1	0	0	2	0	4	0	0	3	0	0	0	0	0	0	0	0	7	5	0	1	1	204	2	206
MODERNA Total			**1410600**	**2602**	**317**	**41**	**3**	**10**	**0**	**16**	**2**	**82**	**8**	**0**	**62**	**0**	**1**	**5**	**0**	**1**	**0**	**3**	**0**	**84**	**82**	**27**	**11**	**18**	**4936**	**43**	**4979**
COVISHIELD																														
	41202003		200000	39	28	5	0	1	0	0	0	11	1	0	9	1	0	1	0	0	0	0	0	2	3	2	1	2	246	3	249
	41202029		300500	26	16	0	0	1	0	0	0	3	0	0	3	0	0	1	0	0	0	0	0	0	2	2	0	0	104	0	104
	UNKNOWN			3	1	0	0	0	0	0	0	3	6	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	25	0	25
COVISHIELD Total			**500500**	**68**	**43**	**5**	**0**	**2**	**0**	**0**	**0**	**17**	**7**	**0**	**12**	**1**	**0**	**2**	**0**	**0**	**0**	**0**	**0**	**3**	**5**	**4**	**1**	**2**	**375**	**3**	**378**
ASTRAZENECA																														
	UNKNOWN			**0**	0	0	0	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	0	0	8	0	**8**
ATRAZENECA Total			**121520**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**8**	**0**	**8**
PFIZER-BIONTECH																														
	EJ1686		57525	19	18	1	2	0	0	0	0	8	0	0	1	0	0	0	0	0	0	1	0	5	6	2	0	0	171	0	171
	EK4175		30225	35	23	2	0	0	0	3	0	15	0	0	7	0	0	0	0	0	0	0	0	2	1	2	0	4	214	6	220
	EK4241		337350	195	150	19	2	1	0	9	3	59	3	0	34	0	1	1	0	0	0	2	0	32	36	21	1	3	1321	19	1340
	EK4245		137475	111	65	9	0	0	1	5	0	30	0	0	23	0	1	0	1	0	0	1	1	17	18	13	1	3	657	9	666
	EL0140		56550	21	10	6	0	1	0	0	0	6	0	0	5	0	0	0	0	0	0	0	0	10	5	1	0	0	154	4	158
	EL0203		219375	133	93	18	1	3	1	6	1	42	1	0	17	0	2	0	0	1	0	3	0	20	29	12	1	4	937	12	949
	EL1404		106665	33	14	4	0	0	0	1	0	3	0	0	4	0	0	0	0	0	0	1	0	12	7	6	0	0	185	1	186
	EL1406		187395	109	54	15	0	1	0	1	2	29	1	0	18	0	0	0	0	0	0	0	0	25	18	7	1	0	660	6	666
	EN1194		95940	8	10	4	0	0	0	2	0	2	0	1	2	0	1	0	0	0	0	0	0	4	4	0	1	1	102	2	104
	EN1196		305370	0	3	2	0	1	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	27	0	27
	EN1198		237510	1	4	4	0	0	0	0	0	1	0	0	2	0	0	0	0	0	0	0	0	0	2	1	0	0	60	0	60
	EP6017		245700	67	61	24	0	2	0	3	0	25	0	0	20	0	1	0	0	0	0	0	0	8	14	9	1	6	629	19	648
	EP6775		475020	69	108	22	1	4	0	6	0	44	0	1	33	0	1	3	1	0	0	1	0	8	27	3	1	4	877	5	882
	ER1742		1096290	87	102	30	1	0	0	3	0	44	0	0	17	0	0	1	1	0	0	1	0	3	14	6	2	3	759	5	764
	EW3344		1366560	2	2	2	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	28	0	28
	UNKNOWN			89	55	5	0	1	0	0	0	16	0	0	9	0	0	1	1	0	1	0	0	27	16	6	1	4	571	5	576
PFIZER-BIONTECH Total			**4954950**	**979**	**772**	**167**	**7**	**14**	**2**	**39**	**6**	**326**		**2**	**193**	**0**	**7**	**6**	**4**	**1**	**1**	**10**	**1**	**173**	**197**	**89**	**10**	**32**	**7352**	**93**	**7445**
																										0	0			
Grand Total			6987570	**3649**	**1132**	**213**	**10**	**26**	**2**	**55**	**8**	**426**	**15**	**2**	**267**	**1**	**8**	**13**	**4**	**2**	**1**	**13**	**1**	**260**	**284**	**120**	**22**	**52**	**12671**	**139**	**12810**

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Canada

Establishing an Advisory Committee on Causality Assessment

[redacted]

COVID-19 Vaccine Surveillance

April 15, 2021

PROTECTING AND EMPOWERING CANADIANS TO IMPROVE THEIR HEALTH

Objective

- Provide an overview on the establishment of a new Advisory Committee on Causality Assessment (ACCA).
- Introduce the proposed elements of the ACCA.
- Seek feedback on proposed elements of the ACCA.

Why does Canada need an ACCA?

- With increasing roll-out of COVID-19 vaccines, it expected that reports of serious adverse events following immunization (AEFIs) will increase.

- Most reports submitted to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) may be straight forward. Others require a primary review while a subset of these are forwarded on for a secondary review.
  - Primary Medical Review
  - Secondary Medical Review

- ACCA can be used to review cases identified as requiring comprehensive expert evaluation.
  - Tertiary Medical Review

Causality Assessment: systematic reviews of data on an AEFI case(s) to determine the likelihood of a causal association between the event and the vaccine received, and considered a critical part of AEFI monitoring.

THE PROPOSAL

ACCA Mandate

- The ACCA will be a national, independent committee assembled to conduct a specialized, tertiary review of events following immunization with a COVID-19 vaccine that have been identified as requiring comprehensive expert evaluation.

- Upon request from a P/T, PHAC, or Health Canada, the committee will:
  1. Investigate AEFIs that are identified as:
     - A cluster of adverse events for more in-depth review
     - Individual complex, serious AEFI reports requiring expert review

     In most cases, these will be Adverse Events of Special Interest (AESIs) identified for COVID-19 vaccines.
  2. Report findings, evidence and conclusions.

Case Findings

- ACCA will report detailed case findings to P/T where case originated.
- Summary of findings will be reported to Health Canada and PHAC committees, such as the National Advisory Committee on Immunization (NACI) to facilitate and inform further actions if needed.
  - ACCA will not make recommendations
- Summary of findings will be reported to VVWG and CIC.
- To be determined – whether any information would be provided publically, e.g., PHAC Weekly Online AEFI Report.
  - Need for transparency vs the concern for privacy.
  - Need for transparency vs misinterpretation of posted information.
  - Communication plan would be required.

Governance

- ACCA to be managed by PHAC: Vaccine Safety Division, COVID-19 Vaccine Surveillance, under the responsibility of the Director.

- To be determined - whether ACCA should fall within an existing governance structure, i.e., as a subcommittee of an already well-established committee (CIC).

Chairs, Membership and Secretariat

Chairs:

- External expert to be invited to chair the committee. An initial term of 18 months is proposed.
- PHAC could serve as co-chair.

Membership:

- Core Membership: PHAC and Health Canada medical advisors/officers, External Reviewers
- External Guest Reviewers: Invited when case is identified that requires medical expertise not found within Core Membership
- Potential Sources for External Expert Reviewers:
  - Canadian Immunization Research Network (CIRN)
  - Canadian Association for Immunization Research and Evaluation (CAIRE)
  - Association of Medical Microbiology and Infectious Disease Canada (AMMI)
  - Canadian Medical Association (CMA)
- Liaison Members: NACI, CIC

Secretariat:

- Vaccine Safety Division, COVID-19 Vaccine Surveillance (PHAC)

Case Selection

- Selected cases to be recommended by P/Ts, Health Canada or PHAC.
- P/Ts will be invited to present the cases that they have submitted for review or are within their jurisdiction.
- PHAC Medical Advisor (conducted secondary review) or external expert reviewer to make recommendations on supplementary medical information needed to proceed with ACCA review.
- P/Ts to identify a point of contact who ACCA can approach with requests for medical information/assistance.
- Meetings to be held on regular basis (frequency to be determined) and by urgent request.

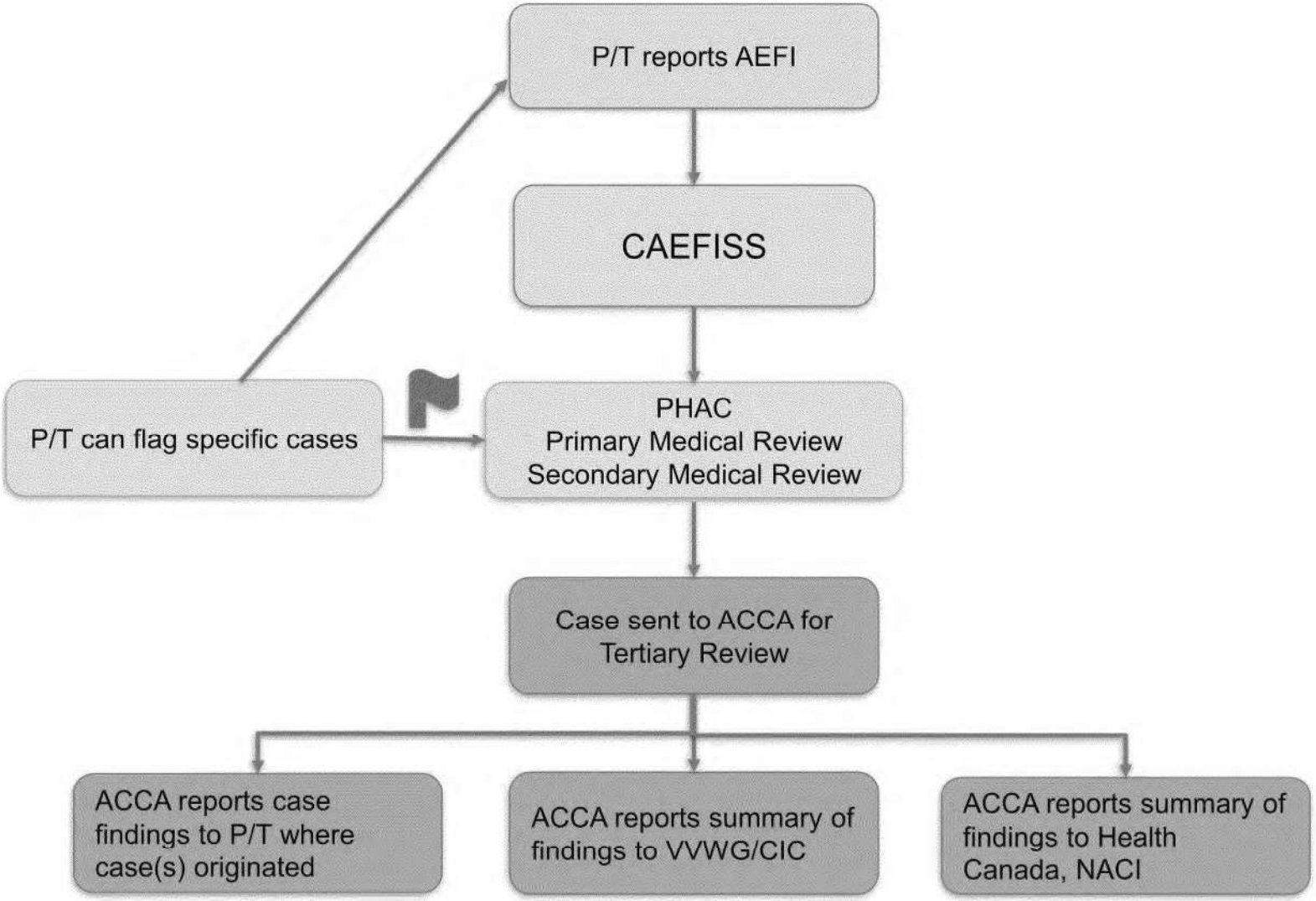
Criteria for Case Selection

- It is anticipated there will be a high volume of cases, which may result in capacity challenges.
  - Not recommended that ACCA takes all serious AEFIs nor all AESIs, as numbers would not be manageable for timely response.

- Following secondary review, strict criteria will need to be applied in order to move a case to tertiary review by ACCA.

- Specific criteria to be developed for an ACCA tertiary review.

Process for Case Selection and Review



Reporting Response Time

- Expectations for response time will need to be clear from outset, as it will impact meeting frequency, e.g., every month, every two weeks.
  - Each review involves: gathering case information, expert review, develop findings and prepare summaries.
- Availability of external experts may be a limiting factor in conducting large numbers of reviews.
  - May require a large roster to draw upon

Privacy and Confidentiality

- No identifying patient information will be shared. Standard procedure to be developed to confirm all identifiers have been removed.
- P/Ts to confirm authorization to share de-identified patient information and that summary of findings can be reported to other committees.
- ACCA members will be asked to sign confidentiality agreements for the content associated with this committee.
- External reviewers will need to attest to not having any conflict of interests.

For Discussion

- Seek feedback on proposed elements of the ACCA.
- Privacy Concerns.
- Public reporting of high-level information on case findings.
  - e.g., provided on PHAC Weekly Online AEFI Report.
  - Content of succinct public report.
- Benefits of having ACCA report to CIC.
- Expectations for appropriate response time in reporting case findings
  - e.g., meetings to be held bi-weekly, monthly, etc.
- Specific criteria for an ACCA tertiary review.

For more information, please contact:

[redacted]

COVID-19 Vaccine Surveillance

Immunization Program of the Vaccine Task Force

Public Health Agency of Canada

Tel: [redacted]

Email: [redacted]

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Canada

Myocarditis following Pfizer vaccine

PROTECTING AND EMPOWERING CANADIANS
TO IMPROVE THEIR HEALTH

Case definition

- Following international news reports of myocarditis following Pfizer, we did an assessment of cases in Canada

- Medra terms used:
  - Myocarditis
  - Perimiocarditis

- 8 cases total in CAEFISS/CVD following Pfizer vaccine
  - (1 following Moderna, 1 following Covishield)
  - Rate following Pfizer: 0.11 per 100,000 doses

- Draft Canadian background rates (CIHI – DAD)
  - 14 per 100,000 (broad)
  - 2 per 100,000 (narrow)

Table 1: Cases of myocarditis (heart inflammation) following Pfizer/BioNTech vaccination in CAEFISS/CVD as of April 26, 2021

	Pfizer/BioNTech					
	# cases	**Dose number**	**Rate per 100,000 doses administered**	**Age range**	**Sex**	**Median Time to onset (range)**
Heart inflammation	8	5 following dose #1 3 following dose #2	0.11	20-53	6 females; 2 male	3 days (5 hours to 21 days)
Total Doses Administered (as of April 17, 2021)	7,164,039					

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Canada

Background rates

[redacted]

Public Health Agency of Canada

Background rates working group

May 6, 2021

PROTECTING AND EMPOWERING CANADIANS TO IMPROVE THEIR HEALTH

Table of Contents

Methodology

- Included all acute hospital (DAD)[1] and emergency department (NACRS)[2] records with an admission diagnosis of the condition of interest between 2015-2019.
- Excluded records:
  - where the condition was flagged as a questionable diagnosis.
  - which occurred within 365 days of a previous event.
    - 72 hours for anaphylaxis
  - which occurred on the same episode as another record.
  - where the individual left the emergency department without being seen (registered and/or triaged and then left).
  - with unknown or other sex.
- Rates calculated using Statistics Canada's population estimates as of July.[3]
- Confidence intervals calculated using the exact method to account for rare events.

1. CIHI Discharge Abstract Database, Canadian Institute for Health Information, fiscal years 2013-2019
2. CIHI National Ambulatory Care Reporting System, Canadian Institute for Health Information, fiscal years 2013-2019
3. Statistics Canada, Centre for Demography

Limitations and considerations

- The reporting coverage to NACRS varies by province/territory and time. Therefore, the background rates may underreport the rate in Canada excluding Quebec.
- Quebec data is excluded as their data is not included in DAD and NACRS.
- As we do not have access to physician billing records, conditions investigated must have been serious enough to warrant a hospital or emergency department visit. Therefore, this may underreport the true rate.
- As we rely on ICD-10-CA codes to identify each condition, there may be misclassification of the outcome.
- Inclusions and exclusions are specific to the definition.
  - For example for thrombosis only, events were only excluded if they had thrombosis only (i.e. events could have occurred within 365 days of an episode of care with both thrombosis and thrombocytopenia)

Coagulation Disorders

Definitions

Definition	ICD-10-CA codes
Pulmonary embolism (PE)	I26, O88.20
Deep vein thrombosis (DVT)	I80.1-I80.3, I80.8, I80.9, O22.30, O87.10
Stroke	H34.1, I60, I61, I62, I63, I64
Intracranial venous thrombosis (IVT)	G08, I63.6, I67.6, O22.50, O87.30
Idiopathic thrombocytopenia - Broad	D69.3, D69.4, D69.5, D69.6, D82.0, M31.1
Idiopathic thrombocytopenia - Narrow	D69.3
Disseminated intravascular coagulation (DIC)	D65, O45.01, O46.01
Thrombosis only[a]	G08, H34.1, I21, I22, I26, I51.3, I63, I64, I67.6, I80.1, I80.2, I80.3, I80.8, I80.9, I81, I82.2, I82.3, I82.8, I82.9, K55.0, O22.30, O22.50, O87.10, O87.30, O88.20
Thrombocytopenia only[b]	D65, D69.3, D69.4, D69.5, D69.6, D82.0, M31.1, O4501, O4601
Thrombosis and thrombocytopenia	H34.1, I21, I22, I26, I51.3, I60, I61, I62, I63, I64, I67.6, I80.1, I80.2, I80.3, I80.8, I80.9, I81, I82.2, I82.3, I82.8, I82.9, K55.0, O22.30, O22.50, O87.10, O87.30, O88.20 AND D65, D69.3, D694, D69.5, D69.6, D82.0, M31.1, O45.01, O46.01

a. Excludes records where the individual had a thrombocytopenia on the same episode of care
b. Excludes records where the individual had a thrombosis on the same episode of care

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
PE	57.92 (57.02 - 58.83)	62.27 (61.35 - 63.2)	63.39 (62.46 - 64.32)	64.21 (63.28 - 65.14)	66.21 (65.28 - 67.15)	62.85 (62.44 - 63.26)
DVT	80.46 (79.4 - 81.52)	80.89 (79.84 - 81.95)	79.91 (78.87 - 80.96)	78.81 (77.79 - 79.85)	77.13 (76.13 - 78.15)	79.42 (78.95 - 79.88)
Stroke	154.48 (153.01 - 155.95)	155.98 (154.52 - 157.46)	156.13 (154.68 - 157.6)	158.16 (156.71 - 159.63)	158.3 (156.86 - 159.76)	156.64 (155.99 - 157.29)
IVT	1.39 (1.25 - 1.53)	1.46 (1.32 - 1.61)	1.52 (1.38 - 1.67)	1.3 (1.17 - 1.44)	1.59 (1.45 - 1.74)	1.45 (1.39 - 1.52)
Idiopathic thrombocytopenia – Broad	34.49 (33.8 - 35.19)	36.75 (36.04 - 37.46)	37.42 (36.71 - 38.14)	37.48 (36.77 - 38.19)	37.97 (37.26 - 38.68)	36.84 (36.53 - 37.16)
Idiopathic thrombocytopenia – Narrow	6.03 (5.74 - 6.32)	6.3 (6.01 - 6.6)	5.92 (5.64 - 6.21)	5.76 (5.48 - 6.04)	5.56 (5.29 - 5.84)	5.91 (5.78 - 6.04)
DIC	1.46 (1.32 - 1.61)	1.47 (1.33 - 1.62)	1.49 (1.35 - 1.64)	1.47 (1.34 - 1.62)	1.5 (1.36 - 1.65)	1.48 (1.41 - 1.54)
Thrombosis only	444.79 (442.3 - 447.29)	458.58 (456.07 - 461.1)	456.33 (453.84 - 458.82)	456.3 (453.83 - 458.78)	460.13 (457.67 - 462.61)	455.3 (454.19 - 456.42)
Thrombocytopenia only	33.36 (32.68 - 34.05)	35.18 (34.49 - 35.89)	35.8 (35.11 - 36.51)	35.68 (34.99 - 36.37)	36.37 (35.68 - 37.07)	35.3 (34.99 - 35.61)
Thrombosis with thrombocytopenia (TTS)	3.06 (2.86 - 3.28)	3.58 (3.36 - 3.8)	3.7 (3.48 - 3.93)	3.73 (3.51 - 3.96)	3.67 (3.46 - 3.9)	3.55 (3.46 - 3.65)

Rate per 100,000 persons

Parts of this material are based on data and information compiled and provided by CIHI. However, the analyses, conclusions, opinions and statements expressed herein are those of the author, and not necessarily those of CIHI.

Anaphylaxis

Definitions

Definition	ICD-10-CA codes
Anaphylaxis 1 – due to vaccination, other serum, or unidentified	T78.2, T80.5
Anaphylaxis 2 – all anaphylaxis related codes	T78.0x, T78.2, T80.5, T88.6
Anaphylaxis 3 – all anaphylaxis and allergic reaction codes	L50.0, T78.0x, T78.2, T78.4, T80.5, T88.6

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
Anaphylaxis 1	19.04 (18.53 - 19.56)	20.7 (20.17 - 21.24)	22.35 (21.8 - 22.91)	25.06 (24.49 - 25.65)	26.09 (25.51 - 26.69)	22.7 (22.45 - 22.95)
Anaphylaxis 2	38.11 (37.38 - 38.84)	42.12 (41.36 - 42.89)	45.65 (44.87 - 46.44)	49.07 (48.27 - 49.89)	51.74 (50.92 - 52.57)	45.43 (45.08 - 45.78)
Anaphylaxis 3	206.29 (204.59 - 207.99)	202.04 (200.38 - 203.72)	206.22 (204.55 - 207.9)	204 (202.35 - 205.66)	199.08 (197.47 - 200.71)	203.49 (202.75 - 204.24)

Rate per 100,000 persons

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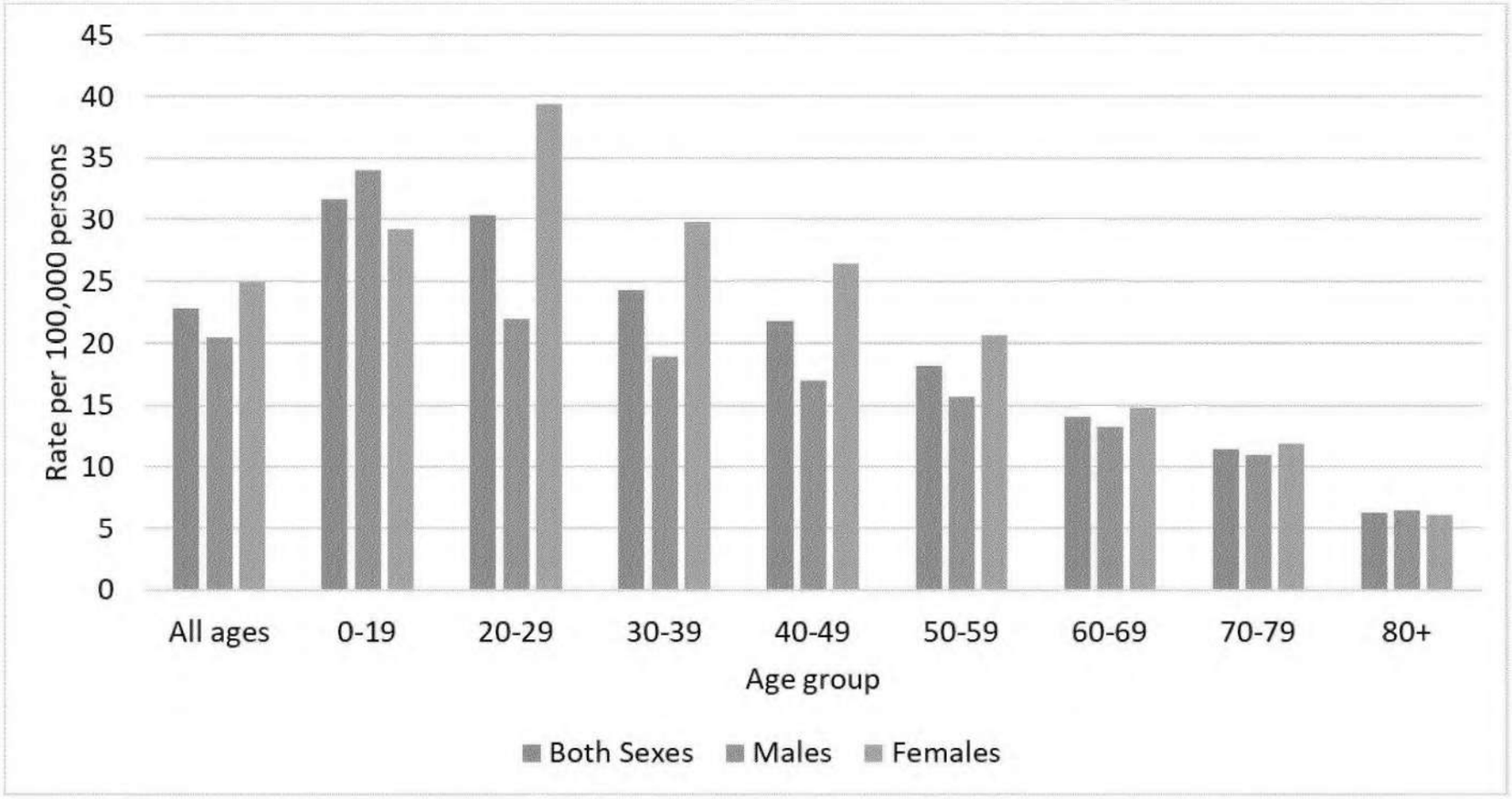
Rate of anaphylaxis 1 by age and sex – Canada excluding Quebec, 2015 – 2019



Rate per 100,000 persons

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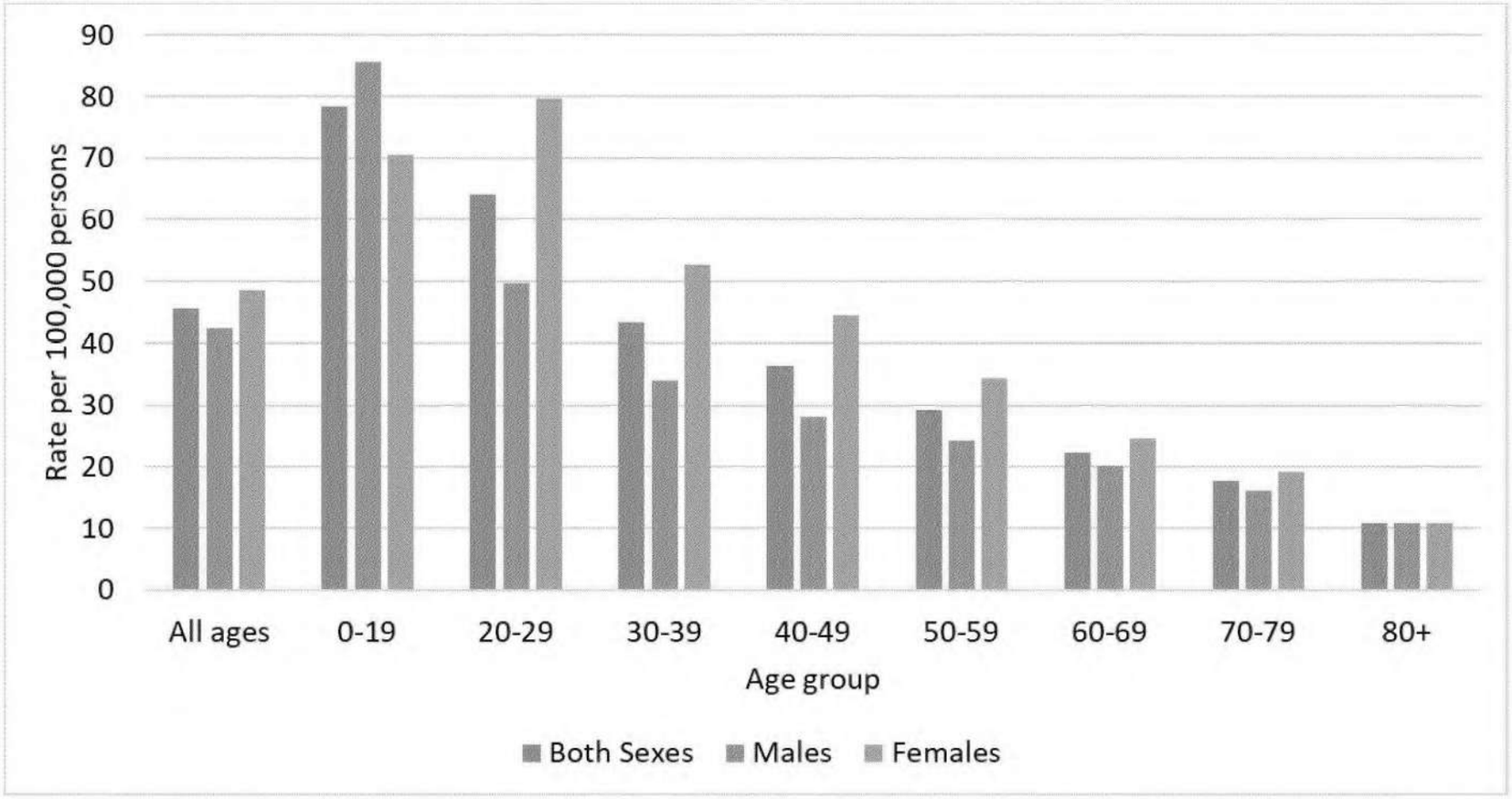
Rate of anaphylaxis 2 by age and sex – Canada excluding Quebec, 2015 – 2019



Rate per 100,000 persons

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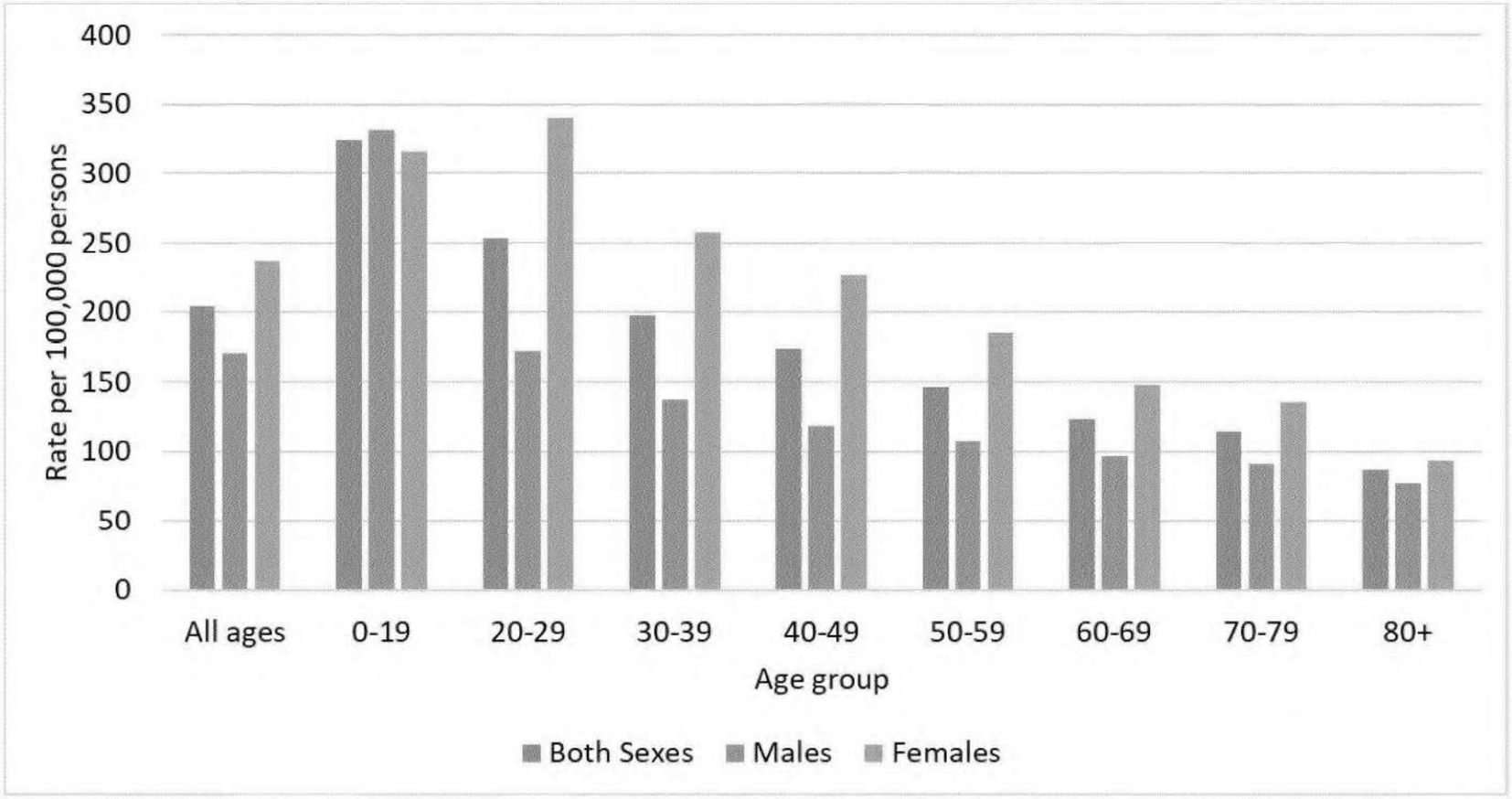
Rate of anaphylaxis 3 by age and sex – Canada excluding Quebec, 2015 – 2019



Rate per 100,000 persons

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Bell's Palsy

Definitions

Definition	ICD-10-CA codes
Bell's Palsy	G51.0

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
Bell's palsy	22.18 (21.63 - 22.75)	22.37 (21.82 - 22.93)	23.28 (22.72 - 23.85)	23.72 (23.16 - 24.29)	24.12 (23.56 - 24.69)	23.15 (22.9 - 23.4)

Rate per 100,000 persons

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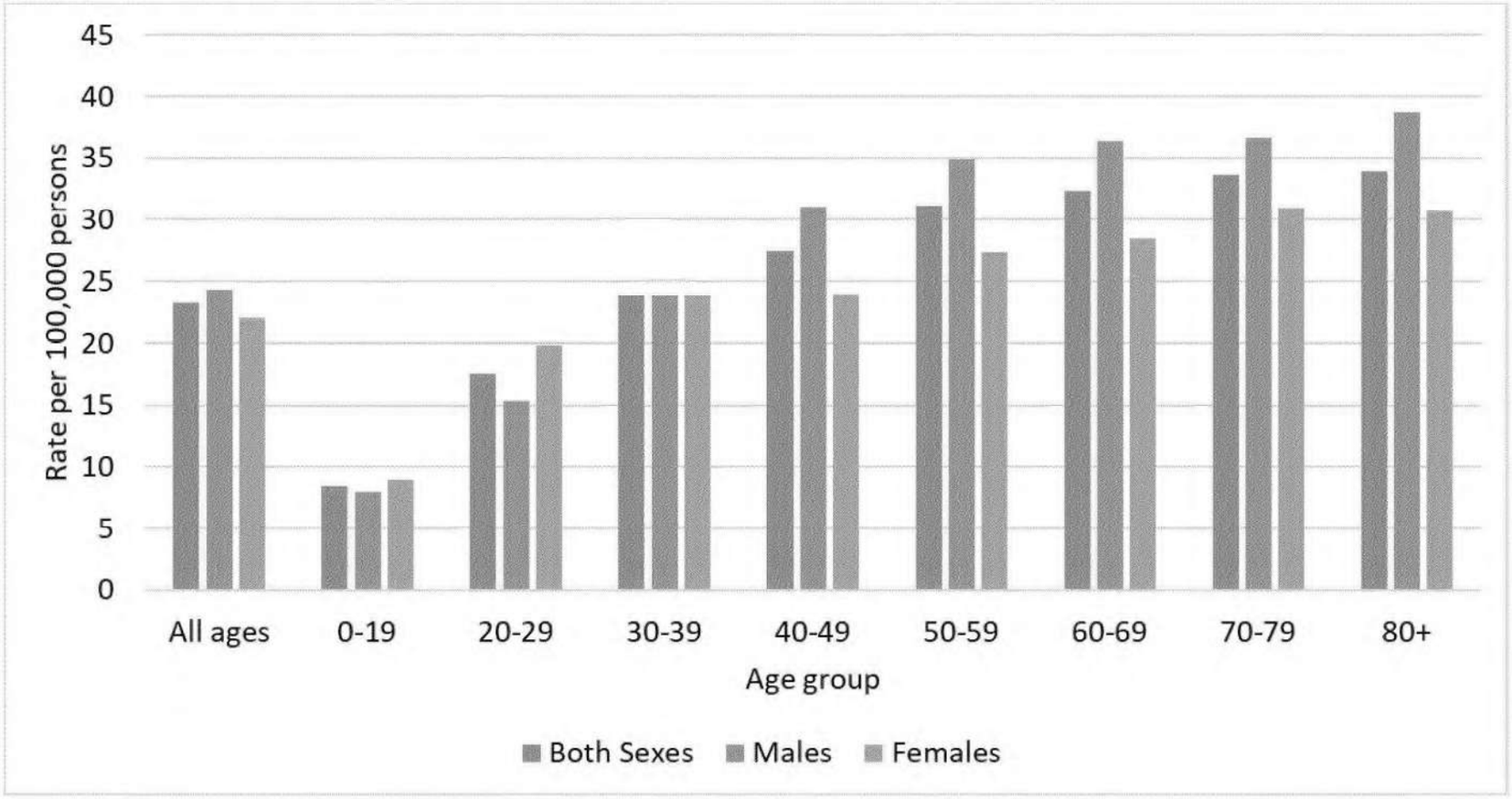
Rate of bell's palsy by age and sex – Canada excluding Quebec, 2015 – 2019



Rate per 100,000 persons

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Myocarditis

Definitions

Definition	ICD-10-CA codes
Myocarditis	I09.0, I40.x, I41.x, I51.4

Background rates – Canada excluding Quebec

Definition	2015	2016	2017	2018	2019	2015 – 2019
Myocarditis	2.99 (2.79 - 3.2)	3.32 (3.11 - 3.54)	3.56 (3.34 - 3.79)	3.19 (2.99 - 3.41)	3.32 (3.11 - 3.53)	3.28 (3.18 - 3.37)

Rate per 100,000 persons

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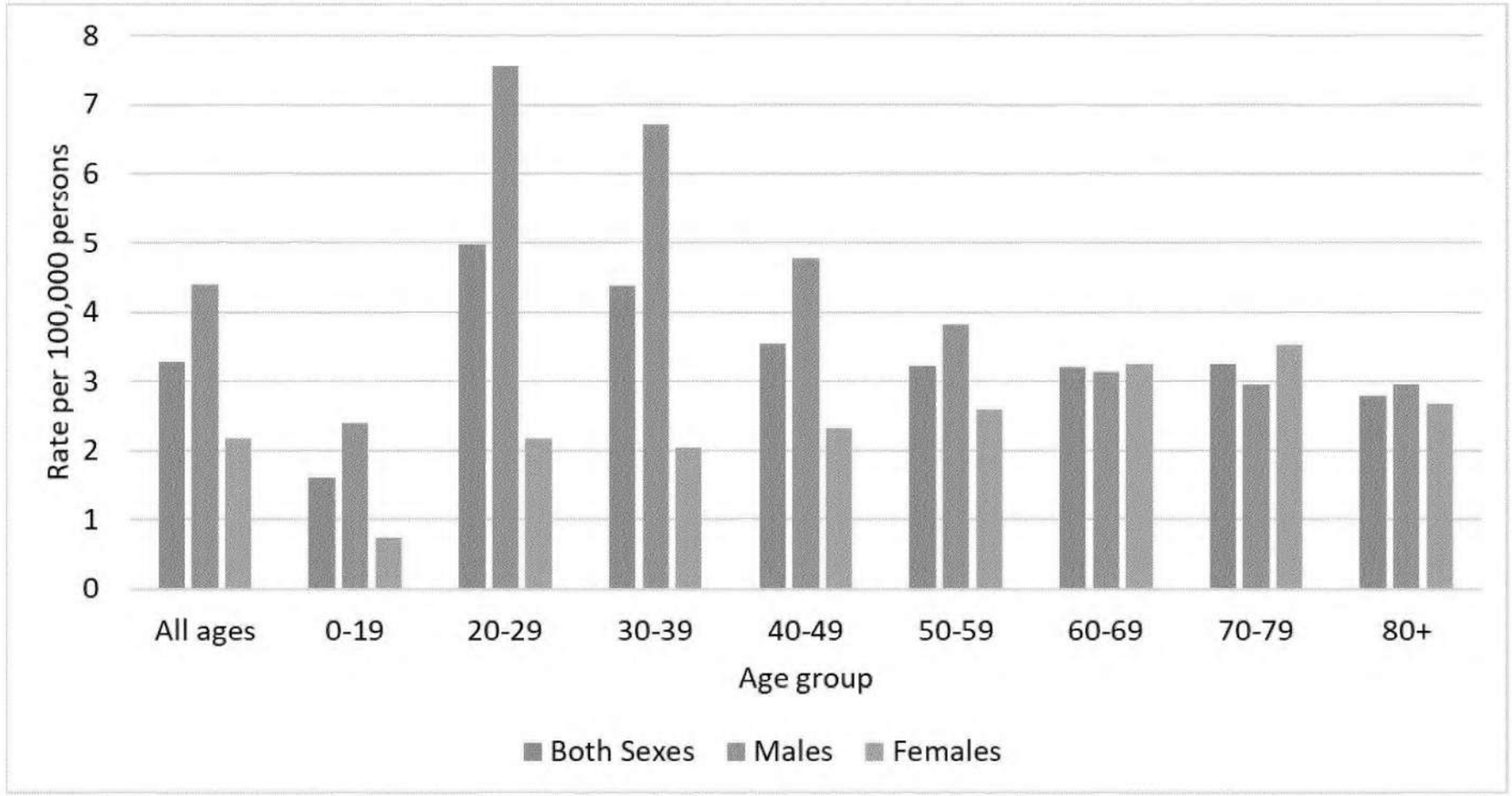
Rate of myocarditis by age and sex – Canada excluding Quebec, 2015 – 2019



Rate per 100,000 persons

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Background Rates Working Group Members

PHAC

[redacted]

[redacted]

Manitoba Health

[redacted]

Government of Alberta

[redacted]

University of Toronto

[redacted]

Health Canada

[redacted]

BC Centre for Disease Control

[redacted]

Contact: [redacted]@canada.ca

Methodology – Number of expected

$$Expected = \sum_{s=1}^{N} [BGR]_s * [PT] * [Proportion]_s$$

- S: 10-year age and sex specific stratum
- BGR: Background rate for each 10-year age and sex specific stratum
- PT: Vaccine specific total person time at risk
  - Calculated using doses administered from vaccine coverage using data from all P/Ts, Canadian Armed Forces, and Correctional Services Canada.
  - Used weekly doses administered data to account for the at risk time available.
    - Eg. If observed data as of May 2nd, then new doses administered as of April 24 would only contribute 9 days to the person time at risk.
- Proportion: Vaccine, sex, and age specific doses administered proportion
  - Calculated using doses administered data by age, sex and vaccine type as of May 1st from vaccine coverage.
  - Data was grouped into the 10-year age categories to match the background rates.

Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, May 13, 2021 from 1:30 – 3:00 PM EST

Record of Decisions (RoD)

Members in Attendance:

BC: [redacted] **MB** [redacted] **NB:** [redacted] **NS:** [redacted] **NT:** [redacted] **NU:** [redacted] **ON: (MOH)** [redacted] **(PHO):** [redacted] **PE:** [redacted] **QC:** [redacted] **SK:** [redacted] **YT:** [redacted]

Liaison Members in Attendance:

DND: [redacted] **FNIHB:** [redacted] **IMPACT:** [redacted] **MHPD** [redacted]

Observers/Presenters in Attendance:

[redacted] (Federal Co-Chair) [redacted] **CANVAS** [redacted]

Regrets:

AB: [redacted] (Provincial Co-Chair), **NL:** [redacted] **CSC:** [redacted] **BRDD:** [redacted] **RCMP:** [redacted]

ACTION ITEMS

1. Action Item Updates

i) CANVAS Update

Bell's Palsy has been added as an agenda item to this week's meeting. This item was discussed during the CANVAS update.

ii) Background Rates Update

[redacted] is still looking into creating a document comparing Canada's background rates to FDA and EMA background rates.

iii) Group Question - Inflammatory flare-ups of autoimmune disease post COVID-19 Immunization

The question from the Yukon was sent out to VVWG on May 10, 2021 for PT's to review and provide a response at the May 13, 2021 VVWG meeting.

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of RoD May 6, 2021	a) Agenda was approved with no additional agenda items. b) RoDs were reviewed. Amendments can be provided to [redacted] by end of day on May 14, 2021.	[redacted]	**ACTION:** a) No action b) Members can provide changes or updates to the RoDs to [redacted] by end of day on May 14, 2021 to approve and finalize the RoD.
2. CANVAS Update	a) [redacted] provided a presentation on "**CANVAS: Active Safety Surveillance for COVID-19 Vaccines: Bell's Palsy**." The presentation will be posted to CNPHI after the meeting.	[redacted]	**ACTION:** a) The presentation will be posted to CNPHI after the meeting.
3. Weekly On-line COVID AEFI Report	a) [redacted] provided a brief summary of the Weekly on-line COVID AEFI Report. The data provided is up to May 7, 2021. The update and the embargoed report will be posted on May 7, 2021 by the end of the day.	[redacted]	**ACTION:** a) No action
4. CAEFISS Analysis	a) [redacted] provided a presentation of the CAEFISS Weekly Report. The data provided is up to May 7, 2021.	[redacted]	**ACTION:** a) The CAEFISS presentation will be posted to CNPHI after the meeting. b) [redacted] will report back at next week's VVWG meeting regarding those specific lot numbers for Bell's Palsy.
5. AstraZeneca Update - TTS case definition update - Summary of TTS cases in Canada	a) [redacted] provided an update on **Thrombocytopenia Thrombosis Syndrome (TTS)** case definition. • The case definition was approved by the Special Advisory Committee (SAC) last week. This is aligned with the Brighton Collaboration case definition for	[redacted] (HC)	**ACTION:** a) The presentation will be shared with VVWG late today or tomorrow (May 14, 2021).

Agenda Item	Description	Lead	Further Actions or Completed
- Summary of international findings	Thrombosis with Thrombocytopenia Syndrome (TTS) following vaccination. b) [redacted] provided an International regulatory update and a Health Canada update. • There is an interest to have a summary of the case definitions that are published internationally in comparison to Canada's and to have a side-by-side comparison, which is being considered to be put in place. • HC is waiting for the company's data for the cumulative data for the TTS coming from AstraZeneca, which is supposed to be received in the next few days.		b) No action
6. PT observations of AEFIs with AstraZeneca/COVISHIELD	a) PTs provided their observations of AEFIs with AstraZeneca/COVISHIELD. The responses have been captured along with agenda item 7 as Appendix A.	All	**ACTION:** a) Please see PT responses in Appendix A. Jurisdictions that were unable to provide a response will be sent an email to obtain their response.
7. Group Question - Inflammatory flare-ups of autoimmune disease post COVID-19 Immunization	a) Yukon has asked the following question to VVWG: Yukon is noting a cluster of significant inflammatory illnesses with onset within 2 weeks of Moderna vaccination, often young persons, often after 2nd dose. Also, exacerbations of pre-existing inflammatory diseases. As a small population, it is unlikely of statistical significance above baseline rates. Are similar trends being seen elsewhere in Canada or the world? Particularly of interest with mRNA vaccines as Yukon only has Moderna. • Diseases of inflammatory or autoimmune nature. Eg, inflammatory arthritis, myositis, connective tissue diseases, inflammatory bowel disease (eg. crohns	All	**ACTION:** a) Please see PT responses in Appendix A. Jurisdictions that were unable to provide a response will be sent an email to obtain their response.

Agenda Item	Description	Lead	Further Actions or Completed
	Ulcerative colitis), neuritis or neurological diseases that have inflammatory process (eg. MS, menigio/encephalopathies, myelitis, GBS, MG, possibly bell's palsy), immune renal disease, uveitis, perimyocarditis. Inflammations or autoimmune diseases of other organ systems not listed and of significant impact to individual *The responses have been captured along with agenda item 6 as Appendix A.		
8. Roundtable	a) No items were discussed during the roundtable discussion.	All	**ACTION:** a) No action
9. Confirm Next Call	a) Next call: May 20, 2021 (1:30 – 3:00 EDT)	[redacted]	**ACTION:** a) No action

APPENDIX A

JURISDITIONS	Question 1: PT observations of AEFIs with AstraZeneca/COVISHIELD	Question 2: Inflammatory flare-ups of autoimmune disease post COVID-19 Immunization
AB	N/A	• Alberta is seeing some, Bell's palsy, Myelitis, acute aseptic arthritis and inflammatory conditions.
BC	• The rates of serious AEFI reports have been very consistent between the viral vectors and the mRNA vaccines. • BC has seen more reports for different thrombotic events, which is probably following just the media of those events occurring in Europe (strokes, etc.). These have been occurring for all the vaccines and not just AstraZeneca and COVISHIELD.	• These are hard to find in their data. BC has had some of the conditions such as, Bell's palsy. They are occurring but BC cannot provide a numeric rate for these conditions.
MB	• MB is seeing significantly more adverse events following AstraZeneca compared to Pfizer. This is for all adverse events and adverse events that are serious. There is not a significant difference between Moderna and AstraZeneca. • With AstraZeneca specifically, MB has received reports with thrombotic events with thrombocytopenia as well as Cerebral Sinus Vein Thrombosis. The observed rate of TTS and of CSVT both exceeded significantly the rate provided by the Background Rate working group. It is significant at a level of 0.01 (as recently as week 15).	• MB has seen cases of MS exacerbation following COVIDSHIELD • There are also cases of Bell's Palsy following AZ, but their occurrence is consistent with background rate.
NB	• COVISHIELD has a higher rate compared to AstraZeneca, which is also noticeably higher compared to Pfizer and Moderna, which are mostly equivalent in terms of serious.	• NB has had 3 cases of Bell's Palsy and one case of myeloradiculopathy
NL	N/A	
NS	N/A	
NT	• NT is not using the AstraZeneca/COVISHIELD product	• Nothing of significance. They have had the occasional incidence but nothing that has standing out.

JURISDITIONS	Question 1: PT observations of AEFIs with AstraZeneca/COVISHIELD	Question 2: Inflammatory flare-ups of autoimmune disease post COVID-19 Immunization
NU	• NU is not using the AstraZeneca/COVISHIELD product	• They have not noted any flare-ups of inflammatory disease at this time.
ON	• ON is seeing a higher serious reporting rate for COVISHIELD/AstraZeneca. As of May 10, 2021, ON has seen 21 reports that met their serious definition.	• ON has not had a chance to look at this yet.
PE	N/A	
QC	N/A	
SK	• There is no difference in the adverse events that they have seen coming compared to Pfizer or Moderna	• SK has had a few GBS cases for all of the vaccines. • They have had a few more reports on thrombotic issues but a lot of them were deemed as not being related to the vaccine or somebody had underlying conditions and they were not diagnosed as a TTS or they did not require that degree of clinical consultation.
YT	• YK is not using the AstraZeneca/COVISHIELD product	• YK has had an MS exacerbation and some reactive arthropathies and YK is also looking at a few other neurological things