

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 Dec 24th saying there was a person who had an allergic reaction at the clinic in the north at the clinic at the hospital. That they received epinephrine and were observed in the ED 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

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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

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

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

We were inquired about an anaphylactic reaction in north on December 23rd 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 Dec 23? 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 December 23rd. 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
Immunization Programs, BCCDC
kathy.leung@bccdc.ca

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

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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

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

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 Brodtkin, Elizabeth <elizabeth.brodtkin@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

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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

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

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, aged s.22, with s.22, was s.22. They received vaccine to ensure no wasted doses from vial provided to vaccinate other s.22 inmates at that institution.

Vaccine administered uneventfully on s.22. s.22 – noted sore arm only, but subsequently experienced a fall (was documented to be s.22 s.22 – ongoing monitoring due to fall, but 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 / Conseillère médicale exécutive

Vice President's Office, Infectious Disease Prevention and Control Branch

Bureau de la Vice-présidente, Direction générale de la prévention et du contrôle des maladies infectieuses

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

Barbara.Raymond@Canada.ca

Mobile: 613 302 4940

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>, Nofall, Kyle [BCCDC] <Kyle.Nofall@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

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

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 [s.1](#)

[s.13](#)
[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](#) 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](#)
[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.15](#)

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

EXTERNAL SENDER. If you suspect this message is malicious, please forward to spam@phsa.ca and **do not** open attachments or click on links.

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
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s.15; s.19

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Phone:**s.17; s.19**

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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

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

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. **s.13** 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. **s.13**

s.13 This has been seen with other vaccines as well e.g., DPT-IPV compared to Tdap-IPV in younger children.

s.22

s.22

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

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Cells.15

Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday) mnds.assist@bccdc.ca Tel 604 707 2519

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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

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

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. **s.13**

s.13

s.13

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 :

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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

.....
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Medical Head, Immunization Programs & Vaccine Preventable Diseases
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Cell **s.15**

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