From:	Dean, Kelly E on behalf of Strang, Robert
To:	Dean, Kelly E
Subject:	Fw: For reference: Communication products on AEFIs and infection post-immunization
Date:	October 4, 2022 8:01:06 AM
Attachments:	PHAC_ML_Testing positive after vaccination_Jan21_FINAL_EN.docx PHAC_KM_Bells Palsy AEFI_2021-01-21_2054_FINAL BIL.docx PHAC_MLQA_Vaccine Safety_AEFI_2021_01_07_FINAL FR.docx PHAC_MLQA_Vaccine Safety_AEFI_2021_01_07_FINAL EN.docx

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From: Strang, Robert
Sent: Sunday, January 24, 2021 4:30 PM
To: Walsh, Tara A <Tara.Walsh@novascotia.ca>
Cc: Barbrick, Tracey L <Tracey.Barbrick@novascotia.ca>; Cole, Teri J <Teri.Cole@novascotia.ca>; Watson-Creed, Gaynor <Gaynor.Watson-Creed@novascotia.ca>
Subject: FW: For reference: Communication products on AEFIs and infection post-immunization
National media lines on some vaccine issues for you.
Rob

From: Auger, Julie (PHAC/ASPC) <julie.auger@canada.ca> **On Behalf Of** CCMOH SECRETARIAT / CMHC (PHAC/ASPC)
Sent: January 24, 2021 2:27 PM
To: Romano, Anna (PHAC/ASPC) <anna.romano@canada.ca>; Avis Gray <avis.gray@gov.mb.ca>; Brent Roussin <brent.roussin@gov.mb.ca>; Catherine Elliott <catherine.elliott@gov.yk.ca>; Simms, Colleen (Ext.) <colleensimms@gov.nl.ca>; Colleen Stockley <ColleenStockley@gov.nl.ca>; Dr. Barb Yaffe <barbara.yaffe@ontario.ca>; Henry, Bonnie (Ext.) <bonnie.henry@gov.bc.ca>; Hanley, Brendan (Ext.) <brendan.hanley@gov.yk.ca>; Emerson, Brian (Ext.) <brian.emerson@gov.bc.ca>; Muecke, Cristin (Ext.) <dr.cristin.muecke@gnb.ca>; Dr. David Williams <dr.david.williams@ontario.ca>; Dr. Deena Hinshaw <deena.hinshaw@gov.ab.ca>; Dr. Denise Werker <denise.werker1@health.gov.sk.ca>; Dr. George Giovinazzo <george.giovinazzo@cic.gc.ca>; Morrison, Heather (Ext.) <hgmorrison@gov.pe.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; Dr. James Worthington <dr.james.worthington@csc-scc.gc.ca>; Dr. Janice Fitzgerald <janice.fitzgerald@gov.nl.ca>; Russell, Jennifer (Ext.) <jennifer.russell@gnb.ca>; Dr. Michael Patterson <mpatterson@gov.nu.ca>; Strang, Robert <Robert.Strang@novascotia.ca>; Shahab, Saqib (Ext.) <saqib.shahab@health.gov.sk.ca>; Sharma, Supriya (HC/SC) <supriya.sharma@canada.ca>; Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Wong, Tom (SAC/ISC) <tom.wong@canada.ca>; Cleary, Eilish (SAC/ISC) <eilish.cleary@canada.ca>; Evan Adams <evan.adams@fnha.ca>; Greg Haley <GREG.Haley@forces.gc.ca>; Arruda, Horacio (Ext.) <horacio.arruda@msss.gouv.qc.ca>; Kandola, Kami (Ext.) <kami_kandola@gov.nt.ca>; Philip Christoff <philip.christoff@gov.yk.ca>; Reka Gustafson <reka.gustafson@phsa.ca>; SK CMOH Single Window <OCMHO@health.gov.sk.ca>; Suzanne Fedorowich <suzanne.fedorowich@health.gov.sk.ca>; Tami Denomie <tami.denomie@health.gov.sk.ca>; Trish Merrithew <Trish.Merrithew-Mercredi@gov.ab.ca>; Vincent Beswick-Escanlar <VINCENT.BESWICK-ESCANLAR@forces.gc.ca>; YK Surveillance <YCDCsurveillance@gov.yk.ca>; Yves Jalbert <yves.jalbert@msss.gouv.qc.ca>
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Subject: For reference: Communication products on AEFIs and infection post-immunization

** EXTERNAL EMAIL / COURRIEL EXTERNE **
Exercise caution when opening attachments or clicking on links / Faites preuve de prudence si vous ouvrez une pièce jointe ou cliquez sur un lien

Dear SAC members,

Please find attached for your reference the following media lines/key messages:

- AEFI (EN & FR)
- Bells Palsy (EN)
- Testing positive after immunization (EN, FR to follow)

Additional communication products will be shared as they become available.

In addition, the COVID-19 Vaccination in Canada Report has now been posted based on available data. The web report provides daily updates on the total number of vaccines administered as of 11:00AM, as well as weekly updates on vaccines distributed and vaccination coverage every Friday.

https://health-infobase.canada.ca/covid-19/vaccination-coverage/

https://sante-infobase.canada.ca/covid-19/couverture-vaccinale/

Weekly updates on AEFIs can also be found here:

https://infobase-dev.com/covid/vaccine-safety/index-en.html

https://infobase-dev.com/covid/vaccine-safety/index-fr.html

Regards,

SAC Secretariat

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

January 21, 2021

Media Lines

Testing positive for COVID-19 after one dose of the vaccine

Issue Statement: Media have reported on multiple individuals who have tested positive for COVID-19 despite having been vaccinated. Media attention on these scenarios is expected to continue. These media lines explain how such a situation may arise.

Key Messages:

- There are multiple reasons a person may become infected with COVID-19 after being vaccinated. A person may have been previously exposed to the virus or exposed shortly after vaccination, before the body has had time to create an immune response.
- Health Canada authorized the Pfizer-BioNTech and Moderna vaccines as two-dose regimens.
- The immune system usually requires 7-14 days after vaccination to begin to create a response that offers protection against COVID-19. A vaccine is thought to offer maximum protection 14 days after the second dose.
- Clinical trails data indicates that both approved vaccines are 95% effective after two doses; however, they are not 100% effective. This means they may not work for a small percentage of recipients.

On asymptomatic infections before vaccination:

- Symptoms can take up to 14 days to appear after exposure to the virus, and some people never develop symptoms at all (asymptomatic). This means it's possible to be unknowingly infected with COVID-19 before vaccination.
- Those who are infected with the virus at the time they are given the vaccine, or shortly thereafter, are unlikely to be protected by the vaccine, as the immune system usually requires 7-14 days to build a response.
- However, someone who was previously infected by the COVID-19 virus but is no longer infected can be immunized to help protect against possible future disease.

On the time needed to build an immune response after vaccination:

- The immune system usually requires 7-14 days after vaccination to create a response that offers protection against COVID-19. A vaccine is thought to offer maximum protection 14 days after the second dose.
- This means that it's possible to become infected within the first 14 days following vaccination, before the body has a chance to create an effective immune response
- The majority of participants in the Pfizer-BioNTech COVID-19 vaccine clinical trial received the second dose 21 to 27 days apart, and efficacy analyses in the Pfizer-

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BioNTech clinical trial included participants who received their second dose 19-42 days after their first dose.

- Efficacy analyses in the Moderna clinical trial included participants who received their second dose 22 to 42 days after their first dose.

Questions and Answers

Q1. If the second dose is not administered within Health Canada's authorized dosing regimen, should Canadians still receive that second dose?

If administration of the second dose of a COVID-19 vaccine is delayed, the second dose should still be given as soon as possible. People do not need to restart a vaccine series as a result of delays between doses. That's because those delays do not generally reduce the final immune response in most multi-dose vaccine products.

Q2. Can a vaccinated person get COVID-19?

The currently authorized COVID-19 vaccines have demonstrated safety and high efficacy (approx. 95%), in the short term, against symptomatic laboratory-confirmed COVID-19 disease from one to two weeks after receiving the full two-dose series. However, as the vaccines are not 100% effective, they may not work for a small percentage of recipients.

Q3. Can vaccinated people spread the virus to others?

There is limited evidence on whether someone who received the vaccine is still able to spread the virus. Everyone must continue following public health measures, regardless of vaccination with COVID-19 vaccines, to protect themselves, their loved ones, as well as people and communities at risk of more severe disease or outcomes from COVID-19. To do this, you need to continue to:

- Follow the guidance of your local public health authority
- Stay home and isolate if you have any symptoms of COVID-19, even if mild
- Limit close contacts to only those in your immediate household
- Maintain a physical distance from people outside of your immediate household
- Avoid the 3C's as much as possible: closed spaces, crowded places, and close interactions (e.g., close-range conversations). Risk is higher in settings where these factors overlap or involve activities such as singing, shouting or heavy breathing (e.g., during exercise).
- Practice regular hand hygiene, respiratory etiquette and avoid touching your eyes, nose and mouth
- Clean and disinfect your personal surfaces and objects
- Limit your outings to only essential activities, especially if you are at risk of more severe disease or outcomes from COVID-19
- Wear a non-medical mask, in situations and settings where they are recommended
- Reduce personal non-essential travel

Q4. Is it true that you can get COVID-19 from the vaccine?

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No, you can't get COVID-19 from the vaccine. Many vaccines are being studied to see if they will prevent COVID-19, and Health Canada is expediting reviews of all COVID-19 vaccine submissions.

Some of the vaccine candidates (including AstraZeneca and Janssen) that are most advanced in development are viral vector-based vaccines. These types of vaccines use a harmless virus (in this case, the adenovirus that can cause the common cold) as a delivery system. The vector virus used is not the virus that causes COVID-19.

Once injected into the body, the virus contained within the vaccine produces the SARS-CoV-2 spike protein. It does its job and then goes away. Through this process, the body is able to mount a strong immune response against the spike protein without exposing you to the virus that causes COVID-19.

The two vaccines currently authorized in Canada are messenger RNA vaccines (called mRNA vaccines). mRNA vaccines are a new type of vaccine that don't contain viruses or bacteria. Instead, they contain instructions that teach our cells how to make antigen proteins that will trigger an immune response. Once triggered, our body then makes antibodies and other immune responses. These immune responses help us fight the infection to prevent us from getting sick. You can't get infected from mRNA vaccines.

Q5. Could the antibodies from the COVID-19 vaccine result in a false positive test result?

Two kinds of tests are currently available for COVID-19:

- A test for active infection (diagnostic) that tells you if you have a current COVID-19 infection. This is done using a swab from your nose or throat, or a saliva sample. These tests are expected to continue to perform accurately in vaccinated individuals.
- An antibody (serology) test tells you if you, at some point, were exposed to the virus and had a COVID-19 infection. These tests can also identify if a person was vaccinated. They are not used to diagnose a current COVID-19 viral infection. This test is done using a sample of your blood.

For more information on testing, visit Canada.ca/coronavirus.

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

FINAL January 22, 2021

Key Messages

Bell's Palsy and AEFI's (Adverse Events Following Immunization)

Issue Statement: The issue of people developing Bell's Palsy—an unexplained episode of facial muscle weakness or paralysis— after getting certain vaccinations has been more prevalent in the media. Media calls are expected, so back-pocket messages have been developed to be included in the AEFI MLQ&A package.

Key Messages:

- The rates of Bell's Palsy, or facial paralysis, reported in the clinical trials for both the Pfizer-BioNTech and Moderna vaccines were no higher than those observed in the general population.
- Health Canada and the Public Heath Agency of Canada (PHAC) continue to monitor for Bell's Palsy through post-market surveillance, which also involves vaccine manufacturers and provinces and territories.
- While there have been reports of Bell's Palsy following COVID-19 vaccination, an assessment of causality has not yet been established.
- NACI (National Advisory Committee on Immunization) is monitoring the evidence and will adjust recommendations on use of the vaccine as needed.

Principaux messages

- Le taux de cas de paralysie de Bell (paralysie faciale) signalés dans les essais cliniques des fabricants de vaccins Pfizer-BioNTech et Moderna n'est pas plus élevé que celui observé dans la population générale.
- Santé Canada et l'Agence de la santé publique du Canada (ASPC) continue de surveiller les cas de paralysie de Bell par son mécanisme de surveillance post-commercialisation, qui mobilise également les fabricants de vaccins ainsi que les provinces et les territoires.
- Des cas de paralysie de Bell ont été signalés à la suite de l'administration d'un vaccin contre la COVID-19, toutefois, aucun lien de causalité n'a encore été établi.
- Le CCNI (Comité consultatif national de l'immunisation) surveille les preuves et, au besoin, modifiera les recommandations relatives à la vaccination.

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Health Canada Santé Canada

FINAL – January 7, 2021

Media Lines
Adverse Events Following Immunization web updates

Issue Statement: COVID-19 vaccination began in provinces and territories the week of December 13, 2020. Transparent communications around how many people have been vaccinated against COVID-19, and how many people have reported adverse events is essential in building public trust and increasing vaccine acceptance among Canadians. Starting on January 8, Health Canada and the Public Health Agency of Canada will begin publishing a weekly web update on reported adverse events following immunization.

Principaux messages

- En date du 23 décembre 2020, Santé Canada a autorisé l'utilisation de deux vaccins contre la COVID-19 au Canada, l'un fabriqué par Pfizer-BioNTech et l'autre, par Moderna.

- Santé Canada a homologué les deux vaccins après un examen scientifique complet et indépendant de leur innocuité, de leur efficacité et de leur qualité.

- Comme tous les médicaments, les vaccins peuvent entraîner des effets secondaires et des réactions, aussi appelés événements indésirables.

- Certains événements indésirables sont décelés pendant le processus d'essais cliniques, mais de nouveaux problèmes peuvent apparaître une fois qu'un produit de santé est offert sur le marché parce qu'il est utilisé par un bien plus grand nombre de personnes.

- Les événements indésirables peuvent être aussi bénins qu'une douleur à l'endroit de l'injection ou une faible fièvre, ou de nature beaucoup plus grave (p. ex. réaction allergique). Il faut s'attendre à ce que des événements indésirables se produisent, et cela n'entraînera pas nécessairement de changements à l'homologation d'un vaccin.

- Le Canada a en place un robuste système de surveillance de l'innocuité des vaccins qui mobilise de manière proactive les professionnels de la santé, les fabricants de vaccins, les provinces, les territoires, l'Agence de la santé publique du Canada (ASPC) et Santé Canada.

- Le gouvernement du Canada est déterminé à communiquer rapidement des renseignements accessibles et factuels pour aider les membres de la population canadienne à prendre des décisions éclairées à propos de la vaccination.

- Dans le contexte de l'engagement continu du gouvernement du Canada en matière d'ouverture et de transparence, Santé Canada et l'ASPC fourniront à la population canadienne des mises à jour hebdomadaires au sujet des événements indésirables associés aux vaccins (EIAV), aussi appelés effets secondaires suivant l'immunisation (ESSI), sur Canada.ca.

- Ces mises à jour hebdomadaires sur le Web présenteront de l'information concernant les déclarations d'EIAV transmises au Système canadien de surveillance des effets secondaires suivant l'immunisation (SCSESSI) et à la base de données Canada Vigilance de Santé Canada.

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- À ce jour, Santé Canada et l'ASPC ont reçu des signalements d'événements indésirables suivant l'administration d'un des vaccins contre la COVID-19 homologués au Canada; du nombre, il n'y a pas d'événements indésirables inattendus ou qui suscitent des préoccupations par rapport à l'innocuité des vaccins. Les détails sont affichés ici : https://sante-infobase.canada.ca/covid-19/securite-vaccins/

Questions et réponses

Q1. Qu'est-ce qu'un événement indésirable associé aux vaccins (EIAV)?

Un événement indésirable associé aux vaccins (EIAV), aussi appelé effet secondaire suivant l'immunisation (ESSI), est un fait médical qui se produit après qu'une personne ait reçu un vaccin et qui peut être causé par ce vaccin. Est considéré comme un événement indésirable tout cas de l'une ou l'autre de ces situations :

- maladie, symptôme ou signe défavorable ou non intentionnel;
- résultat de laboratoire anormal (notamment le résultat d'une culture indiquant une cellulite [infection de peau] au site d'injection).

Q2. Qu'est-ce qu'un événement indésirable associé aux vaccins (EIAV) grave ou un événement indésirable d'intérêt particulier (EIIP)?

Un événement indésirable est considéré comme grave dans n'importe laquelle de ces circonstances :

- s'il entraîne la mort;
- s'il met la vie en danger;
- s'il exige l'hospitalisation du patient ou la prolongation d'une hospitalisation en cours;
- s'il entraîne une incapacité ou un handicap persistent ou important;
- s'il entraîne une anomalie congénitale.

Un événement indésirable d'intérêt particulier (grave ou non) est une préoccupation d'ordre scientifique et médical propre au vaccin d'un fabricant qui exige un suivi permanent et une communication rapide. Les fabricants de vaccins et Santé Canada font le suivi des événements indésirables d'intérêt particulier associés aux vaccins contre la COVID-19.

Q3. Où pouvons-nous trouver de l'information sur le nombre de personnes chez qui des événements indésirables associés aux vaccins (EIAV) sont survenus?

Le Canada a en place un robuste système de surveillance de l'innocuité des vaccins après leur mise sur le marché pour la détection d'événements indésirables rares pouvant se produire après l'homologation de vaccins. À compter de janvier 2021, Santé Canada et l'ASPC fourniront à la population canadienne des rapports hebdomadaires sur le Web au sujet des données tirées du Système canadien de surveillance des effets secondaires suivant l'immunisation (SCSESSI) de la base de données Canada Vigilance de Santé Canada. Ces rapports fourniront à la population canadienne de l'information transparente à propos des événements indésirables survenus après l'administration de vaccins contre la COVID-19. Les données seront regroupées

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en fonction de caractéristiques démographiques, du nom du vaccin en cause, de la raison de la gravité des événements indésirables et du type d'événement indésirable.

Les données d'innocuité tirées des essais cliniques menés avec les vaccins contre la COVID-19 homologués montrent que les événements indésirables survenus (p. ex. douleur au site d'injection, fatigue, courbatures) étaient surtout bénins ou modérément graves, comme c'est le cas pour les autres vaccins. En raison de la taille de la population, il se pourrait que des événements indésirables qui n'ont pas été relevés au cours des essais cliniques soient signalés au fur et à mesure que le nombre de personnes vaccinées au Canada augmentera. Dans l'éventualité où des problèmes liés à l'innocuité sont confirmés, Santé Canada n'hésitera pas à prendre les mesures qui s'imposent.

Q4. L'ASPC fera-t-elle rapport sur le pourcentage de personnes ayant reçu chaque vaccin une fois que l'utilisation d'un plus grand nombre de vaccins aura été autorisée au Canada?

Oui, l'Agence de la santé publique du Canada (ASPC) recevra les données des provinces et des territoires concernant la couverture vaccinale de chaque vaccin, une fois que l'utilisation d'un plus grand nombre de vaccins aura été autorisée au Canada, et fera rapport à ce sujet. Un lien vers ces renseignements sera affiché sur la page des rapports sur les événements indésirables associés aux vaccins (EIAV).

Q5. L'ASPC publiera-t-elle la ventilation provinciale et territoriale des événements indésirables?

L'ASPC diffusera des rapports hebdomadaires dont les données seront regroupées en fonction de caractéristiques démographiques, du nom du vaccin en cause, de la raison de la gravité des événements indésirables et du type d'événement indésirable, mais ne divulguera pas la ventilation par administration. Cette approche garantira la transparence à l'égard de la population canadienne dans le respect des considérations relatives à la protection de la confidentialité.

Q6. Pourquoi est-ce important de déclarer un événement indésirable associé à un vaccin (EIAV)?

La déclaration d'un événement indésirable associé à un vaccin (EIAV) fournit de l'information cruciale requise pour déceler et évaluer les problèmes concernant l'innocuité des vaccins qui peuvent constituer un risque pour la santé publique. Cette information est utilisée de concert avec d'autres renseignements relatifs à l'innocuité des vaccins pour déterminer s'il faut prendre des mesures afin de protéger la santé et la sécurité de la population canadienne. Ces mesures peuvent inclure d'avertir la population canadienne des possibles effets secondaires, de modifier l'utilisation recommandée du produit ou de retirer le produit du marché.

Les personnes chez qui un EIAV se produit devraient le signaler à un professionnel de la santé. Les professionnels de la santé doivent remplir le Formulaire de rapport des effets secondaires suivant l'immunisation qui convient pour leur province ou leur territoire et l'acheminer aux autorités de santé publique de la région.

Q7. Qu'en est-il si un événement indésirable associé à un vaccin (EIAV) est signalé?

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Santé Canada est résolu à protéger la santé et la sécurité de la population canadienne et a en place un système d'examen scientifique rigoureux de l'innocuité des vaccins et de leur efficacité à prévenir les maladies qu'ils ciblent.

Avant que tout vaccin puisse être distribué au Canada, il doit être homologué au moyen du système d'examen scientifique rigoureux de Santé Canada. Santé Canada n'homologue pas un vaccin à moins que des données probantes démontrent que ses avantages l'emportent sur ses risques. Les programmes de santé publique au Canada recommandent de nombreux vaccins pour empêcher les gens de contracter des maladies. Ces vaccins sont administrés à de grandes quantités de personnes en santé. C'est pourquoi il est particulièrement important de réglementer l'innocuité, l'efficacité et la qualité des vaccins. Les événements indésirables associés aux vaccins (EIAV) vont de réactions bénignes (p. ex. courbatures, contusions, légers maux de tête) jusqu'à de très rares réactions graves (p. ex. paralysie, atteintes nerveuses). En plus de l'examen scientifique, il y a aussi des systèmes de production de rapports en place pour la surveillance de l'innocuité des vaccins en continu.

Une fois que la vente d'un vaccin est autorisée, les fabricants ont l'obligation de continuer de présenter de l'information sur l'innocuité et l'efficacité de ce vaccin, de surveiller et de signaler tout EIAV possible ainsi que de prendre des mesures pour atténuer les risques. Santé Canada n'hésitera pas à intervenir dans l'éventualité où un nouveau problème touchant l'innocuité est découvert ou si un problème connu s'aggrave.

Toute personne qui est témoin ou qui subit un effet secondaire associé à un vaccin est vivement encouragée à le déclarer à un professionnel de la santé. Les professionnels de la santé ont l'obligation de déclarer les EIAV aux autorités de santé publique de la région. Les autorités de santé publique les signalent ensuite à l'Agence de la santé publique du Canada (ASPC).

Les déclarations d'EIAV transmises à l'ASPC par les administrations fédérale, provinciales et territoriales (FPT) sont rassemblées dans le Système canadien de surveillance des effets secondaires suivant l'immunisation (SCSESSI). Les déclarations d'événements indésirables graves sont présentées à l'ASPC dans les sept jours suivant leur réception par les administrations. Les administrations FPT déclarent aussi à l'ASPC tout signalement de décès dans les 24 heures suivant leur prise de connaissance de la situation. Les déclarations d'événements indésirables graves sont traitées le jour ou le lendemain de leur communication, et l'examen du dossier médical s'amorce dans les trois jours suivant la fin du traitement des données. Si les nombres ou les taux d'EIAV dépassent les nombres ou les taux de fond établis en fonction des normes internationales, un avertissement en matière d'innocuité sera diffusé, ce qui entraînera la prise de diverses mesures. Ces mesures peuvent inclure d'avertir la population canadienne des possibles effets secondaires, de modifier l'utilisation recommandée du produit ou de retirer le produit du marché.

Q8. Quelle forme prendra un programme de soutien en cas de lésions causées par un vaccin?

L'Agence de la santé publique du Canada (ASPC), en collaboration avec les provinces et les territoires, travaille actuellement à la mise en œuvre d'un programme de soutien en cas de lésions causées par un vaccin (PSLV) pancanadien sans égard à la responsabilité. L'établissement d'un PSLV permettra au Canada de renforcer sa stratégie globale en matière de vaccination, ce qui l'aidera à demeurer concurrentiel quant à l'accès aux nouveaux vaccins au fur et à mesure qu'ils sont offerts et, en définitive, à protéger la population canadienne. Cette

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mesure permettra aussi au Canada de se mettre au diapason de ses homologues du G7, qui offrent tous un PSLV national.

Comme la portée de ce programme fait actuellement l'objet de discussions avec les provinces et les territoires, aucun autre détail ne peut être divulgué pour le moment.

Q9. L'innocuité d'un vaccin fait-elle l'objet d'une surveillance de la part du gouvernement du Canada après son homologation?

Le Canada dispose d'un système robuste et bien établi de surveillance des vaccins. Une fois un vaccin sur le marché, Santé Canada et l'Agence de la santé publique du Canada surveilleront les effets indésirables après l'immunisation, en collaboration avec les provinces, les territoires et le fabricant.

La base de données Canada Vigilance de Santé Canada est le programme canadien de surveillance des vaccins sur le marché qui permet de recueillir et d'évaluer les signalements d'effets indésirables présumés pour les produits de santé vendus au Canada. La surveillance des produits offerts sur le marché permet à Santé Canada de surveiller le profil d'innocuité de produits de santé une fois qu'ils sont sur le marché pour veiller à ce que les avantages continuent de l'emporter sur les risques.

Les fabricants de vaccins sont tenus de continuer à recueillir des données sur l'innocuité et l'efficacité à long terme de leurs produits. Pfizer et BioNTech, par exemple, feront un suivi des participants des essais cliniques pendant au moins deux ans après l'administration de la deuxième dose du vaccin. Santé Canada continuera d'évaluer toutes les données accessibles sur l'innocuité des vaccins provenant des études cliniques et de la surveillance après la mise en marché et n'hésitera pas à prendre les mesures appropriées, le cas échéant, pour protéger la santé et la sécurité des Canadiens, notamment, avertir la population canadienne des possibles effets secondaires, modifier l'utilisation recommandée du produit ou même retirer le produit du marché.

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From: Dean, Kelly E on behalf of Strang, Robert
To: Dean, Kelly E
Subject: Fw: Serious AEFI in LTC resident
Date: October 4, 2022 8:00:21 AM

From: Strang, Robert
Sent: Thursday, January 28, 2021 5:35 PM
To: Carew, Maureen <Maureen.Carew@novascotia.ca>; Watson-Creed, Gaynor <Gaynor.Watson-Creed@novascotia.ca>
Subject: RE: Serious AEFI in LTC resident
Thanks for the heads up.
Rob

From: Carew, Maureen <Maureen.Carew@novascotia.ca>
Sent: January 28, 2021 5:26 PM
To: Watson-Creed, Gaynor <Gaynor.Watson-Creed@novascotia.ca>; Strang, Robert <Robert.Strang@novascotia.ca>
Subject: Serious AEFI in LTC resident
Hi Rob and Gaynor
In case you receive any queries, I am looking into a AEFI following the death of a resident vaccinated in a LTCF 20(1) female received Moderna Covid-19 vaccine 20(1) and died 20(1)
20(1)
20(1) There is a temporal association but I don't think a causal one. I will be obtaining more information on cause of death etc but wanted you to be aware.
Maureen
Maureen Carew MD, MSc, FRCPC
Medical Officer of Health
Nova Scotia Department of Health and Wellness
Maureen.Carew@novascotia.ca
Tel: 613-404-6815

From: Dean, Kelly E on behalf of Strang, Robert
To: Dean, Kelly E
Subject: Fw: AEFI - Encephalopathy
Date: October 4, 2022 7:58:36 AM

From: Strang, Robert
Sent: Friday, April 16, 2021 7:07 PM
To: Barbrick, Tracey L <Tracey.Barbrick@novascotia.ca>
Cc: Deeks, Shelley <Shelley.Deeks@novascotia.ca>
Subject: Re: AEFI - Encephalopathy
Can you send any details you have

Rob

Sent from my iPhone

> On Apr 16, 2021, at 7:03 PM, Barbrick, Tracey L <Tracey.Barbrick@novascotia.ca> wrote:
>
> Doesn't sound like the one I'm hearing about…
>
> **From:** Deeks, Shelley <Shelley.Deeks@novascotia.ca>
> **Sent:** April 16, 2021 6:51 PM
> **To:** Barbrick, Tracey L <Tracey.Barbrick@novascotia.ca>; Strang, Robert <Robert.Strang@novascotia.ca>
> **Subject:** Fw: AEFI - Encephalopathy
> This is with Moderna
>
> **From:** Carew, Maureen <Maureen.Carew@novascotia.ca>
> **Sent:** Friday, April 16, 2021 6:36 PM
> **To:** Cole, Teri J <Teri.Cole@novascotia.ca>; Deeks, Shelley <Shelley.Deeks@novascotia.ca>; SURVEILLANCEDHW <SURVEILLANCEDHW@novascotia.ca>
> **Subject:** AEFI - Encephalopathy
> Hi everyone
> Please be aware of an AEFI reported today of confirmed encephalopathy in a 20(1) male. Received Moderna 20(1) and developed neurological symptoms 20(1) 20(1) Will send an update when more information becomes available. I have asked the PHN to enter in Panorama.
> Maureen
> Maureen Carew MD, MSc, FRCPC
> Medical Officer of Health

Nova Scotia Department of Health and Wellness
Maureen.Carew@novascotia.ca
Tel: 613-404-6815

From: Dean, Kelly E on behalf of Strang, Robert
To: Dean, Kelly E
Subject: Fw: SBAR Serious AEFI VITT
Date: October 4, 2022 7:57:08 AM

From: Strang, Robert
Sent: Tuesday, June 1, 2021 10:45 PM
To: Deeks, Shelley <Shelley.Deeks@novascotia.ca>; Kiritsis, Tony <Tony.Kiritsis@novascotia.ca>; Walsh, Tara A <Tara.Walsh@novascotia.ca>
Cc: Barbrick, Tracey L <Tracey.Barbrick@novascotia.ca>; Chouinard, Vanessa P <Vanessa.Chouinard@novascotia.ca>
Subject: RE: SBAR Serious AEFI VITT
Thanks Shelley and good from me too.
Rob

From: Deeks, Shelley <Shelley.Deeks@novascotia.ca>
Sent: June 1, 2021 8:30 PM
To: Kiritsis, Tony <Tony.Kiritsis@novascotia.ca>; Walsh, Tara A <Tara.Walsh@novascotia.ca>; Strang, Robert <Robert.Strang@novascotia.ca>
Cc: Barbrick, Tracey L <Tracey.Barbrick@novascotia.ca>; Chouinard, Vanessa P <Vanessa.Chouinard@novascotia.ca>
Subject: RE: SBAR Serious AEFI VITT
See red suggestions below. 14(1)

14(1)

Shelley Deeks, MD, MHSc, FRCPC, FAFPHM
Deputy Chief Medical Officer of Health
Department of Health and Wellness

From: Kiritsis, Tony <Tony.Kiritsis@novascotia.ca>
Sent: June 1, 2021 7:57 PM
To: Walsh, Tara A <Tara.Walsh@novascotia.ca>; Strang, Robert <Robert.Strang@novascotia.ca>
Cc: Deeks, Shelley <Shelley.Deeks@novascotia.ca>; Barbrick, Tracey L <Tracey.Barbrick@novascotia.ca>; Chouinard, Vanessa P <Vanessa.Chouinard@novascotia.ca>
Subject: RE: SBAR Serious AEFI VITT
Below is what was drafted today, from which we can pull a line or two for tomorrow. 14(1)

14(1)

COVID-19/HEALTH/WELLNESS--Province Reports First VITT Case

14(1)

14(1)

Tony Kiritsis
Communications Advisor
Department of Health and Wellness

From: Walsh, Tara A <Tara.Walsh@novascotia.ca>
Sent: June 1, 2021 6:15 PM
To: Strang, Robert <Robert.Strang@novascotia.ca>
Cc: Deeks, Shelley <Shelley.Deeks@novascotia.ca>; Barbrick, Tracey L <Tracey.Barbrick@novascotia.ca>; Chouinard, Vanessa P <Vanessa.Chouinard@novascotia.ca>; Kiritsis, Tony <Tony.Kiritsis@novascotia.ca>
Subject: Re: SBAR Serious AEFI VITT
I can yes. We have a separate rls drafted that tony can share now that we have these details.

Sent from my iPhone

On Jun 1, 2021, at 6:03 PM, Strang, Robert <Robert.Strang@novascotia.ca> wrote:

Thanks. 14(1) but would like Comms to comment.
Suggest we bring to PO for their awareness before we include in tomorrow's release. Tara, can you do this through Jane?
Rob

From: Deeks, Shelley <Shelley.Deeks@novascotia.ca>
Sent: June 1, 2021 5:57 PM
To: Strang, Robert <Robert.Strang@novascotia.ca>; Barbrick, Tracey L <Tracey.Barbrick@novascotia.ca>; Walsh, Tara A <Tara.Walsh@novascotia.ca>; Chouinard, Vanessa P <Vanessa.Chouinard@novascotia.ca>
Subject: SBAR Serious AEFI VITT
Hi all
The VITT case has now been reported. Below is the detail.
Abbreviated SBAR with medical detail removed; 14(1); 20(1)

14(1); 20(1)

Please let me know what else is needed. Team can now report to PHAC tomorrow.

Client Demographics	Male 20(1)
Situation	Serious AEFI-Client received 1st dose of Astra Zeneca 20(1) 20(1) symptoms including progressive headache
Background	20(1)
Assessment	Reportable To PHAC Fits temporal criteria VITT occurred within 42 days.
Recommendations	Second dose whether it be Moderna or Pfizer to be determined by Specialist.

Shelley Deeks, MD, MHSc, FRCPC, FAFPHM
Deputy Chief Medical Officer of Health
Department of Health and Wellness

From: Dean, Kelly E on behalf of Strang, Robert
To: Dean, Kelly E
Subject: Fw: COVID AEFIs
Date: October 4, 2022 8:01:12 AM

From: Strang, Robert
Sent: Wednesday, December 23, 2020 4:48 PM
To: Fleming, Sarah A <Sarah.Fleming@novascotia.ca>
Cc: Watson-Creed, Gaynor <Gaynor.Watson-Creed@novascotia.ca>; Cole, Teri J <Teri.Cole@novascotia.ca>; Billard, Bev A <Bev.Billard@novascotia.ca>
Subject: Re: COVID AEFIs

Thank you Sarah. No questions from me at this time.

Rob

Sent from my iPhone

> On Dec 23, 2020, at 4:40 PM, Fleming, Sarah A <Sarah.Fleming@novascotia.ca> wrote:
>
> Hi everyone,
> Just wanted to make you aware that we had 2 reports of AEFIs from the immunization clinics.
> -1 20(1) symptoms included swollen and tingling lips. It was recommended that the client should consult with Shelly MacNeil before receiving the 2nd dose of vaccine.
> -1 20(1) symptoms included eye redness and itchiness of the eyes, forearm and neck. It was recommended that the client could proceed with the next dose of vaccine with monitoring.
> Both AEFIs were reviewed by MOHs and reported to PHAC.
> Although these AEFIs occurred 20(1) we were not sent notification until last night and today. We are going to follow-up with Krissy Rose-Muise to determine the status of the development of and SOP and training for AEFI reporting. If that documentation is not ready we may want to send a reminder to NSH Public Health about the reporting process so that we are notified in a timely manner.
> Let me know if you have any questions.
> Thanks,
> Sarah
> Sarah Fleming
> Senior Epidemiologist
> Nova Scotia Department of Health and Wellness
> Barrington Tower, 4th Floor

1894 Barrington Street, P.O. Box 488
Halifax, NS B3J 2R8
Ph. 902-943-9877
sarah.fleming@novascotia.ca

From:	Dean, Kelly E on behalf of Strang, Robert
To:	Dean, Kelly E
Subject:	Fw: For information: Media Lines on AEFIs
Date:	October 4, 2022 8:01:26 AM
Attachments:	ML_vaccine_adverse reactions-general_2020-12-23.docx ATT00001.htm

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From: Strang, Robert
Sent: Thursday, December 24, 2020 11:19 AM
To: Walsh, Tara A <Tara.Walsh@novascotia.ca>
Cc: Cole, Teri J <Teri.Cole@novascotia.ca>; Barbrick, Tracey L <Tracey.Barbrick@novascotia.ca>
Subject: Fwd: For information: Media Lines on AEFIs

FYI

Rob

Sent from my iPhone

Begin forwarded message:

> **From:** "CCMOH SECRETARIAT / CMHC (PHAC/ASPC)" <phac.ccmoh.secretariat-cmhc.aspc@canada.ca>
> **Date:** December 24, 2020 at 10:51:38 AM AST
> **To:** "Romano, Anna (PHAC/ASPC)" <anna.romano@canada.ca>, Avis Gray <Avis.Gray@gov.mb.ca>, Brent Roussin <Brent.roussin@gov.mb.ca>, Catherine Elliott <catherine.elliott@gov.yk.ca>, "Simms, Colleen (Ext.)" <colleensimms@gov.nl.ca>, Colleen Stockley <ColleenStockley@gov.nl.ca>, "Dr. Barb Yaffe" <barbara.yaffe@ontario.ca>, "Henry, Bonnie (Ext.)" <bonnie.henry@gov.bc.ca>, "Hanley, Brendan (Ext.)" <brendan.hanley@gov.yk.ca>, "Emerson, Brian (Ext.)" <brian.emerson@gov.bc.ca>, "Muecke, Cristin (Ext.)" <dr.cristin.muecke@gnb.ca>, "Dr. David Williams" <Dr.David.Williams@ontario.ca>, "Dr. Deena Hinshaw" <deena.hinshaw@gov.ab.ca>, "Dr. Denise Werker" <denise.werker1@health.gov.sk.ca>, "Dr. George Giovinazzo" <george.giovinazzo@cic.gc.ca>, "Morrison, Heather (Ext.)" <hgmorrison@gov.pe.ca>, "Njoo, Howard (PHAC/ASPC)" <howard.njoo@canada.ca>, "Dr. James Worthington" <dr.james.worthington@csc-scc.gc.ca>, "Dr. Janice Fitzgerald" <janice.fitzgerald@gov.nl.ca>, "Russell, Jennifer (Ext.)" <jennifer.russell@gnb.ca>, "Dr. Michael Patterson" <MPatterson@GOV.NU.CA>, "Strang, Robert" <Robert.Strang@novascotia.ca>, "Shahab, Saqib (Ext.)" <saqib.shahab@health.gov.sk.ca>, "Sharma, Supriya (HC/SC)" <supriya.sharma@canada.ca>, "Tam, Dr Theresa (PHAC/ASPC)" <drtheresa.tam@canada.ca>, "Wong, Tom (SAC/ISC)" <tom.wong@canada.ca>, "Cleary, Eilish (SAC/ISC)" <eilish.cleary@canada.ca>, Evan Adams <Evan.Adams@fnha.ca>, Greg Haley <GREG.Haley@forces.gc.ca>, "Arruda,

Horacio (Ext.)" <horacio.arruda@msss.gouv.qc.ca>, "Kandola, Kami (Ext.)" <kami_kandola@gov.nt.ca>, Philip Christoff <Philip.christoff@gov.yk.ca>, Reka Gustafson <reka.gustafson@phsa.ca>, SK CMOH Single Window <OCMHO@health.gov.sk.ca>, Suzanne Fedorowich <Suzanne.Fedorowich@health.gov.sk.ca>, Tami Denomie <tami.denomie@health.gov.sk.ca>, Trish Merrithew <Trish.Merrithew-Mercredi@gov.ab.ca>, Vincent Beswick-Escanlar <VINCENT.BESWICK-ESCANLAR@forces.gc.ca>, YK Surveillance <YCDCSurveillance@gov.yk.ca>, Yves Jalbert <Yves.Jalbert@msss.gouv.qc.ca>
Cc: Ashley Halicki <Ashley.Halicki@gov.bc.ca>, "Auger, Julie (PHAC/ASPC)" <julie.auger@canada.ca>, Bailey Muir-Cressman <Bailey.Muir-Cressman@gov.yk.ca>, "Barton, Kimby (PHAC/ASPC)" <kimby.barton@canada.ca>, "Bent, Stephen (PHAC/ASPC)" <stephen.bent@canada.ca>, Carol Kurbis <Carol.Kurbis@gov.mb.ca>, "Carter, Luke (HC/SC)" <luke.carter@canada.ca>, "CCMOH SECRETARIAT / CMHC (PHAC/ASPC)" <phac.ccmoh.secretariat-cmhc.aspc@canada.ca>, "Charos, Gina (PHAC/ASPC)" <gina.charos@canada.ca>, Cindy Kruger <cindy.kruger@csc-scc.gc.ca>, "Rogers, Cindy (Ext.)" <cindy.rogers@health.gov.sk.ca>, Colleen Dudar <colleen.dudar@gov.mb.ca>, "Sabapathy, David (Ext.)" <dsabapathy@gov.pe.ca>, "David, Renee (PHAC/ASPC)" <renee.david@canada.ca>, "Davies, Stephanie (PHAC/ASPC)" <stephanie.davies@canada.ca>, Dawn Osciak <dawn.osciak@gov.mb.ca>, "Panchyshyn, Debbie (Ext.)" <debbie.panchyshyn@gov.mb.ca>, "Denis, Joel (PHAC/ASPC)" <joel.denis@canada.ca>, Diane Lu <diane.lu@forces.gc.ca>, Donna Milne <Donna.Milne@gov.yk.ca>, Elaine Barrett-Cramer <elaine.barrett-cramer@cic.gc.ca>, "Look, Elaine (Ext.)" <elaine_look@gov.nt.ca>, "Elmslie, Kim (PHAC/ASPC)" <kim.elmslie@canada.ca>, "Evans, Cindy (PHAC/ASPC)" <cindy.evans@canada.ca>, "Everitt, Louisa (PHAC/ASPC)" <louisa.everitt@canada.ca>, "Fournier, Sarah (PHAC/ASPC)" <sarah.fournier@canada.ca>, Gillian MacDonald <gillian.macdonald2@ontario.ca>, "Guenette, Tara-Lynn (PHAC/ASPC)" <tara-lynn.guenette@canada.ca>, "Hamel, Sonia (PHAC/ASPC)" <sonia.hamel@canada.ca>, Heidi Liston <Heidi.Liston@gnb.ca>, "Henry, Erin (PHAC/ASPC)" <erine.henry@canada.ca>, "Hill, Allison (HC/SC)" <allison.hill@canada.ca>, "Hostrawser, Bonnie (PHAC/ASPC)" <bonnie.hostrawser@canada.ca>, "HPOC PHM / COPS MSP (PHAC/ASPC)" <phac.hpoc.phm-msp.cops.aspc@canada.ca>, "Ingraham, Erin (HC/SC)" <erin.ingraham@canada.ca>, "Sherren, Janice (Ext.)" <jesherren@gov.pe.ca>, Jasmine Pawa <jpawa@gov.nu.ca>, Jazz Atwal <Jazz.Atwal@gov.mb.ca>, Jennifer White <jennifer.white2@gov.mb.ca>, Jocelyn LeBlond <Jocelyn.LeBlond@health.gov.sk.ca>, Johnatha Smith <Jonathan.Smith@CSC-SCC.GC.CA>, "Follett, Juanita (Ext.)" <juanitafollett@gov.nl.ca>, Karen Scherle <Karen.Scherle@health.gov.sk.ca>, "Cadorette, Katie (HC/SC)" <katie.cadorette@canada.ca>, "Dean, Kelly E" <Kelly.Dean@novascotia.ca>, "King2, Arlene (PHAC/ASPC)" <arlene.king2@canada.ca>, "Seeds, Laura (Ext.)" <laura.seeds@ontario.ca>, Laurel Thompson <laurel.thompson@gov.bc.ca>, "Hunter, Laurie (PHAC/ASPC)" <laurie.hunter@canada.ca>, "Lebans, Anne (PHAC/ASPC)" <anne.lebans@canada.ca>, "Lewis, Darlene (SAC/ISC)" <darlene.lewis@canada.ca>, "Lior, Lee (PHAC/ASPC)" <lee.lior@canada.ca>,

Lori Carpenter <lori.carpenter@fnha.ca>, "Yeo, Lyn (Ext.)" <lyn.yeo@health.gov.sk.ca>, "MacDonald2, Tammy (PHAC/ASPC)" <tammy.macdonald2@canada.ca>, "MacKenzie, Sara (HC/SC)" <sara.mackenzie@canada.ca>, Maureen Carew <maureen.carew@forces.gc.ca>, "Maher, Maurica (Ext.)" <maurica.maher@forces.gc.ca>, "McCarney, Jane (PHAC/ASPC)" <jane.mccarney@canada.ca>, "McGarr, Holly (PHAC/ASPC)" <holly.mcgarr@canada.ca>, "McLeod, Robyn (PHAC/ASPC)" <robyn.mcleod@canada.ca>, "McNeill, Robin (PHAC/ASPC)" <robin.mcneill@canada.ca>, "Conly, Meghan (HC/SC)" <meghan.conly@canada.ca>, "Sveinson, Michelle (Ext.)" <michelle.sveinson@gov.mb.ca>, "Mitra, Debjani (PHAC/ASPC)" <debjani.mitra@canada.ca>, NB Secretariat <NB-PT-PHNC-Secretariat@gnb.ca>, "Paddle, Lisa (PHAC/ASPC)" <lisa.paddle@canada.ca>, "Huber, Pamela (PHAC/ASPC)" <pamela.huber@canada.ca>, Pamela MacMillan <pamela.macmillan@gnb.ca>, Pat Seaman <pat.seaman@gnb.ca>, Penny Higdon <penny.higdon@gnb.ca>, "Ponic, Pamela (PHAC/ASPC)" <pamela.ponic@canada.ca>, Rachel Comeau <rachel.comeau@gnb.ca>, Rachel Mailhot <rachel.mailhot@cic.gc.ca>, "Almond, Richard (Ext.)" <richard.almond@gov.bc.ca>, Richard Baydack <Richard.Baydack@gov.mb.ca>, "Robinson, Kerry (PHAC/ASPC)" <kerry.robinson@canada.ca>, "Romano, Anna (PHAC/ASPC)" <anna.romano@canada.ca>, "Russo, Laura (HC/SC)" <laura.russo@canada.ca>, "Rutledge-Taylor, Katie (PHAC/ASPC)" <katie.rutledge-taylor@canada.ca>, "Salvadori, Marina (PHAC/ASPC)" <marina.salvadori@canada.ca>, "Poirier, Samantha (Ext.)" <samantha.poirier@gnb.ca>, "Siu, Winnie (PHAC/ASPC)" <winnie.siu@canada.ca>, "Smith, Cheryl (HC/SC)" <cheryl.smith@canada.ca>, "Taylor, Stephanie (Ext.)" <stephanie.taylor@gov.bc.ca>, Sylvie Poirier <sylvie.poirier@msss.gouv.qc.ca>, "Cidsc Secretariat (PHAC/ASPC)" <phac.cidsc.secretariat.aspc@canada.ca>, "Taylor, Dorcas (PHAC/ASPC)" <dorcas.taylor@canada.ca>, "Cole, Teri J" <Teri.Cole@novascotia.ca>, Tracey Aylward <traceyaylward@gov.nl.ca>, Vanessa Blyan <vanessa.blyan@gov.ab.ca>
Subject: For information: Media Lines on AEFIs

** EXTERNAL EMAIL / COURRIEL EXTERNE **
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Dear SAC members,

You will find attached media lines regarding AEFIs. Please note that the French version will follow.

The media lines will be posted on CNPHI for ease of reference.

Thank you

SAC Secretariat

Health Canada Santé Canada

December 22, 2020, 10:17 a.m.

Media Lines

Vaccine adverse reactions – general

Issue Statement: With the roll-out of COVID-19 vaccines across Canada, reports of adverse events following immunization are expected and will lead to media questions.

Key Messages:

- Like any medication, vaccines can cause side effects and reactions.
- Some adverse events are identified during the clinical trial process; however, new issues can arise once a health product is on the market because it is being used by a much larger number of people.
- Adverse events could be as mild as soreness at the site of injection or a slight fever, or more serious in nature, such as an allergic reaction. Such events are to be expected, and will not necessarily change the risk/benefit profile of a vaccine.
- Canada has a strong vaccine safety monitoring system in place that involves healthcare professionals, vaccine manufacturers, the provinces and territories, the Public Health Agency of Canada, and Health Canada.
- Health Canada will examine and assess any new safety concerns brought to its attention and will take appropriate action if any new safety issues are confirmed. This could include communicating new risks to Canadians and healthcare providers or changing the recommended use of the product.

Supplementary Messages on allergic reactions:

- Some individuals may experience serious allergic reactions to vaccines. Warnings about allergic reactions are included in the product monographs of all vaccines, including those for COVID-19 vaccines and in educational materials for health care professionals and for consumers.
- In addition, measures are to be in place at COVID-19 vaccination clinics to identify and manage allergic reactions if they arise.
- People with allergies to any of the ingredients in a COVID-19 vaccine should not receive that vaccine. People with a history of serious allergic reactions to other vaccines, a drug or a food should speak to their health professional before receiving a COVID-19 vaccine.

Questions and Answers:

Q1. What is the difference between an adverse event following immunization (AEFI) and a side effect?

An AEFI is any health problem that happens following immunization but is not necessarily caused by the vaccine. Post-market surveillance of vaccines in Canada includes monitoring AEFIs in order to:

- continuously assess the safety of marketed vaccines in Canada;

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- identify increases in the frequency or severity of previously identified vaccine-related reactions;
- identify previously unknown AEFIs that could possibly be related to a vaccine;
- identify areas that require further investigation and/or research; and,
- provide timely information on AEFI reporting profiles for vaccines marketed in Canada that can help inform immunization programs and guidelines.

Side effects are those AEFI that are known to be related to the vaccine. The majority are minor reactions, but sometimes more serious events can occur. This can include rare serious events such as allergic reactions or other events that result in hospitalization or an extended hospital stay, chronic or significant disability, death, or that are life threatening.

Side effects include known unpleasant or negative side effects caused by a particular vaccine. Usually, vaccine side effects are minor and go away on their own within a few days.

Q2. Should Canadians expect short-term side effects following vaccination with the Pfizer-BioNTech vaccine?

No serious safety concerns were identified in the Pfizer-BioNTech vaccine clinical trials.

Mild side effects were reported by clinical trial participants, including:

- injection site pain (84.1%)
- fatigue (62.9%)
- headache (55.1%)
- muscle pain (38.3%)
- chills (31.9%)
- joint pain (23.6%)
- fever (14.2%)

Some of the reported side effects, including fever, were more frequent after the second dose. In clinical tests, adverse events were generally milder and less frequent in those over 55 years of age.

Vaccine providers are asked to report AEFIs through local public health officials and to follow AEFI reporting requirements that are specific to their province or territory. Any serious or unexpected adverse event felt to be temporally related to vaccination should be reported immediately.

Q3. What about long-term side effects? How can we know Canadians who get the vaccine now won't experience adverse effects years from now?

Health Canada is reviewing vaccines to treat COVID-19 under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*. The Interim Order allows Health Canada to expedite the review and approval of COVID-19 drugs and vaccines, while maintaining Canada's high standards for safety, efficacy and quality.

Canada has a robust and well-established vaccine safety surveillance system. Once the vaccine is on the market, Health Canada and the Public Health Agency of Canada will monitor for any adverse events after immunization, in collaboration with the provinces and territories and the manufacturer.

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All vaccines have potential risks associated with them, though most (95%) occur in the first 42 days following immunization.

Vaccine manufacturers are expected to continue to collect information about the long-term safety and effectiveness of their products. Pfizer and BioNTech, for example, will be following clinical trial participants for at least two years after receiving the second dose of the vaccine. Health Canada will continue to review all the available safety data from clinical studies and post-market surveillance and will not hesitate to take appropriate action, if required, to protect the health and safety of Canadians. This could include warning Canadians about potential side effects, changing the recommended use of the product, or even removing the product from the market.

To further support Health Canada's efforts to monitor the safety of COVID-19 vaccines, the Interim Order provides the authority to impose terms and conditions on any authorization at any time, such as risk mitigation measures and additional assessments of safety information.

At this time, safety data from clinical trials show that these new generation vaccines are performing similarly to other vaccines. If any safety issues are confirmed, Health Canada will not hesitate to take appropriate action.

Q4. How should Canadians report adverse events following immunization?

Individuals who experience an adverse event following immunization should report it to a healthcare professional. Healthcare professionals should complete the Adverse Events Following Immunization (AEFI) Form appropriate to their province or territory and send it to their local Health Unit.

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From: Dean, Kelly E on behalf of Strang, Robert
To: Dean, Kelly E
Subject: Fw: AEFI event
Date: October 4, 2022 8:00:47 AM

From: Strang, Robert
Sent: Thursday, January 14, 2021 4:30 PM
To: Carew, Maureen <Maureen.Carew@novascotia.ca>; Watson-Creed, Gaynor <Gaynor.Watson-Creed@novascotia.ca>
Subject: RE: AEFI event
Thanks.
Rob

From: Carew, Maureen <Maureen.Carew@novascotia.ca>
Sent: January 14, 2021 4:19 PM
To: Strang, Robert <Robert.Strang@novascotia.ca>; Watson-Creed, Gaynor <Gaynor.Watson-Creed@novascotia.ca>
Subject: AEFI event
Hi Rob and Gaynor
I wanted you to be aware of an AEFI event 20(1) following the second dose of Pfizer vaccine. The individual is 20(1) who had some generalized itchiness after 20(1) first dose of Pfizer vaccine. 20(1) was referred to 20(1) through Shelly McNeil for assessment to determine the requirement for a second dose 20(1) 20(1) 20(1). Following the second dose 20(1) the individual immediately experienced a headache, increasing itchiness, was flushed and experienced a feeling of fullness in the throat and tongue. 20(1)

I don't have a status report on the person at this time but will follow-up with 20(1) I wanted you both to be aware.

Did you want to discuss?

thanks,

Maureen
Maureen Carew MD, MSc, FRCPC
Medical Officer of Health, Long-Term Care and COVID19 response
Department of Health and Wellness

email: maureen.carew@novascotia.ca
tel: 1-613-404-6815

Not responsive

From: Carew, Maureen <Maureen.Carew@novascotia.ca>
Sent: April 15, 2021 6:29 PM
To: Deeks, Shelley <Shelley.Deeks@novascotia.ca>
Cc: Sommers, Ryan <Ryan.Sommers@nshealth.ca>; Cram, Jennifer <Jennifer.Cram@nshealth.ca>
Subject: Re: AEFIs today

Not responsive

Some unusual AEFIs have come in today– stroke, thrombotic events (PE), thrombocytenia alone (no thrombosis with thrombocytopenia).

Maureen
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