RE: AEFI post covid vaccine

From: Bonnie.Henry@gov.bc.ca
To: XT:Kim, Jong HLTH:IN <jong.kim@northernhealth.ca>, XT:McDonald, Shannon HLTH:IN <Shannon.McDonald@fnha.ca>
Sent: January 5, 2021 6:36:05 PM PST

I received a call or email (I don't recall)on s.22 saying there was a person who had an allergic reaction at the clinic in the north at the clinic s.22 That they received epinephrine and were observed in s.22 for a few hours. I understand it was a s.22 . I don't recall who sent me the info Jong, sorry.

Then there was a second one later that day in FH.
b

Dr Bonnie Henry
Provincial Health Officer
Office of the PHO
Ministry of Health
s.15; s.19
Mailing address: PO Box 9648, STN PROV GOVT
Victoria, BC
V8W 9P4
Bonnie.henry@gov.bc.ca

Phone: s.17; s.19

I gratefully acknowledge that I live and work on the traditional unceded territory of the Lekwungen Peoples, specifically the Songhees and Esquimalt First Nations. Hay'sxw'qu Si'em

---

From: Kim, Jong <Jong.Kim@northernhealth.ca>
Sent: January 5, 2021 6:17 PM
To: XT:McDonald, Shannon HLTH:IN <Shannon.McDonald@fnha.ca>
Cc: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Subject: FW: AEFI post covid vaccine

Shannon, could I ask if there was any **anaphylactic reaction from the north**ern First Nation communities vaccinated?

We were inquired about an anaphylactic reaction in north on s.22 that Bonnie notified Monika. We are not aware of any such event reported from NH vaccination. We might need to look more into, so checking with you first. Thanks so much for your help.

Bonnie, could I ask if you have any more details of the anaphylactic case from North on s.22 s.22 Thanks for your help.

Jong

From: Leung, Kathy [BCCDC] <kathy.leung@bccdc.ca>
Sent: Tuesday, January 05, 2021 10:53
To: Gagel, Mike <Mike.Gagel@northernhealth.ca>; Strim, Patricia <Patricia.Strim@northernhealth.ca>
Cc: Kallos, Suzanne [BCCDC] <suzanne.kallos@bccdc.ca>
Subject: AEFI post covid vaccine

Hi Mike,

We spoke yesterday on the phone, thanks for looking into this for us.

On December 24, Bonnie Henry emailed Monika Naus, notifying her that there was an anaphylactic reaction in the north on s.22 . We don't have any other details about this event and as you can expect we are trying to collect the details of any adverse event quickly. If you have an AEFI form completed, and it can be entered into CMOIS and Panorama that would be great, but any information you can give us would also be extremely helpful.

You can fax it to 604-707-2516, attention Kathy/Arlene. Arlene is Suzanne Kallos, cc'd above.

Please let me know if you need any more information.

Best,
Kathy

Kathy Leung BScN
Public Health Resource Nurse
Immunizaton Programs, BCCDC
kathy.leung@bccdc.ca

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ílwətaʔ/Selilwitulh Nations.

RE: HEADS UP: CSC death

From:	Raymond, Barbara (PHAC/ASPC) <barbara.raymond@canada.ca>
To:	Henry, Bonnie (Ext.) <bonnie.henry@gov.bc.ca>, Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Sent:	January 17, 2021 1:43:26 PM PST
Attachments:	image001.gif

Thanks Bonnie – Happy Sunday.
Stay warm.

From: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Sent: 2021-01-17 4:39 PM
To: Raymond, Barbara (PHAC/ASPC) <barbara.raymond@canada.ca>; XT:Naus, Monika HLTH:IN <monika.naus@bccdc.ca>; XT:HLTH Brodkin, Elizabeth <elizabeth.brodkin@fraserhealth.ca>; Gustafson, Reka [BCCDC] <reka.gustafson@phsa.ca>; Lapointe, Lisa PSSG:EX <Lisa.Lapointe@gov.bc.ca>
Cc: Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; Elmslie, Kim (PHAC/ASPC) <kim.elmslie@canada.ca>; Wheatley Jennifer (NHQ-AC) <Jennifer.Wheatley@CSC-SCC.GC.CA>
Subject: RE: HEADS UP: CSC death

Thank you Barbara,
It is very helpful to get a heads up and I am very sad to hear of the death.
I have copied Dr Monika Naus who is leading our AEFI reporting and causality team. We have been working nationally on how to report deaths temporally associated with vaccination especially considering the population we are immunizing right now.

I have also copied our Chief Coroner so we are all aware and can coordinate on messages.
My best,
Bonnie

Dr Bonnie Henry
Provincial Health Officer
Office of the PHO
Ministry of Health
s.15; s.19

Mailing address: PO Box 9648, STN PROV GOVT
Victoria, BC
V8W 9P4
Bonnie.henry@gov.bc.ca

Phone: s.17; s.19

I gratefully acknowledge that I live and work on the traditional unceded territory of the Lekwungen Peoples, specifically the Songhees and Esquimalt First Nations. Hay'sxw'qu Si'em

---

From: Raymond, Barbara (PHAC/ASPC) <barbara.raymond@canada.ca>
Sent: January 17, 2021 1:27 PM

To: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Cc: Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; Elmslie, Kim (PHAC/ASPC) <kim.elmslie@canada.ca>; Wheatley Jennifer (NHQ-AC) <Jennifer.Wheatley@CSC-SCC.GC.CA>
Subject: HEADS UP: CSC death

Hello Bonnie,

I wanted to give you a heads up regarding a death in a CSC inmate who received Moderna vaccine on s.22 (first dose), and who subsequently died on s.22

This individual, s.22 , was an inmate s.22 s.22 of CSC s.22 s.22

Vaccine administered uneventfully on s.22 s.22 s.22 s.22 no adverse events attributed to vaccination. s.22 became unresponsive, emergency code called, BC Ambulance attended, however resuscitation unsuccessful. s.22 – individual declared deceased.

At this point in time, CSC does not consider the death to be linked to the vaccine. However:

- CSC protocol is that coroner is notified of all inmate deaths and determines what further investigation will take place
- CSC reports adverse events following immunization (AEFI) via local public health units (in this case, s.22 in BC).
- All CSC deaths in custody are reported publicly with a news release.

CSC colleagues wanted to ensure that you were aware, and that there be coordination on communications products, given temporal association with vaccine.
CSC will reach out to s.22 to coordinate reporting/comms etc.
I've included Jennifer Wheatley who is the Assistant Commissioner for CSC Health Services nationally on this email.
Let us know if there are others who should be looped in.
Thanks
Barbara

Barbara J Raymond MD
Executive Medical Advisor / Conseillere médicale exécutive
Vice President's Office, Infectious Disease Prevention and Control Branch
Bureau de la Vice-presidente, Direction générale de la prévention et du côntrole des maladies infectieuses
Public Health Agency of Canada / Agence de la santé publique du Canada
Barbara.Raymond@Canada.ca
Mobile:s.16

Today's AEFI report

From:	Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
To:	Henry, Bonnie [EXT] <bonnie.henry@gov.bc.ca>, Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Cc:	Amos, Heather [BCCDC] <heather.amos@bccdc.ca>, Noftall, Kyle [BCCDC] <Kyle.Noftall@bccdc.ca>, Gustafson, Reka [BCCDC] <reka.gustafson@phsa.ca>
Sent:	January 21, 2021 10:09:23 AM PST
Attachments:	COVID19_AEFI_Summary_Report_2021-01-21.html

Hi Bonnie

As requested, for your media briefing the full report based on reporting to today is enclosed.
In summary, we have had a total of 56 reports of adverse events (1 or more events/ report), for a rate of 46.7 reports per 100K doses distributed.
With respect to allergic/ anaphylaxis events:

- 10 anaphylaxis reports that meet the Brighton case definition have been reported, for a rate of 8 per 100K doses. This is a higher rate than reported in BC with influenza vaccine (for comparison) and higher than what has been reported in the US data (about 1 per 100K doses). One of these required hospitalization but recovered fully, and the others have not required hospitalization.
- 16 reports have been of other allergic events, including hives, some with onset days after immunization so

s.13

Other events of note, just fyi:

- The Bell's palsy was in a s.22 6 days after vaccination. s.13
  s.13
  s.13 We will follow to outcome including causal assessment for other causes.
- We've had s. cases of cellulitis reported but none meet the Brighton definition as none were microbiologically confirmed. s.13
  s.13

I forwarded your request on wastage to Noorjean and Julie Wilson as they're dealing with the logistics. You should hear from them directly.

Thank you,
Monika

. . . . . .

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell s.16
Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday) mnds.assist@bccdc.ca Tel 604 707 2519

I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

From: Henry, Bonnie HLTH:EX [mailto:Bonnie.Henry@gov.bc.ca]
Sent: Wednesday, January 20, 2021 2:59 PM
To: Galanis, Eleni [BCCDC] <Eleni.Galanis@bccdc.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>; Krajden, Mel [BCCDC] <Mel.Krajden@bccdc.ca>
Cc: Gustafson, Reka [BCCDC] <reka.gustafson@phsa.ca>
Subject: data for Thursday media avail

Hi Monika, Mel and Eleni,
Could I get a quick update tomorrow of

1. Numbers of cases of MISC and ages/outcome
2. Numbers of AEFI and number of those that were 'allergic reactions'
3. Any vaccine wastage
4. Numbers of variants: SA (so far I am aware of 2, both NOT travel related) and UK (4, two travel and 2 contact of travel)

Thank you!
bonnie

Dr Bonnie Henry
Provincial Health Officer
Office of the PHO
Ministry of Health
s.15; s.19
Mailing address: PO Box 9648, STN PROV GOVT
Victoria, BC
V8W 9P4
Bonnie.henry@gov.bc.ca

Phone: s.17; s.19

I gratefully acknowledge that I live and work on the traditional unceded territory of the Lekwungen Peoples, specifically the Songhees and Esquimalt First Nations. Hay'sxw'qu Si'em

BC COVID-19 AEFI Summary Report - January 21, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by January 18, 2021 there have been a total of 119,875 distributed doses. As of Jan 21, 2021, there have been 56 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 46.7 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 18 (32.1%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 75 adverse events reported, giving a ratio of 1.3 events per COVID-19 AEFI report.

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Jan 21, 2021 **(N=56)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2020-53	2021-1	2021-2	2021-3	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	7	9	23	14	**56**	**46.72**	**100.0**	6.50	**7.2**	100.0	**1.0**	32.30	**1.4**	100.0	**1.0**
Serious AEFI[g]	4	4	8	1	**18**	**15.02**	**32.1**	1.48	**10.1**	22.8	**1.4**	7.23	**2.1**	22.4	**1.4**
Events															
Anaphylaxis	2	3	6	1	**13**	**10.84**	**23.2**	0.47	**23.1**	7.3	**3.2**	2.70	**4.0**	8.3	**2.8**
Anaphylaxis Brighton levels 1/2/3[h]	2	1	5	1	**10**	**8.34**	**17.9**	0.19	**43.9**	2.8	**6.4**	NA	**–**	NA	**–**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2020-53	2021-1	2021-2	2021-3	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
Other allergic	2	2	7	3	**16**	**13.35**	**28.6**	2.09	**6.4**	32.1	**0.9**	5.64	**2.4**	17.5	**1.6**

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Jan 21, 2021 **(N=56)**

Vaccine information			Reports				Events											
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Enceph rate
COVID-19 mRNA		300042460	30	148.51	6	29.70	4	19.80	2	9.90	6	29.70	0	0.00	0	0.00	0	0.0
	Moderna mRNA-1273	300042698	2	9.66	1	4.83	1	4.83	1	4.83	1	4.83	0	0.00	0	0.00	0	0.0
		Moderna mRNA-1273 total	**32**	**78.24**	**7**	**17.11**	**5**	**12.22**	**3**	**7.33**	**7**	**17.11**	**0**	**0.00**	**0**	**0.00**	**0**	**0.0**
	Pfizer mRNA BNT162b2	EK4175	4	102.56	4	102.56	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.0

Abbreviations:
GBS = Guillain Barre Syndrome
Notes:
[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event c
[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.
[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/re
[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

Vaccine information	Reports				Events											
Lot	Total AEFI	Total AEFI	Serious AEFI	Serious AEFI	Anaphylaxis	Anaphylaxis	Anaphylaxis Brighton levels 1/2/3	Anaphylaxis Brighton levels 1/2/3	Other allergic	Other allergic	Bell's Palsy	Bell's Palsy	GBS	GBS	Encephalitis	Enceph

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2020-53	Jan-21	Feb-21	Mar-21	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	7	9	23	14	**56**	**46.72**	**100**	6.5	**7.2**	100	**1**	32.3	**1.4**	100	**1**
Serious AEFI[g]	4	4	8	1	**18**	**15.02**	**32.1**	1.48	**10.1**	22.8	**1.4**	7.23	**2.1**	22.4	**1.4**
Events															
Anaphylaxis	2	3	6	1	**13**	**10.84**	**23.2**	0.47	**23.1**	7.3	**3.2**	2.7	**4**	8.3	**2.8**
Anaphylaxis Brighton levels 1/2/3[h]	2	1	5	1	**10**	**8.34**	**17.9**	0.19	**43.9**	2.8	**6.4**	NA	–	NA	–
Other allergic	2	2	7	3	**16**	**13.35**	**28.6**	2.09	**6.4**	32.1	**0.9**	5.64	**2.4**	17.5	**1.6**
Bell's Palsy	1	0	0	0	**1**	**0.83**	**1.8**	0.02	**41.5**	0.3	**6**	0.06	**13.8**	0.2	**9**
GBS	0	0	0	0	**0**	**0**	**0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0**	**0**	0.02	–	0.3	–	0	–	0	–
Meningitis	0	0	0	0	**0**	**0**	**0**	0	–	0	–	0.12	–	0.4	–
Other paralysis	0	0	0	0	**0**	**0**	**0**	0.05	–	0.8	–	0	–	0	–
Seizure	0	0	0	0	**0**	**0**	**0**	0.27	–	4.1	–	1.53	–	4.7	–
Thrombocytopenia	0	0	0	0	**0**	**0**	**0**	0.02	–	0.3	–	0	–	0	–
Cellulitis	1	1	2	0	**4**	**3.34**	**7.1**	0.27	**12.4**	4.1	**1.7**	0.31	**10.8**	0.9	**7.9**
Recommendations															
No further immunizations	1	0	1	0	**3**	**2.5**	**5.4**	0.24	**10.4**	3.6	**1.5**	0.67	**3.7**	2.1	**2.6**
Outcomes															
Hospitalization	0	0	0	0	**1**	**0.83**	**1.8**	0.19	**4.4**	2.8	**0.6**	3	**0.3**	9.3	**0.2**
Permanent disability	0	0	0	0	**0**	**0**	**0**	0	–	0	–	0	–	0	–
Death	0	0	0	0	**0**	**0**	**0**	0.02	–	0.3	–	0.18	–	0.6	–
Health Authority															
IHA	4	3	6	11	**25**	**111.61**	**44.6**	10.1	**11.1**	24.4	**1.8**	66.52	**1.7**	34.5	**1.3**
FHA	1	2	7	0	**11**	**31.32**	**19.6**	4.34	**7.2**	22	**0.9**	20.32	**1.5**	19.4	**1**
VCHA	2	2	1	0	**6**	**24.72**	**10.7**	2.28	**10.8**	10.4	**1**	10.19	**2.4**	9.7	**1.1**
VIHA	0	1	6	3	**10**	**40.04**	**17.9**	9.55	**4.2**	25.9	**0.7**	38.38	**1**	20.7	**0.9**
NHA	0	1	3	0	**4**	**30.53**	**7.1**	26.36	**1.2**	17.4	**0.4**	115.42	**0.3**	15.7	**0.5**
Age Group															
<18	0	0	0	0	**0**	**0**	**0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	7	8	21	14	**53**	**1.62**	**94.6**	1.39	**1.2**	46.1	**2.1**	10.62	**0.2**	58.6	**1.6**
65+	0	1	2	0	**3**	**0.3**	**5.4**	0.95	**0.3**	8.8	**0.6**	5.09	**0.1**	6.3	**0.9**
Gender															
Female	7	8	22	14	**54**	**2.08**	**96.4**	2.32	**0.9**	60.4	**1.6**	16.58	**0.1**	69.8	**1.4**
Male	0	1	1	0	**2**	**0.08**	**3.6**	1.56	**0.1**	39.6	**0.1**	7.26	**0**	30.2	**0.1**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

a Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

b Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

c Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

d Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

e Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

f Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

g Seious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

h Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

Vaccine information			Reports				Events																		Outcomes	
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Seizure count	Seizure rate[b]	Other paralysis count	Other paralysis rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
COVID-19 mRNA	Moderna mRNA-1273	3E+08	30	148.51	6	29.7	4	19.8	2	9.9	6	29.7	0	0	0	0	0	0	0	0	0	0	2	9.9	0	0	0	0
		3E+08	2	9.66	1	4.83	1	4.83	1	4.83	1	4.83	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		Moderna mRNA-1273 total	**32**	**78.24**	**7**	**17.11**	**5**	**12.22**	**3**	**7.33**	**7**	**17.11**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**4.89**	**0**	**0**	**0**	**0**
	Pfizer mRNA BNT162b2	EK4175	4	102.56	4	102.56	2	51.28	2	51.28	0	0	0	0	0	0	0	0	0	0	0	0	2	51.28	0	0	0	0
		EK4241	9	40.13	4	17.84	3	13.38	2	8.92	4	17.84	1	4.46	0	0	0	0	0	0	0	0	0	0	1	4.46	0	0
		EK4245	9	36.92	2	8.21	2	8.21	2	8.21	5	20.51	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		EL0203	1	3.54	1	3.54	1	3.54	1	3.54	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		EL1406	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
		Pfizer mRNA BNT162b2 total	**24**	**30.39**	**11**	**13.93**	**8**	**10.13**	**7**	**8.86**	**9**	**11.4**	**1**	**1.27**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**2.53**	**1**	**1.27**	**0**	**0**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**56**	**46.72**	**18**	**15.02**	**13**	**10.84**	**10**	**8.34**	**16**	**13.35**	**1**	**0.83**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**4**	**3.34**	**1**	**0.83**	**0**	**0**

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

a Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

b Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.

c Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

d Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

COVID-19 AEFI report BC Jan 28

From:	Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
To:	Henry, Bonnie [EXT] <bonnie.henry@gov.bc.ca>, Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Cc:	Rose, Caren [BCCDC] <Caren.Rose@bccdc.ca>, Lavoie, Martin <Martin.Lavoie@gov.bc.ca>, Amos, Heather [BCCDC] <heather.amos@bccdc.ca>, Gustafson, Reka [BCCDC] <reka.gustafson@phsa.ca>, Lavoie, Martin HLTH:EX <Martin.Lavoie@gov.bc.ca>
Sent:	January 28, 2021 10:07:10 AM PST
Attachments:	COVID19_AEFI_Summary_Report_2021-01-28.html

Good morning Bonnie

Here is today's cumulative AEFI report for BC.

Main points:
The most commonly reported events are allergic in nature, and include anaphylaxis which is a recognized and rare event that can occur with any vaccine. The reported rate of anaphylaxis in BC is about 1 case / 10,000 doses. All cases have been managed at the site and transferred for care to the ER; only one required hospitalization and all have recovered. A history of anaphylaxis to a dose of the vaccine is a contraindication to receipt of future doses.

We are seeing events reported as 'cellulitis' with an appreciably higher rate for the Moderna vaccine compared to Pfizer. We believe that these are likely not true cellulitis; none meet Brighton level 1 i.e., none were microbiologically confirmed. Some were not treated with antibiotics. The large differential rate between the products is consistent with the higher mRNA content (100 compared to 30 ug) per dose between the products; the mRNA acts as an adjuvant and this would be in keeping with what we see with adjuvanted vaccines and higher doses. These are likely large local reactions that are being managed as cellulitis preemptively by the care providers, but are not likely to be infections. This has been seen with other vaccines as well e.g., DPT-IPV compared to Tdap-IPV in younger children.

The one death was an inmate of a correctional facility s.13; s.22 and results of that investigation are pending. We may not have this information for some time given the length of time these can take to complete.

We have two temporally associated thrombocytopenia reports. This is NOT being seen in the US analytic data comparing rates of this event in vaccinees and compared to non-vaccinees; there was some media coverage of an O+G who died following COVID-19 vaccine in the US from this condition, but as you know this is associated with a variety of causes and the VSD rapid cycle analysis data are pretty solid (see slide 24):
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-01/06-COVID-Shimabukuro.pdf

Thank you,
Monika

. . . . . .

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell s.16
Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday) mnds.assist@bccdc.ca Tel 604 707 2519

I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

COVID-19 vaccine safety update

Advisory Committee on Immunization Practices (ACIP)
January 27, 2021

Tom Shimabukuro, MD, MPH, MBA
CDC COVID-19 Vaccine Task Force
Vaccine Safety Team

Page 017 of 217 to/à Page 051 of 217

Withheld pursuant to/removed as

Copyright

BROWN
School of Public Health

Genesis™

NIH National Institute on Aging

Genesis Healthcare analysis

This research was supported, in part, by a grant from the National Institute on Aging [5U54AG063546-02S5] with supplemental funding from the Centers for Disease Control and Prevention (CDC) under an inter-agency agreement.

BROWN
School of Public Health

Vaccine Safety Monitoring among Residents of 284 Genesis Skilled Nursing Facilities

On behalf of: Barbara Bardenheier, PhD, MPH, MA
Assistant Professor of Health Services, Policy, and Practice
Assistant Professor of Epidemiology
Brown University School of Public Health

BROWN
School of Public Health

Page 054 of 217 to/à Page 061 of 217

Withheld pursuant to/removed as

Copyright

World Health Organization

Health Topics | Countries | Newsroom | Emergencies | Data | About Us

Home / News / GACVS COVID-19 Vaccine Safety subcommittee meeting to review reports of deaths of very frail elderly individuals vaccinated with Pfizer BioNTech COVID-19 vaccine, BNT162b2

GACVS COVID-19 Vaccine Safety subcommittee meeting to review reports of deaths of very frail elderly individuals vaccinated with Pfizer BioNTech COVID-19 vaccine, BNT162b2

22 January 2021 | Statement | Reading time:

Related

https://www.who.int/news/item/22-01-2021-gacvs-review-deaths-pfizer-biontech-covid-19-vaccine-bnt162b2

Page 063 of 217 to/à Page 071 of 217

Withheld pursuant to/removed as

Copyright

BC COVID-19 AEFI Summary Report - January 28, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by January 25, 2021 there have been a total of 144,250 distributed doses. As of January 28, 2021, there have been 142 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 98.4 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 42 (29.6%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 195 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Jan 28, 2021 **(N=142)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-1	2021-2	2021-3	2021-4	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	12	41	51	27	**142**	**98.44**	**100.0**	6.50	**15.1**	100.0	**1.0**	32.30	**3.0**	100.0	**1.0**
Serious AEFI[g]	4	11	14	8	**42**	**29.12**	**29.6**	1.48	**19.7**	22.8	**1.3**	7.23	**4.0**	22.4	**1.3**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-1	2021-2	2021-3	2021-4	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
Events															
Anaphylaxis	3	8	8	2	**24**	**16.64**	**16.9**	0.47	**35.4**	7.3	**2.3**	2.70	**6.2**	8.3	**2.0**
Anaphylaxis Brighton levels 1/2/3[h]	1	6	3	0	**13**	**9.01**	**9.2**	0.19	**47.4**	2.8	**3.3**	NA	–	NA	–
Other allergic	4	16	18	8	**51**	**35.36**	**35.9**	2.09	**16.9**	32.1	**1.1**	5.64	**6.3**	17.5	**2.1**

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Jan 28, 2021 **(N=142)**

Vaccine information			Reports				Events											
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Enceph rate
COVID-19 mRNA	**Moderna mRNA-1273**	300042460	66	326.73	16	79.21	6	29.70	2	9.90	22	108.91	0	0.00	0	0.00	0	0.0

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event c

[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.

[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/re

[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

Vaccine information			Reports				Events											
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b],[c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b],[d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Enceph rate
		300042698	18	86.96	6	28.99	3	14.49	2	9.66	5	24.15	0	0.00	0	0.00	0	0.0
		Moderna mRNA-1273 total	**84**	**205.38**	**22**	**53.79**	**9**	**22.00**	**4**	**9.78**	**27**	**66.01**	**0**	**0.00**	**0**	**0.00**	**0**	**0.0**

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement (https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement)
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement (https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement)
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w (https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w)
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w (https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w)

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	Jan-21	Feb-21	Mar-21	Apr-21	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	12	41	51	27	**142**	**98.44**	**100**	6.5	**15.1**	100	**1**	32.3	**3**	100	**1**
Serious AEFI[g]	4	11	14	8	**42**	**29.12**	**29.6**	1.48	**19.7**	22.8	**1.3**	7.23	**4**	22.4	**1.3**
Events															
Anaphylaxis	3	8	8	2	**24**	**16.64**	**16.9**	0.47	**35.4**	7.3	**2.3**	2.7	**6.2**	8.3	**2**
Anaphylaxis Brighton levels 1/2/3[h]	1	6	3	0	**13**	**9.01**	**9.2**	0.19	**47.4**	2.8	**3.3**	NA	–	NA	–
Other allergic	4	16	18	8	**51**	**35.36**	**35.9**	2.09	**16.9**	32.1	**1.1**	5.64	**6.3**	17.5	**2.1**
Bell's Palsy	0	0	0	0	**1**	**0.69**	**0.7**	0.02	**34.5**	0.3	**2.3**	0.06	**11.5**	0.2	**3.5**
GBS	0	0	0	0	**0**	**0**	**0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0**	**0**	0.02	–	0.3	–	0	–	0	–
Meningitis	0	0	0	0	**0**	**0**	**0**	0	–	0	–	0.12	–	0.4	–
Other paralysis	0	0	0	0	**0**	**0**	**0**	0.05	–	0.8	–	0	–	0	–
Seizure	0	0	0	0	**0**	**0**	**0**	0.27	–	4.1	–	1.53	–	4.7	–
Thrombocytopenia	0	0	1	1	**2**	**1.39**	**1.4**	0.02	**69.5**	0.3	**4.7**	0	–	0	–
Cellulitis	1	3	4	5	**14**	**9.71**	**9.9**	0.27	**36**	4.1	**2.4**	0.31	**31.3**	0.9	**11**
Recommendations															
No further immunizations	0	1	0	0	**3**	**2.08**	**2.1**	0.24	**8.7**	3.6	**0.6**	0.67	**3.1**	2.1	**1**
Outcomes															
Hospitalization	0	0	0	0	**1**	**0.69**	**0.7**	0.19	**3.6**	2.8	**0.2**	3	**0.2**	9.3	**0.1**
Permanent disability	0	0	0	0	**0**	**0**	**0**	0	–	0	–	0	–	0	–
Death	0	0	1	0	**1**	**0.69**	**0.7**	0.02	**34.5**	0.3	**2.3**	0.18	**3.8**	0.6	**1.2**
Health Authority															
IHA	3	8	19	14	**49**	**179.65**	**34.5**	10.1	**17.8**	24.4	**1.4**	66.52	**2.7**	34.5	**1**
FHA	3	17	14	4	**41**	**91.36**	**28.9**	4.34	**21.1**	22	**1.3**	20.32	**4.5**	19.4	**1.5**
VCHA	3	6	5	0	**17**	**62.5**	**12**	2.28	**27.4**	10.4	**1.2**	10.19	**6.1**	9.7	**1.2**
VIHA	1	6	8	9	**24**	**80.4**	**16.9**	9.55	**8.4**	25.9	**0.7**	38.38	**2.1**	20.7	**0.8**
NHA	2	4	5	0	**11**	**73.09**	**7.7**	26.36	**2.8**	17.4	**0.4**	115.42	**0.6**	15.7	**0.5**
Age Group															
<18	0	0	0	0	**0**	**0**	**0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	10	39	46	19	**125**	**3.81**	**88**	1.39	**2.7**	46.1	**1.9**	10.62	**0.4**	58.6	**1.5**
65+	2	2	5	8	**17**	**1.72**	**12**	0.95	**1.8**	8.8	**1.4**	5.09	**0.3**	6.3	**1.9**
Gender															
Female	11	37	49	25	**133**	**5.12**	**93.7**	2.32	**2.2**	60.4	**1.6**	16.58	**0.3**	69.8	**1.3**
Male	1	4	2	2	**9**	**0.35**	**6.3**	1.56	**0.2**	39.6	**0.2**	7.26	**0**	30.2	**0.2**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

a Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

b Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

c Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

d Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

e Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

f Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

g Seious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

h Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

Vaccine information			Reports				Events																		Outcomes			
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Seizure count	Seizure rate[b]	Other paralysis count	Other paralysis rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
COVID-19 mRNA	Moderna mRNA-1273	3E+08	66	326.73	16	79.21	6	29.7	2	9.9	22	108.91	0	0	0	0	0	0	0	0	0	0	9	44.55	0	0	1	4.95
		3E+08	18	86.96	6	28.99	3	14.49	2	9.66	5	24.15	0	0	0	0	0	0	0	0	0	0	2	9.66	0	0	0	0
		Moderna mRNA-1273 total	**84**	**205.38**	**22**	**53.79**	**9**	**22**	**4**	**9.78**	**27**	**66.01**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**11**	**26.89**	**0**	**0**	**1**	**2.44**
	Pfizer mRNA BNT162b2	EK4175	7	179.49	4	102.56	2	51.28	2	51.28	1	25.64	0	0	0	0	0	0	0	0	0	0	2	51.28	0	0	0	0
		EK4241	13	57.97	5	22.3	3	13.38	2	8.92	6	26.76	1	4.46	0	0	0	0	0	0	0	0	0	0	1	4.46	0	0
		EK4245	17	69.74	2	8.21	2	8.21	2	8.21	9	36.92	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		EL0203	14	49.51	5	17.68	5	17.68	3	10.61	5	17.68	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		EL1406	7	28.72	4	16.41	3	12.31	0	0	3	12.31	0	0	0	0	0	0	0	0	0	0	1	4.1	0	0	0	0
		Pfizer mRNA BNT162b2 total	**58**	**56.12**	**20**	**19.35**	**15**	**14.51**	**9**	**8.71**	**24**	**23.22**	**1**	**0.97**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3**	**2.9**	**1**	**0.97**	**0**	**0**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**142**	**98.44**	**42**	**29.12**	**24**	**16.64**	**13**	**9.01**	**51**	**35.36**	**1**	**0.69**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**14**	**9.71**	**1**	**0.69**	**1**	**0.69**

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

a Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

b Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.

c Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

d Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

delayed local reactions after mRNA Moderna COVID vaccine

From: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>

To: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>, XT:Naus, Monika HLTH:IN <monika.naus@bccdc.ca>

Sent: February 10, 2021 10:52:01 AM PST

Dear BCIC, MHO, Vaccine Safety working group and HealthLinkBC colleagues

We are receiving an increasing number of reports unfamiliar to health care professionals accustomed to local reactions after vaccines, of unusual local reactions following the Moderna vaccine, in which there may be an initial local reaction (pain, redness and swelling at the injection site), which resolves over a few days, and then returns around days 8-10 after vaccine receipt and may be accompanied by an unusual appearing area of ringed erythema as well as pruritus. These events may be biphasic as I've outlined, or simply delayed local reactions. In some instances, it appears that these types of reactions are being reported as 'cellulitis', but none of the cellulitis reports received to date have been microbiologically confirmed and some of these do not appear to have been treated with antibiotics, suggesting that these are not cellulitis after all.

These events, if not meeting the severity criteria for reporting of AEFI, are not 'reportable' as AEFI, and are 'expected' events. While these are seen in a small proportion of recipients, given the large number of doses of Moderna vaccine that will be administered in BC, the number of such reports would be overwhelming for reporting. Please share this information with those involved in reporting of AEFI in order to ensure they're familiar with this phenomenon.

There is a reference to this type of event observed in a small number of phase 3 clinical trial participants in the Moderna submission to the US FDA for the Emergency Use Authorization at the December 17th VRBPAC meeting:

https://www.fda.gov/media/144452/download

At the bottom of page 58 of the above document, there is this paragraph :

> "Several participants reported injection site reactions after Day 7 that were characterized by erythema, induration, and often pruritis. A review of these events showed that the vast majority of the unsolicited TEAEs categorized as local injection or vaccination site reactions in the second week after immunization were a subset of the solicited local AR with a duration beyond Day 7. Consultation with a dermatopathologist suggested that these were most likely dermal hypersensitivity reactions and were unlikely to represent a long term safety concern."

We have further confirmed with Moderna the following:

- a biphasic local reaction was seen in about 1% of recipients, and largely with dose 1 and without potentiation with dose 2. Redness, and swelling, and often itchiness, which had occurred initially, resolved and then recurred around day 8.
- In addition to the biphasic reaction, there were also reports from individuals who did not have redness and swelling in the first few days after vaccination, but who had a late onset reaction, again around day 8-10, as outlined above.

As well, Moderna Medical Information has provided the following additional information on February 9th:

> "Delayed injection-site reactions (> Day 8 after vaccination) were reported in 244 COVE Phase 3 clinical study participants (0.8%) after the first dose and in 68 participants (0.2%) after the second dose. These delayed reactions included erythema, induration, tenderness, and occasionally pruritus and are thought to represent dermal hypersensitivity. They resolved after 4 to 5 days. Topical corticosteroids and diphenhydramine were occasionally used to manage symptoms. Study participants who experienced delayed injection-site reactions after the first dose continued on to receive the second vaccine dose with no additional adverse reactions."

We will be incorporating this information into the clinical materials supporting Moderna mRNA vaccine administration, including the biologicals product page for this vaccine, and the aftercare form.

We are producing regular reports of the AEFIs reported by public health, and these are updated and posted daily Monday through Friday in the SharePoint site at the following link. All HA members of BCIC and the Vaccine Safety working group are set up to access this information. For those MHOs who don't currently have access, if you would like to 'self-serve' retrieval of these reports please click link and it will take you to a page from which you can submit a request for access.

Thank you,
Monika

. . . . . .

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell s.16
Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday) mnds.assist@bccdc.ca Tel 604 707 2519

I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

Vaccines and Related Biological Products Advisory Committee Meeting Presentation

Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

MRNA-1273

SPONSOR BRIEFING DOCUMENT

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

MEETING DATE: 17 DECEMBER 2020

AVAILABLE FOR PUBLIC RELEASE

Page 083 of 217 to/à Page 164 of 217

Withheld pursuant to/removed as

Copyright

AEFI report from today

From:	Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
To:	Henry, Bonnie [EXT] <bonnie.henry@gov.bc.ca>, Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Cc:	Amos, Heather [BCCDC] <heather.amos@bccdc.ca>, Gustafson, Reka [BCCDC] <reka.gustafson@phsa.ca>, XT:Amos, Heather HLBC:IN <heather.amos@bccdc.ca>
Sent:	March 11, 2021 1:47:19 PM PST
Attachments:	COVID19_AEFI_Summary_Report_2021-03-11.html

Hi Bonnie

This is today's report. You will also see my note about the AstraZeneca suspension. Nothing concerning based on BC rates but we are continuing to see anaphylaxis reported at higher rates than the Canadian average; we are apparently not the highest P/T but in the top 3. We are reviewing these on a case by case basis and are doing the Brighton leveling; it's clear that some people are being overtreated e.g., 'vomiting 5 minutes after receiving vaccine; received adrenaline'.

We have had 4 Bell's reported and this is signaling against influenza vaccine (PRR) with 2 expected, 4 reported. But as you know this signal as questioned in both mRNA trials and not seen in the US VSD to date.

Apologies that I've been in back to back meetings all day and trying to get the information together about the AstraZeneca lot hold.

We will be producing a public facing report (the enclosed is for public health, and accessible on SharePoint for MHOs/ others) shortly, and updating – we can do weekly for now and then perhaps drop down to q2 weeks.

Thank you,
Monika

. . . . . .

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell s.16
Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday) mnds.assist@bccdc.ca Tel 604 707 2519

I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

BC COVID-19 AEFI Summary Report - March 11, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by March 08, 2021 there have been a total of 378,340 distributed doses. As of March 11, 2021, there have been 450 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 118.9 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 115 (25.6%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 615 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Mar 11, 2021 **(N=450)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-07	2021-08	2021-09	2021-10	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	30	54	57	12	**450**	**118.94**	**100.0**	6.50	**18.3**	100.0	**1.0**	32.30	**3.7**	100.0	**1.0**
Serious AEFI[g]	8	15	21	4	**115**	**30.40**	**25.6**	1.48	**20.5**	22.8	**1.1**	7.23	**4.2**	22.4	**1.1**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-07	2021-08	2021-09	2021-10	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
Events															
Anaphylaxis	6	12	15	2	**71**	**18.77**	**15.8**	0.47	**39.9**	7.3	**2.2**	2.70	**7.0**	8.3	**1.9**
Anaphylaxis Brighton levels 1/2/3[h]	5	8	6	2	**41**	**10.84**	**9.1**	0.19	**57.1**	2.8	**3.2**	NA	–	NA	–
Other allergic	18	24	20	6	**185**	**48.90**	**41.1**	2.09	**23.4**	32.1	**1.3**	5.64	**8.7**	17.5	**2.3**

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Mar 11, 2021 **(N=450)**

Vaccine information			Reports				Events											
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Enceph rate
COVID-19 mRNA	**Moderna mRNA-1273**	300042460	110	544.55	22	108.91	7	34.65	3	14.85	38	188.12	0	0.00	0	0.00	0	0.0

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event c

[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report or the lot number w

[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/re

[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

Vaccine information		Reports					Events										
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b],[c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b],[d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Enceph rate
		300042698	67	323.67	16	77.29	5	24.15	3	14.49	22	106.28	1	4.83	0	0.00	0	0.0
		300042722	16	71.11	3	13.33	2	8.89	2	8.89	9	40.00	0	0.00	0	0.00	0	0.0
		3000489	7	34.83	1	4.98	1	4.98	0	0.00	1	4.98	0	0.00	0	0.00	0	0.0

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement (https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement)
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement (https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement)
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w (https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w)
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w (https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w)

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	Jul-21	Aug-21	Sep-21	Oct-21	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	30	54	57	12	**450**	**118.94**	**100**	6.5	**18.3**	100	**1**	32.3	**3.7**	100	**1**
Serious AEFI[g]	8	15	21	4	**115**	**30.4**	**25.6**	1.48	**20.5**	22.8	**1.1**	7.23	**4.2**	22.4	**1.1**
Events															
Anaphylaxis	6	12	15	2	**71**	**18.77**	**15.8**	0.47	**39.9**	7.3	**2.2**	2.7	**7**	8.3	**1.9**
Anaphylaxis Brighton levels 1/2/3[h]	5	8	6	2	**41**	**10.84**	**9.1**	0.19	**57.1**	2.8	**3.2**	NA	–	NA	–
Other allergic	18	24	20	6	**185**	**48.9**	**41.1**	2.09	**23.4**	32.1	**1.3**	5.64	**8.7**	17.5	**2.3**
Bell's Palsy	1	0	1	0	**4**	**1.06**	**0.9**	0.02	**53**	0.3	**3**	0.06	**17.7**	0.2	**4.5**
GBS	0	0	0	0	**0**	**0**	**0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0**	**0**	0.02	–	0.3	–	0	–	0	–
Other paralysis	0	0	0	0	**0**	**0**	**0**	0.05	–	0.8	–	0	–	0	–
Seizure	0	0	0	1	**1**	**0.26**	**0.2**	0.27	**1**	4.1	**0**	1.53	**0.2**	4.7	**0**
Anaesthesia/ paraesthesia[i]	3	7	4	1	**31**	**8.19**	**6.9**	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	0	0	0	0	**2**	**0.53**	**0.4**	0.02	**26.5**	0.3	**1.3**	0	–	0	–
Cellulitis	0	0	1	0	**24**	**6.34**	**5.3**	0.27	**23.5**	4.1	**1.3**	0.31	**20.5**	0.9	**5.9**
Adenopathy/ lymphadenitis	0	1	3	1	**17**	**4.49**	**3.8**	0.07	**64.1**	1	**3.8**	0.43	**10.4**	1.3	**2.9**
Recommendations															
No further immunizations	5	9	2	0	**29**	**7.67**	**6.4**	0.25	**30.7**	3.9	**1.6**	0.67	**11.4**	2.1	**3**
Outcomes															
Hospitalization	2	1	2	1	**10**	**2.64**	**2.2**	0.19	**13.9**	2.8	**0.8**	3	**0.9**	9.3	**0.2**
Permanent disability	0	0	0	0	**0**	**0**	**0**	0	–	0	–	0	–	0	–
Death	1	0	0	1	**3**	**0.79**	**0.7**	0.02	**39.5**	0.3	**2.3**	0.18	**4.4**	0.6	**1.2**
Health Authority															
IHA	6	17	18	7	**122**	**181.26**	**27.1**	10.1	**17.9**	24.4	**1.1**	66.52	**2.7**	34.5	**0.8**
FHA	9	18	12	1	**110**	**87.98**	**24.4**	4.34	**20.3**	22	**1.1**	20.32	**4.3**	19.4	**1.3**
VCHA	9	9	11	0	**82**	**100.76**	**18.2**	2.28	**44.2**	10.4	**1.7**	10.19	**9.9**	9.7	**1.9**
VIHA	1	8	14	3	**92**	**127.07**	**20.4**	9.55	**13.3**	25.9	**0.8**	38.38	**3.3**	20.7	**1**
NHA	5	2	2	1	**44**	**136.54**	**9.8**	26.36	**5.2**	17.4	**0.6**	115.42	**1.2**	15.7	**0.6**
Age Group															
<18	0	0	0	0	**0**	**0**	**0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	27	46	50	11	**390**	**11.9**	**86.7**	1.39	**8.6**	46.1	**1.9**	10.62	**1.1**	58.6	**1.5**
65+	3	8	7	1	**60**	**6.09**	**13.3**	0.95	**6.4**	8.8	**1.5**	5.09	**1.2**	6.3	**2.1**
Gender															
Female	25	44	48	9	**403**	**15.53**	**89.6**	2.32	**6.7**	60.4	**1.5**	16.58	**0.9**	69.8	**1.3**
Male	5	10	9	3	**47**	**1.85**	**10.4**	1.56	**1.2**	39.6	**0.3**	7.26	**0.3**	30.2	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

a Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

b Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

c Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

d Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

e Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

f Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

g Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

h Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

i Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Vaccine information			Reports						Events																		Outcomes	
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
COVID-19 mRNA	Moderna mRNA-1273	3E+08	110	544.55	22	108.91	7	34.65	3	14.85	38	188.12	0	0	0	0	0	0	0	0	0	0	2	9.9	13	64.36	1	4.95	1	4.95
		3E+08	67	323.67	16	77.29	5	24.15	3	14.49	22	106.28	1	4.83	0	0	0	0	0	0	0	0	3	14.49	8	38.65	1	4.83	1	4.83
		3E+08	16	71.11	3	13.33	2	8.89	2	8.89	9	40	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	4.44	0	0
		3000489	7	34.83	1	4.98	1	4.98	0	0	1	4.98	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		Unknown	1	NA	1	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
		Moderna mRNA-1273 total	**201**	**240.72**	**43**	**51.5**	**16**	**19.16**	**8**	**9.58**	**70**	**83.83**	**1**	**1.2**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**5**	**5.99**	**21**	**25.15**	**3**	**3.59**	**2**	**2.4**
	Pfizer mRNA BNT162b2	EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0	0	0	0	0	0	0	0	0	1	25.64	2	51.28	0	0	0	0
		EK4241	32	142.7	5	22.3	3	13.38	2	8.92	14	62.43	1	4.46	0	0	0	0	0	0	0	0	1	4.46	0	0	1	4.46	0	0
		EK4245	31	127.18	3	12.31	2	8.21	2	8.21	14	57.44	0	0	0	0	0	0	0	0	0	0	5	20.51	0	0	0	0	0	0
		EL0140	19	121.79	6	38.46	5	32.05	2	12.82	8	51.28	0	0	0	0	0	0	0	0	0	0	3	19.23	0	0	0	0	0	0
		EL0203	45	159.15	10	35.37	6	21.22	4	14.15	26	91.95	2	7.07	0	0	0	0	0	0	0	0	5	17.68	0	0	2	7.07	0	0
		EL1404	1	17.09	1	17.09	1	17.09	1	17.09	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		EL1406	37	151.79	7	28.72	6	24.62	2	8.21	20	82.05	0	0	0	0	0	0	0	0	0	0	6	24.62	1	4.1	0	0	0	0
		EP6017	40	89.19	19	42.36	18	40.13	10	22.3	14	31.22	0	0	0	0	0	0	0	0	0	0	5	11.15	0	0	2	4.46	0	0
		EP6775	29	45.07	12	18.65	8	12.43	5	7.77	15	23.31	0	0	0	0	0	0	0	0	1	1.55	0	0	0	0	2	3.11	0	0
		ER1742	6	9.86	5	8.22	4	6.57	3	4.93	2	3.29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1.64
		Pfizer mRNA BNT162b2 total	**249**	**84.45**	**72**	**24.42**	**55**	**18.65**	**33**	**11.19**	**115**	**39**	**3**	**1.02**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0.34**	**26**	**8.82**	**3**	**1.02**	**7**	**2.37**	**1**	**0.34**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**450**	**118.94**	**115**	**30.4**	**71**	**18.77**	**41**	**10.84**	**185**	**48.9**	**4**	**1.06**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0.26**								

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

a Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

b Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.

c Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

d Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

higher rates of anaphylaxis associated with one of the Pfizer lots

From:	Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
To:	Henry, Bonnie [EXT] <bonnie.henry@gov.bc.ca>, Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Cc:	Gustafson, Reka [BCCDC] <reka.gustafson@phsa.ca>
Sent:	March 11, 2021 7:25:59 PM PST
Attachments:	COVID19_AEFI_Summary_Report_2021-03-11.html

Hi Bonnie

As we just discussed, we notified the feds today that we have noted a higher rate of reported anaphylaxis with one lot of the Pfizer vaccine. We asked them to take a look at the lot specific anaphylaxis rates for the Pfizer vaccine to see whether this is being noted elsewhere in the country, or whether we are the only place reporting high rates. We know that overall BC is reporting higher rates of anaphylaxis - appreciably higher than US, where they reported 11 per million doses, and in asking PHAC where we figure compared to the rest of the country, we are in the top 3, apparently, by P/T.

I don't know how many doses there are per lot. I know for other vaccines, it's often in the ballpark of 250K doses.

Here is the relevant information:

BC has received a total of 18 AEFI reports for events managed as anaphylaxis following a dose of the Pfizer COVID-19 mRNA vaccine lot number EP6017. There were 44,850 doses of this lot distributed in BC (shipped February 17), for a rate of anaphylaxis of 40 per 100,000 doses distributed. These events constitute 33% of all anaphylaxis events reported following receipt of Pfizer mRNA vaccine in BC, for which the overall anaphylaxis reporting rate has been 18.7 per 100,000. This lot accounts for about 12% of Pfizer mRNA doses distributed in BC to date.

Ten of the anaphylaxis reports were assessed as meeting the Brighton Collaboration anaphylaxis case definition levels 1, 2, or 3 criteria of diagnostic certainty (rate of 22 per 100,000 doses distributed). Two individuals were admitted to hospital following the anaphylaxis event. One of the hospitalized cases was hospitalized not because of anaphylaxis but because they received 3 doses of adrenaline and had a cardiac event (not an MI, but arrythmia). Both recovered fully. There were also 13 other allergic events reported for the same lot number, accounting for about 12% of allergic events following Pfizer mRNA vaccine in BC (in line with this being 12% of Pfizer doses distributed); the lot-specific rate of allergic events was somewhat lower than the overall provincial rate for this vaccine.

Reports were received from all BC health authorities. Fifteen of the individuals were female, and the average age was 46 (range 23-68).

Today's full daily report of our AEFI is enclosed (same as I sent you earlier today); the 18 AEFI reports were reported by all regions and we will run the regional rates tomorrow to look if there was much off at that level.

s.13

Thank you,
Monika

. . . . . .

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell s.16
Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday) mnds.assist@bccdc.ca Tel 604 707 2519

I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

Fwd: AEFI report

From: Nicola Lambrechts <nicola@nlkstrategies.ca>
To: Bonnie Henry <Bonnie.henry@gov.bc.ca>, Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Sent: March 15, 2021 9:57:15 AM PDT
Attachments: COVID19_AEFI_Summary_Report_2021-03-15.html

FYI

Begin forwarded message:

From: "Amos, Heather [BCCDC]" <heather.amos@bccdc.ca>
Subject: RE: AEFI report
Date: March 15, 2021 at 9:55:31 AM PDT
To: "NLK_Strategies, Nicola" <Nicola@nlkstrategies.ca>

Hi,

We don't get updated rates in time on Mondays so here are the counts:

	Cumulative COVID19 Count
Total AEFI	469
Serious AEFI	124
Anaphylaxis	79
Anaphylaxis Brighton levels 1/2/3	46
Other allergic	189

Heather

From: Nicola Lambrechts [mailto:nicola@nlkstrategies.ca]
Sent: Monday, March 15, 2021 9:15 AM
To: Amos, Heather [BCCDC]
Subject: Re: AEFI report

Sure! Thank you.

Nicola Lambrechts
nicola@nlkstrategies.ca
604-970-9113

On Mar 15, 2021, at 9:07 AM, Amos, Heather [BCCDC] <heather.amos@bccdc.ca> wrote:

See attached. Would you like me to see if I can an update today?

From: Nicola Lambrechts [mailto:nicola@nlkstrategies.ca]
Sent: Monday, March 15, 2021 9:06 AM
To: Amos, Heather [BCCDC]
Subject: AEFI report

Hi Heather - Would you mind please sending me the weekly AEFI report?

Thank you,
Nicola

Nicola Lambrechts
NLK Strategies
604.970.9113
nicola@nlkstrategies.ca
www.nlkstrategies.ca

<mime-attachment>

Nicola Lambrechts
NLK Strategies
604.970.9113
nicola@nlkstrategies.ca

www.nlkstrategies.ca

BC COVID-19 AEFI Summary Report - March 15, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by March 15, 2021 there have been a total of 378,340 distributed doses. As of March 15, 2021, there have been 469 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 124.0 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 124 (26.4%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 646 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Mar 15, 2021 **(N=469)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-08	2021-09	2021-10	2021-11	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	56	61	25	0	**469**	**123.96**	**100.0**	6.50	**19.1**	100.0	**1.0**	32.36	**3.8**	100.0	**1.0**
Serious AEFI[g]	16	23	9	0	**124**	**32.77**	**26.4**	1.48	**22.1**	22.8	**1.2**	7.23	**4.5**	22.3	**1.2**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-08	2021-09	2021-10	2021-11	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
Events															
Anaphylaxis	13	17	7	0	**79**	**20.88**	**16.8**	0.47	**44.4**	7.3	**2.3**	2.70	**7.7**	8.3	**2.0**
Anaphylaxis Brighton levels 1/2/3[h]	8	8	5	0	**46**	**12.16**	**9.8**	0.19	**64.0**	2.8	**3.5**	NA	–	NA	–
Other allergic	25	22	7	0	**189**	**49.96**	**40.3**	2.09	**23.9**	32.1	**1.3**	5.70	**8.8**	17.6	**2.3**

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Mar 15, 2021 **(N=469)**

Vaccine information			Reports				Events											
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Enceph rate
COVID-19 mRNA	**Moderna mRNA-1273**	300042460	110	544.55	23	113.86	7	34.65	3	14.85	38	188.12	0	0.00	0	0.00	0	0.0

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event c

[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report or the lot number w

[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the fol

[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

Vaccine information		Reports					Events										
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b],[c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b],[d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Enceph rate
		300042698	68	328.50	16	77.29	5	24.15	3	14.49	22	106.28	1	4.83	0	0.00	0	0.0
		300042722	19	84.44	4	17.78	3	13.33	3	13.33	10	44.44	0	0.00	0	0.00	0	0.0
		3000489	7	34.83	1	4.98	1	4.98	0	0.00	1	4.98	0	0.00	0	0.00	0	0.0

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement (https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement)
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement (https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement)
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w (https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w)
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w (https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w)

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	Aug-21	Sep-21	Oct-21	Nov-21	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	56	61	25	0	**469**	**123.96**	**100**	6.5	**19.1**	100	**1**	32.36	**3.8**	100	**1**
Serious AEFI[g]	16	23	9	0	**124**	**32.77**	**26.4**	1.48	**22.1**	22.8	**1.2**	7.23	**4.5**	22.3	**1.2**
Events															
Anaphylaxis	13	17	7	0	**79**	**20.88**	**16.8**	0.47	**44.4**	7.3	**2.3**	2.7	**7.7**	8.3	**2**
Anaphylaxis Brighton levels 1/2/3[h]	8	8	5	0	**46**	**12.16**	**9.8**	0.19	**64**	2.8	**3.5**	NA	**–**	NA	**–**
Other allergic	25	22	7	0	**189**	**49.96**	**40.3**	2.09	**23.9**	32.1	**1.3**	5.7	**8.8**	17.6	**2.3**
Bell's Palsy	0	1	0	0	**4**	**1.06**	**0.9**	0.02	**53**	0.3	**3**	0.06	**17.7**	0.2	**4.5**
GBS	0	0	0	0	**0**	**0**	**0**	0.03	**–**	0.5	**–**	0.12	**–**	0.4	**–**
Encephalitis	0	0	0	0	**0**	**0**	**0**	0.02	**–**	0.3	**–**	0	**–**	0	**–**
Transverse myelitis	1	0	0	0	**1**	**0.26**	**0.2**	0	**–**	0	**–**	0	**–**	0	**–**
Seizure	0	0	1	0	**1**	**0.26**	**0.2**	0.27	**1**	4.1	**0**	1.53	**0.2**	4.7	**0**
Anaesthesia/ paraesthesia[i]	7	4	6	0	**36**	**9.52**	**7.7**	NA	**–**	NA	**–**	NA	**–**	NA	**–**
Thrombocytopenia	0	0	0	0	**2**	**0.53**	**0.4**	0.02	**26.5**	0.3	**1.3**	0	**–**	0	**–**
Cellulitis	0	1	0	0	**24**	**6.34**	**5.1**	0.27	**23.5**	4.1	**1.2**	0.31	**20.5**	0.9	**5.7**
Adenopathy/ lymphadenitis	1	3	2	0	**18**	**4.76**	**3.8**	0.07	**68**	1	**3.8**	0.43	**11.1**	1.3	**2.9**
Recommendations															
No further immunizations	9	3	2	0	**34**	**8.99**	**7.2**	0.25	**36**	3.9	**1.8**	0.67	**13.4**	2.1	**3.4**
Outcomes															
Hospitalization	1	3	2	0	**12**	**3.17**	**2.6**	0.19	**16.7**	2.8	**0.9**	3	**1.1**	9.3	**0.3**
Permanent disability	0	0	0	0	**0**	**0**	**0**	0	**–**	0	**–**	0	**–**	0	**–**
Death	0	0	1	0	**3**	**0.79**	**0.6**	0.02	**39.5**	0.3	**2**	0.18	**4.4**	0.6	**1**
Health Authority															
IHA	17	18	9	0	**124**	**184.24**	**26.4**	10.1	**18.2**	24.4	**1.1**	66.52	**2.8**	34.5	**0.8**
FHA	19	16	10	0	**124**	**99.18**	**26.4**	4.34	**22.9**	22	**1.2**	20.32	**4.9**	19.3	**1.4**
VCHA	9	11	1	0	**83**	**101.99**	**17.7**	2.28	**44.7**	10.4	**1.7**	10.19	**10**	9.7	**1.8**
VIHA	8	14	3	0	**92**	**127.07**	**19.6**	9.55	**13.3**	25.9	**0.8**	38.38	**3.3**	20.6	**1**
NHA	3	2	2	0	**46**	**142.75**	**9.8**	26.36	**5.4**	17.4	**0.6**	116.81	**1.2**	15.9	**0.6**
Age Group															
<18	0	0	0	0	**0**	**0**	**0**	5.03	**–**	45.1	**–**	21.73	**–**	35	**–**
18-64	48	53	23	0	**407**	**12.42**	**86.8**	1.39	**8.9**	46.1	**1.9**	10.62	**1.2**	58.5	**1.5**
65+	8	8	2	0	**62**	**6.29**	**13.2**	0.95	**6.6**	8.8	**1.5**	5.24	**1.2**	6.4	**2.1**
Gender															
Female	45	52	22	0	**421**	**16.22**	**89.8**	2.32	**7**	60.4	**1.5**	16.63	**1**	69.9	**1.3**
Male	11	9	3	0	**48**	**1.89**	**10.2**	1.56	**1.2**	39.6	**0.3**	7.26	**0.3**	30.1	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

a Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

b Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

c Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

d Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

e Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

f Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

g Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

h Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

i Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Vaccine information			Reports						Events																		Outcomes			
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Transverse myelitis count	Transverse myelitis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
COVID-19 mRNA	Moderna mRNA-1273	3E+08	110	544.55	23	113.86	7	34.65	3	14.85	38	188.12	0	0	0	0	0	0	0	0	0	0	2	9.9	13	64.36	1	4.95	1	4.95
		3E+08	68	328.5	16	77.29	5	24.15	3	14.49	22	106.28	1	4.83	0	0	0	0	1	4.83	0	0	3	14.49	8	38.65	1	4.83	1	4.83
		3E+08	19	84.44	4	17.78	3	13.33	3	13.33	10	44.44	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	4.44	0	0
		3000489	7	34.83	1	4.98	1	4.98	0	0	1	4.98	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		Unknown	1	NA	1	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
		Moderna mRNA-1273 total	**205**	**245.51**	**45**	**53.89**	**17**	**20.36**	**9**	**10.78**	**71**	**85.03**	**1**	**1.2**	**0**	**0**	**0**	**0**	**1**	**1.2**	**0**	**0**	**5**	**5.99**	**21**	**25.15**	**3**	**3.59**	**2**	**2.4**
	Pfizer mRNA BNT162b2	EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0	0	0	0	0	0	0	0	0	1	25.64	2	51.28	0	0	0	0
		EK4241	32	142.7	5	22.3	3	13.38	2	8.92	14	62.43	1	4.46	0	0	0	0	0	0	0	0	1	4.46	0	0	1	4.46	0	0
		EK4245	31	127.18	3	12.31	2	8.21	2	8.21	14	57.44	0	0	0	0	0	0	0	0	0	0	5	20.51	0	0	0	0	0	0
		EL0140	20	128.21	6	38.46	5	32.05	2	12.82	8	51.28	0	0	0	0	0	0	0	0	0	0	3	19.23	0	0	0	0	0	0
		EL0203	47	166.22	10	35.37	6	21.22	4	14.15	27	95.49	2	7.07	0	0	0	0	0	0	0	0	5	17.68	0	0	2	7.07	0	0
		EL1404	1	17.09	1	17.09	1	17.09	1	17.09	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		EL1406	37	151.79	7	28.72	6	24.62	2	8.21	20	82.05	0	0	0	0	0	0	0	0	0	0	6	24.62	1	4.1	0	0	0	0
		EP6017	40	89.19	19	42.36	18	40.13	10	22.3	14	31.22	0	0	0	0	0	0	0	0	0	0	6	13.38	0	0	2	4.46	0	0
		EP6775	35	54.39	14	21.76	10	15.54	6	9.32	16	24.86	0	0	0	0	0	0	0	0	1	1.55	2	3.11	0	0	3	4.66	0	0
		ER1742	11	18.08	9	14.79	8	13.15	5	8.22	3	4.93	0	0	0	0	0	0	0	0	0	0	2	3.29	0	0	1	1.64	1	1.64
		ER1742-CC01	1	NA	1	NA	1	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
		Pfizer mRNA BNT162b2 total	**264**	**89.54**	**79**	**26.79**	**62**	**21.03**	**37**	**12.55**	**118**	**40.02**	**3**	**1.02**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0.34**	**31**	**10.51**	**3**	**1.02**	**9**	**3.05**	**1**	**0.34**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**469**	**123.96**	**124**	**32.77**	**79**	**20.88**	**46**	**12.16**	**189**	**49.96**	**4**	**1.06**	**0**	**0**	**0**	**0**	**1**	**0.26**	**1**	**0.26**	**36**	**9.52**	**24**	**6.34**	**12**	**3.17**	**3**	**0.79**

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

a Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

b Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.

c Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

d Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

RE: Concern about the risk of CSVT associated with AZ vaccine

From:	Gustafson, Reka [BCCDC] <reka.gustafson@phsa.ca>
To:	Henry, Bonnie [EXT] <bonnie.henry@gov.bc.ca>, Galanis, Eleni [BCCDC] <Eleni.Galanis@bccdc.ca>, XT:HLTH Galanis, Eleni <eleni.galanis@bccdc.ca>, Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Cc:	Skowronski, Danuta [BCCDC] <Danuta.Skowronski@bccdc.ca>, Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>, Patrick, David [BCCDC] <David.Patrick@bccdc.ca>, XT:Naus, Monika HLTH:IN <monika.naus@bccdc.ca>, XT:Patrick, David HLTH:IN <david.patrick@bccdc.ca>
Sent:	March 25, 2021 3:57:55 PM PDT

Hi Bonnie,

I spoke with Monika and she will be bringing considerations for discussion to PHEC tomorrow.

Thank you

Reka

Dr. Réka Gustafson MD FRCPC
Vice President, Public Health and Wellness, PHSA & Deputy Provincial Health Officer
Provincial Health Services Authority

From: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Sent: Thursday, March 25, 2021 3:13 PM
To: Galanis, Eleni [BCCDC] <Eleni.Galanis@bccdc.ca>
Cc: Skowronski, Danuta [BCCDC] <Danuta.Skowronski@bccdc.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>; Gustafson, Reka [BCCDC] <reka.gustafson@phsa.ca>; Patrick, David [BCCDC] <David.Patrick@bccdc.ca>
Subject: RE: Concern about the risk of CSVT associated with AZ vaccine

---

Thank you. I am aware of the data that you have seen and Danuta shared her synopsis. We have also discussed in some detail at SAC and with my CMHO colleagues. We will be discussing again at 5.
Needless-to-say I take this very seriously and have been following very closely and considering all options.
Bonnie

Dr Bonnie Henry
Provincial Health Officer
Office of the PHO
Ministry of Health
s.15; s.19
Mailing address: PO Box 9648, STN PROV GOVT
Victoria, BC
V8W 9P4
Bonnie.henry@gov.bc.ca

Phone: s.17; s.19

I gratefully acknowledge that I live and work on the traditional unceded territory of the Lekwungen Peoples, specifically the Songhees and Esquimalt First Nations. Hay'sxw'qu Si'em

---

From: Galanis, Eleni [BCCDC] <Eleni.Galanis@bccdc.ca>
Sent: March 25, 2021 3:10 PM
To: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Cc: Skowronski, Danuta [BCCDC] <Danuta.Skowronski@bccdc.ca>; XT:Naus, Monika HLTH:IN <monika.naus@bccdc.ca>; Gustafson, Reka [BCCDC] <reka.gustafson@phsa.ca>; XT:Patrick, David HLTH:IN <david.patrick@bccdc.ca>
Subject: Concern about the risk of CSVT associated with AZ vaccine

Hi Bonnie,
The BCCDC COVID19 Oversight Cmte met yesterday and was presented with a summary of European CSVT cases following AstraZeneca (AZ) vaccination by Danuta. As chair of this cmte, I want to share my high level of concern with the findings, namely:

- Severe nature of the AEFI (high case fatality and sequelae risk)
- Young age of cases
- Unusual features which make this a unique clinical phenotype
- Excess risk associated with AZ vaccination

I urge that decision-makers review this information as soon as possible to consider whether to pause the use of the AZ/COVISHIELD vaccine until further investigations are completed, to understand the extent of risk for BC residents.
Eleni

Eleni Galanis, MD, MPH, FRCPC
Physician Epidemiologist
BC Centre for Disease Control 655 W12th Ave. Vancouver BC V5Z 4R4
(t) 604-707-2558 (f) 604-707-2516 (c) s.16

Re: concerning adverse reactions to Pfizer vaccine

From: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
To: XT:Naus, Monika HLTH:IN <monika.naus@bccdc.ca>
Cc: Gustafson, Reka [BCCDC] <reka.gustafson@phsa.ca>, XT:Ballem, Penny HLTH:IN <pballem@telus.net>
Sent: March 25, 2021 7:48:40 AM PDT

Thanks Monika,
That would be good. Perhaps connect with Jong in the north first so he is aware.
Bonnie

Dr Bonnie Henry
Provincial Health Officer
Ministry of Health
Bonnie.henry@gov.bc.ca
s.17; s.19

On Mar 25, 2021, at 7:39 AM, Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca> wrote:

Hi Bonnie
She is right that the AEFI reporting system is not public to provincial reporting and needs to go trough a health care provider, but many reports are public reports to public health. Specific diagnoses need to be physician verified however and if this person suspects TM, then they would need to be seen and assessed. s.13
s.13

I would be happy to phone this lady and discuss the process further with her. I can explain why there have not been customized events for the mRNA vaccines and why the events are associated with specific timelines that have not been similarly customized.

Thank you,

Monika

. . . . . .

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell s.16

From: Bonnie.Henry@gov.bc.ca
Sent: March 25, 2021 6:27 AM
To: Monika.Naus@bccdc.ca; reka.gustafson@phsa.ca; pballem@telus.net
Subject: Fwd: concerning adverse reactions to Pfizer vaccine

FYI. Ideas on how we can make it more transparent?
Bonnie

Dr Bonnie Henry
Provincial Health Officer
Ministry of Health
Bonnie.henry@gov.bc.ca
s.17; s.19

Begin forwarded message:

From: s.22
Date: March 24, 2021 at 10:38:38 PM PDT
To: "Henry, Bonnie HLTH:EX" <Bonnie.Henry@gov.bc.ca>
Cc: "Baker-French, Sophia MCF:EX" <Sophia.BakerFrench@gov.bc.ca>, "Behn Smith, Daniele HLTH:EX" <Daniele.BehnSmith@gov.bc.ca>, "Berkes, Andrea TACS:EX" <Andrea.Berkes@gov.bc.ca>
Subject: concerning adverse reactions to Pfizer vaccine

s.22

1) We would like to ensure that you are aware of these concerning adverse reactions to the vaccine.
2) We would like to request that you consider more straightforward and transparent processes for reporting adverse reactions to vaccines, for both healthcare professionals, and for individual citizens.
s.22

s.22 She received her first shot of the Pfizer vaccine s.22
s.22 she began having neurological symptoms, s.22
s.22

s.22

When I looked into options for reporting adverse reactions from vaccinations, on the BCCDC website, I found instructions for medical professionals, including the form to use and criteria for when adverse reactions must be reported. It is concerning that there are no special instructions for adverse reactions to Covid-19 vaccines, given the rapid development and relative newness of the mRNA-type vaccines. Moreover, the form refers to two types of traditionally-used vaccines when referring to timelines for adverse reactions, with no mention of mRNA vaccines and their specific timeline for adverse reactions of concern.
As individual healthcare consumers, we rely on healthcare professionals to report adverse events, but there is no way to report our own symptoms or to ensure that a report has been made about our situation. The criteria for reporting have not been updated for the current vaccination roll-out and in news articles I've found for the province (CTV), the very low numbers of adverse reactions and the lack of any mention of neurological symptoms, leads me to believe that not all adverse reactions are being reported. s.22
s.22

s.22 If these types of neurological symptoms are occurring after vaccinations for healthy s.22
s.22
s.22 , then it is quite possible that others are having these types of experiences, but they don't know how to report their concerns, or they are worried about how they will be treated when they report their concerns. There are many reasons why someone would not report adverse reactions: fear of being perceived as someone who is anti-vaccine, fear of not being believed, fear of not being treated respectfully, lack of access to healthcare, lack of awareness for how to report, etc.
I am fairly certain you must already be aware of these types of adverse reactions and that there is some form of tracking/investigating taking place within the province. In the slim chance you were not aware, I wanted to ensure you knew

about these concerns. s.22

s.22

Please consider strengthening the approach within the province to reporting adverse reactions to vaccines. Individual citizens should know what to watch for and who to tell. There should be a feedback mechanism so that individuals know that their report has been made. There should be rapid access pathways to healthcare for anyone who has serious symptoms so that these cases can be investigated thoroughly, treated appropriately, and understood completely. Healthcare consumers should know about all potential reactions so they can make an informed decision about getting vaccines, and so that they know when to seek medical attention if they have concerning reactions.

Sincerely,

s.22

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to April 03, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including April 03, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in the reports received in BC to date. These results are in keeping with observed events elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of the vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed and reported as anaphylaxis out of an abundance of caution. Serious events have not been reported at rates higher than expected compared to background rates.

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[5] When an AEFI report is received at a local public health unit, it is reviewed and recorded in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[6] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[7]

Definitions

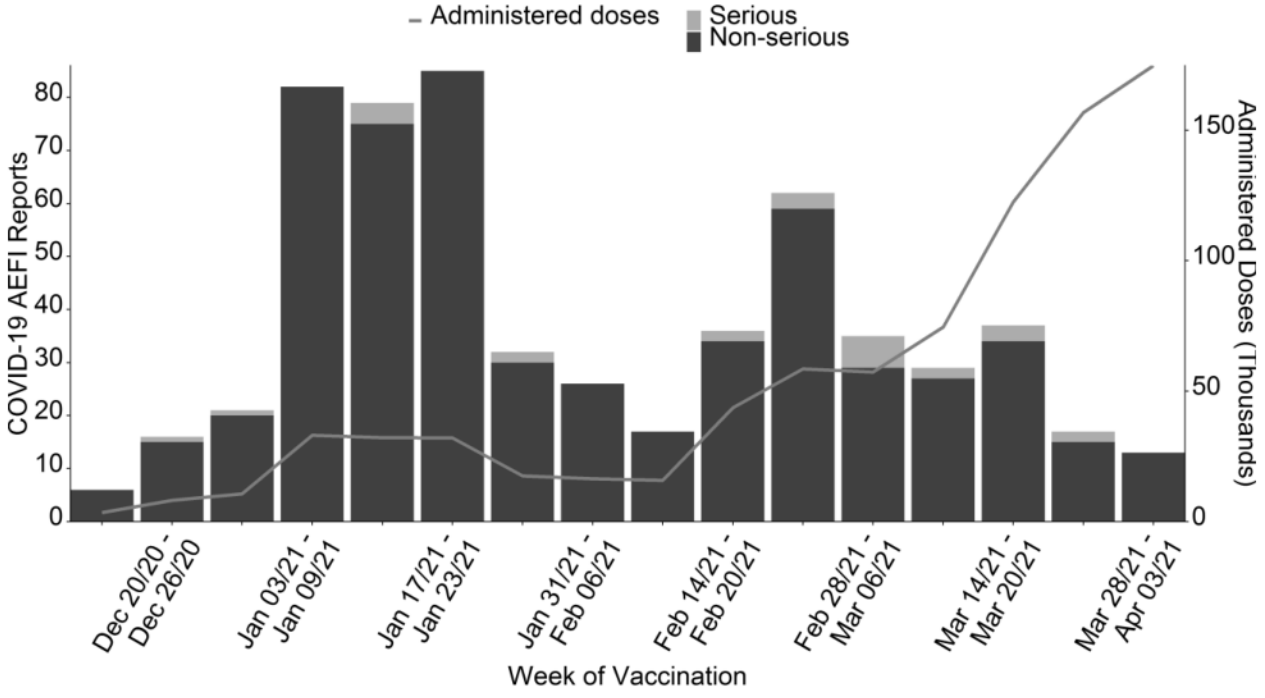
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[8]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of April 03, 2021, there have been 857,644 COVID-19 vaccine doses administered in BC and 593 COVID-19 AEFI reports (69.1 reports per 100,000 doses administered)
- 26 reports (4.4%) met the serious definition, for a rate of 3.0 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec.13, 2020 - Apr.03, 2021 **(N=593)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including April 03, 2021, a total of 857,644 doses have been administered. During this period, there have been 593 AEFI reports following a COVID-19 vaccine, for a reporting rate of 69.1 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive,

investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec.13, 2020 - Apr.03, 2021 **(N=593)**

	COVID-19 Vaccine			
	All COVID-19 Vaccines	**COVISHIELD**	**Moderna mRNA**	**Pfizer mRNA**
Total reports	**593**	**10**	**239**	**344**
Non-serious reports	567	9	230	328
Serious reports	26	1	9	16
Proportion serious	4.4%	10%	3.8%	4.7%
Dose 1 reports	507	10	213	284
Dose 2 reports	86	0	26	60
Total doses administered	**857,644**	**34,058**	**144,338**	**679,248**
Dose 1 administered	770,236	34,058	127,228	608,950
Dose 2 administered	87,408	0	17,110	70,298
Total reporting rate	**69.1**	**29.4**	**165.6**	**50.6**
Serious rate	3.0	2.9	6.2	2.4
Dose 1 rate	65.8	29.4	167.4	46.6
Dose 2 rate	98.4	--	152.0	85.4

Note: Rates calculated per 100,000 doses administered

Serious Reports

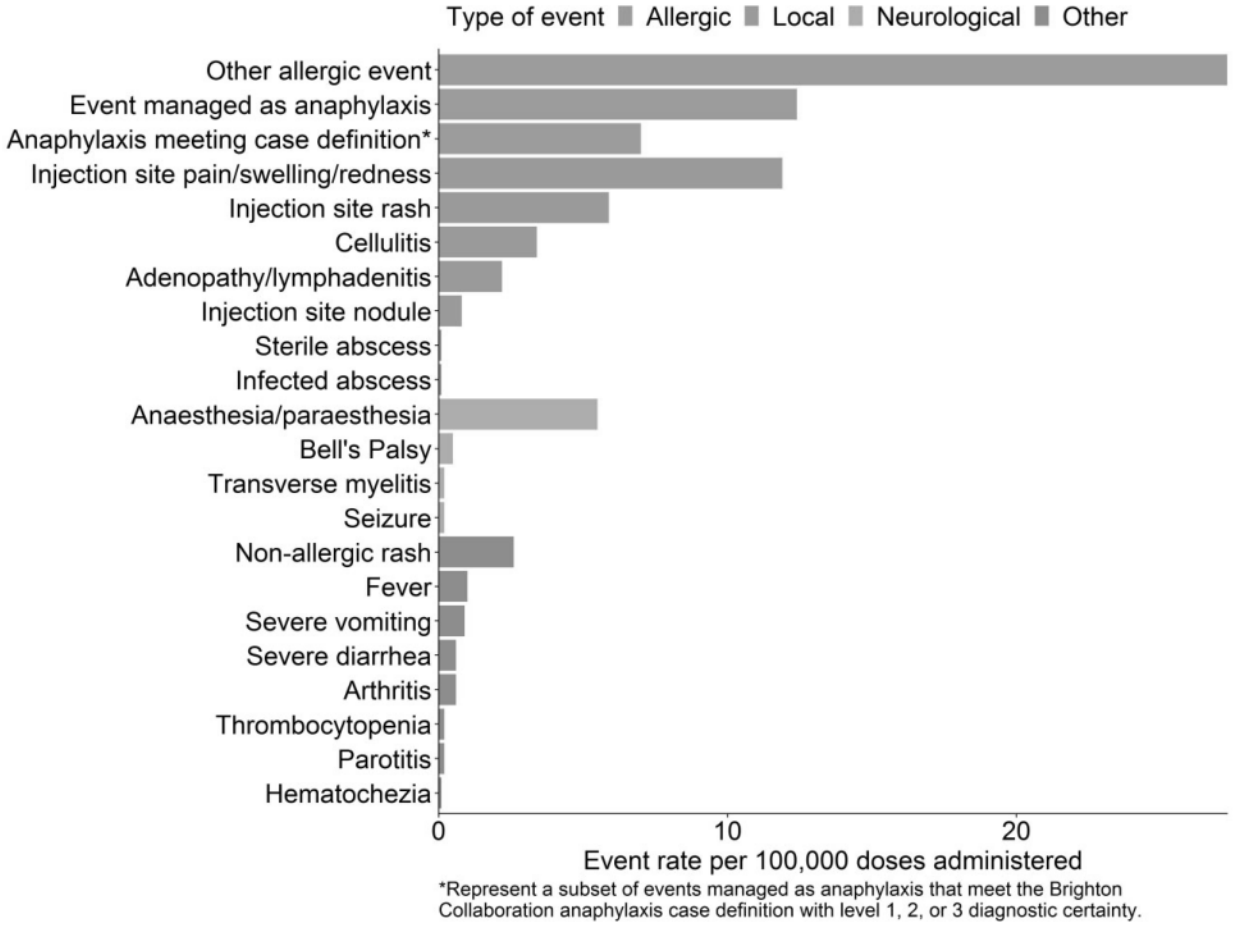
Twenty-six reports (4.4%) were considered serious (refer to serious AEFI definition above). Of these, 23 individuals were admitted to hospital. These included nine individuals hospitalized after anaphylaxis or other allergic event, eight for neurological investigations/monitoring (including two for transverse myelitis, one for a seizure, and five for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), five for chest pain/cardiac events, and one for a pregnancy related complication.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[5] Death may also be recorded as the outcome of a specific reportable event. Three serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death. The other death, which was still being investigated at the time of this report, was the outcome of a cardiac event that occurred in an elderly individual with multiple underlying medical conditions.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 593 AEFI reports received up to April 03, 2021 contained a total of 809 adverse events for a ratio of 1.4 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and injection site pain/swelling/redness (Figure 2). Of the events managed as anaphylaxis, roughly half met the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.[9]

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec.13, 2020 - Apr.03, 2021 **(N=809)**



Event Descriptions

One hundred six reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 60 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[9] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Twenty-nine reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[10] None of these reports were confirmed by microbial testing.

Seven reports contained a diagnosed neurological event. Four individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Two individuals were admitted to hospital and diagnosed with transverse myelitis. One individual, with a history of a seizure disorder, was admitted to hospital for seizures.

There were two reports of thrombocytopenia, although one was unconfirmed with no platelet count provided and still under investigation at the time of this report. The other report was for an individual who had a prior episode of thrombocytopenia pre-vaccination and was found to have a low platelet count roughly two weeks after vaccination when seen in the emergency department for signs of bleeding.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on April 08, 2021. Only AEFIs reported and doses administered up to April 03, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

References

1. BC Centre for Disease Control. Adverse events following immunization [Internet]; 2021 [cited 2021 Mar 23]. Available from: http://www.bccdc.ca/health-professionals/clinical-resources/adverse-events-following-immunization
2. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
3. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
4. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Weekly summary: adverse events following immunization (AEFIs) for COVID-19 in Ontario [Internet]. Toronto, ON: Queen's Printer for Ontario; 2021 [cited 2021 Apr 7]. Available from: https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-aefi-report.pdf?la=en
5. BC Centre for Disease Control. Communicable disease control manual. Chapter 2: Immunization. Part 5 - Adverse events following immunization [Internet]; 2019 [cited 2021 Mar 23]. Available from: http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Epid/CD%20Manual/Chapter%202%20-%20Imms/Part_5_AEFI.pdf
6. Government of Canada. Canadian adverse events following immunization surveillance system (CAEFISS) [Internet]; 2019 [cited 2021 Mar 23]. Available from: https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html
7. Government of Canada. Reported side effects following COVID-19 vaccination in Canada [Internet]; 2021 [cited 2021 Mar 23]. Available from: https://health-infobase.canada.ca/covid-19/vaccine-safety/
8. Council for International Organizations of Medical Sciences (CIOMS). Definition and application of terms for vaccine pharmacovigilance [Internet]. Geneva, Switzerland: WHO Press; 2012 [cited 2021 Mar 23]. Available from: https://vaccine-safety-training.org/tl_files/vs/pdf/report-of-cioms-who-working-group.pdf
9. Ruggeberg JU, Gold MS, Bayas J-M, Blum MD, Bonhoeffer J, Friedlander S, et al. Anaphylaxis: case definition and guidelines for data collection, analysis, and presentation of immunization safety data. Vaccine. 2007;25(31):5675-84. Available from: https://doi.org/10.1016/j.vaccine.2007.02.064

10. Blumenthal KG, Freeman EE, Staff RR, Robinson LB, Wolfson AR, Foreman RK, et al. Delayed large local reactions to mRNA-1273 vaccine against SARS-CoV-2. N Eng J Med. 2021;384(13). Available from: https://www.nejm.org/doi/full/10.1056/NEJMc2102131

RE: Devastating Vaccine Injuries among residents of Lytton

From: Bonnie.Henry@gov.bc.ca
To: XT:Naus, Monika HLTH:IN <monika.naus@bccdc.ca>
Sent: April 8, 2021 11:45:12 AM PDT

Talk to him first and then let us know whether this is something we should bring to the attention of the College.
Thanks,
b

Dr Bonnie Henry
Provincial Health Officer
Office of the PHO
Ministry of Health
s.15; s.19

Mailing address: PO Box 9648, STN PROV GOVT
Victoria, BC
V8W 9P4
Bonnie.henry@gov.bc.ca

Phone: s.17; s.19

I gratefully acknowledge that I live and work on the traditional unceded territory of the Lekwungen Peoples, specifically the Songhees and Esquimalt First Nations. Hay'sxw'qu Si'em

---

From: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Sent: April 8, 2021 11:31 AM
To: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Subject: RE: Devastating Vaccine Injuries among residents of Lytton

Bonnie

given this context, do you want me to PHONE Dr. Hoffe as requested by Penny? I'm concerned s.13
s.13 if a formal complaint against him has been initiated.

Thank you,
Monika

. . . . . .

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell s.16
Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday) mnds.assist@bccdc.ca Tel 604 707 2519

I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

From: Smith, Dr. Douglas <Douglas.Smith@interiorhealth.ca>
Sent: Thursday, April 08, 2021 11:27 AM

To: Henry, Bonnie [EXT] <bonnie.henry@gov.bc.ca>; Fenton, Carol [IHA] <Carol.Fenton@interiorhealth.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: RE: Devastating Vaccine Injuries among residents of Lytton

Thank you Bonnie,
Just confirming that I have submitted a formal complaint to the CPSBC on behalf of the patients and communities affected by the actions of Dr Hoffe.

Regards,

Doug

Douglas W. Smith, MSc, MD, CCFP
Executive Medical Director, Clinical Operations, IH North
Medical Staff co-Lead, IH Pandemic Response Coordination Committee (PRCC)

Cell phone s.22

From: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Sent: Thursday, April 08, 2021 11:02 AM
To: Fenton, Dr. Carol <Carol.Fenton@interiorhealth.ca>; Naus, Monika [PHSA] <Monika.Naus@bccdc.ca>
Cc: Smith, Dr. Douglas <Douglas.Smith@interiorhealth.ca>
Subject: RE: Devastating Vaccine Injuries among residents of Lytton

Thanks for following up. I believe we should also report this person to the College.
Bonnie

Dr Bonnie Henry
Provincial Health Officer
Office of the PHO
Ministry of Health
s.15; s.19
Mailing address: PO Box 9648, STN PROV GOVT
Victoria, BC
V8W 9P4
Bonnie.henry@gov.bc.ca

Phone: s.17; s.19

I gratefully acknowledge that I live and work on the traditional unceded territory of the Lekwungen Peoples, specifically the Songhees and Esquimalt First Nations. Hay'sxw'qu Si'em

---

From: Fenton, Dr. Carol <Carol.Fenton@interiorhealth.ca>
Sent: April 8, 2021 10:45 AM
To: XT:Naus, Monika HLTH:IN <monika.naus@bccdc.ca>
Cc: XT:Smith, Dr. Douglas HLTH:IN <Douglas.Smith@interiorhealth.ca>; Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Subject: RE: Devastating Vaccine Injuries among residents of Lytton

[EXTERNAL] This email came from an external source. Only open attachments or links that you are expecting from a known sender.

Hi Monika,

He sent the same letter to myself and copied numerous people, including community and First Nations partners. I am in the process of crafting a response with our communications department to try and mitigate the harm.

He has repeated these unsubstantiated claims previously and we gave feedback that it was inappropriate and made ourselves available as resources and for discussion. We are now in the process of both escalation of the issue within IH and are working with the College.

Carol Fenton BHSc MSc MD FRCPC
Medical Health Officer | Interior Health | she/her/hers
519A Columbia St | Kamloops, British Columbia

I live, work and play in the ancestral and unceded territory of the Tk'emlúps te Sewcépemc people

For 2021: "Side effects of the vaccine include hope, optimism, and a sense of a brighter future".

From: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Sent: Thursday, April 08, 2021 10:17 AM
To: Fenton, Dr. Carol <Carol.Fenton@interiorhealth.ca>
Subject: FW: Devastating Vaccine Injuries among residents of Lytton

Hello Carol

Please see the enclosed letter from a physician in Lytton.

Do you have any insight into his concerns? We are checking Panorama for AEFI reported among residents of Lytton. Has he been in touch with the health unit?

I may also connect with Helena and Marion in case First Nations Health Authority is hearing/ following this.

I will get in touch with him and have a conversation but wanted to connect with you first.
Thank you,
Monika

. . . . . .

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell s.16
Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday) mnds.assist@bccdc.ca Tel 604 707 2519

I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

From: Charles Hoffe <hoffe.charles@gmail.com>
Sent: April 7, 2021 8:09 PM
To: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Subject: Devastating Vaccine Injuries

[EXTERNAL] This email came from an external source. Only open attachments or links that you are expecting from a known sender.

Dear Dr Henry,

I am a family physician in Lytton, BC. I greatly appreciate the work that you have been doing on our behalf. Sadly I have been seeing terrible side-effects from the covid vaccines in my medical practice.
Please read my attached letter, which I send to you with much sadness, for those who have been harmed.

Yours sincerely.
Charles Hoffe

RE: Pfizer vaccine and blood clots in my lungs

From:	Hasselback, Paul (Dr) <Paul.Hasselback@VIHA.CA>
To:	Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>, XT:Naus, Monika HLTH:IN <monika.naus@bccdc.ca>
Cc:	Henry, Bonnie [EXT] <bonnie.henry@gov.bc.ca>, Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Sent:	May 18, 2021 2:56:53 PM PDT
Attachments:	image001.jpg

PS – 9 days post Pfizer.
s.22

I will complete full investigation when we have done interview and obtained some additional information.

Paul

From: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Sent: Tuesday, May 18, 2021 12:35 PM
To: Hoyano, Dee (Dr) <Dee.Hoyano@viha.ca>; Benusic, Michael <Michael.Benusic@VIHA.CA>
Cc: Henry, Bonnie [EXT] <bonnie.henry@gov.bc.ca>; Stanwick, Richard (Dr) <Richard.Stanwick@viha.ca>; Hasselback, Paul (Dr) <Paul.Hasselback@VIHA.CA>; Ord, Desiree <Desiree.Ord@viha.ca>; McNeal, Jade <Jade.McNeal@viha.ca>; Palmer, Kathy <Kathy.Palmer@viha.ca>
Subject: RE: Pfizer vaccine and blood clots in my lungs

Hello Mike and Dee
Will VIHA staff be able to follow up with this lady?
I've copied the VIHA members of the COVID-19 vaccine safety working group.
Thank you,
Monika

. . . . . .

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell s.16
Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday) mnds.assist@bccdc.ca Tel 604 707 2519

I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

From: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Sent: Tuesday, May 18, 2021 11:42 AM
To: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>; Stanwick, Richard (Dr) [VIHA] <Richard.Stanwick@viha.ca>
Subject: FW: Pfizer vaccine and blood clots in my lungs

Would someone please reach out to this person and see if this has been reported as a AEFI. And support any further assessment. Etc.
Thanks,
Bonnie

Dr Bonnie Henry
Provincial Health Officer
Office of the PHO
Ministry of Health
s.15; s.19

Mailing address: PO Box 9648, STN PROV GOVT
Victoria, BC
V8W 9P4
Bonnie.henry@gov.bc.ca

Phone: s.17; s.19

I gratefully acknowledge that I live and work on the traditional unceded territory of the Lekwungen Peoples, specifically the Songhees and Esquimalt First Nations. Hay'sxw'qu Si'em

From: s.22
Sent: May 18, 2021 9:48 AM
To: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Subject: Pfizer vaccine and blood clots in my lungs

Dear Dr. Bonnie Henry.

I have been following your weekly reports since March 2020 and thank you for keeping British Columbia's well informed during the pandemic.

I was diagnosed with blood clots in my lungs s.22 after receiving the Pfizer vaccine s.22

s.22

If at all possible, I would appreciate your assistance to help expedite an appointment to see the recommended specialist by s.22 My hope would be that you, your team and the Pfizer Pharmaceutical Industry Company would also be interested to follow up and investigate further, as to why my first vaccine resulted with blood clots in my lungs and to add these findings to the ongoing research in a timely manner.

s.22

I look forward to your reply and any direction that you may be able to provide.
Much appreciated and thank you for your consideration.

s.22

s.22

Re: TTS case in FHA -possible

From: Brodkin, Elizabeth Dr. [FH] <Elizabeth.Brodkin@fraserhealth.ca>
To: Lajeunesse, Carol [FH] <carol.lajeunesse@fraserhealth.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>, Bigham, Mark [FH] <Mark.Bigham@fraserhealth.ca>, Henry, Bonnie [EXT] <bonnie.henry@gov.bc.ca>, Tyler, Ingrid [FH] <ingrid.tyler@fraserhealth.ca>, XT:HLTH Bigham, Mark <mark.bigham@fraserhealth.ca>, Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>, XT:Tyler, Ingrid FHA:IN <ingrid.tyler@fraserhealth.ca>, XT:Naus, Monika HLTH:IN <monika.naus@bccdc.ca>
Sent: May 22, 2021 10:41:45 AM PDT

Please make sure the MRP is also included.

Sent from my iPhone

On May 22, 2021, at 10:39, Lajeunesse, Carol [FH] <carol.lajeunesse@fraserhealth.ca> wrote:

Hi Monika
The individual has no AEFI in our system at FH. He does however show up as living in and receiving ChAdOx-SViral Vector vaccine on 05 April 2021.
Will initiate follow-up processes.
C

Carol LaJeunesse, RN BScN
Fraser Health CDNC
carol.lajeunesse@fraserhealth.ca
604 897-4635

From: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Sent: Friday, May 21, 2021 9:25 PM
To: Tyler, Ingrid [FH] <ingrid.tyler@fraserhealth.ca>
Cc: Bigham, Mark [FH] <Mark.Bigham@fraserhealth.ca>; Brodkin, Elizabeth Dr. [FH] <Elizabeth.Brodkin@fraserhealth.ca>; Henry, Bonnie [EXT] <bonnie.henry@gov.bc.ca>; Lajeunesse, Carol [FH] <carol.lajeunesse@fraserhealth.ca>
Subject: TTS case in FHA -possible

Hi Ingrid
Just heard from Agnes Lee that there was a man on Global news saying that he is VITT case.
Name is Hal Fraser Bringeland.
He said he was hospitalized at Peace Arch Apr 29th.
1st dose Apr 5th.
Apr 29th SOB.
CT scan confirmed PE.

Thank you,

Monika

. . . . . .

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell s.16

RE: Pfizer Adverse Reaction s.22

From:	Bartel, Kim <Kim.Bartel@interiorhealth.ca>
To:	Naus, Monika [PHSA] <Monika.Naus@bccdc.ca>, Henry, Bonnie [EXT] <bonnie.henry@gov.bc.ca>, De Villiers, Albert <Albert.DeVilliers@interiorhealth.ca>, Fenton, Dr. Carol <Carol.Fenton@interiorhealth.ca>, Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>, XT:Naus, Monika HLTH:IN <monika.naus@bccdc.ca>
Cc:	Smith, Kristiina <Kristiina.Smith@interiorhealth.ca>, Parker, Dr. Robert <Robert.Parker@interiorhealth.ca>, Adverse Events <Adverse.Events@interiorhealth.ca>, XT:HLTH Parker, Robert <ROBERT.PARKER@interiorhealth.ca>
Sent:	June 8, 2021 2:32:52 PM PDT
Attachments:	image001.jpg

Just thought I would give a quick update on what we know so far – this is from the s.22

- s.22 – Pfizer vaccine administered.
- s.22
-
-
-
-

- s.22 was diagnosed with having a right sided stroke s.22
  s.22
-
-
-
-
-
-

PHN is working to obtain further information/reports from Meditech for IH visits. Will update further once more information obtained.

Kim

Kim Bartel RN MN
Immunization Specialist ~ Population Health
| Vernon Health Centre – T2 | 1440 14th Ave, Vernon, BC V1B 2T1
Phone: 1-866-778-7736 |Fax: 250-549-6310

Interior Health

I gratefully acknowledge that my workplace is within the ancestral, traditional, and unceded territory of the Syilx Nation

From: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Sent: Tuesday, June 08, 2021 9:22 AM

To: Henry, Bonnie [EXT] <bonnie.henry@gov.bc.ca>; De Villiers, Albert <Albert.DeVilliers@interiorhealth.ca>; Fenton, Dr. Carol <Carol.Fenton@interiorhealth.ca>
Cc: Smith, Kristiina <Kristiina.Smith@interiorhealth.ca>; Bartel, Kim <Kim.Bartel@interiorhealth.ca>
Subject: RE: Pfizer Adverse Reaction

Thanks Bonnie.

There are likely a few issues that will need to be clarified s.22 Albert and Carol, if s.22 received Pfizer vaccine which is not known to be associated with strokes.
Let me know if you need me to connect with s.22 for anything.

Thank you,
Monika

. . . . . .

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell s.16
Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday) mnds.assist@bccdc.ca Tel 604 707 2519

I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

From: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Sent: Tuesday, June 08, 2021 8:01 AM
To: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>; Devilliers, Albert [IHA] <albert.devilliers@interiorhealth.ca>
Subject: FW: Pfizer Adverse Reaction

Could someone please follow up on this.
Thanks,
Bonnie

Dr Bonnie Henry
Provincial Health Officer
Office of the PHO
Ministry of Health
s.15; s.19
Mailing address: PO Box 9648, STN PROV GOVT
Victoria, BC
V8W 9P4
Bonnie.henry@gov.bc.ca

Phone: s.17; s.19

I gratefully acknowledge that I live and work on the traditional unceded territory of the Lekwungen Peoples, specifically the Songhees and Esquimalt First Nations. Hay'sxw'qu Si'em

From: s.22
Sent: June 7, 2021 10:14 PM
To: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Subject: Pfizer Adverse Reaction

s.22 received his Pfizer vaccine on s.22 On the afternoon of s.22 s.22 had a severe stroke. s.22 stroke was reported as an adverse reaction. s.22
s.22

I have yet to be contacted by anyone to look into this and I believe it warrants looking into. Doctors s.22 s.22 agree that the vaccine was the catalyst for his stroke. We can not change this s.22 but investigating this might prevent someone else from suffering the same outcome.

Sincerely,
s.22

Get Outlook for iOS

RE: AstraZeneca vaccine caused Guillain-Barré Syndrome (GBS) and Bell's Palsy

From: van Baarsen, Amanda HLTH:EX <Amanda.vanBaarsen@gov.bc.ca>
To: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Cc: MacDonald, Alex HLTH:EX <Alex.MacDonald@gov.bc.ca>
Sent: June 9, 2021 11:03:01 AM PDT

Thanks very much.

-----Original Message-----
From: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Sent: June 9, 2021 11:03 AM
To: van Baarsen, Amanda HLTH:EX <Amanda.vanBaarsen@gov.bc.ca>
Cc: MacDonald, Alex HLTH:EX <Alex.MacDonald@gov.bc.ca>
Subject: RE: AstraZeneca vaccine caused Guillain-Barré Syndrome (GBS) and Bell's Palsy

Forwarded to IH and BCCDC and it is already under investigation.
b

Dr Bonnie Henry
Provincial Health Officer
Office of the PHO
Ministry of Health
s.15; s.19
Mailing address: PO Box 9648, STN PROV GOVT Victoria, BC V8W 9P4 Bonnie.henry@gov.bc.ca

Phone: s.17; s.19

I gratefully acknowledge that I live and work on the traditional unceded territory of the Lekwungen Peoples, specifically the Songhees and Esquimalt First Nations. Hay'sxw'qu Si'em

-----Original Message-----
From: van Baarsen, Amanda HLTH:EX <Amanda.vanBaarsen@gov.bc.ca>
Sent: June 9, 2021 11:01 AM
To: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Cc: MacDonald, Alex HLTH:EX <Alex.MacDonald@gov.bc.ca>
Subject: RE: AstraZeneca vaccine caused Guillain-Barré Syndrome (GBS) and Bell's Palsy

Thanks very much.

-----Original Message-----
From: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Sent: June 9, 2021 10:40 AM
To: van Baarsen, Amanda HLTH:EX <Amanda.vanBaarsen@gov.bc.ca>
Cc: MacDonald, Alex HLTH:EX <Alex.MacDonald@gov.bc.ca>
Subject: RE: AstraZeneca vaccine caused Guillain-Barré Syndrome (GBS) and Bell's Palsy

Yes, GBS is most often related to infection so that would need to be investigated but has been associated with vaccination (particularly influenza). This should be reported by his physicians to public health as an AEFI and investigated by public health. And yes, the new vaccine injury support program is designed for things like this if it is found to be causally related to vaccine.

I will forward to Monika Naus and IH MHO for investigation.
Bonnie

Dr Bonnie Henry
Provincial Health Officer
Office of the PHO
Ministry of Health
s.15; s.19
Mailing address: PO Box 9648, STN PROV GOVT Victoria, BC V8W 9P4 Bonnie.henry@gov.bc.ca

Phone: s.17; s.19

I gratefully acknowledge that I live and work on the traditional unceded territory of the Lekwungen Peoples, specifically the Songhees and Esquimalt First Nations. Hay'sxw'qu Si'em

-----Original Message-----
From: van Baarsen, Amanda HLTH:EX <Amanda.vanBaarsen@gov.bc.ca>
Sent: June 9, 2021 10:35 AM
To: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Cc: MacDonald, Alex HLTH:EX <Alex.MacDonald@gov.bc.ca>
Subject: FW: AstraZeneca vaccine caused Guillain-Barré Syndrome (GBS) and Bell's Palsy

Is this an AFI we were unaware of?

-----Original Message-----
From: Letnick.MLA, Norm <Norm.Letnick.MLA@leg.bc.ca>
Sent: June 7, 2021 8:25 AM
To: van Baarsen, Amanda HLTH:EX <Amanda.vanBaarsen@gov.bc.ca>
Subject: FW: AstraZeneca vaccine caused Guillain-Barré Syndrome (GBS) and Bell's Palsy

Good Morning Amanda!

I hope you had a great weekend?

Any advice I can pass on to this person please?

Norm

-----Original Message-----
From: s.22
Sent: June 4, 2021 7:35 AM
To: Letnick.MLA, Norm <Norm.Letnick.MLA@leg.bc.ca>
Cc: s.22
Subject: AstraZeneca vaccine caused Guillain-Barré Syndrome (GBS) and Bell's Palsy

Norm,

s.22 had s.22 AstraZeneca vaccine on or about s.22
s.22 began experiencing some body pain and by the following weekend he was completely immobile in
s.22
s.22 diagnosis was confirmed as GBS and Bell's Palsy.
s.22 attending Drs believe his condition is a result of the vaccine.
s.22

There must be some sort of governmental support for rare cases such as his. Health Canada apparently has a program but it must be "serious and permanent " to trigger support.
s.22

This morning a CBC radio broadcast mentioned 15 people across Canada similarly affected.

s.22

Sent from my iPad

RE: Negative Covid Reaction to Pfizer Vaccine

From: Daly, Patty [VCH] <Patricia.Daly@vch.ca>
To: Henry, Bonnie [EXT] <bonnie.henry@gov.bc.ca>, Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Sent: June 11, 2021 10:26:12 AM PDT

[EXTERNAL] This email came from an external source. Only open attachments or links that you are expecting from a known sender.

Yes we will.

Patricia Daly, MD, FRCPC
Vice-President, Public Health & Chief Medical Health Officer
Vancouver Coastal Health

office 604 675 3924
e-mail patricia.daly@vch.ca

Erika Bell
Executive Assistant
office 604 675 3918
e-mail erika.bell@vch.ca

I acknowledge that my place of work lies on the unceded traditional homelands of the Musqueam, Squamish and Tsleil-Waututh Nations.

-----Original Message-----
From: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Sent: Thursday, June 10, 2021 8:02 PM
To: Daly, Patty [VCH] <Patricia.Daly@vch.ca>
Subject: Fwd: Negative Covid Reaction to Pfizer Vaccine

Could someone perhaps follow up with these folk?
Thanks
B

Dr Bonnie Henry
Provincial Health Officer
Ministry of Health
Bonnie.henry@gov.bc.ca
s.17; s.19

Begin forwarded message:

From: s.22
Date: June 10, 2021 at 6:53:17 PM PDT
To: "Henry, Bonnie HLTH:EX" <Bonnie.Henry@gov.bc.ca>
Subject: Negative Covid Reaction to Pfizer Vaccine
Reply-To: s.22

[EXTERNAL] This email came from an external source. Only open attachments or links that you are expecting from a known sender.

TO Bonnie Henry

s.22 , adverse reaction to s.22 first shot of the Pfizer Vaccine so we decided to ask your advice.

s.22

s.22 first shot of Pfizer she has had an anaphylaxis reaction of hives that has spread all over body and been very itchy. s.22
s.22

s.22 is now due to receiver her second vaccination on s.22
doesn't know whether s.22 should proceed with taking a second shot of Pfizer, opt for the Moderna vaccine or wait until s.22 can consult with s.22 family physician or some other physician knowledgeable about the COVID procedures.

s.22 or via my email. Thank you

RE: possible AEFIs for follow up

From:	Tillyer, Lauren [FH] <Lauren.Tillyer@fraserhealth.ca>
To:	Tyler, Ingrid [FH] <ingrid.tyler@fraserhealth.ca>, Gahunia, Jasmeen [FH] <Jasmeen.Gahunia@fraserhealth.ca>, Schultz, Caroline [FH] <Caroline.Schultz@fraserhealth.ca>, XT:Tyler, Ingrid FRHA:IN <ingrid.tyler@fraserhealth.ca>
Cc:	Bark, Diana <diana.bark@fraserhealth.ca>, Bigham, Mark [FH] <Mark.Bigham@fraserhealth.ca>, Henry, Bonnie [EXT] <bonnie.henry@gov.bc.ca>, Chilton, Katharine [BCCDC] <Katharine.Chilton@bccdc.ca>, Brodkin, Elizabeth Dr. [FH] <Elizabeth.Brodkin@fraserhealth.ca>, Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>, XT:HLTH Bigham, Mark <mark.bigham@fraserhealth.ca>, XT:HLTH Brodkin, Elizabeth <elizabeth.brodkin@fraserhealth.ca>, Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Sent:	August 25, 2021 10:35:37 AM PDT
Attachments:	image002.png, image003.jpg

Hello All

I will connect with the client to our AEFI process and have this expedited for dose 2 recommendations.

Thank you.

Lauren Tillyer RN, BScN

CDNC - Cell: s.16

fraserhealth

From: Tyler, Ingrid [FH] <ingrid.tyler@fraserhealth.ca>
Sent: Wednesday, August 25, 2021 10:02 AM
To: Tillyer, Lauren [FH] <Lauren.Tillyer@fraserhealth.ca>
Cc: Bark, Diana <diana.bark@fraserhealth.ca>; Bigham, Mark [FH] <Mark.Bigham@fraserhealth.ca>
Subject: possible AEFIs for follow up

Thank you, ingrid

From: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Sent: Wednesday, August 25, 2021 9:43 AM
To: Brodkin, Elizabeth Dr. [FH] <Elizabeth.Brodkin@fraserhealth.ca>; Tyler, Ingrid [FH] <ingrid.tyler@fraserhealth.ca>
Cc: Henry, Bonnie [EXT] <bonnie.henry@gov.bc.ca>; Chilton, Katharine [BCCDC] <Katharine.Chilton@bccdc.ca>
Subject: RE: I've had covid (positive lab test), I've had my first pfizer - science says I don't need a second shot - please read I have an important question

Hi Elizabeth / Ingrid
Let us know please if you want BCCDC to follow-up directly; otherwise I assume someone from FHA will be able to.

In terms of documentation on the vaccine passport of an exemption to dose 2 on account of a contraindication, I've yet to see how this will be incorporated but understand that the government is working on finalizing an approach. Contraindications are documented in the immunization registry and this information could be displayed; it does not appear in Health Gateway at this time.

Thank you,
Monika

. . . . . .

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell s.16
Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday) mnds.assist@bccdc.ca Tel 604 707 2519

I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

From: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>
Sent: Wednesday, August 25, 2021 8:58 AM
To: Brodkin, Elizabeth Dr. [FH] <Elizabeth.Brodkin@fraserhealth.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: FW: I've had covid (positive lab test), I've had my first pfizer - science says I don't need a second shot - please read I have an important question

---

Could someone follow up with these folk? It sounds like s.22 may have had myocarditis? Right now the recommendation would be to wait and not receive a dose 2.
b

Dr Bonnie Henry
Provincial Health Officer
Office of the PHO
Ministry of Health
s.15; s.19
Mailing address: PO Box 9648, STN PROV GOVT
Victoria, BC
V8W 9P4
Bonnie.henry@gov.bc.ca

Phone: s.17; s.19

I gratefully acknowledge that I live and work on the traditional unceded territory of the Lekwungen Peoples, specifically the Songhees and Esquimalt First Nations. Hay'sxw'qu Si'em

---

From: s.22
Sent: August 25, 2021 8:43 AM
To: Henry, Bonnie HLTH:EX <Bonnie.Henry@gov.bc.ca>; premier@gov.ba.ca

Subject: I've had covid (positive lab test), I've had my first pfizer - science says I don't need a second shot - please read I have an important question

[EXTERNAL] This email came from an external source. Only open attachments or links that you are expecting from a known sender.

Hi office of Dr Bonnie and the Premier,

s.22 received positive covid test results s.22
s.22

I got my first shot of Pfizer s.22 . Felt fine….about a few days later for a couple of months – experienced bouts of heart flutters that continued to get more frequent over the course of a couple of months. One day is was so many s.22 took me to ER, where my blood pressure was through the roof. Since then, it has been a lot better – so I cannot say for sure if that was vaccine related.

My s.22 got s.22 first shot s.22
s.22 some fluttering in s.22 chest and having a bit of a hard time breathing… s.22
s.22
s.22

I
s.22 told her it was a reaction to vaccine – which is normal and to go home and not exert
s.22 blood pressure and resting heart rate stayed very high for 4 days while still experiencing shortness of breath. Its been about 3 weeks now and s.22 is much better but not 100%.

My question:

Having lab proof of a positive covid infection and proof of first dose I know science says s.22 and I are more protected than someone with 2 doses without prior covid infection. I also see from many science based reports that a second dose in previous positive covid positive person doesn't give more immunity but can bring on more significant adverse effects.

s.22

We have followed all the rules – we continued to wear our masks indoors even when told it was unnecessary, we socially distanced, hand sanitize……

I really feel uncomfortable advising my s.22 that s.22 should get a second shot considering the reaction s.22 had to s.22 first and knowing that it isn't necessary – it will not be providing s.22 with anymore protection. I'm also wondering if my heart flutters for 2 months were a result of my vaccine as well. We were told by the nurse who vaccinated us having Covid prior could result in a bigger reaction as it is like our second dose. -which we knew going in.

We are doing our part – we have protected ourselves and our community and I really don't want to get a second shot and risk a more severe reaction just so we can participate in life again. For my s.22 and I getting a second shot dose not offer us or the community any added protection and we run the risk of another, possibly more serious reaction and/or side effects.

I am really hoping that this can be recognized. I understand you may be hesitant because you don't want people to say "well I think I had it back in Feb, so one dose is good"….but with lab proof of positive infection and proof of first dose – we know through scientific data to date that we are just as protected if not more than someone with 2 doses. And in articles you have agreed with this information.

Our scenario is different than a medical exemption, and I hope that can be recognized by our province, it should be, so that we can obtain our full vaccine passport without having to take an unnecessary second dose and risk a more severe reaction.

We completely support the work you are doing and we are 100% doing our part to help. I look forward to hearing from someone in regards to this.

Sincerely,

s.22