Document Released Under the Access to Information Act by the Public Health Agency of Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par l'Agence de la santé publique du Canada

De : Weeks, Ashley (PHAC/ASPC)
À : Patel, Nimeshkumar (PHAC/ASPC)
Objet : FW: Draft Blurb For the Vaccine Safety Website
Date : 2024-06-20 13:34:00
Pièces jointes : COVID AEFIs InfoBase.docx

From: Joanette, Quenby (HC/SC)
Sent: Monday, March 11, 2024 10:25 AM
To: Panic, Mirna (PHAC/ASPC) ; Manhire, Sheila (HC/SC)
Cc: Weeks, Ashley (PHAC/ASPC) ; Ogunnaike-Cooke, Susanna (PHAC/ASPC)
Subject: RE: Draft Blurb For the Vaccine Safety Website

Good morning, all!
I took Mirna's blurb and edited it with tracked changes. Please let me know if this still gets your message across. Since Web reviewed for plain language, I can get the translation sorted.
Also, are you looking to archive each page in the content block, and therefore put this blurb on each page? When we archive pages, we ask Google to de-index them from searches so users don't find old data. You can keep it linked from your various report pages, but it will be removed as a crosslink across Canada.ca outside your specific CAEFISS pages.
We can certainly discuss this at our meeting.
Cheers,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Friday, March 8, 2024 5:04 PM
To: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Sheila

Thank you so much for this update – I appreciate the work you have done to make it more "straight to the point" and succinct. I have made some small tweaks,. I moved the last sentence to the first paragraph, as I think it helps with flow (personal preference – feel free to ignore it). We have also added a bit of nuance in the text as we just think it is important to highlight that we are not just stopping the reporting because the response is getting downgraded. There has been a shift in the disease epidemiology, in vaccine uptake AND in the amount of data we

Document Released Under the Access to Information Act by the Public Health Agency of Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par l'Agence de la santé publique du Canada

have to establish the vaccine's safety profile. Our suggestion is below:

**

This page is no longer being updated. *With transmission becoming endemic, as opposed to being a global health emergency, the response to COVID-19 is being downgraded. Frequent reporting on COVID-19 vaccine safety is no longer required as the safety profile of COVID-19 vaccines has been well established following extensive research and monitoring.*

COVID-19 vaccine safety monitoring will continue as part of routine safety monitoring of all authorized vaccines in Canada. Recent reports and publications on vaccine safety are available: https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html

**

Sheila and Quenby; we have also received an info request from the public asking when the next report will be. We are asked to respond before March 26. Is it realistic to hope that this blurb (or a modified version of it, following Quenby's magic) could be put online before that date? Thanks for your advice and guidance

Have a lovely and restful weekend!

Mirna

Mirna Panić (elle/she/her)
Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Wednesday, March 6, 2024 3:15 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Mirna,

Thanks for meeting with me yesterday! I like the text you've provided; and think it will be very useful for developing MLQAs on the discontinuation of this tool for COVID vaccine safety reporting. However, for web, I recommend keeping it shorter and more plain language. I've attached a revised version that Quenby can send for plain language review if you are comfortable with the main points.

Thanks again,

Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205
Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada

Document Released Under the Access to Information Act by the Public Health Agency of Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par l'Agence de la santé publique du Canada

Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Tuesday, March 5, 2024 5:58 PM
To: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: Draft Blurb For the Vaccine Safety Website

Hi Sheila,

Thank you for taking the time to meet with us today. Based on our discussion, I have modified our initial draft blurb to indicate the transition of the COVID-19 reporting. I did not have time to run this by the lovely Ashley before she wrapped up her work for the day, so I hope I am doing her proud

As a reminder, we were hoping to put the disclaimer on this page: COVID-19 vaccine safety: Report on side effects following immunization - Canada.ca

Given the transition of COVID-19 epidemiology from a pandemic to an endemic state, and the fact that the safety profile of COVID-19 vaccines has been well established following extensive research and monitoring in Canada and globally, the Public Health Agency of Canada and Health Canada will be transitioning back towards routine surveillance data publication and communication of vaccine safety concerns. As such, this is the last web update of the quarterly report on adverse events following immunization with a COVID-19 vaccine. This change aligns with national and international shifts in practice, which recognize that rapid reporting is no longer needed to gather and share new or emerging evidence on potential vaccine safety issues specific to the COVID-19 pandemic vaccination campaign.

Though no new safety signals have appeared since June 2021, robust routine safety monitoring of COVID-19 vaccines administered in Canada will continue, along with prompt communication on any updated safety advice when needed. In the coming months, we will be transitioning to new vaccine safety communication and reporting tools aiming to support individuals and families across Canada in making evidence-informed decisions to protect their health. Our most recent reports and publications on vaccine safety can be accessed on the following page: https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html .

We are looking forward to your feedback and insights

M

Mirna Panić (elle/she/her)
Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

Document Released Under the Access to Information Act by the Public Health Agency of Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par l'Agence de la santé publique du Canada

This contentpage is no longer being updated. because:

- the response to COVID-19 has been downgraded, as it's no longer considered a global health emergencyWith transmission becoming endemic, as opposed to being a global health emergency, the response to COVID-19 is being downgraded.
- Ffrequent reporting on COVID-19 vaccine safety is no longer required, as the safety profile of theCOVID-19 vaccines has been well established following extensive research and monitoring.

Reporting on COVID-19 vaccine safety monitoring will continue as part of routine safety monitoring of all approvedauthorized vaccines in Canada. Recent reports and technical publications on vaccine safety are available.: https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html

Commenté [QJ1]: Put what's happened up front. You don't even need to mention pandemic to endemic. It cuts back words to make the notice more precise.

I've also made bullet points as they're both reasons the report is being discontinued.

Commenté [QJ2]: I've pointed this out all over Canada.ca when we're provided this phrase. We don't explain what a safety profile is anywhere on the site that I've been pointed to for gen pop. As this is the case, we shouldn't be using terms that need to be defined, as it means nothing to the everyday user. We've opted for 'safe' on Canada.ca, so I'm recommending the same on InfoBase.

I do note it on this page, but it's undefined, though it shouldn't be. I still recommend following what we do on Canada.ca.

Commenté [QJ3]: Removed for repetition.

Commenté [QJ4]: Changed this up to remove the repetition of 'monitoring.'

Commenté [QJ5]: This is the word HC agreed to use on gen pop pages for Canada.ca. I note that wasn't conveyed in InfoBase content here. I still recommend using the plain language we've established on Canada.ca.

If you want users to understand these reports, I recommend a plain language summary moving forward.

Commenté [QJ6]: Because we need to create descriptive link text for screen readers, as spelled out URLs aren't accessible, I put the link on the text about available reports.

I will note that we normally don't link out to technical documents for gen pop, but as I understand it, this is a shared audience page. Given this, I've specified that the reports are technical.

ATIA - 19(1)

Document Released Under the Access to Information Act by the Public Health Agency of Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par l'Agence de la santé publique du Canada

De : Weeks, Ashley (PHAC/ASPC)
À : Ogunnaike-Cooke, Susanna (PHAC/ASPC)
Cc : El Jaouhari, Maryem (PHAC/ASPC)
Objet : RE: Bullets for VP/OCPHO bilat for the week of Jan 22
Date : 2024-01-25 10:38:00
Pièces jointes : Online report discontinuation - communique.docx

---

Hi Susanna,

Thank you for sharing this, I think the bullets you provided for VP/OCPHO were great so I just rearranged it a little and added in some text to thank everyone and celebrate this milestone (draft email attached).

Please let me know if you have any edits. Would you prefer to send out the communiqué yourself (it might sound nice coming from the director), or would you prefer I send it? Either way, I'd recommend we send to:

1. **Strategic comms**: Sheila Manhire (sheila.manhire@hc-sc.gc.ca)
2. **Digital comms**: Andrea Friesen (andrea.friesen@hc-sc.gc.ca), Karen Wu (karen.wu@hc-sc.gc.ca), and their team account is datadashboards-donneestableauxbords@hc-sc.gc.ca
3. **Infobase**: Scott Van Millingen (scott.vanmillingen@phac-aspc.gc.ca), Benoit Tremblay (benoit.tremblay@phac-aspc.gc.ca), Cody (cody.douris-peeke@phac-aspc.gc.ca), and their team account is infobase@phac-aspc.gc.ca
4. **Health Canada**: Patrick Fandja, Jhona Rose, Marie-Eve Moreau, Riley Thompson (riley.thompson@hc-sc.gc.ca), and William Oukouomi Tchatchouang (william.oukouomitchatchouang@hc-sc.gc.ca)
5. **VVWG members** (via Carmen and/or Julie)

[redacted]

On the HC and comms sides, there has been a lot of staff turnover so I don't know that I can be able to pinpoint any award recommendations from those teams just yet.

Thanks so much to you and to Maryem for helping review,

Ashley

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC)
Sent: Tuesday, January 23, 2024 1:15 PM
To: Weeks, Ashley (PHAC/ASPC)
Subject: FW: Bullets for VP/OCPHO bilat for the week of Jan 22

Hi Ashley,

Please see below the briefing info I provided for OCPHO to be informed of our discontinuation of the online report, for your use in drafting a short communique that we can send to VVWG, Comms, etc. Also, please advise if there are specific individuals in Comms, Infobase and HC that we should recognize with instant awards for their work on this.

Thanks,

Susanna

==========

Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

Document Released Under the Access to Information Act by the Public Health Agency of Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par l'Agence de la santé publique du Canada

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC)
Sent: Friday, January 19, 2024 5:37 PM
To: Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>
Cc: Leinan, Valerie (PHAC/ASPC) <valerie.leinan@phac-aspc.gc.ca>
Subject: Bullets for VP/OCPHO bilat for the week of Jan 22

Hi DGO,

Here are some bullets for Don's bilat with OCPHO:

For information: Transition to endemic: Integrating COVID-19 AEFI reporting into regular vaccine safety report format and timeline

Issue: VSS will be transitioning from the COVID-19-specific online AEFI report towards an integrated all-vaccine AEFI report.

Background and current status: The COVID-19 specific online AEFI report was launched in January 2021 on a weekly posting schedule. With the evolution of the pandemic and transition from primary to booster schedules, the online report schedule was modified to a monthly schedule in spring 2022, and then a quarterly schedule in spring 2023. The report posted on January 19, 2024 was the last iteration of this COVID-specific AEFI report.

Rationale: Given the transition from pandemic to endemic and the decrease in COVID-19 vaccine uptake, the regular COVID-19 AEFI report no longer serves its initially conceived purpose of providing regular updates on emerging safety issues for a pandemic vaccine campaign.

Considerations:

- Over 100,000 million doses of vaccines have been administered in Canada alone, with billions administered internationally. The general safety profile of the vaccines is now well characterized, with any new knowledge emerging from other sources e.g. enhanced surveillance or research.
- Going forward, the online report is less informative on new safety issues given that COVID-19 vaccine uptake has decreased significantly (and therefore identification of rare safety issues would occur over longer timelines).
- PTs are making changes to their provision of doses administered data, which will impact the data quality and required format for the AEFI report, e.g. without data on doses administered, the AEFI report would need to shift to using doses distributed data, after which sex and age analysis for AEFI rates will no longer be possible.
- International counterparts with COVID-specific AEFI reporting have discontinued their reports.
- Web analytics indicates that interest in the online report in 2023 was low for most of the year, with a slight increase during the flu season (when COVID-19 vaccine campaigns were co-occurring).
- HC colleagues are supportive of regularizing the reporting of COVID-19 AEFI into a more routine report (frequency to be determined) due to decrease in their COVID-19-specific resources.

Next steps:

- PHAC will work with HC to discuss plans and options for AEFI reporting (all vaccines) going forward that balances transparency in providing public information on AEFI with available resources in implicated HC and PHAC teams
- Lessons learned from the pandemic will be leveraged to provide information tailored to specific audiences, in consultation/collaboration with Comms and the IDVPB Immunization Support and Knowledge Mobilization Teams,

Thanks,

Susanna

==========

Document Released Under the Access to Information Act by the Public Health Agency of Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par l'Agence de la santé publique du Canada

Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

*Note I am sending this message at a time that suits me and which may not be part of your regular working hours. Please do not feel as though you need to respond right away
*Notez que j'envoie ce message à un moment qui me convient et qui peut ne pas faire partie de vos heures de travail habituelles. Ne vous sentez pas obligé de répondre tout de suite.

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC)
Sent: Monday, January 15, 2024 2:33 PM
To: COVID-19 Vaccine Surveillance / Surveillance Du Vaccin de la COVID-19 (PHAC/ASPC) <phac.vaccinesurveillance-surveillanceduvaccin.aspc@canada.ca>
Cc: Wan, Natalie (PHAC/ASPC) <natalie.wan@phac-aspc.gc.ca>; Yome, Julie (PHAC/ASPC) <julie.yome@phac-aspc.gc.ca>
Subject: FW: DG-VP bilat bullets - Jan 15

Hi DGO,
Here are some bullets re the Data Sharing MRAP items.
I'll need to develop some additional bullets for another item: COVID-19online report.
Thanks,
Susanna

==========

Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

From: Yome, Julie (PHAC/ASPC) <julie.yome@phac-aspc.gc.ca>
Sent: Monday, January 15, 2024 10:32 AM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Cc: Henry, Minoo (PHAC/ASPC) <minoo.henry@phac-aspc.gc.ca>
Subject: DG-VP bilat bullets - Jan 15

Hi Susanna,
Here is a draft of the DG-VP bilat update on the MRAP:
Subject: OAG Audit (COVID-19 vaccines) MRAP item on data sharing
For information.
Update: A proposal for HC read-only access to CAEFISS has been sent to FPTs for consideration, an important step in the PHAC-led consultation on the data sharing MRAP item.
Background:

- PHAC launched consultation sessions in spring 2023 with FPT partners on a proposal for HC staff to have access to the PHAC-led CAEFISS database.
- After some delays, a proposal summary for read-only access for HC to CAEFISS was sent to PTs for review and decision by February 22.
- Data sharing discussions with PTs will continue in March to discuss outcomes and next steps for consultation on data sharing with manufacturers and the WHO.
- While there are several interdependent components to data sharing, making progress on this first item will maintain momentum and engagement with FPT immunization partners.
- Discussing PT issues in this step-wise manner will allow incremental progress to be made and targeted solutions to be identified for outstanding issues.

Considerations:

Document Re
Information A
Canada / Doc
l'accès à l'info
publique du C

- Stakeholder relations risk: PHAC has received numerous requests from FPT partners for clarity on the HC parameters for access to CAEFISS and have cited frustration/impatience at the delays and the resultant impact on them re postponing their internal consultation discussions.
- Portfolio risk: If successful, this initiative would represent a significant and positive incremental step to resolve a longstanding challenge in vaccine safety surveillance. Given this decade-plus challenge, it is critical that PHAC and HC build on previous discussions and make progress on the long standing issues that have been identified.
- Portfolio risk: PHAC has sought an extension for this MRAP item due to the delays in obtaining information from HC. In addition, extensions have also been sought for the subsequent two MRAP items as these also involve discussions with the same FPT Immunization program partners on data sharing with manufacturers and with WHO.

Hi all,

We wanted to reach out to confirm the discontinuation of our COVID-19 AEFI online report. Last Friday, January 19th's web update was our last time updating this website in its current format. This milestone comes after 3 years of routine web postings including a total of 84 iterations since January 2021.

Given the transition from pandemic to endemic and the decrease in COVID-19 vaccine uptake, the regular COVID-19 AEFI online report no longer serves its initially conceived purpose of providing regular updates on emerging safety issues for a pandemic vaccine campaign.

The general safety profile of the vaccines is now well characterized, with any new knowledge emerging from other sources e.g. enhanced surveillance or research. Going forward, the online report is less informative on new safety issues given that COVID-19 vaccine uptake has decreased significantly (and therefore identification of rare safety issues would occur over longer timelines). Additionally, jurisdictions are making changes to their provision of doses administered data, which will impact the data quality and required format for the AEFI report; International counterparts with COVID-specific AEFI reporting have discontinued their reports; and colleagues are generally supportive of shifting the reporting of COVID-19 AEFIs into a more routine report (frequency to be determined) with focus on all vaccines due to decrease in their COVID-19-specific resources.

PHAC will work with HC to discuss plans and options for AEFI reporting for all vaccines going forward that balances transparency in providing public information on AEFI with available resources in implicated HC and PHAC teams. Lessons learned from the pandemic will be leveraged to provide information tailored to specific audiences, in consultation/collaboration with Comms and the IDVPB Immunization Support and Knowledge Mobilization Teams.

Lastly, we just wanted to extend an sincere thank you to all of you for your invaluable contributions to this report! It's been a pleasure working with you on this product and we look forward to our future collaborations.

Best,
The Vaccine Safety Analytics team

De : Pader, Joy (PHAC/ASPC)
À : Weeks, Ashley (PHAC/ASPC)
Objet : RE: Environmental Scan and CAEFISS Routine Report
Date : 2024-03-01 14:29:18
Pièces jointes : Environmental scan.docx

Good afternoon Ashely,
Here is what I have for the Environmental Scan of AFEI reporting from various organizations in Canada and internationally. I tried to find as much information I could from the provinces and territories, but many of their current websites don't provide link to dashboards or recent reports. Please let me know if I have missed anything and I would be happy to fill them out in the table. I hope I have provided enough information. I can continue to look if anything else comes up.
Best,
Joy

From: Weeks, Ashley (PHAC/ASPC)
Sent: Wednesday, February 14, 2024 10:56 AM
To: Pader, Joy (PHAC/ASPC)
Subject: Environmental Scan and CAEFISS Routine Report
Hi Joy,
Here are a few more details on the tasks that I mentioned during today's meeting. No rush to start on these, I hope you feel better soon!

An environmental scan of AEFI reporting

- For COVID-19 and other vaccines to help inform our online reporting planning.
- Why don't we aim to have a draft ready within the next 2 or so weeks? We can keep in touch about the progress though
- This scan would be important to gauge how other jurisdictions (international and provincial/territorial) disseminate vaccine safety information to the public to help people make informed decisions about vaccination.
- I'd like to please include the following information, at minimum, in addition to any other fun pieces of info that you find
    - Type of report (webpage, dashboard, manuscript, infographic, etc.)
    - Which vaccine(s) they report on
    - Frequency of report updates
    - Information included (age, sex, rates, doses administered, AEFIs, etc)
    - Anything else of relevance
    - Other international jurisdictions to try could be: Australia, European CDC, Eurosurveillance journal, etc.
- Example of what I'm thinking of (feel free to modify as you see fit!) is attached
- Example of what Hana is working on for SDR is attached

CAEFISS routine report:

- I thought it might be worthwhile having you as a backup for weeks that I'm busy or not in the office. Once your familiar with it maybe we can rotate out who does it on alternating weeks?
- The routine report has been really important in helping flag any new AEFI reports on a timely basis to our team; for example I've been relying on it for the RSV surveillance given it's a new vaccine!
- I also thought it might be a good learning opportunity for you to familiarize yourself with

more codes regarding vaccines other than COVID too if you have interest! It's also something we can use as a base code in case of any future data requests.

- SOP is attached

Please let me know if you have any questions on anything.

Thanks so much,

Ashley

Ashley Weeks (she / elle)
Epidemiologist | Épidémiologiste
Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada | Agence de la santé publique du Canada
ashley.weeks@phac-aspc.gc.ca | +1-613-286-1328

Environmental scan: AEFI reporting
Date created: 2024-02-14

Updated: 2024-03-01

Purpose: To inform future reports, dashboards and/or other publications of vaccine safety data for Canadians.

Table 1. Adverse event following immunization reporting

Source (both international and P/T)	**Frequency of reporting**	**Information included in report**	**Notes**
United Kingdom Medicines and Healthcare Products Regulatory Agency Coronavirus vaccine - summary of Yellow Card reporting - GOV.UK (www.gov.uk)	Appears to be frequent. Last date of data extraction was January 31, 2024. Contains data from 2020 to 2024.	Interactive online COVID-19 vaccine report – Separate report/dashboard by vaccine type/brand – Provides a reaction profile for each vaccine – Reactions (AFEIs) are grouped by System Organ Class (SOC) – Age groups – Sex – Reported by (Patient or Healthcare professional) – Seriousness – Route of administration	Targeted active monitoring – Yellow Card Vaccine Monitor. AEFIs reported by vaccine type. Adverse reactions grouped by System Organ Class. COVID-19 Vaccine Pfizer/BioNTech monovalent | Making medicines and medical devices safer (mhra.gov.uk) – Interactive dashboard
US CDC (VAERS) Vaccine Adverse Event Reporting System (VARES)	Several publications released throughout the year. Most recent year was 2023. VARES publishes vaccine safety data through CDC'sMorbidity and Mortality Weekly Report (MMWR). Other	In a recent published MMWR report: – Adverse events are provided by a specific vaccine type	Published MMWR vaccine safety reports are a web page with tables.

	vaccine safety reports are released as journal publications.	– Age groups – Sex – Race and ethnicity – MedDRA PT – Various vaccine types	
Singapore Health Sciences Authority HSA | Safety updates on COVID-19 vaccines	HSA Safety Update Report 2021 – monthly reports 2022 – quarterly reports 2023- annual report Most recent report published (February 2, 2023)	– Names of vaccines used – Number of does (within a given time period) – Adverse events in children aged 6 months to 11 years with the monovalent mRNA COVID-19 vaccines – Adverse events with the bivalent Original/ Omicron mRNA COVID-19 vaccines	Latest report is short (3 pages) without any graphics or tables.
European Medicines Agency – Safety of COVID-19 vaccines | European Medicines Agency (europa.eu) – Reports: EudraVigilance European database	Frequently updated. Most recent data up to February 25, 2024. EudraVigilance European database provides suspected adverse drug reaction reports on COVID-19 by vaccine type. Each report has an interactive dashboard.	– Number of individual cases by age group, country, reporter group (health care professional, non healthcare professional) – Number of individual cases received over time – Number of individual cases by country – Number of individuals by reaction groups, age group, sex, seriousness, reporter group, geography – Number of individuals by specific reaction groups	Interactive Oracle website and dashboard report. Multiple tabs with tables, maps and charts

		and suspected reactions – Line Lists – Vaccines include Moderna, Astrazeneca, Novavax, Janssen, Pfizer, Valena, Vidprevtyn o Omicron BA.1 and XBB.1.5	
Australia - Australia's COVID-19 vaccine safety monitoring system | Therapeutic Goods Administration (TGA) https://www.ausvaxsafety.org.au/vaccine-safety-data/covid-19-vaccines	COVID-19 Vaccine Safety data by vaccine published monthly via dashboards and/or infographic	Most recent published update (February 6, 2023) – COVID-19 vaccine safety data is provided for specific population groups and vaccine type – Data provided for adults and children (5-11 years) – Vaccines include Moderna, Astrazeneca, Novavax, Pfizer and Pfizer for children o Omicron BA.1 and XBB.1.5 for Moderna and Pfizer	Dashboards are available for specific population groups • Visual graphic information on common adverse events by dose • Medical attendance data • Impact on routine activities • Respondent demographics
Canadian Provinces and Territories			
Alberta	Not often. Last published report was February 2022.	Previous releases were a PDF report with graphs and tables.	Alberta was previously releasing reports on COVID-19 vaccine safety surveillance from 2021 to 2022. PDF Reports appear to have been discontinued (at least publicly)
British Colombia Immunize BC	No current available report on COVID-19 AFEIs	Previous releases were a PDF report with graphs and tables.	British Columbia was previously releasing reports on COVID-19 vaccine safety but now appear to

			have been discontinued (at least publicly) Website mentions that AEFIs are still being monitored through their PDF reporting form.
Saskatchewan	AEFI Summary Reports are updated every four weeks. Latest update was January 27, 2024.	– Vaccines include Moderna (6month+, children, adult original, XBB.15), Pfizer (6month+, children, adult original, XBB.15), Astrazeneca (18+), Novavax (XBB and 12+), COVI-SHIELD (18+), Janssen (21+) Table 1 - Vaccine type/brand and adult or child dose – Total doses administered – Total AEFI reports received – Number and proportions of serious and non-serious reports – Total AEFIs reported per 1000 doses administered – Serious AFEI per 1000 doses administered Table 2 - Cumulative Frequency of AEFI reports – Adverse event types and the number of events reported	Report is a web page with tables.
Manitoba	No current available report on COVID-19 AFEIs.	No current report or dashboard on COVID-19 AEFIs.	Website mentions that AEFIs are still being monitored through

			their PDF reporting form. However, recent reports, data or visualizations on AFEIs are not available to the public.
Ontario Report: Adverse Events Following Immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to January 28, 2024 (publichealthontario.ca)	Published report on AEFIs in Ontario released monthly. Most recent report published Feb 2, 2024, for data Dec 13 2020 – Jan 28, 2024.	– Report contains background information on AEFIs – Total AEFI reports to date – Number of AEFIs that meet serious definition – Most common reported AEFIs (Top 10) – AEFIs by COVID-19 vaccine type/brand – Doses administered – Total reporting rate per 100,000 doses – Serious reporting rate per 100,000 doses – Age groups (total AEFIs and reporting rate per 100,000 doses) – Sex (total AEFIs and reporting rate per 100,000 doses) – AEFIs reported by geography (local public health unit) – Appendix with number of AEFI reports by adverse event and vaccine type/brand – Vaccines include Moderna (original, BA.1, BA.4/5, XBB1.5), Pfizer (original, BA.1, BA.4/5, XBB1.5), Astrazeneca/COVISHEILD,	The report is in PDF form.

		Novavax, Janssen	
Quebec	No current available report on COVID-19 AFEIs	n/a	n/a
New Brunswick	No current available report on COVID-19 AFEIs	n/a	Website mentions that AEFIs are still being monitored through their PDF reporting form.
Nova Scotia	No longer frequent. Published reports on AEFIs in Nova Scotia was previously released monthly and now discontinued. Most recent report published for September 13, 2023. https://novascotia.ca/coronavirus/docs/COVID-19-epidemiologic-summary_2023-09-13.pdf	– Highlights of AEFI reporting – Doses administered – AEFIs by severity, age group and sex – AEFIs by reaction type and severity (reaction, local, neurological, other) – Top 10 common AFEIs with a graph – Top 10 serious AEFIs with a graph – AESIs (myocarditis, TTS, GBS) – Vaccine types/brands not included	The report is in PDF form.
Prince Edward island	No current available report on COVID-19 AFEIs	n/a	Website mentions that AEFIs are still being monitored through their PDF reporting form.
Newfoundland and labrador	No current available report on COVID-19 AFEIs	n/a	Website mentions that AEFIs are still being monitored through their PDF reporting form.
Yukon	No current available report on COVID-19 AFEIs	n/a	n/a
Northwest territories	No current available report on COVID-19 AFEIs	n/a	n/a
Nunavut	No current available report on COVID-19 AFEIs	n/a	n/a

De :	Holmes, Nathalie (PHAC/ASPC) pour le compte de Centre for Immunization Surveillance - CIS / Centre de surveillance de l"immunisation - CSI(PHAC/ASPC)
À :	Ogunnaike-Cooke, Susanna (PHAC/ASPC); Ugnat, Anne-Marie (PHAC/ASPC)
Cc :	Centre for Immunization Surveillance - CIS / Centre de surveillance de l"immunisation - CSI(PHAC/ASPC); Panic, Mirna (PHAC/ASPC); Leinan, Valerie (PHAC/ASPC)
Objet :	RE: FOG DG and VP approval: Language to add to AEFI online report page re transition to routine reporting
Date :	2024-04-05 14:52:06
Pièces jointes :	FW For VP approval Language to add to AEFI online report page re transition to routine reporting.msg

Hi Susanna, it's with VPO for Don's review and approval. We will let you know when it's returned.
Nathalie

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Sent: Friday, April 5, 2024 2:40 PM
To: Ugnat, Anne-Marie (PHAC/ASPC) <anne-marie.ugnat@phac-aspc.gc.ca>
Cc: Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>; Leinan, Valerie (PHAC/ASPC) <valerie.leinan@phac-aspc.gc.ca>
Subject: FW: FOG DG and VP approval: Language to add to AEFI online report page re transition to routine reporting

Hi Anne-Marie,

I think this got missed…?

Thanks,

Susanna

==========

Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Friday, April 5, 2024 2:39 PM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: FW: FOG DG and VP approval: Language to add to AEFI online report page re transition to routine reporting

---

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Sent: Wednesday, March 27, 2024 11:18 AM
To: Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>

Cc: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; Holliday, Ashley-Anne (PHAC/ASPC) <ashley-anne.holliday@phac-aspc.gc.ca>
Subject: FOG DG and VP approval: Language to add to AEFI online report page re transition to routine reporting

Good morning,

For DG and VP approval (background/context is below):

Per the decision taken in January 2024 to transition from a COVID-only online AEFI report to regular reporting, VSSD has worked with Comms to develop some language that will be added to the web page for the last posted report, as follows:

++++++++++

> This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada* because:
>
> - the COVID-19 response has evolved from a global pandemic to an ongoing health issue
> - extensive evidence on adverse events following COVID-19 vaccination has been gathered globally.
>
> Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available.

++++++++++

Context: As you know, we are no longer going to be reporting on COVID-19 vaccine AEFIs in an independent web report. Instead, we will be reporting on COVID vaccine safety as part of our routine reporting for all vaccines. VSSD is working on developing a surveillance analysis plan and associated knowledge translation plan for all vaccine AEFIs, which will also cover the COVID-19 vaccines. In the meantime, we are adding the proposed wording to the COVID-19 online report webpages to advise the public that we will no longer be updating that report.

Who has reviewed: The proposed language was developed in collaboration with Sheila Manhire (senior communications advisor) and Quenby Joanette (senior digital communications advisor) – both are copied.

Thanks,
Susanna

==========

Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

This is the last regular postingpublication of the Rreported side effects following COVID-19 vaccination in Canada because the:

- the COVID-19 response has evolved *from a global pandemic to an ongoing* health issue
- the safety profile of the COVID-19 vaccines is stable

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available.

Commenté [QJ1]: A publication is a very particular thing online. Something with an ISBN is called a publication, even though we do say 'publishing live' in-house when we go live with content.

Commenté [QJ2]: I've pointed this out all over Canada.ca when we're provided this phrase. We don't explain what a safety profile is anywhere on the site that I've been pointed to for gen pop. As this is the case, we shouldn't be using terms that need to be defined, as it means nothing to the everyday user. We've opted for 'safe' on Canada.ca, so I'm recommending the same on InfoBase.

I do note it on this page, but it's undefined, though it shouldn't be. I still recommend following what we do on Canada.ca.

De : Weeks, Ashley (PHAC/ASPC)
À : Ogunnaike-Cooke, Susanna (PHAC/ASPC); MacKenzie, Andrew (PHAC/ASPC)
Cc : El Jaouhari, Maryem (PHAC/ASPC)
Objet : Online report rationale for last posting
Date : 2024-01-15 14:36:22
Pièces jointes : image001.png

Hi Susanna and Andrew,

Here is the document that Yuhui and I have been working on for the future of the online report. The main limitations driving the rationale to stop reporting are outlined on pages 1-2, with more details about each in the Appendix.

The appendix also includes a table with various options for future AEFI dissemination products once the decision is finalized for the last report posting. This isn't yet complete (I wanted to add in some examples of infographics or dashboards), but we can discuss these details once we get approval for the last online report date.

Online report schedule options_v5.docx

Thank you and please let me know if you have any questions!
Ashley

Ashley Weeks (she / elle)

Epidemiologist | Épidémiologiste
Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada | Agence de la santé publique du Canada
ashley.weeks@phac-aspc.gc.ca | +1-613-286-1328

Online COVID-19 AEFI report: considerations for future

Purpose

The purpose of this document is to describe the current Online COVID-19 Adverse Event Following Immunization (AEFI) Report web reporting timelines and data sources in order to inform the schedule and plans for web postings moving forward. We aim to inform the following questions:

- What will next year's online report schedule be?
- Will it continue to be a full online report or other web communications product (i.e. dashboard?)
- Will it continue to contain data from Health Canada or include only CAEFISS data?

Current report process

- The Public Health Agency of Canada (PHAC), currently, publishes an online report of side effects following COVID-19 vaccination in Canada (Online report) every 12 weeks.
- The Online report production from data extraction through to approval require 2 weeks.
- The production of the Online report requires adverse event (AEFI) data from the Canadian Adverse Events Following Immunization System (CAEFISS), the Canada Vigilance Database (CVD), and COVID-19 vaccine dose administered data from Canadian COVID-19 Vaccination Coverage Surveillance System (CCVSS).
- The next Online report posting is on January 19, 2024, with data extracted on January 5, 2024.

Emerging issue

#1. Misalignment of data production schedule. There is misalignment of timing of vaccine administered data availability and the Online report schedule. Revised AEFI rate calculations requires that the same vaccine administered date is applied to the AEFI and dose administered data. It further requires a minimum of 5 weeks to have passed since vaccination at the time of AEFI data extraction. For example, to create the Online report for December 22, 2023, an AEFI data extraction is done on December 8, 2023 (2 weeks report production). This aligns with a dose administered data of November 3, 2023 (5 weeks since vaccination). However, the latest dose administered data that satisfy these requirement dates back to September 14, 2023.

#2. Long-term data availability. There is uncertainly around availability of COVID-19 vaccine administered data beyond the next agreed release date of December 3, 2023. For example, certain jurisdictions such as Ontario will only be providing information on XBB.1.5 strains starting December 3 and may not contribute data moving forward in 2024. Additionally, we do not receive denominator information on coadministration of vaccines, which is becoming increasingly practiced across Canada.

#3. Data provider workload. There has been delay in data receipt from HC during the most recent Online report production period. There is also a desire from HC and PHAC to shift demands for data including AEFI data from CVD to pre-pandemic levels.

Short term plan

Addressing issue # 1.

- Minor adjustment to current reporting schedule to more closely match CCVCSS schedule with next report on January 19, 2024, doses and date vaccine administered up to December 3, AEFI reports received up to and including January 5.

Addressing issue #2.

- Vaccine coverage (VC) intends to request additional dose administered data from P/Ts for February 25, 2024. Follow up with VC on P/T response to the February 25, 2024 data request following CIRC on November 15, 2023.
    - Note: Ontario has expressed interest in no longer submitting data to CCVCSS in 2024.
- Follow up with VC on their plan for data request past February 25, 2024.

Addressing issue #3.

- Follow up with HC to understand current barriers regarding the scope and frequency of COVID-19 AEFI data provision.
- Follow up with HC to develop strategies to remove or reduce barriers of COVID-19 AEFI data provision; including but not limited to
    - Reduce number of variables request
    - Remove specific variables requested
    - Reduce depth of review by HC
    - Reduce frequency of reporting
- Solicit P/T partner opinion regarding scope and frequency of COVID-19 AEFI report including usage, scope, and frequency.
- Identify public usage of COVID-19 AEFI report through web analytics.

Long term plan

Please see Tables 3 and 4 in the Appendix below for more details on each option being proposed.

- Assuming we have data from VC then options we can move forward are:
    - Continue with current quarterly schedule, or move to biannual schedule
    - Continue reporting rates as is
- Assuming we do not have data from VC:
    - Can use doses distributed as a proxy
    - Otherwise, we will have to remove rates from the online report (serious and non-serious report rate over time; age and sex rates, rates by vaccine, rates of top 50 AEFIs, and rates of AESIs)
- Assuming we have limited HC data:
    - Can change reporting schedule to biannual and/or to a 3-week processing time
    - Can remove CVD data
- Assuming we have full HC data:
    - Can continue any of the options presented

Appendix

Data contribution from Public Health Agency of Canada

PHAC currently pulls AEFI report data for the online report on a 12-week basis from the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). Data is pulled on Monday with reports received up to and including the previous Friday. The vaccine administration date is adjusted to match the doses administered date, with a minimum 5-week (+/- 3 days) reporting lag from the date report received in order to account for the time at risk for an individual to experience and report an adverse event following immunization (AEFI). More on the 5-week lag can be found in this SOP.

Certain adverse events of special interest (AESIs) and all deaths are reviewed in-depth by the Medical and Applied Epidemiology team at PHAC and information is included in the AESI linelists.

Data contributions from Health Canada

Health Canada currently contributes data for the online report on a 12-week basis to align with the online report posting timelines from their Canada Vigilance Database (CVD). Data is pulled on Monday, includes reports received up to and including the previous Friday, and is submitted to PHAC by Wednesday.

Table 1. Inventory of data that Health Canada currently contributes to PHAC.

Data	Source	Current Frequency	Product(s)
Overall counts	CVD	Quarterly	Online COVID-19 AEFI report
Death linelist with causality assessment	CVD and the MHPD medical assessment team	Quarterly	- Online COVID-19 AEFI report - PHAC Internal Death Summary
Detailed AESI linelists: GBS, Myocarditis/pericarditis, TTS, Glomerulonephritis and nephrotic syndrome, Bell's palsy, Anaphylaxis, Multisystem inflammatory syndrome	CVD and the MHPD medical assessment team	Biweekly (internal monitoring) and Quarterly (for online report)	- Online COVID-19 AEFI report - Internal monitoring and summaries

CVD: Canada Vigilance Database; AESI: Adverse events of special interest; GBS: Guillain-Barré syndrome; TTS: Thrombosis with thrombocytopenia syndrome.

Limitations with including Canada Vigilance data in online COVID-19 report

1. Differences in serious definition
    a. Health Canada includes "Other medically important events" as serious, causing inflation in their number of serious reports
2. Inability to effectively detect duplicates between CAEFISS and CVD
3. Extensiveness of missing key variable data from CVD data. For example,
    a. A large number of CVD reports are missing DVA, which is used as a filter to the date cutoff methodology for rate calculations
    b. Many COVID-19 vaccines are unspecified, or listed with multiple other vaccines together

4. Staff turnover leading to increased processing time to fill out Google Sheets required to put together online report draft within the 2-week timeframe.

Data contributions from Vaccine Coverage

Vaccine Coverage (VC) provides data on the number of COVID-19 vaccine doses administered in Canada, broken down by age group, sex, vaccine product, and dose number in series through the Canadian COVID-19 Vaccination Coverage Surveillance System (CCVCSS). The CCVCSS dataset is typically provided to the Vaccine Safety Surveillance (VSS) team on the Thursday following each data cutoff period.

The reporting frequency is subject to the Canadian Immunization Registries and Coverage Network (CIRC) approval. The dataset is currently provided every 12 weeks, with fixed data cut-offs set by the Vaccine Coverage team. At this time, only the December 3, 2023, CCVCSS report date has been agreed upon by CIRC. They intend on submitting a report with the February 25, 2024 cut-off date, but have yet to discuss this at CIRC, so it is still pending their approval. We will have more information in November following their next CIRC meeting discussing the new NACI guidelines.

It is important to note that due to the changes in reporting frequencies with CCVCSS, the Online COVID AEFI report schedule is currently offset from the CCVCSS schedule. The online report reporting dates were initially determined based on the assumption of a 5- and 6-day lag between doses administered and the observed reports. The new five-week lag minimum was determined based on the assumption that most AEFIs should occur within 30 days of vaccination and the allotment of a week to be submitted/entered into CAEFISS. This aligned nicely with the reporting schedule when the doses administered moved to a monthly reporting frequency. With the new reporting frequencies of 12 weeks, the doses administered dates available to us are currently one week, or approximately 13 weeks. This does not align well with the new 5 week lag minimum method. Ideally, the online report dates should more closely reflect the latest CCVCSS data available (Table 2).

Table 2. Data cutoff dates for doses administered in 2023-2024.

Date cutoff for doses administered	Date doses administered dataset available to VSS	Ideal AEFI report cutoff based on the 5-week minimum lag
January 1, 2023	January 5, 2023	
January 29, 2023	February 2, 2023	
February 26, 2023	March 2, 2023	
March 26, 2023	March 30, 2023	
April 23, 2023	April 27, 2023	May 26, 2023 (used for June 9 report)[1]
June 18, 2023	June 22, 2023	July 21, 2023
September 10, 2023	September 14, 2023	October 13, 2023
December 3, 2023	December 7, 2023	January 5, 2024
February 25, 2024[2]	February 29, 2024[2]	March 29, 2024[2]
May 19, 2024[2]	May 23, 2024[2]	June 21, 2024[2]

[1] Start of implementation of minimum 5-week reporting lag.
[2] Pending CIRC approval (not yet confirmed).

Note on online COVID-19 AEFI report timelines

It takes 2 weeks from the date that the AEFI data is pulled to prepare the online report before it goes live on the canada.ca webpage.

Doses distributed (not currently used for online report)

If CIRC decides to stop submitting doses administered data to PHAC, PHAC can use the doses distributed database. The doses distributed data for COVID-19 vaccines are entered by the Data Management Team at PHAC, and they reach out to the National Operations Centre quarterly to request doses information (it takes one to two months to receive the data following the request). However, there are many limitations with doses distributed; mainly that the data is not broken down by age, sex, dose number, or month, so our ability to report out rates will drastically diminish. For overall rates, we could use doses distributed and apply a proxy to estimate vaccine wastage, though this is something that the public may not understand for an online report and the added value may not be worth it.

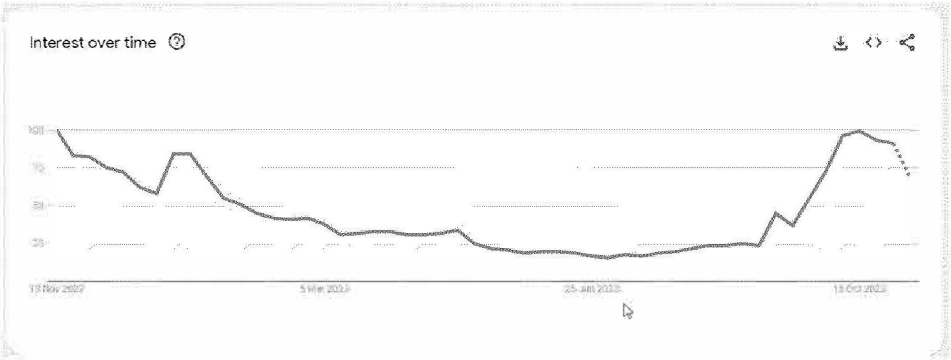
A quick look at our current doses distributed database compared to the number of doses administered from CCVCSS estimated about an 80% wastage, but this may vary by year and will likely vary by vaccine products, so more analyses can be initiated on this topic if needed.

Web analytics for current online COVID-19 AEFI report

After reaching out to Infobase regarding analytics on how many people have been opening the report webpage, it was discovered that the number of page visits has increased in October 2023, after slowing down in the summer months. This may indicate a seasonal pattern, where interest in the report peaks during the typical seasonal vaccination campaigns in the fall.

Commenté [X(1]: Provide figure given by web analytics.

Figure 1. Google trends report for the online COVID-19 AEFI report. The Y-axis is a scale of 1-100 which represents search interest relative to the highest point on the chart for the given region and time period. A value of 100 is the peak popularity for the term, 50 means that the term is half as popular and 1 being the lowest popularity of the term.



Questions for VVWG involvement

1. Do you currently use the online COVID-19 report?
    a. If so, how often?
    b. For what purpose? What type of information do you use it for?
2. Do you have any concerns about the discontinuation of the report?
3. What would you be interested in seeing in public reporting from PHAC vaccine safety moving forward?
4. Would you have interest in seeing reports for other/all vaccines?

Options for future of online COVID-19 AEFI report

Table 3. Options to consider for the future of the online COVID-19 report schedule timing.

Option	Issue that it addresses	Schedule	Advantages	Considerations
1. Current schedule		**Every 12 weeks** Next report: Go live January 19 • Doses and date vaccine administered up to December 3 • AEFI reports received up to and including January 5 Following report: Go live Friday April 19 • Doses and date vaccine administered up to February 25 AEFI reports received up to and including Friday April 5.	• No changes to any of the currently scheduled report updates for data providers and stakeholders	• Future quarterly updates may not be possible should doses administered data no longer be provided and/or would have to investigate alternative plans like using doses distributed instead • Further delays in receiving CVD and doses administered data on time • The need for this report on such a frequent basis may have decreased due to the rollout of the mass pandemic vaccination campaign having slowed and becoming more routine • Can only continue providing rates per doses administered into next year if CIRC continues to agree to provide CCVCSS data
2. Move online report to biannual schedule	Could reduce some of HC's dedicated time	Every 6 months	• More PHAC/HC resources available for other vaccine safety priorities (e.g. implementation of an all vaccines dashboard, papers) • Less of a commitment for HC partners.	• Less timely data • Just as extensive of work during the 2-week period of creating the report, just less often. Therefore, not sure if this would help HC or if there would still be timeline concerns in receiving CVD data.

3. Position the report so that we have 3 weeks to get the data ready (instead of 2 weeks as current practiced)	Could reduce some of HC's dedicated time	Can follow a 12-week or 6-month schedule	• Provide PHAC and HC with more time to prepare the data and report mock-ups	• Less timely
4. Follow a seasonal reporting schedule		Can follow a more frequent schedule in the fall and winter months, with less frequent reporting in the summer	• Close alignment with the COVID-19 vaccination roll-out (similar to how we analyze flu data) • Aligns with the peak public interest as provided by web analytics.	• Would require more work in the "in-season" months, so HC might not be able to comply

Table 4. Options to consider for the future of the online COVID-19 report content. Note that the schedule can vary, and the options are not mutually exclusive.

Option	Advantages	Considerations
1. CAEFISS-only report with content as is	• PHAC can have autonomy over the data rather than wait on HC to submit it (often late) • Can add variables that CV wasn't able to include • More reliable data (no more concerns about missing CVD variables, data quality or duplicates)	• We should anticipate lots of public pushback if we were to completely remove CVD the way that we currently report out: the public may not understand why the sudden change, might worry we're hiding things, and may claim that our previous way of reporting wasn't proper

2. Reduce the content provided in the report	• Can choose to only update the total number of reports and maybe add in the number of new reports • May help if the amount of work is too much for HC	• Similar to #3, we can anticipate public pushback: People may think we're hiding things if we decide to stop reporting on indicators previously reported on • How meaningful would it be to the public if specific information isn't being provided?
3. PHAC requests CVD data directly through the database team instead of BRDD	• PHAC can have autonomy over the data rather than wait on HC to submit it (often late)	• Would require at least one full-time analyst to be able to focus on pulling/analyzing this data as it is so different from CAEFISS that PHAC may not have the capacity to do • Would have to have MAE review all of the HC data
4. COVID-19 AEFI Dashboard (CAEFISS only with emphasis that the reports are through public health reporting) PREFERRED	• If CAEFISS only, can add more variables that CV is not currently able to submit • More reliable data (no more concerns about missing CVD variables, data quality or duplicates) • Innovative and interesting way to present high-quality data • Timely reporting • Aligns with what other jurisdictions present (Public Health Ontario, WHO, etc.) • Can expand to adding in information about other vaccines and be a trusted resource for all vaccine safety • Can look into options regarding posting options: infobase, R Studio Connect, web, other software?	• Would need to consider web and Infobase capacity to do this. During previous consultations with Infobase last year, they were keen to work on the dashboard, but it's been on hold for a while, so it may have lessened in priority for them.

5. Report COVID like the annual reports, in a peer-reviewed manuscript once a year	• Very high quality report • Being able to have intro/discussions allows for more fulsome topics and conversations about different aspects of the results and implications	• Time consuming • Harder for the public to find and not as plain language (more for a scientific audience) • Public may think we're trying to hide something if they don't see it directly on Canada.ca anymore

De : Ogunnaike-Cooke, Susanna (PHAC/ASPC)
À : Manhire, Sheila (HC/SC); Wu, Karen (HC/SC); Friesen, Andrea (HC/SC); Data and Dashboards-Données et tableaux de bords (HC/SC); Millingen, Scott Van (PHAC/ASPC); Tremblay, Benoit (PHAC/ASPC); Douris-Peeke, Cody (PHAC/ASPC); infobase (PHAC/ASPC); Thompson, Riley (HC/SC); Oukouomi Tchatchouang, William (HC/SC); Moreau, Marie-Eve (HC/SC); Rose, Jhona (HC/SC)
Cc : Fandja, Patrick (HC/SC); Weeks, Ashley (PHAC/ASPC); El Jaouhari, Maryem (PHAC/ASPC); MacKenzie, Andrew (PHAC/ASPC); Yome, Julie (PHAC/ASPC); Hutchings, Kimberley (PHAC/ASPC); Hussein, Wissam (PHAC/ASPC)
Objet : COVID-19 online AEFI report - transition to post-pandemic
Date : 2024-01-26 19:09:00

Dear All,

The purpose of this email is to inform you of a significant milestone – a transition from the COVID-19 online AEFI report to routine all-vaccine reports (format and schedule in development).

As such, the report posted on Friday, January 19th, 2024 was the last time update of this website in its current format. This milestone comes after 3 years of routine web postings, including a total of **84 reports** posted since January 2021.

Lastly, we just wanted to extend our sincere gratitude to everyone that contributed to the development and posting of these reports over the past three years. Your contributions have been invaluable, and we look forward to our future collaborations.

Thanks,

Susanna

==========

Susanna Ogunnaike-Cooke (She/Elle)
Executive Director | Directrice exécutive
Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada | Agence de la santé publique du Canada

613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

*Note I am sending this message at a time that suits me and which may not be part of your regular working hours. Please do not feel as though you need to respond right away

*Notez que j'envoie ce message à un moment qui me convient et qui peut ne pas faire partie de vos heures de travail habituelles. Ne vous sentez pas obligé de répondre tout de suite.

De : Xu, Yuhui (PHAC/ASPC)
À : Weeks, Ashley (PHAC/ASPC)
Objet : COVID-19 online report - considerations
Date : 2023-10-05 09:25:55

Hi Ashley,

Notes from Susanna.

Online AEFI report: Patrick would like us to look at options to reduce the frequency and scale of the online COVID AEFI report. I tend to agree – we should consider if we really need to maintain a COVID-only report or if we can move to something else. Also, if we maintain the COVID-only report, let's explore a bi-annual one, with timing lined up with coverage data. Also for consideration: Do we continue to do a report that combines CVD data with CAEFISS data? If so, is HC able to take on the workload? Or are we able to get useful and usable extracts from CVD/ Some of that work/thinking was started over a year ago, so we should be able to pull together the lessons learned and considerations in order to craft some options. (Yuhui to lead) We can discuss briefly at tomorrow's management meeting.

Thanks,

Yuhui

Yuhui Xu
(he, him, his)
Acting Manager | Géstionnaire intérimaire
Vaccine Safety Surveillance Division / Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance / Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) / Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada / Agence de la santé publique du Canada

DG-VP Bilat Agenda

January 9, 2024

11:00 to 11:30

Agenda

Items for decision

1. We propose to discontinue the COVID-19-specific online AEFI report.

Items for information

1. A proposal for HC read-only access to CAEFISS has been sent to FPTs for consideration, an important step in the PHAC-led consultation on the data sharing MRAP item.
2. VCES items.

DG/VP Bilat Document
January 19, 2024
11:00 – 11:30

Document Released Under the Access to Information Act by the Public Health Agency of Canada / Document divulgué en vertu de la Loi su l'accès à l'information par l'Agence de la santé publique du Canada

Agenda

1) Discontinuation of COVID-19 online AEFI report
Action: ☐For Information ☐For Discussion ☒For Decision
• We are proposing a discontinuation of the COVID-19-specific online AEFI report. • Given the transition from pandemic to endemic and the decrease in COVID-19 vaccine uptake, the regular COVID-19 AEFI report no longer serves its initially conceived purpose of providing regular updates on emerging safety issues for a pandemic vaccine campaign. • Over 100,000 million doses of vaccines have been administered in Canada alone, with billions administered internationally. The general safety profile of the vaccines is now well characterized, with any new knowledge emerging from other sources e.g. enhanced surveillance or research. • Going forward, the online report is less informative on new safety issues given that COVID-19 vaccine uptake has decreased significantly (and therefore identification of rare safety issues would occur over longer timelines) • PTs are making changes to their provision of doses administered data, which will impact the data quality and required format for the AEFI report, e.g. without data on doses administered, the AEFI report would need to shift to using doses distributed data, after which sex and age analysis for AEFI rates will no longer be possible. • International counterparts with COVID-specific AEFI reporting have discontinued their reports • Web analytics indicates that interest in the online report in 2023 was low for most of the year, with a slight increase during the flu season (when COVID-19 vaccine campaigns were co-occurring) • HC colleagues are supportive of regularizing the reporting of COVID-19 AEFI into a more routine report (frequency to be determined) due to decrease in their COVID-19-specific resources • PHAC will work with HC to discuss plans and options for AEFI reporting (all vaccines) going forward • In consultation with Comms and the IDVPB Immunization Support and Knowledge Mobilization Teams, lessons learned from the pandemic will be leveraged to provide information tailored to specific audiences
2) OAG Audit (COVID-19 vaccines) MRAP item on data sharing
Action: ☒For Information ☐For Discussion ☐For Decision
• A proposal for HC read-only access to CAEFISS has been sent to FPTs for consideration, an important step in the PHAC-led consultation on the data sharing MRAP item. • PHAC launched consultation sessions in spring 2023 with FPT partners on a proposal for HC staff to have access to the PHAC-led CAEFISS database.

Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par l'Agence de la santé publique du Canada

- After some delays, a proposal summary for read-only access for HC to CAEFISS was sent to PTs for review and decision by February 22.
- Data sharing discussions with PTs will continue in March to discuss outcomes and next steps for consultation on data sharing with manufacturers and the WHO.
- While there are several interdependent components to data sharing, making progress on this first item will maintain momentum and engagement with FPT immunization partners.
- Discussing PT issues in this step-wise manner will allow incremental progress to be made and targeted solutions to be identified for outstanding issues
- Considerations:
    - *Stakeholder relations risk:* PHAC has received numerous requests from FPT partners for clarity on the HC parameters for access to CAEFISS and have cited frustration/impatience at the delays and the resultant impact on them re postponing their internal consultation discussions.
    - *Portfolio risk*: If successful, this initiative would represent a significant and positive incremental step to resolve a longstanding challenge in vaccine safety surveillance. Given this decade-plus challenge, it is critical that PHAC and HC build on previous discussions and make progress on the long standing issues that have been identified.
    - *Portfolio risk*: PHAC has sought an extension for this MRAP item due to the delays in obtaining information from HC. In addition, extensions have also been sought for the subsequent two MRAP items as these also involve discussions with the same FPT Immunization program partners on data sharing with manufacturers and with WHO.

3) VCES items

Action: ☒For Information ☐For Discussion ☐For Decision

- x
-

Environmental scan: AEFI reporting

Date created: 2024-02-14

Updated: 2024-03-06

Purpose: To inform future reports, dashboards and/or other publications of vaccine safety data for Canadians.

Summary:

International:

- New Zealand and South Africa are no longer providing recent or frequent AEFI reports
- The United States does not provide recent or frequent AEFI reports but may publish related journal articles intermittently
- Japan only reports on the total number of vaccines administered and does not provide AEFI information
- Australia, Singapore, Sweden, the Netherlands, the European Medicines Agency, and the United Kingdom are still providing AEFI reports

Canadian context:

- The majority of Canadian provinces and territories have discontinued their COVID-19 AEFI safety reports
    - Ontario, Alberta and Saskatchewan are the only provinces frequently providing vaccine safety reports and/or updating their online website

Table 1. Adverse event following immunization reporting

Source (international and P/T)	**Frequency of reporting**	**Information included in report**	**Notes**
United Kingdom Medicines and Healthcare Products Regulatory Agency https://yellowcard.mhra.gov.uk/idaps	Appears to be frequent. Last date of data extraction was January 31, 2024. Contains data from 2020 to 2024.	Online COVID-19 vaccine report : – Separate report and dashboard by vaccine type/brand – Provides a reaction profile for each vaccine – Reactions (AFEIs) are grouped by System Organ Class (SOC) – Age groups, sex – Reported by (Patient or Healthcare	Targeted passive monitoring – Yellow Card Vaccine Monitor AEFIs reported by vaccine type. Adverse reactions grouped by System Organ Class. COVID-19 Vaccine Pfizer/BioNTech monovalent | Making medicines and medical devices safer (mhra.gov.uk)

		professional) – Seriousness – Route of administration	– Interactive dashboard
US CDC (VAERS) Vaccine Adverse Event Reporting System (VARES)	Several publications released throughout the year. Most recent year was 2023. VARES publishes vaccine safety data through CDC's Morbidity and Mortality Weekly Report (MMWR). Other vaccine safety reports are released as journal publications.	In a published MMWR report from Aug 2023: – Adverse events are provided by a specific vaccine type – Age groups – Sex – Race and ethnicity – MedDRA PT – Various vaccine types	Published MMWR vaccine safety reports are a web page with tables.
Singapore Health Sciences Authority HSA | Safety updates on COVID-19 vaccines	HSA Safety Update Report 2021 – monthly reports 2022 – quarterly reports 2023- annual report Most recent report published February 2, 2023.	– Names of vaccines used – Number of does (within a given time period) – Adverse events in children aged 6 months to 11 years with the monovalent mRNA COVID-19 vaccines – Adverse events with the bivalent Original/ Omicron mRNA COVID-19 vaccines	Latest report is short (3 pages) without any graphics or tables.
Netherlands – Netherlands Pharmacovigilance Centre Lareb – AFEIs by mRNA vaccines	Online report last updated March 5, 2024.	Reports are by vaccine type (mRNA, viral vectors, Valena, Novavax) – Total number of AEFI reports – Number of serious AEFIs – Sex/gender – Age – Year of reports – Detector (physician, pharmacist, patient, other) – Number of reports by AFEIs	Online report includes graphs, pie charts, and tables.

Sweden Reported suspected adverse reactions - corona vaccines | Swedish Medical Products Agency | Läkemedelsverket (lakemedelsverket.se)	Online report last updated February 1, 2024.	Reports are by vaccine type/brand (Pfizer, Moderna etc.) – Total AEFI reports – Reports with unknown vaccines – Number of doses – Most reported suspected adverse reactions and number of reports	Online report includes list of vaccines by type and number of AEFIs reported in bullet points
European Medicines Agency – Safety of COVID-19 vaccines | European Medicines Agency (europa.eu) – Reports: EudraVigilance European database	Frequently updated. Most recent data up to February 25, 2024. EudraVigilance European database provides suspected adverse drug reaction reports on COVID-19 by vaccine type. Each report has an interactive dashboard.	– Number of individual cases by age group, country, reporter group (health care professional, non healthcare professional) – Number of individual cases received over time – Number of individual cases by country – Number of individuals by reaction groups, age group, sex, seriousness, reporter group, geography – Number of individuals by specific reaction groups and suspected reactions – Line Lists – Vaccines include Moderna, Astrazeneca, Novavax, Janssen, Pfizer, Valena, Vidprevtyn – Omicron BA.1 and XBB.1.5	Interactive Oracle website and dashboard report. Multiple tabs with tables, maps and charts
Australia - Australia's COVID-19 vaccine safety monitoring system | Therapeutic Goods Administration (TGA)	COVID-19 Vaccine Safety data by vaccine published monthly via dashboards and/or infographic. Most recent published update February 6, 2023	– COVID-19 vaccine safety data is provided for specific population groups and vaccine type – Data provided for adults and children (5-11 years) – Vaccines include Moderna,	Dashboards are available for specific population groups – Visual graphic information on common adverse events by dose – Medical attendance data

https://www.ausvaxsafety.org.au/vaccine-safety-data/covid-19-vaccines		Astrazeneca, Novavax, Pfizer and Pfizer for children ○ Omicron BA.1 and XBB.1.5 for Moderna and Pfizer	– Impact on routine activities – Respondent demographics
New Zealand – COVID-19 Overview of Vaccine Reports (medsafe.govt.nz) – https://www.tewhatuora.govt.nz/publications/final-report-of-the-covid-19-vaccine-independent-safety-monitoring-board-cv-ismb/ – COVID-19 vaccine data – Health New Zealand | Te Whatu Ora	No current available report on COVID-19 AFEIs.	Final Report of the COVID-19 Vaccine Independent Safety Monitoring Board was published July 2023 for the previous year. Online AEFI reports by the New Zealand Medicines sand Medical Devices Safety Authority was last published in Nov. 2022.	
South Africa South African Health Products Regulatory Authority	No current available updates on COVID-19 AFEIs.	AEFI Reports dashboard last updated with data from May 2021 to June 2023.	
Japan PM's Office of Japan COVID-19 Vaccines (kantei.go.jp)	Frequent reporting on total COVID-19 vaccine doses administered. However, no data/reports on COVID-19 AEFIs.	Last update of total number of vaccines was March 5, 2024. Vaccine report only includes total doses, number of doses and vaccination rate.	
Canadian Provinces and Territories			
Alberta – Alberta (Previous reports) – Respiratory virus dashboard | alberta.ca	The dashboard has an immunization section with graphs and tables. Immunizations include influenza vaccines and COVID-19	Respiratory Virus Dashboard last updated Feb 24, 2024. (Vaccine type/brand not reported) Influenza Vaccines: – Weekly reports – Doses administered by week – Doses administered and coverage by Alberta Health Services health zone and provider	Alberta was previously releasing reports on COVID-19 vaccine safety surveillance from 2021 to 2022. PDF Reports appear to have been discontinued (at least publicly). The reports have been replaced with an online dashboard.

		– Dose administered and coverage by age groups – Dose administered and coverage by season and provider – Map of vaccine coverage – Number of AEFIs by condition (allergic reaction, pain, rash, anaphylaxis etc.) COVID-19 Vaccines: – Cumulative vaccine doses administered by week – Doses administered by week – Coverage by week and age groups – Doses administered and coverage by AHS health zone and provider – Dose administered and coverage by age groups and provider – Map of vaccine coverage – Number of AEFIs by condition (allergic reaction, pain, rash, anaphylaxis etc.)	
British Colombia Immunize BC – Vaccine Safety (bccdc.ca)	No current available report on COVID-19 AFEIs.	Previous releases were a PDF report with graphs and tables. Last published report was on Feb. 3, 2023.	British Columbia was previously releasing reports on COVID-19 vaccine safety but now appear to have been discontinued (at least publicly) Website mentions that AEFIs are still being monitored through their PDF reporting form.
Saskatchewan	AEFI Summary Reports are updated every four weeks.	– Vaccines include Moderna (6month+, children, adult original, XBB.15), Pfizer (6month+, children,	Report is a web page with tables.

	Latest update was January 27, 2024.	adult original, XBB.15), Astrazeneca (18+), Novavax (XBB and 12+), COVI-SHIELD (18+), Janssen (21+) Table 1 - Vaccine type/brand and adult or child dose – Total doses administered – Total AEFI reports received – Number and proportions of serious and non-serious reports – Total AEFIs reported per 1000 doses administered – Serious AFEI per 1000 doses administered Table 2 - Cumulative Frequency of AEFI reports – Adverse event types and the number of events reported	
Manitoba	No current available report on COVID-19 AFEIs.	No current report or dashboard on COVID-19 AEFIs.	Website mentions that AEFIs are still being monitored through their PDF reporting form. However, recent reports, data or visualizations on AFEIs are not available to the public.
Ontario Report: Adverse Events Following Immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to January 28, 2024 (publichealthontario.ca)	Published report on AEFIs in Ontario released monthly. Most recent report published Feb 2, 2024, for data Dec 13 2020 – Jan 28, 2024.	– Report contains background information on AEFIs – Total AEFI reports to date – Number of AEFIs that meet serious definition – Most common reported AEFIs (Top 10) – AEFIs by COVID-19 vaccine type/brand – Doses administered	The report is in PDF form.

		– Total reporting rate per 100,000 doses – Serious reporting rate per 100,000 doses – Age groups (total AEFIs and reporting rate per 100,000 doses) – Sex (total AEFIs and reporting rate per 100,000 doses) – AEFIs reported by geography (local public health unit) – Appendix with number of AEFI reports by adverse event and vaccine type/brand – Vaccines include Moderna (original, BA.1, BA.4/5, XBB1.5), Pfizer (original, BA.1, BA.4/5, XBB1.5), Astrazeneca/COVISHEILD, Novavax, Janssen	
Quebec	No current available report on COVID-19 AFEIs	n/a	n/a
New Brunswick	No current available report on COVID-19 AFEIs	n/a	Website mentions that AEFIs are still being monitored through their PDF reporting form.
Nova Scotia	No longer frequent. Published reports on AEFIs in Nova Scotia was previously released monthly and now discontinued. Most recent report published for September 13, 2023. https://novascotia.ca/coronavirus/docs/COVID-19-epidemiologic-summary_2023-09-13.pdf	– Highlights of AEFI reporting – Doses administered – AEFIs by severity, age group and sex – AEFIs by reaction type and severity (reaction, local, neurological, other) – Top 10 common AFEIs with a graph – Top 10 serious AEFIs with a graph – AESIs (myocarditis, TTS, GBS) – Vaccine types/brands not included	The report is in PDF form.

Prince Edward island	No current available report on COVID-19 AFEIs	n/a	Website mentions that AEFIs are still being monitored through their PDF reporting form.
Newfoundland and labrador	No current available report on COVID-19 AFEIs	n/a	Website mentions that AEFIs are still being monitored through their PDF reporting form.
Yukon	No current available report on COVID-19 AFEIs	n/a	n/a
Northwest territories	No current available report on COVID-19 AFEIs	n/a	n/a
Nunavut	No current available report on COVID-19 AFEIs	n/a	n/a

Environmental scan: AEFI reporting

Date created: 2024-02-14 by Joy Pader

Updated: 2024-09-06 by Ashley Weeks

Purpose: To inform future reports, dashboards and/or other publications of vaccine safety data for Canadians.

Summary:

International:

- New Zealand and South Africa are no longer providing recent or frequent AEFI reports
- The United States does not provide recent or frequent AEFI reports but may publish related journal articles intermittently
- Japan only reports on the total number of vaccines administered and does not provide AEFI information
- Australia, Singapore, Sweden, the Netherlands, the European Medicines Agency, and the United Kingdom are still providing AEFI reports

Canadian context:

- The majority of Canadian provinces and territories have discontinued their COVID-19 AEFI safety reports
    - Ontario, Alberta and Saskatchewan are the only provinces frequently providing vaccine safety reports and/or updating their online website

Table 1. Adverse event following immunization reporting

Source	Vaccines presented in report	Frequency of reporting	Information included in report	Notes
United Kingdom Medicines and Healthcare Products Regulatory Agency https://yellowcard.mhra.gov.uk/idaps	COVID-19	• Quarterly. • Last date of data extraction was May 20, 2024. • Contains data from 2020 to 2024.	Online COVID-19 vaccine report : – Separate report and dashboards by vaccine type/brand – They have a separate COVID summary document but was only last updated March 8, 2023. – Provides a reaction profile for each vaccine – Reactions (AFEIs) are grouped by System Organ Class (SOC) – Age groups, sex – Reported by (Patient or Healthcare professional) – Seriousness	Targeted passive monitoring – Yellow Card Vaccine Monitor AEFIs reported by vaccine type. Adverse reactions grouped by System Organ Class. COVID-19 Vaccine Pfizer/BioNTech monovalent | Making medicines and medical devices safer (mhra.gov.uk) – Interactive dashboard

Source	Vaccines presented in report	Frequency of reporting	Information included in report	Notes
			– Route of administration	
US CDC (VAERS) Vaccine Adverse Event Reporting System (VAERS)	All vaccines (VAERS database) Select publications on specific vaccines	Several publications released throughout the year. Most recent year was 2023. VAERS publishes vaccine safety data through CDC's Morbidity and Mortality Weekly Report (MMWR). Other vaccine safety reports are released as journal publications.	In a published COVID MMWR report from Aug 2023: – Adverse events are provided by a specific vaccine type – Age groups – Sex – Race and ethnicity – MedDRA PT – Various vaccine types	Published MMWR vaccine safety reports are a web page with tables.
Singapore Health Sciences Authority HSA | Safety updates on COVID-19 vaccines	COVID-19	HSA Safety Update Report 2021 – monthly reports 2022 – quarterly reports 2023- annual report Most recent report published February 2, 2023.	– Names of vaccines used – Number of does (within a given time period) – Adverse events in children aged 6 months to 11 years with the monovalent mRNA COVID-19 vaccines – Adverse events with the bivalent Original/ Omicron mRNA COVID-19 vaccines	Latest report is short (3 pages) without any graphics or tables.
Netherlands – Netherlands Pharmacovigilance Centre Lareb – AFEIs by mRNA vaccines	All vaccines	Online report last updated March 5, 2024.	COVID Reports are by vaccine type (mRNA, viral vectors, inactivated, protein subunit) – Total number of AEFI reports – Number of serious AEFIs – Sex/gender – Age – Year of reports – Detector (physician, pharmacist, patient, other) – Number of reports by AFEIs They also have individual reports by vaccine group (routine childhood immunizations, flu, pneumococcal, traveller, other)	Online report includes graphs, pie charts, and tables.

Source	Vaccines presented in report	Frequency of reporting	Information included in report	Notes
Sweden Reported suspected adverse reactions - corona vaccines | Swedish Medical Products Agency | Läkemedelsverket (lakemedelsverket.se)	COVID-19	Online report last updated August 2, 2024.	COVID-19 reports by vaccine type/brand (Pfizer, Moderna etc.) – Total AEFI reports – Reports with unknown vaccines – Number of doses – Most reported suspected adverse reactions and number of reports	Online report includes list of vaccines by type and number of AEFIs reported in bullet points
European Medicines Agency – Safety of COVID-19 vaccines | European Medicines Agency (europa.eu) – Reports: EudraVigilance European database	All vaccines	Frequently updated. Most recent data up to September 1, 2024. EudraVigilance European database provides suspected adverse drug reaction reports on COVID-19 by vaccine type. Each report has an interactive dashboard.	– Number of individual cases by age group, country, reporter group (health care professional, non healthcare professional) – Number of individual cases received over time – Number of individual cases by country – Number of individuals by reaction groups, age group, sex, seriousness, reporter group, geography – Number of individuals by specific reaction groups and suspected reactions – Line Lists – Vaccines include Moderna, Astrazeneca, Novavax, Janssen, Pfizer, Valena, Vidprevtyn – Omicron BA.1 and XBB.1.5	Interactive Oracle website and dashboard report. Multiple tabs with tables, maps and charts
Australia Home | AusVaxSafety	Select vaccines: RSV, Shingrix, influenza, COVID-19, national immunization program	COVID-19 Vaccine Safety data by vaccine published monthly via dashboards and/or infographic. Most recent published update April 15, 2024.	– COVID-19 vaccine safety data is provided for specific population groups and vaccine type – Data provided for adults and children (5-11 years) – Vaccines include Moderna, Astrazeneca, Novavax, Pfizer and Pfizer for children o Omicron BA.1 and XBB.1.5 for Moderna and Pfizer	Dashboards are available for specific population groups – Visual graphic information on common adverse events by dose – Medical attendance data – Impact on routine activities – Respondent demographics
New Zealand – COVID-19 Overview of Vaccine Reports (medsafe.govt.nz)	COVID – archived since 2022	No current available report on COVID-19 AFEIs.	Final Report of the COVID-19 Vaccine Independent Safety Monitoring Board was published July 2023 for the previous year.	

Source	Vaccines presented in report	Frequency of reporting	Information included in report	Notes
– https://www.tewhatuora.govt.nz/publications/final-report-of-the-covid-19-vaccine-independent-safety-monitoring-board-cv-ismb/			Online AEFI reports by the New Zealand Medicines sand Medical Devices Safety Authority was last published in Nov. 2022.	
South Africa South African Health Products Regulatory Authority	COVID-19	Last updated June 2023.	AEFI Reports dashboard last updated with data from May 2021 to June 2023.	
Japan PM's Office of Japan COVID-19 Vaccines (kantei.go.jp)	COVID-19 doses administered but not AEFIs – discontinued April 2024	Frequent reporting on total COVID-19 vaccine doses administered. However, no data/reports on COVID-19 AEFIs.	Last update of total number of vaccines was March 5, 2024. Vaccine report only includes total doses, number of doses and vaccination rate.	
Canadian Provinces and Territories				
Alberta – Alberta (Previous reports) – Respiratory virus dashboard | alberta.ca – http://www.ahw.gov.ab.ca/IHDA_Retrieval/	-Influenza and COVID-19 -COVID-19-specific was discontinued February 2022	The dashboard has an immunization section with graphs and tables. Immunizations include influenza vaccines and COVID-19	Respiratory Virus Dashboard last updated Feb 24, 2024. (Vaccine type/brand not reported) Influenza Vaccines: – Weekly reports – Doses administered by week – Doses administered and coverage by Alberta Health Services health zone and provider – Dose administered and coverage by age groups – Dose administered and coverage by season and provider – Map of vaccine coverage – Number of AEFIs by condition (allergic reaction, pain, rash, anaphylaxis etc.)	Alberta was previously releasing reports on COVID-19 vaccine safety surveillance from 2021 to 2022. PDF Reports appear to have been discontinued (at least publicly). The reports have been replaced with an online dashboard.

Source	Vaccines presented in report	Frequency of reporting	Information included in report	Notes
			COVID-19 Vaccines: – Cumulative vaccine doses administered by week – Doses administered by week – Coverage by week and age groups – Doses administered and coverage by AHS health zone and provider – Dose administered and coverage by age groups and provider – Map of vaccine coverage – Number of AEFIs by condition (allergic reaction, pain, rash, anaphylaxis etc.)	
Immunize BC – Vaccine Safety (bccdc.ca)	COVID-19 (not updated)	No current available report on COVID-19 AFEIs.	Previous releases were a PDF report with graphs and tables. Last published report was on Feb. 3, 2023.	British Columbia was previously releasing reports on COVID-19 vaccine safety but now appear to have been discontinued (at least publicly) Website mentions that AEFIs are still being monitored through their PDF reporting form.
Saskatchewan	COVID-19	AEFI Summary Reports are updated every four weeks. Latest update was August 10, 2024.	– Vaccines include Moderna (6month+, children, adult original, XBB.15), Pfizer (6month+, children, adult original, XBB.15), Astrazeneca (18+), Novavax (XBB and 12+), COVI-SHIELD (18+), Janssen (21+) Table 1 - Vaccine type/brand and adult or child dose – Total doses administered – Total AEFI reports received – Number and proportions of serious and non-serious reports – Total AEFIs reported per 1000 doses administered – Serious AFEI per 1000 doses administered Table 2 - Cumulative Frequency of AEFI reports – Adverse event types and the number of events	Report is a web page with tables.

Source	Vaccines presented in report	Frequency of reporting	Information included in report	Notes
			reported	
Manitoba	None	No current available report on COVID-19 AFEIs.	No current report or dashboard on COVID-19 AEFIs.	Website mentions that AEFIs are still being monitored through their PDF reporting form. However, recent reports, data or visualizations on AFEIs are not available to the public.
General webpage: Ontario All vaccines dashboard: Vaccine Safety Surveillance Tool | Public Health Ontario COVID-19: COVID-19 Vaccine Uptake in Ontario: December 14, 2020 to June 30, 2024 (publichealthontario.ca)	All vaccines and COVID-19 as separate products	Published report on AEFIs in Ontario released monthly. Most recent COVID-19 report published August 1, 2024. Dashboard with all vaccines published Feb 7, 2024.	– Report contains background information on AEFIs – Total AEFI reports to date – Number of AEFIs that meet serious definition – Most common reported AEFIs (Top 10) – AEFIs by COVID-19 vaccine type/brand – Doses administered – Total reporting rate per 100,000 doses – Serious reporting rate per 100,000 doses – Age groups (total AEFIs and reporting rate per 100,000 doses) – Sex (total AEFIs and reporting rate per 100,000 doses) – AEFIs reported by geography (local public health unit) – Appendix with number of AEFI reports by adverse event and vaccine type/brand – Vaccines include Moderna (original, BA.1, BA.4/5, XBB1.5), Pfizer (original, BA.1, BA.4/5, XBB1.5), Astrazeneca/COVISHEILD, Novavax, Janssen – All vaccines: specific vaccine named, but colour coating for the vaccine groups (by immunization schedule)	The COVID-19 report is in PDF form.
Quebec		No current available report on COVID-19 AFEIs	n/a	n/a
New Brunswick		No current available report on COVID-19 AFEIs	n/a	Website mentions that AEFIs are still being monitored through their PDF reporting form.
Nova Scotia		No longer frequent. Published reports on AEFIs	– Highlights of AEFI reporting – Doses administered	The report is in PDF form.

Source	Vaccines presented in report	Frequency of reporting	Information included in report	Notes
		in Nova Scotia was previously released monthly and now discontinued. Most recent report published for September 13, 2023. https://novascotia.ca/coronavirus/docs/COVID-19-epidemiologic-summary_2023-09-13.pdf	– AEFIs by severity, age group and sex – AEFIs by reaction type and severity (reaction, local, neurological, other) – Top 10 common AFEIs with a graph – Top 10 serious AEFIs with a graph – AESIs (myocarditis, TTS, GBS) – Vaccine types/brands not included	
Prince Edward island		No current available report on COVID-19 AFEIs	n/a	Website mentions that AEFIs are still being monitored through their PDF reporting form.
Newfoundland and labrador		No current available report on COVID-19 AFEIs	n/a	Website mentions that AEFIs are still being monitored through their PDF reporting form.
Yukon		No current available report on COVID-19 AFEIs	n/a	n/a
Northwest territories		No current available report on COVID-19 AFEIs	n/a	n/a
Nunavut		No current available report on COVID-19 AFEIs	n/a	n/a

De : Weeks, Ashley (PHAC/ASPC)
À : Patel, Nimeshkumar (PHAC/ASPC); Panic, Mirna (PHAC/ASPC)
Cc : Spruin, Sarah (PHAC/ASPC)
Objet : FW: Blurb For the Vaccine Safety Website
Date : 2024-06-28 10:53:58

Hi both,

Just looping you in on a conversation that Sarah and I had with Andrew this morning so that you can follow the latest when you're back on Tuesday!

Andrew has confirmed that the below blurb has been approved by VP, and both Andrew and Susanna agreed with the minor edits Shiela proposed and said it didn't re-require VP approved since it was so minor. I also proposed some small tweaks to the French given the usual comms people didn't translate it this time so I updated some of the technical text to match the current online language (e.g. "securité des vaccines" instead of "innocuité, and matched the title of the webpage).

As such, **these blurbs are ready to go for Infobase web coding next week** – woohoo!! I was originally going to send it today, but 1) the coder is off today and 2) I wanted to give you an opportunity to agree or disagree with this on Tuesday, especially since I think Mirna had been working with comms on a slightly different version. Please let me know if you see any red flags and if not. Nimesh, should Mirna need to extend her leave, I'm thinking that we should still proceed with web posting to help get it off all of our plates and seeing that sr management is good with this too.

> *This is the last regular posting of Reported side effects following COVID-19 vaccination in Canada. We will no longer be updating this online report. Instead, COVID-19 vaccine safety data will be shared in a surveillance report that will include data on all vaccines approved in Canada. We will provide a link to this new report as soon as it is available. In the meantime, recent reports and technical publications on vaccine safety are available.*
>
> *This decision was made because the COVID-19 response has evolved from a global pandemic to an ongoing health issue and extensive evidence on COVID-19 vaccine safety has been gathered globally.*
>
> *Robust vaccine safety monitoring efforts continue. If any COVID-19 vaccine safety concerns are detected, we will communicate them promptly.*
> //
> *Il s'agit de la dernière publication régulière des* manifestations cliniques inhabituelles à la suite de l'immunisation *contre la COVID-19 au Canada. Nous ne mettrons plus à jour ce rapport en ligne. Au lieu de cela, les données sur* la sécurité *des vaccins contre la COVID-19 seront partagées dans un rapport de surveillance qui inclura des données sur tous les vaccins approuvés au Canada. Nous fournirons un lien vers ce nouveau rapport dès qu'il sera disponible. Entre-temps, des rapports récents et des publications techniques sur la sécurité des vaccins sont disponibles.*

Cette décision a été prise parce que la réponse à la COVID-19 est passée d'une pandémie mondiale à un problème de santé continu et que de nombreuses données probantes sur la sécurité des vaccins contre la COVID-19 ont été recueillies à l'échelle mondiale.

De solides efforts de surveillance de la sécurité des vaccins se poursuivent. Si des problèmes de la sécurité des vaccins contre la COVID-19 sont détectés, nous les communiquerons rapidement.

Best,
Ashley

From: Lalonde, Danielle (PHAC/ASPC) <Danielle.Lalonde@phac-aspc.gc.ca>
Sent: Wednesday, June 26, 2024 2:12 PM
To: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>
Cc: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>
Subject: FW: Blurb For the Vaccine Safety Website

Hi Ashley,
Seeing Nimesh is away I'd figure to send this to you as well as this is urgent
Thank you,
Danielle

From: Lalonde, Danielle (PHAC/ASPC)
Sent: Wednesday, June 26, 2024 2:09 PM
To: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>
Subject: RE: Blurb For the Vaccine Safety Website

Hi Nimesh,

As requested here is the French blurb translation.
Let me know if you need anything else

Cheers,
Danielle

From: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>
Sent: Tuesday, June 25, 2024 1:29 PM
To: Lalonde, Danielle (PHAC/ASPC) <Danielle.Lalonde@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>
Subject: FW: Blurb For the Vaccine Safety Website

Hi Danielle,

Please see the below blurb for the translation:

The VP approved blurb:

> This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada*. We will no longer be updating this online report. Instead, COVID-19 vaccine safety data will be shared in a surveillance report that will include data on all vaccines approved in Canada. We will provide a link to this new report as soon as it is available. In the meantime, recent reports and technical publications on vaccine safety are available.
>
> This decision was made because the COVID-19 response has evolved from a global pandemic to an ongoing health issue and extensive evidence on COVID-19 vaccine safety has been gathered globally.
>
> Robust vaccine safety monitoring efforts continue. If any COVID-19 vaccine safety concerns are detected, we will communicate them promptly.

Thanks,
Nimesh

Nimesh Patel (He/his)
Acting Senior Epidemiologist | Épidémiologiste principale
Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada | Agence de la santé publique du Canada
nimeshkumar.patel@phac-aspc.gc.ca / Tel: 343-574-8609

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Tuesday, June 25, 2024 11:10 AM
To: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>; MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>
Subject: RE: Blurb For the Vaccine Safety Website

Hi Nimesh,

I'm not sure if Quenby (web) will take care of translation. Web usually only translates when they do a plain language review of the web content. She can let us know when returns Thursday.

If you'd prefer to go ahead with translation, your admin would likely have a contact for a translation

service your directorate uses.

Take care,
Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205

Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>
Sent: Tuesday, June 25, 2024 12:06 PM
To: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>; MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>
Subject: RE: Blurb For the Vaccine Safety Website

Hi Sheila,

Thank you for your response. This is super helpful! The proposed changes look fine with us. Here is the revised blurb:

The VP approved blurb:

> This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada*. We will no longer be updating this online report. Instead, COVID-19 vaccine safety data will be shared in a surveillance report that will include data on all vaccines approved in Canada. We will provide a link to this new report as soon as it is available. In the meantime, recent reports and technical publications on vaccine safety are available.
>
> This decision was made because the COVID-19 response has evolved from a global pandemic to an ongoing health issue and extensive evidence on COVID-19 vaccine safety has been gathered globally.
>
> Robust vaccine safety monitoring efforts continue. If any COVID-19 vaccine safety concerns are detected, we will communicate them promptly.

I am wondering if Comms could please help us with French Translation, and have this posted on the InfoBase. If you would like us to reach out for the translation, it would be great if you could share a contact for that. I sincerely appreciate all the assistance we have received on this, and your patience!

We look forward to having this posted on our webpage soon.

Thanks,
Nimesh

Nimesh Patel (He/his)
Acting Senior Epidemiologist | Épidémiologiste principale
Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada | Agence de la santé publique du Canada
nimeshkumar.patel@phac-aspc.gc.ca / Tel: 343-574-8609

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Tuesday, June 25, 2024 8:07 AM
To: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>
Subject: RE: Blurb For the Vaccine Safety Website

Hi Nimesh!

Thank you so much for getting back to us. I have proposed a small change below. Please let me know if you are ok with this and Quenby can move ahead with getting it posted.

Thanks,
Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205

Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>
Sent: Friday, June 21, 2024 3:13 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>
Subject: Blurb For the Vaccine Safety Website

Hello Sheila and Quenby,

Please see the below blurb, approved by our VP, that we intend to put on one of our webpage. I know Mirna was in touch with you about the blurb, but she is out of the office until end of the next week. Hence, I am reaching out with the request. Apologies if the request needs to be directed somewhere else (InfoBase) indeed!

The VP approved blurb:

> This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada*. We will no longer be updating this online report. Instead, COVID-19 vaccine safety data will be shared in a surveillance report that will include data on all vaccines approved in Canada. We will provide a link to this new report as soon as it is available. In the meantime, recent reports and technical publications on vaccine safety are available.
>
> This decision was made because the COVID-19 response has evolved from a global pandemic to an ongoing health issue and extensive evidence on COVID-19 vaccine safety has been gathered globally.
>
> ~~Rest assured that~~ Robust vaccine safety monitoring efforts continue. If any COVID-19 vaccine safety concerns are detected, we will communicate them promptly.

**

Context:

As you know, we are no longer going to be reporting on COVID-19 vaccine AEFIs in an independent web report. Our reporting team have been working on developing a surveillance analysis plan and associated knowledge translation plan for all vaccine AEFIs, which will also cover the COVID-19 vaccines from now on. In the meantime, we would like to advise the public that we will no longer be updating the COVID-19 web report. We have developed a blurb, that we hope to have posted on the existing report page advising the public that the January report was the last report.

Where it will be:

At the top of these pages
https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html
https://health-infobase.canada.ca/covid-19/vaccine-safety/

Thank you for all your assistance on this.

Nimesh

Nimesh Patel (He/his)
Acting Senior Epidemiologist | Épidémiologiste principale
Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada | Agence de la santé publique du Canada
nimeshkumar.patel@phac-aspc.gc.ca / Tel: 343-574-8609

De : Weeks, Ashley (PHAC/ASPC)
À : El Jaouhari, Maryem (PHAC/ASPC)
Objet : FW: DG-VP bilat bullets - Jan 15
Date : 2024-01-16 09:04:00

FYI Susanna is seeking approval to have this be our last online report!!

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC)
Sent: Tuesday, January 16, 2024 8:49 AM
To: COVID-19 Vaccine Surveillance / Surveillance Du Vaccin de la COVID-19 (PHAC/ASPC) ; Laroche, Julie A (PHAC/ASPC)
Cc: Wan, Natalie (PHAC/ASPC) ; Yome, Julie (PHAC/ASPC) ; Weeks, Ashley (PHAC/ASPC)
Subject: RE: DG-VP bilat bullets - Jan 15

Hi DGO,

Here is the second item for the CG/VP bilat.

@Laroche, Julie A (PHAC/ASPC) I've highlighted a bullet related to data on doses administered, as this is your area. Please advise if you would recommend any edits to that bullet or if you have any new information to add on this issue. Also, this may trigger questions on what the changes are that PTs are making to the data they provide, so we'll need to provide an update on CIRC discussions to Anne-Marie.

++++++++++++++

For decision: Discontinuation of the COVID-19 online AEFI report

Issue: VSS is proposing a discontinuation of the COVID-19-specific online AEFI report

Rationale: Given the transition from pandemic to endemic and the decrease in COVID-19 vaccine uptake, the regular COVID-19 AEFI report no longer serves its initially conceived purpose of providing regular updates on emerging safety issues for a pandemic vaccine campaign.

Considerations:

- Over 100,000 million doses of vaccines have been administered in Canada alone, with billions administered internationally. The general safety profile of the vaccines is now well characterized, with any new knowledge emerging from other sources e.g. enhanced surveillance or research.
- Going forward, the online report is less informative on new safety issues given that COVID-19 vaccine uptake has decreased significantly (and therefore identification of rare safety issues would occur over longer timelines)
- PTs are making changes to their provision of doses administered data, which will impact the data quality and required format for the AEFI report, e.g. without data on doses administered, the AEFI report would need to shift to using doses distributed data, after which sex and age analysis for AEFI rates will no longer be possible.
- International counterparts with COVID-specific AEFI reporting have discontinued their reports
- Web analytics indicates that interest in the online report in 2023 was low for most of the year, with a slight increase during the flu season (when COVID-19 vaccine campaigns were co-occurring)
- HC colleagues are supportive of regularizing the reporting of COVID-19 AEFI into a more routine report (frequency to be determined) due to decrease in their COVID-19-specific resources

Next steps:

- PHAC will work with HC to discuss plans and options for AEFI reporting (all vaccines) going forward
- In consultation with Comms and the IDVPB Immunization Support and Knowledge Mobilization Teams, lessons learned from the pandemic will be leveraged to provide information tailored to specific audiences

Thanks,
Susanna

==========

Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

*Note I am sending this message at a time that suits me and which may not be part of your regular working hours. Please do not feel as though you need to respond right away
*Notez que j'envoie ce message à un moment qui me convient et qui peut ne pas faire partie de vos heures de travail habituelles. Ne vous sentez pas obligé de répondre tout de suite.

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC)
Sent: Monday, January 15, 2024 2:33 PM
To: COVID-19 Vaccine Surveillance / Surveillance Du Vaccin de la COVID-19 (PHAC/ASPC) <phac.vaccinesurveillance-surveillanceduvaccin.aspc@canada.ca>
Cc: Wan, Natalie (PHAC/ASPC) <natalie.wan@phac-aspc.gc.ca>; Yome, Julie (PHAC/ASPC) <julie.yome@phac-aspc.gc.ca>
Subject: FW: DG-VP bilat bullets - Jan 15

Hi DGO,
Here are some bullets re the Data Sharing MRAP items.
I'll need to develop some additional bullets for another item: COVID-19online report.
Thanks,
Susanna

==========

Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

From: Yome, Julie (PHAC/ASPC) <julie.yome@phac-aspc.gc.ca>
Sent: Monday, January 15, 2024 10:32 AM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Cc: Henry, Minoo (PHAC/ASPC) <minoo.henry@phac-aspc.gc.ca>
Subject: DG-VP bilat bullets - Jan 15

Hi Susanna,
Here is a draft of the DG-VP bilat update on the MRAP:
Subject: OAG Audit (COVID-19 vaccines) MRAP item on data sharing
For information.
Update: A proposal for HC read-only access to CAEFISS has been sent to FPTs for consideration, an important step in the PHAC-led consultation on the data sharing MRAP item.
Background:

- PHAC launched consultation sessions in spring 2023 with FPT partners on a proposal for HC staff to have access to the PHAC-led CAEFISS database.
- After some delays, a proposal summary for read-only access for HC to CAEFISS was sent to PTs for review and decision by February 22.
- Data sharing discussions with PTs will continue in March to discuss outcomes and next steps for consultation on data sharing with manufacturers and the WHO.
- While there are several interdependent components to data sharing, making progress on this first item will maintain momentum and engagement with FPT immunization partners.

Document Released Under the Access to Information Act by the Public Health Agency of Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par l'Agence de la santé publique du Canada

- Discussing PT issues in this step-wise manner will allow incremental progress to be made and targeted solutions to be identified for outstanding issues.

Considerations:

- Stakeholder relations risk: PHAC has received numerous requests from FPT partners for clarity on the HC parameters for access to CAEFISS and have cited frustration/impatience at the delays and the resultant impact on them re postponing their internal consultation discussions.
- Portfolio risk: If successful, this initiative would represent a significant and positive incremental step to resolve a longstanding challenge in vaccine safety surveillance. Given this decade-plus challenge, it is critical that PHAC and HC build on previous discussions and make progress on the long standing issues that have been identified.
- Portfolio risk: PHAC has sought an extension for this MRAP item due to the delays in obtaining information from HC. In addition, extensions have also been sought for the subsequent two MRAP items as these also involve discussions with the same FPT Immunization program partners on data sharing with manufacturers and with WHO.

De :	MacKenzie, Andrew (PHAC/ASPC)
À :	Spruin, Sarah (PHAC/ASPC); Patel, Nimeshkumar (PHAC/ASPC)
Objet :	FW: For Approval by DG: Draft Blurb For the Vaccine Safety Website
Date :	2024-06-21 09:27:41

Good morning Sarah & Nimesh,
Could you please look into the status of this blurb so we can discuss during our trilat? I sent the DG & VP approved version to Mirna a while ago for implementation but not sure what happened from there.
Thank you,
Andrew

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC)
Sent: Thursday, June 20, 2024 5:41 PM
To: MacKenzie, Andrew (PHAC/ASPC)
Subject: FW: For Approval by DG: Draft Blurb For the Vaccine Safety Website
Hi Andrew,
Checking in: What is the status with this web update? I thought it was done and dusted already? Is there something awaiting my approval?
Thanks,
Susanna
==========
Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Thursday, June 20, 2024 2:59 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; Ingraham, Erin (HC/SC) <erin.ingraham@hc-sc.gc.ca>; Lorincz, Jessica (HC/SC) <jessica.lorincz@hc-sc.gc.ca>; Hunter, Josee (HC/SC) <Josee.Hunter@hc-sc.gc.ca>; Tremblay, Benoit (PHAC/ASPC) <benoit.tremblay@phac-aspc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website
Hi folks,
Just poking on this since we've not heard back on the banner since the VP had edits. Is this still on the docket before the overall content condensing in anticipation of a more generalized AEFI dashboard?
Merci,

Quenby

Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Tuesday, March 26, 2024 4:34 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; Tremblay, Benoit (PHAC/ASPC) <benoit.tremblay@phac-aspc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi Quenby

No OT needed, indeed! Thank you all for working so quickly on this. We will route this to our DG for approval and let you know when we have it so that it can be posted. Thank you all for your high response speed here.

M

Mirna Panić (elle/she/her)
Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Tuesday, March 26, 2024 3:06 PM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Thanks, Susanna!

That's fine with me from a plain language perspective. Normally, on gen pop pages, we avoid the 'adverse events' phrase but it's all over this shared audience page, so everyone should be accustomed to it by now.

Is this ready for translation? If so, Web will get on that right away for ideal posting tomorrow. I know we're a day late, but this small hiccup shouldn't warrant OT from InfoBase.

Kind regards,

Quenby

Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Sent: Tuesday, March 26, 2024 2:27 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Sorry to be difficult, but we can't/shouldn't say this statement "… COVID-19 vaccines are safe…" given that there have been a few (though rare) causally associated adverse events that caused serious morbidity and even some deaths. Throughout the vaccine rollout, w argued against HC using such language and they eventually stopped doing so in some documents. We shifted to talking about vaccines having a good "safety profile".

That said, recognizing the need to use lay language, I could be ok with this:

This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada* because:

- the COVID-19 response has evolved from a global pandemic to an ongoing health issue
- extensive evidence on adverse events following COVID-19 vaccination has been gathered globally.

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available.

Thanks,
Susanna

==========

Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Tuesday, March 26, 2024 2:01 PM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Cc: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: FW: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi Susanna

Quenby kindly reviewed the blurb and made two small changes to your proposal:

- She replaced the word *publication* by posting because an online publication tends to be a formal document (think a report with an ISBN or a manuscript)
- She removed the term "safety profile" as it is not defined and it is not a term an everyday user would be familiar with. I tweaked her suggestion slightly.

New proposed blurb for approval:

This is the last regular posting of reported side effects following COVID-19 vaccination in Canada because:

- the COVID-19 response has evolved from a global pandemic to an ongoing health issue
- extensive scientific evidence has indicated that COVID-19 vaccines are safe.

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available.

**

Context:

As you know, we are no longer going to be reporting on COVID-19 vaccine AEFIs in an independent web report. Ashley and the team have been working on developing a surveillance analysis plan and associated knowledge translation plan for all vaccine AEFIs, which will also cover the COVID-19 vaccines from now on. In the meantime, we would like to advise the public that we will no longer be updating the COVID-19 web report. We have developed a blurb, that we hope to have posted on the existing report page advising the public that the January report was the last report.

Who has reviewed:

The blurb was developed collaboratively by Ashley Weeks (acting senior epidemiologist), Mirna Panic (SDAR manager), Susanna Ogunnaike-cooke, Sheila Manhire (senior communications advisor) and was edited for clarity and use of plain language by Quenby Joanette (senior digital communications advisor). Mirna and Ashley have reviewed the final version.

Where it will be:

At the top of these pages

https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html

https://health-infobase.canada.ca/covid-19/vaccine-safety/

Thank you all for the thoughtful consideration of the wording for this blurb

M

Mirna Panić (elle/she/her)
Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Tuesday, March 26, 2024 12:59 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Absolutely! That's perfectly okay. I just wanted to flag that profile doesn't mean anything to gen pop because nowhere on our website (InfoBase or Canada.ca) has it ever been explained. If the statement was inaccurate, 'tis why I ask the subject matter experts to check my work.

Feel free to update that line and seek full approvals. And Web will translate quickly.

Thanks,

Quenby

Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Tuesday, March 26, 2024 12:57 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi Quenby

I noted you were away and thank you for the very quick reply! My only concern is with the second bullet; we say the safety of the COVID vaccines is stable. I understand that safety profile is a technical term, but we cannot say that the safety of the vaccine is *stable* ; this is why we continue to do surveillance and monitoring of vaccine safety (ex: there could be a situation where there is something wrong with a specific vaccine lot – granted, these events are very, very rare).
Could we say something like : "extensive scientific research and evidence indicates that vaccines are safe"
Thanks !
M

Mirna Panić (elle/she/her)
Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Tuesday, March 26, 2024 12:42 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi Mirna,

I was away yesterday but have just added the edits back into a Word doc and tracked my edits again. Do you know how long program wants this message up before we do that consolidation I mentioned as phase 2?

Thanks,

Quenby

Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Monday, March 25, 2024 11:15 AM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: FW: For Approval by DG: Draft Blurb For the Vaccine Safety Website
Importance: High

Hi Quenby!

Happy Tuesday – my apologies for the quick turn around on this request (I fully left a message in my drafts and thought I had sent it, which resulted in delays in obtaining approvals). Susanna (my director) reviewed and proposed some edits to our blurb. I quite like her proposal. Sheila recommended that you take a peak for plain language and let us know if you have any concerns. If you could get back to us ASAP, I would be very appreciative and you would be doing me a huge favor in helping me make up for my poor email management these past two weeks. If not, just send me a note on teams.

Susanna's proposed blurb

This is the last regular publication of the *Reported side effects following COVID-19 vaccination in Canada* because:

- the COVID-19 response has evolved *from global pandemic to an ongoing health issue*
- the safety profile of the COVID-19 vaccines is stable

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available

What do you think? Thank you in advance for your input

Cordialement,
Mirna

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Monday, March 25, 2024 8:51 AM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Lalonde, Danielle (PHAC/ASPC) <Danielle.Lalonde@phac-aspc.gc.ca>; Vaccine Safety / Sécurité Des Vaccins (PHAC/ASPC) <vaccinesafetysurveillance-surveillancedelasecuritedesvaccins@phac-aspc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi all,

The revised text is fine from my perspective.

Mirna, I recommend sharing it with Quenby for a quick plain language check, but I don't anticipate any concerns with it.

Thanks and happy Monday!
Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205
Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Sent: Friday, March 22, 2024 7:53 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Lalonde, Danielle (PHAC/ASPC) <Danielle.Lalonde@phac-aspc.gc.ca>; Vaccine Safety / Sécurité Des Vaccins (PHAC/ASPC) <vaccinesafetysurveillance-surveillancedelasecuritedesvaccins@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi Mirna,

Thanks for all the work on this.

I'm a bit concerned that the proposed wording does not align with the kind of messaging our VP wanted, as it talks a lot about what we **won't** do rather than just signaling a transition.

I would like to propose some edits:

This is the last regular publication of the *Reported side effects following COVID-19 vaccination in Canada* because:

- the COVID-19 response has evolved from global pandemic to an ongoing health issue
- the safety profile of the COVID-19 vaccines is stable

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available

Let me know if you think I need to talk with Sheila about why I don't think Don would approve the proposed wording below.

Thanks,
Susanna

==========

Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

*Note I am sending this message at a time that suits me and which may not be part of your regular working hours. Please do not feel as though you need to respond right away
*Notez que j'envoie ce message à un moment qui me convient et qui peut ne pas faire partie de vos heures de travail habituelles. Ne vous sentez pas obligé de répondre tout de suite.

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Friday, March 22, 2024 11:19 AM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Cc: Lalonde, Danielle (PHAC/ASPC) <Danielle.Lalonde@phac-aspc.gc.ca>; Vaccine Safety / Sécurité Des Vaccins (PHAC/ASPC) <vaccinesafetysurveillance-surveillancedelasecuritedesvaccins@phac-

aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: For Approval by DG: Draft Blurb For the Vaccine Safety Website
Importance: High
Hi Susanna,
I am a little mortified, but I was about to follow up with this and I think I am the culprit – I don't think this message made it out of my drafts. My apologies. Could we get Anne-Marie to quickly look this over and provide her approval (or let us know if she has concerns/does not approve)?
Context: As you know, we are no longer going to be reporting on COVID-19 vaccine AEFIs in an independent web report. Ashley and the team have been working on developing a surveillance analysis plan and associated knowledge translation plan for all vaccine AEFIs, which will also cover the COVID-19 vaccines from now on. In the meantime, we would like to advise the public that we will no longer be updating the COVID-19 web report. We have developed a blurb, that we hope to have posted on the existing report page advising the public that the January report was the last report.
Who has reviewed: The blurb was developed collaboratively by Ashley Weeks (acting senior epidemiologist), Mirna Panic (SDAR manager), Susanna Ogunnaike-cooke, Sheila Manhire (senior communications advisor) and was edited for clarity and use of plain language by Quenby Joanette (senior digital communications advisor). Mirna and Ashley have reviewed the final version.
For action by Anne-Marie: Review and (hopefully) approval of the blurb below before March 26 (if timeline is unrealistic, please let us know as the delay is my fault).
Blurb (78 words):
This content is no longer being updated because:

- the response to COVID-19 has been downgraded, as it's no longer considered a global health emergency
- frequent reporting on COVID-19 vaccine safety is no longer required, as the safety of the vaccines has been well established following extensive research and monitoring

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available.
Where it will be:
At the top of these pages
https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html
https://health-infobase.canada.ca/covid-19/vaccine-safety/
Thank you for your help and my sincere apologies for the inconvenience
Mirna
Mirna Panić (elle/she/her)
Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>

Sent: Monday, March 11, 2024 2:07 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Mirna and Quenby,

I would recommend DG approval on the blurb, given we are archiving a once very high-profile web page.

Thanks!

Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205
Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 1:59 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Awesome sauce. Level of approval will always depend on the topic and how high-profile the request is. If this isn't considered high profile, then I'm coolio with just your approval to proceed with translation.

Sheila, thoughts on level on your end?

I'm happy to connect up with InfoBase and share our approach with them and to get some info on how long they think the first phase will take to code (the blurb) followed by the consolidation/redirects.

Thanks,

Quenby

Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>

Sent: Monday, March 11, 2024 1:56 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Quenby

I would consider them approved for translation (unless you require director-level sign off in writing, in which case I will poke Susanna to send you a note). I am relieved that you have a FRE concurrence editor and don't feel the need to review the translation if you already have in-house capacity to ensure the translation aligns with the terminology used in francophone media/science discourse in Canada.

Regarding archiving, both suggestions make sense to me. We are ok to add the blurb to the summary/detailed report page now for a limited time, decide what that timeframe on one of our upcoming calls, and then delete those pages (setting up a redirect to the consolidated page for anyone with a bookmark or direct link to our pages).

Thanks

Mirna Panić (elle/she/her)
Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 1:22 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Mirna,

Glad you like the edits. Would you consider them approved for translation?

And if you'd like to look at the FRE translation, then I'll send to you before I send it to our FRE concurrence editor. We have 2 editors who check the content we plain language to ensure it resonates in the same way with a Francophone audience.

In terms of archiving pages, what I mean is that you have several pages in this content block:
https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html
https://health-infobase.canada.ca/covid-19/vaccine-safety/
https://health-infobase.canada.ca/covid-19/vaccine-safety/utd.html
https://health-infobase.canada.ca/covid-19/vaccine-safety/archive/

While you do have archived reports, that's not what I meant. The whole content block will no longer be 'current' and so we don't usually leave pieces like this without a notification that they too are

archived as a package. We add archive banners to archived content—for example, this NACI publication: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-guidance-additional-covid-19-booster-dose-spring-2023-individuals-high-risk-severe-illness-due-covid-19.html. This is what I mean when I ask how many pages are getting archived.

In looking at all the pages, we could avoid an archive banner if we consolidate the 'Understanding the data' and the 'Archived reports' page. Since the former page explains the offerings of the latter page. So, in the interim, we add the blurb to the summary/detailed report page now for a limited time (we can decide what that timeframe is), and then delete those pages (setting up a redirect to the consolidated page for anyone with a bookmark or direct link to our pages). Those pages will soon no longer serve a purpose.

Let me know if this jives with you.

Thanks,

Document Released Under the Access to Information Act by the Public Health Agency of Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par l'Agence de la santé publique du Canada

Quenby

Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Monday, March 11, 2024 1:08 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Quenby and Sheila

Thanks so much for your quick turn around on this.

Quenby : We quite like your edits and appreciate the notes on your editorial changes. I appreciate your willingness to coordinate translation. I am francophone so I would be happy to look the final blurb over to make sure the technical translation is correct.

Regarding Archiving: We are a bit confused because we were under the impression that the older reports were already archived on Canada.ca (via these links: Public Health Infobase - Public Health Agency of Canada).

As such, the note would need to be put on the summary + detailed report pages of the January 19 editions:

a. COVID-19 vaccine safety: Summary of weekly report on side effects following immunization - Canada.ca
b. COVID-19 vaccine safety: Report on side effects following immunization - Canada.ca

If your question is: "Yes, Mirna, I am wondering if you want the summary+detailed

report+understanding the data pages of the Jan 19 report archived"; I would say that I am happy to take your guidance here. Intuitively, I would leave them up until May, in case people are searching the website to see if a new report will be posted.

Thanks again, everyone

Mirna Panić (elle/she/her)
Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

Document Released Under the Access to Information Act by the Public Health Agency of Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par l'Agence de la santé publique du Canada

---

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 12:05 PM
To: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Sheila,

That question would need to be directed at InfoBase, so they code their own stuff.

The blurb is easy enough to code. InfoBase will also need to know if the whole content block is being archived. They're generally pretty quick if identified as an urgency.

Please confirm the archiving question and then I'll loop them in.

Thanks,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 12:03 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Thanks for everyone edits!
Quenby, are you able to answer Mirna's question of whether it can be up by March 26 as they have received a question on when the next report will be published?
Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205
Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 10:25 AM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Good morning, all!
I took Mirna's blurb and edited it with tracked changes. Please let me know if this still gets your message across. Since Web reviewed for plain language, I can get the translation sorted.
Also, are you looking to archive each page in the content block, and therefore put this blurb on each page? When we archive pages, we ask Google to de-index them from searches so users don't find old data. You can keep it linked from your various report pages, but it will be removed as a crosslink across Canada.ca outside your specific CAEFISS pages.
We can certainly discuss this at our meeting.
Cheers,

Quenby

Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Friday, March 8, 2024 5:04 PM
To: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Sheila

Thank you so much for this update – I appreciate the work you have done to make it more "straight to the point" and succinct. I have made some small tweaks,. I moved the last sentence to the first paragraph, as I think it helps with flow (personal preference – feel free to ignore it). We have also added a bit of nuance in the text as we just think it is important to highlight that we are not just stopping the reporting because the response is getting downgraded. There has been a shift in the disease epidemiology, in vaccine uptake AND in the amount of data we have to establish the vaccine's safety profile. Our suggestion is below:

**

This page is no longer being updated. *With transmission becoming endemic, as opposed to being a global health emergency, the response to COVID-19 is being downgraded. Frequent reporting on COVID-19 vaccine safety is no longer required as the safety profile of COVID-19 vaccines has been well established following extensive research and monitoring.*

COVID-19 vaccine safety monitoring will continue as part of routine safety monitoring of all authorized vaccines in Canada. Recent reports and publications on vaccine safety are available: https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html

**

Sheila and Quenby; we have also received an info request from the public asking when the next report will be. We are asked to respond before March 26. Is it realistic to hope that this blurb (or a modified version of it, following Quenby's magic) could be put online before that date? Thanks for your advice and guidance

Have a lovely and restful weekend!

Mirna

Mirna Panić (elle/she/her)
Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Wednesday, March 6, 2024 3:15 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Mirna,

Thanks for meeting with me yesterday! I like the text you've provided; and think it will be very useful for developing MLQAs on the discontinuation of this tool for COVID vaccine safety reporting.

However, for web, I recommend keeping it shorter and more plain language. I've attached a revised version that Quenby can send for plain language review if you are comfortable with the main points.
Thanks again,
Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205
Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

Document Released Under the Access to Information Act by the Public Health Agency of Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par l'Agence de la santé publique du Canada

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Tuesday, March 5, 2024 5:58 PM
To: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: Draft Blurb For the Vaccine Safety Website

Hi Sheila,

Thank you for taking the time to meet with us today. Based on our discussion, I have modified our initial draft blurb to indicate the transition of the COVID-19 reporting. I did not have time to run this by the lovely Ashley before she wrapped up her work for the day, so I hope I am doing her proud

As a reminder, we were hoping to put the disclaimer on this page: COVID-19 vaccine safety: Report on side effects following immunization - Canada.ca

Given the transition of COVID-19 epidemiology from a pandemic to an endemic state, and the fact that the safety profile of COVID-19 vaccines has been well established following extensive research and monitoring in Canada and globally, the Public Health Agency of Canada and Health Canada will be transitioning back towards routine surveillance data publication and communication of vaccine safety concerns. As such, this is the last web update of the quarterly report on adverse events following immunization with a COVID-19 vaccine. This change aligns with national and international shifts in practice, which recognize that rapid reporting is no longer needed to gather and share new or emerging evidence on potential vaccine safety issues specific to the COVID-19 pandemic vaccination campaign.
Though no new safety signals have appeared since June 2021, robust routine safety monitoring of COVID-19 vaccines administered in Canada will continue, along with prompt communication on any updated safety advice when needed. In the coming months, we will be transitioning to new vaccine safety communication and reporting tools aiming to support individuals and families across Canada in making evidence-informed decisions to protect their health. Our most recent reports and publications on vaccine safety can be accessed on the following page:
https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html .
We are looking forward to your feedback and insights
M

Mirna Panić (elle/she/her)
Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

De :	MacKenzie, Andrew (PHAC/ASPC)
À :	Spruin, Sarah (PHAC/ASPC); Patel, Nimeshkumar (PHAC/ASPC)
Objet :	FW: For VP approval: Language to add to AEFI online report page re transition to routine reporting
Date :	2024-06-21 10:04:13

From: MacKenzie, Andrew (PHAC/ASPC)
Sent: Friday, May 10, 2024 1:42 PM
To: Panic, Mirna (PHAC/ASPC)
Subject: RE: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Hi Mirna,

This blurb has been VP approved so it's ready to send to Comms.

Thank you,

Andrew

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Friday, May 10, 2024 9:37 AM
To: MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>
Subject: RE: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Yes- Anne-Marie had requested a VP approval last time, would you/Susanna like to do the same?

M

Mirna Panić (elle/she/her)
Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>
Sent: Thursday, May 9, 2024 5:22 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Subject: FW: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Well done, your blurb is DG approved! Have you been working with a Comms contact? My only contact is Sheila Manhire.

Thanks!

Andrew

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Sent: Thursday, May 9, 2024 4:28 PM
To: MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>
Cc: Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>; Vaccine Safety / Sécurité Des Vaccins (PHAC/ASPC) <vaccinesafetysurveillance-

surveillancedelasecuritedesvaccins@phac-aspc.gc.ca>
Subject: RE: For VP approval: Language to add to AEFI online report page re transition to routine reporting
Please consider A/DG approved.
Thanks,
Susanna
==========
Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

From: MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>
Sent: Thursday, May 9, 2024 11:33 AM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Cc: Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>
Subject: FW: For VP approval: Language to add to AEFI online report page re transition to routine reporting
Importance: High
Hi Susanna,
Here's the latest proposed blurb about the change in the online report. Mirna briefed me on the previous comments, hopefully this version addresses them.
Proposed blurb

> This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada*. We will no longer be updating this online report. Instead, COVID-19 vaccine safety data will be shared in a surveillance report that will include data on all vaccines approved in Canada. We will provide a link to this new report as soon as it is available. In the meantime, recent reports and technical publications on vaccine safety are available.
> This decision was made because the COVID-19 response has evolved from a global pandemic to an ongoing health issue and extensive evidence on COVID-19 vaccine safety has been gathered globally.
> Rest assured that robust vaccine safety monitoring efforts continue: if any COVID-19 vaccine safety concerns are detected, we will communicate them promptly.

Thank you!
Andrew

From: Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>
Sent: Monday, April 8, 2024 9:23 AM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Yome, Julie (PHAC/ASPC) <julie.yome@phac-aspc.gc.ca>
Cc: Vaccine Safety / Sécurité Des Vaccins (PHAC/ASPC) <vaccinesafetysurveillance-surveillancedelasecuritedesvaccins@phac-aspc.gc.ca>; Leinan, Valerie (PHAC/ASPC) <valerie.leinan@phac-aspc.gc.ca>; Holmes, Nathalie (PHAC/ASPC) <nathalie.holmes@phac-aspc.gc.ca>; Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>

Subject: FW: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Good morning,

Please see the comment below from the VP for revisions.

Thanks,

Caroline

From: Infectious Disease and Vaccination Programs Branch / Direction générale des programmes sur les maladies infectieuses et de la vaccination (PHAC/ASPC) <idvp-pmiv@phac-aspc.gc.ca>

Sent: Monday, April 8, 2024 6:48 AM

To: Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>; Infectious Disease and Vaccination Programs Branch / Direction générale des programmes sur les maladies infectieuses et de la vaccination (PHAC/ASPC) <idvp-pmiv@phac-aspc.gc.ca>

Subject: RE: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Good morning. Please see below comment from VP. Tks, Nicky

VP has revied the proposed text and has provided the following feedback to the team

I find it too cryptic and short. Could use a better plain language introduction. As of x we will be moving to integration of ….. This decision has been made because…..

Infectious Diseases and Vaccination Programs Branch

Public Health Agency of Canada

Direction générale des programmes sur les maladies infectieuses et de la vaccination

Agence de la santé publique du Canada

From: Holmes, Nathalie (PHAC/ASPC) <nathalie.holmes@phac-aspc.gc.ca> **On Behalf Of** Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC)

Sent: Friday, April 5, 2024 10:56 AM

To: Infectious Disease and Vaccination Programs Branch / Direction générale des programmes sur les maladies infectieuses et de la vaccination (PHAC/ASPC) <idvp-pmiv@phac-aspc.gc.ca>

Cc: Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>

Subject: FW: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Hello VPO, I am sending the following DG-approved request for VP approval. Thank you.

Per the decision taken in January 2024 to transition from a COVID-only online AEFI report to regular reporting, the CIS has worked with Comms to develop some language that will be added to the web page for the last posted report.

Context: As you know, we are no longer going to be reporting on COVID-19 vaccine AEFIs in an independent web report. Instead, we will be reporting on COVID vaccine safety as part of our routine reporting for all vaccines. We are working on developing a surveillance analysis plan and associated knowledge translation plan for all vaccine AEFIs, which will also cover the COVID-19 vaccines. In the meantime, we are proposing to add the wording below to the COVID-19 online report webpages to advise the public that we will no longer be updating that report.

Who has reviewed: The proposed language was developed by the CIS in collaboration with Sheila Manhire (senior communications advisor) and Quenby Joanette (senior digital communications advisor).

++++++++++

This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada* because:

- the COVID-19 response has evolved from a global pandemic to an ongoing health issue
- extensive evidence on adverse events following COVID-19 vaccination has been gathered globally.

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available.

++++++++++

Nathalie Holmes
(Elle | She) on behalf of
Single Window - Director General's Office / Guichet Unique - Bureau de la Directrion générale
Centre for Immunization Surveillance / Centre de surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch / Direction générale des programmes sur les maladies infectieuses et de la vaccination
Public Health Agency of Canada / Agence de la santé publique du Canada
vaccinesurveillance-surveillanceduvaccin@phac-aspc.gc.ca
This Single Window is monitored Mon-Fri 0800-1600 hrs.
Note that the Single Window is not monitored during weekends or public holidays
Le guichet unique est surveillé du lundi au vendredi de 8 h à 16 h.
Notez que le guichet unique n'est pas surveillé pendant les week-ends et les jours fériés

Hi all,

We wanted to reach out to confirm the discontinuation of our COVID-19 AEFI online report. Last Friday, January 19th's web update was our last time updating this website in its current format. This milestone comes after 3 years of routine web postings including a total of 84 iterations since January 2021.

Given the transition from pandemic to endemic and the decrease in COVID-19 vaccine uptake, the regular COVID-19 AEFI online report no longer serves its initially conceived purpose of providing regular updates on emerging safety issues for a pandemic vaccine campaign.

The general safety profile of the vaccines is now well characterized, with any new knowledge emerging from other sources e.g. enhanced surveillance or research. Going forward, the online report is less informative on new safety issues given that COVID-19 vaccine uptake has decreased significantly (and therefore identification of rare safety issues would occur over longer timelines). Additionally, PTs are making changes to their provision of doses administered data, which will impact the data quality and required format for the AEFI report; International counterparts with COVID-specific AEFI reporting have discontinued their reports; and colleagues are generally supportive of regularizing the reporting of COVID-19 AEFI into a more routine report (frequency to be determined) due to decrease in their COVID-19-specific resources.

PHAC will work with HC to discuss plans and options for AEFI reporting (all vaccines) going forward that balances transparency in providing public information on AEFI with available resources in implicated HC and PHAC teams. Lessons learned from the pandemic will be leveraged to provide information tailored to specific audiences, in consultation/collaboration with Comms and the IDVPB Immunization Support and Knowledge Mobilization Teams.

Lastly, we just wanted to extend an sincere thank you to all of you for your invaluable contributions to this report! It's been a pleasure working with you on this product and we look forward to our future collaborations.

Best,
The Vaccine Safety Analytics team

Commenté [AW1]: Consider cutting out the yellow text? Might be too detailed/not relevant for the people we're sending it to? I feel like VVWG might want to know about this, but unsure if comms needs to know about it? Doesn't hurt to keep it though

Hi all,

We wanted to reach out to confirm the discontinuation of our COVID-19 AEFI online report. Last Friday, January 19th's web update was our last time updating this website in its current format. This milestone comes after 3 years of routine web postings including a total of 84 iterations since January 2021.

Given the transition from pandemic to endemic and the decrease in COVID-19 vaccine uptake, the regular COVID-19 AEFI online report no longer serves its initially conceived purpose of providing regular updates on emerging safety issues for a pandemic vaccine campaign.

The general safety profile of the vaccines is now well characterized, with any new knowledge emerging from other sources e.g. enhanced surveillance or research. Going forward, the online report is less informative on new safety issues given that COVID-19 vaccine uptake has decreased significantly (and therefore identification of rare safety issues would occur over longer timelines). Additionally, PTs are making changes to their provision of doses administered data, which will impact the data quality and required format for the AEFI report; International counterparts with COVID-specific AEFI reporting have discontinued their reports; and colleagues are generally supportive of ~~regularizing~~ shifting the reporting of COVID-19 AEFIs into a more routine report (frequency to be determined) with focus on all vaccines due to decrease in their COVID-19-specific resources.

PHAC will work with HC to discuss plans and options for AEFI reporting ~~{~~for all vaccines~~}~~ going forward that balances transparency in providing public information on AEFI with available resources in implicated HC and PHAC teams. Lessons learned from the pandemic will be leveraged to provide information tailored to specific audiences, ~~in consultation/collaboration with Comms and the IDVPB~~ Immunization Support and Knowledge Mobilization Teams.

Lastly, we just wanted to extend an sincere thank you to all of you for your invaluable contributions to this report! It's been a pleasure working with you on this product and we look forward to our future collaborations.

Best,
The Vaccine Safety Analytics team

Commenté [ME1]: Looks great!

Commenté [ME2]: WOW!!

Commenté [AW3]: Consider cutting out the yellow text? Might be too detailed/not relevant for the people we're sending it to? I feel like VVWG might want to know about this, but unsure if comms needs to know about it? Doesn't hurt to keep it though

Commenté [ME4R3]: I think it's a good point to include! The doses administered part is important to mention since this will cause discrepancies between jurisdictions and confuse the public

Online AEFI Surveillance Planning

Created by: Ashley Weeks
Reviewed by:
Last updated: 2024-02-29

Objective

This document aims to describe a plan to streamline the reporting of adverse events following immunization (AEFIs) submitted to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) to the public via an interactive web data platform. We aim to leverage lessons learned from the COVID-19 pandemic vaccination rollout and past CAEFISS reporting mechanisms to improve on current practices and create a modern data tool that is informative for helping Canadians make informed vaccination decisions.

Background

CAEFISS is a provincial, territorial, and federal public health post-market vaccine safety surveillance system. The database is managed by PHAC and includes both passive and active surveillance components. Despite being a robust surveillance system for over twenty years, there have been several inconsistencies in national public reporting of the AEFIs submitted to CAEFISS over time.

During the COVID-19 pandemic, the Public Health Agency of Canada (PHAC) published a detailed online report of side effects following COVID-19 vaccination in Canada in collaboration with Health Canada from 2021 to 2024. The production of the online COVID-19 report contained AEFI report data from CAEFISS, the Canada Vigilance Database (Health Canada), and dose administered data from Canadian COVID-19 Vaccination Coverage Surveillance System (CCVSS). Given the transition from pandemic to endemic and the decrease in COVID-19 vaccine uptake, the regular COVID-19 AEFI report no longer serves its initially conceived purpose of providing regular updates on emerging safety issues for a pandemic vaccination campaign and was therefore discontinued on January 19, 2024.

Prior to the COVID-19 pandemic and for other vaccines, there have been various inconsistencies for public-facing AEFI reports, in terms of: how they were published (website versus journal article); what information was included; and how frequently the reports were produced. More information on past CAEFISS reporting can be found in the Appendix.

Current status of AEFI reporting

PHAC has discontinued the routine COVID-19 online report as of January 19, 2024, while aiming to transition to a new webpage inclusive to all vaccines. The Signal Detection, Analysis and Reporting (SDAR) team aims to complete planning and approvals by May 1, 2024, with launch of new web product in the fall of 2024 (subject to SDAR and Infobase team workloads) prior to the 2024-2025 influenza season.

Reporting from other jurisdictions

An environmental scan was conducted in order to determine trends among public health agencies with regards to reporting vaccine safety data. More details may be found here.

Internationally, it appears that many countries are providing public-facing AEFI reports, but others do not. New Zealand and South Africa are no longer providing recent or frequent AEFI reports. The United States does not provide recent or frequent AEFI reports but may publish related journal articles intermittently. Japan only reports on the total number of vaccines administered and does not provide AEFI information. However, Australia, Singapore, Sweden, the Netherlands, the European Medicines Agency, and the United Kingdom are still providing AEFI reports.

The majority of Canadian provinces and territories have discontinued their COVID-19 AEFI safety reports. Ontario, Alberta and Saskatchewan are the only provinces frequently providing vaccine safety reports and/or updating their online website.

Feedback from Vaccine Vigilance Working group (VVWG)

A VVWG member survey was sent out on February 26, 2024, in order to enrich our learnings with how the relevance of the Online COVID-19 AEFI report applied to the work of our provincial/territorial/departmental surveillance partners. We sought feedback on frequently they accessed the report, for what purpose, and for suggestions as to what they're interested in seeing in the future. A full summary of results can be found here [*input summary from Joy when complete*].

We received responses from 15 individuals who primarily worked in the provincial/territorial public health units. Most respondents used the report for information only, while some reporting using it for various uses such as stakeholder engagement, policy development, and receiving timely updates on emerging safety signals. For future reports, they many suggested a dashboard for all vaccine products for transparency. Others were interested in seeing messaging to address vaccine hesitancy, statistical testing, more lay terms for the public, sand infographics.

Operational lessons learned from reporting during the COVID-19 pandemic

What worked:

- Having dedicated staff members who worked full-time on online reporting.
- Having coordinated communications staff who prioritized online reporting and streamlined the process for us
    - It was agreed upon that COVID-19 AEFI reporting was on their work plans.
    - Streamline between digital comms, strategic comms, program, and greenlights Infobase web coding.
- Having timely doses administered data on a routine basis.

What didn't work:

- Short approval turnaround time.
- Incorporating feedback from so many groups was often conflicting. Most notably, feedback from comms about plain language that changed the technical meanings at times.
- Data often delayed from Health Canada.
- Having to rely on doses administered data for report scheduling.
- Manual entry of data into Google Sheets and Word document for approvals.
- Manual process invites data entry errors.
- Very time consuming.

Reporting infrastructure

Infobase, a web coding team within PHAC, is recommended as the web platform by communications and SDAR staff given the versatility in posting various national health data visualizations in a cohesive web format. Other Infobase dashboards and reports from PHAC are all similar in format to what we plan on reporting. This platform and working relationships really excelled during the COVID-19 pandemic, and Infobase is knowledgeable in advising the appropriate Government of Canada accessibility requirements in addition to being able to help coordinate reviews and approvals with the various communications groups. Lastly, Infobase also learned web coding lessons during the COVID-19 vaccination rollout and now have certain technologies which will help aide the process of future web postings.

SDAR is meeting with strategic comms, digital comms, and Infobase to discuss further on April 8, 2024.

Timelines

PHAC senior management would like to see a first product launch prior to the 2024-2025 influenza vaccination campaign, so September/October 2024 could be a reasonable goal to post the first iteration of the online report. That being said, all of the proposed timelines are highly subject to SDAR and Infobase workloads (to be discussed on April 8). We can also consider updating on November 10th, World Immunization Day.

Quarterly reporting is proposed:

- Users have been expecting regular routine reporting over COVID-10 pandemic, and when this was discontinued it was at a quarterly report period.
- In the past, quarterly reports were used to supplement larger reports, so it's a frequency that was used between 2018 and 2019 before the pandemic.
- Can always aim for quarterly, then re-evaluate if not operationally feasible.

Note on doses distributed

The timeline of updating rates will depend on when the doses distributed are updated for each vaccine as some vaccines have different timelines (depending on vaccine supply receives data from manufacturers). The doses distributed database currently has some other limitations worth exploring, and the data management team is working to improve these with the development of a new database. [*can spend time over next weeks looking into availability of doses distributed data*?].

Analysis plan

Inclusion criteria

All AEFI reports submitted to CAEFISS within the past 10 years that meet the data cutoff date, are complete, and are active will be included in the online report.

Analysis

Data will be presented as numbers and potentially rates per 100,000 doses distributed (given that SDAR deems the doses distributed an appropriate measurement given the data nuances). Should doses distributed not be available as a denominator, consider instead using the proportion of one vaccine compared to all vaccines as a way to give the public a comparison group to work off of.

Commenté [AW1]: I'd like to see something simple go out in september/october but then we can consider adding in more more info each update? But will require Mirna, Susanna, and Infobase's input to see what's possible, especially given the SDAR staffing considerations. I'm also acknowledging that quarterly might be too ambitious so super opened to other intervals if not operationally feasible.

Commenté [AW2]: Will need to discuss with Helen and Nooshin

Data elements

Table 1. Minimum key variables to include for online reporting.

Variable	Rationale	Considerations
Seriousness	• To demonstrate the level of severity that the adverse event had on the individual. • Aim to communicate that the majority of CAEFISS reports are non-serious to increase confidence in the vaccine. • Will increase knowledge and transparency about serious reports by showing what could be expected.	Changes to definition/coding practices over time may impact numbers over time.
Date vaccine administered (DVA)	• Used to derive the year of vaccine administration in order to provide temporal chart. • Aim to communicate that reports have been analysed consistently over time and the numbers have remained stable (i.e. no major increased with the exception of COVID-19). • Emphasize that the increase of reports since 2021 is a successful use of the CAEFISS reporting system to capture adverse events of a novel vaccine during the pandemic.	Can also use date report received (DRR) to PHAC, but DVA may be more meaningful to audience since not subjected to surveillance system/reporting nuances. We used DRR during COVID-19 but was a limitation.
Reporter	• To demonstrate to the audience how reports are typically submitted in the public health system in Canada. • Aim to communicate to the public to seek these individuals if they want to submit reports.	Although this wasn't in the COVID-19 report, we received questions about how to report so might be nice to highlight this to provide insight into how reporting works. This was also provided in historical CAEFISS annual reports.
Vaccine	• To demonstrate differences among vaccines. • Audience may be interested in finding specific information. about a vaccine they received/are considering receiving.	
Age	• Used to derive age groups. • To demonstrate to the audience how safety profiles differ across age groups. • Good opportunity to communicate differences in reporting behaviours.	Can expect parents to report more on behalf of their children/enhanced scrutiny versus adults who may be less likely to seek care on behalf of themselves.
Sex	• To demonstrate to the audience how AEFI reporting differs by biological sex. • May be good opportunity to communicate differences in reporting behaviours and biological differences, and encourage men to report too.	Women may be more likely to report and have biological predispositions to certain responses.

Commenté [AW3]: I think this is acceptable though as a regular part of maintaining a surveillance system

Commenté [AW4]: Happy to discuss this further! 😊 Depends on the story we're trying to tell, whether it's a) This is when people who submitted AEFI reports were vaccinated or b) This is when PHAC received and processed reports submitted to us.

I think the first may be more interesting for the audience, whereas the second is a bit more technically nuanced and more for "surveillance" audience. I don't think the public will care about reporting lags and processing time as much as knowing when the vaccines were administered.

Note can also depend on the denominator we have.

Commenté [AW5]: This is talked about a bit in the COVID report, can use similar messaging

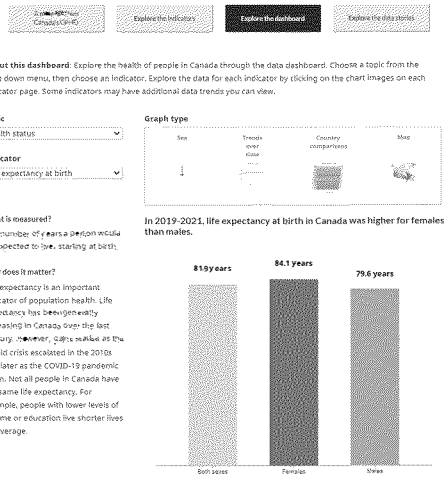
Adverse event following immunization	• To be transparent in the types of adverse events that are reported so individuals have a better idea of what to expect after vaccinations.	Can use either PT or SOC

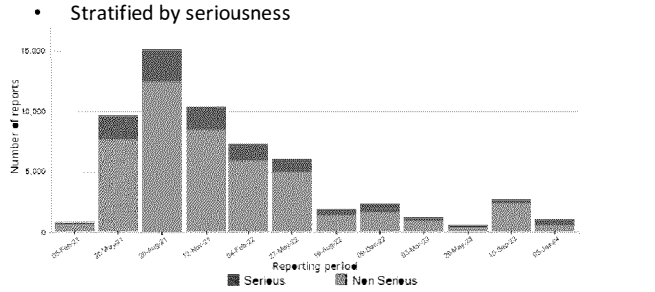
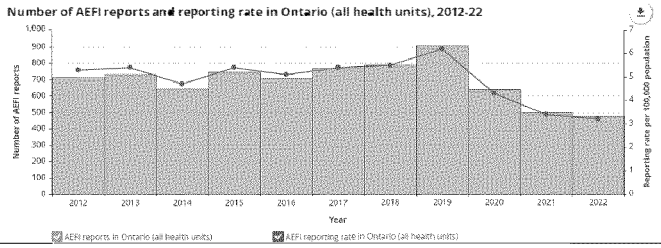
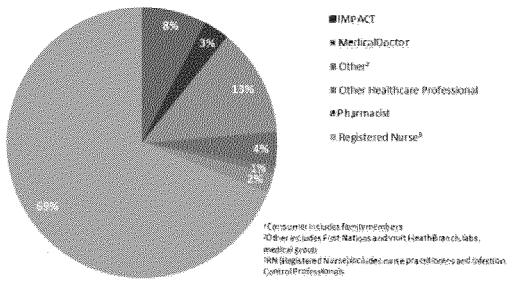
Future variables to consider adding in

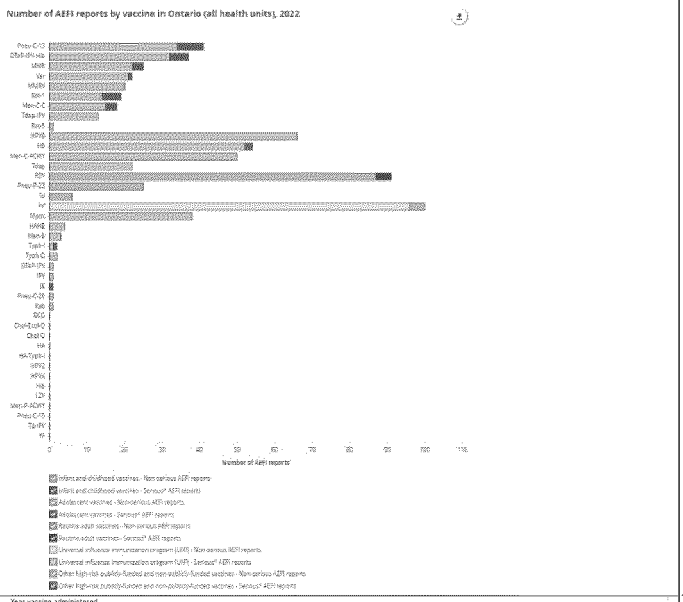
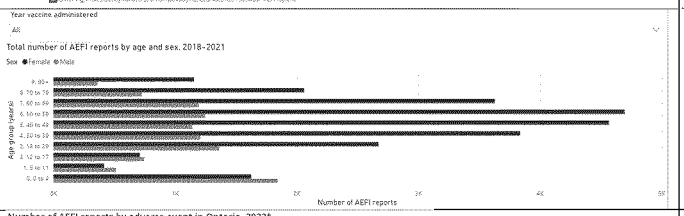
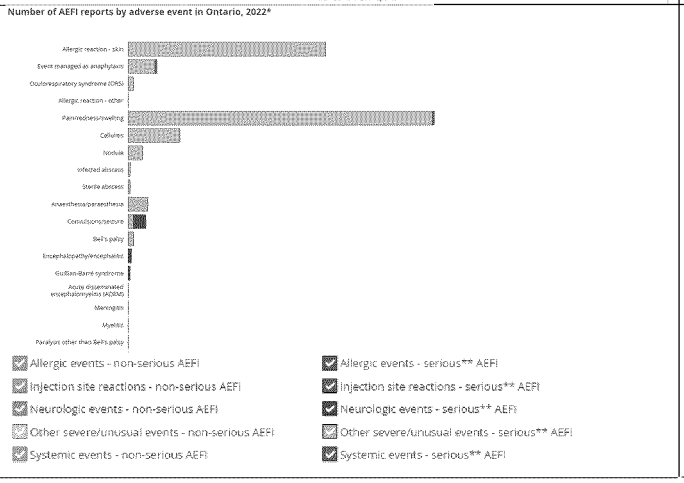
- Time to onset, to demonstrate that individuals can expect that most adverse events would be experienced within a certain time frame.
    - Note that this will have to be per AEFI, not report
- Highest level of care (risks of misinterpretation?)
- Rates
- Can add a tab for observed/expected analyses (can be updated from Sarah's team once a year rather than publish)
- Can add tab for infographic and/or factsheets called "Explore the data stories"

Webpage mock-up

Table 2. Mock-up of web report using dummy data and screenshots of other web products.

Section	Demonstration	Notes
Overall format	• Similar to CPHO dashboard, with interpretation text on one side and interactive chart on the other. • Two tabs to start: one for Technical data notes and one for dashboard. 	• Can expand to more tabs for additional information in future releases
Interpretation note	• An interpretation note at the top regarding important data explanation as a "check to continue" or at the top of page before user can scroll down. Can be called "Essential context to understand the data"	
	•	

AEFI reports over time	• Stratified by seriousness  	Can filter by vaccine
Reporter	 [1]Consumer includes family members [2]Other includes First Nations and Inuit Health Branch, labs, medical group [3]RN (Registered Nurse) includes nurse practitioners and Infection Control Professionals.	

Vaccine		Colour coated by vaccine grouping
Demographics		Can filter by vaccine
AEFI		Can filter by vaccine

Appendix

Appendix 1. Reporting of CAEFISS AEFIs between 2000 and 2024 as per the current CAEFISS website.

Title of report on CAEFISS webpage	Timeframe	Data included	Reporting mechanism	Frequency of reporting
Annual report	• 2013-2016 data was all published in one report in September 2018 • 2017 data was published in one report in December 2018 • 2018-2021 data published in one report in February 2024	• Inconsistencies in the years of data that was included in the summaries • Full-length intro, methods, discussion • All vaccines combined • Number and rate of serious/non-serious reports over time, age/sex distribution, reason for reporting, healthcare utilization, outcome, serious analysis	CCDR pee-reviewed article	Various
Biannual report	Posted online regularly from 2018 to 2018	Same as above, includes analysis by vaccine type	Webpage	Two times a year
Quarterly report	Posted online regularly from 2018 to 2018	Same as above, but shorter summary	Webpage	Four times a year
"Other" report	• 1990 to 2014: ad hoc analyses, some archived • Reports on specific vaccines: 2002, 2005, IMPACT (2019), Influenza (2021-2022) • Select reports on specific adverse events: ORS 2000, 2005, both archived	Various	Webpage and select CCDR peer-reviewed journal articles	Various/ad hoc

Online AEFI Surveillance Planning

Created by: Ashley Weeks
Reviewed by: Sarah Spruin
Last updated: 2024-02-29

a mis en forme : Police :Non Gras

Objective

This document aims to describe a plan to streamline the reporting of adverse events following immunization (AEFIs) submitted to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) to the public via an interactive web data platform. We aim to leverage lessons learned from the COVID-19 pandemic vaccination rollout and past CAEFISS reporting mechanisms to improve on current practices and create a modern data tool that is informative and ~~for~~ helpsing Canadians make informed vaccination decisions.

Background

CAEFISS is a provincial, territorial, and federal public health post-market vaccine safety surveillance system. The database is managed by the Public Health Agency of Canada (PHAC) and includes both passive and active surveillance components. Despite being a robust surveillance system for over twenty years, there have been several inconsistencies in national public reporting of the AEFIs submitted to CAEFISS over time.

Commenté [SS1]: Should we mention that the majority of the database is passive surveillance?

During the COVID-19 pandemic, the Public Health Agency of Canada (PHAC) published ~~a~~the detailed online report of side effects following COVID-19 vaccination in Canada in collaboration with Health Canada from 2021 to 2024. The production of the online COVID-19 report contained AEFI report data from CAEFISS, the Canada Vigilance Database (Health Canada), and dose administered data from Canadian COVID-19 Vaccination Coverage Surveillance System (CCVSS). Given the transition from pandemic to endemic and the decrease in COVID-19 vaccine uptake, the regular COVID-19 AEFI report no longer serves its initially conceived purpose of providing regular updates on emerging safety issues for a pandemic vaccination campaign and was therefore discontinued on January 19, 2024.

Commenté [SS2]: Not sure how formal you need to be here but it may be worth a little paragraph on CVD above this before you mention it? Kind of like you have for CAEFISS

Prior to the COVID-19 pandemic and for other vaccines, there have been various inconsistencies for public-facing AEFI reports, in terms of: how they were published (website versus journal article); what information was included; and how frequently the reports were produced. More information on past CAEFISS reporting can be found in the Appendix.

Current status of AEFI reporting

PHAC has discontinued the routine COVID-19 online report as of January 19, 2024, while aiming to transition to a new webpage inclusive to all vaccines approved by Health Canada. The Signal Detection, Analysis and Reporting (SDAR) team aims to complete planning and approvals by May 1, 2024, with a launch of new web product in the fall of 2024 (subject to SDAR and Infobase team workloads) prior to the 2024-2025 influenza season.

Reporting from other jurisdictions

An environmental scan was conducted in order to determine trends among public health agencies with regards to reporting vaccine safety data. More details may be found here.

Internationally, it appears that many countries are providing public-facing AEFI reports, but others do not. New Zealand and South Africa are no longer providing recent or frequent AEFI reports. The United States does not provide recent or frequent AEFI reports but may publish related journal articles intermittently. Japan only reports on the total number of vaccines administered and does not provide AEFI information. However, Australia, Singapore, Sweden, the Netherlands, the European Medicines Agency, and the United Kingdom are still providing public-facing AEFI reports.

The majority of Canadian provinces and territories have discontinued their public-facing COVID-19 AEFI safety reports. Ontario, Alberta and Saskatchewan are the only provinces frequently providing vaccine safety reports and/or updating their online website.

Feedback from Vaccine Vigilance Working group (VVWG)

A VVWG member survey was sent out on February 26, 2024, in order to enrich our learnings with how the relevance of the Online COVID-19 AEFI report applied to the work of our provincial/territorial/departmental surveillance partners. We sought feedback on how frequently they accessed the report, for what purpose, and for suggestions as to what they're interested in seeing in the future. A full summary of results can be found here [*input summary from Joy when complete*].

We received responses from 15 individuals who primarily worked in the provincial/territorial public health units. Most respondents used the report for information only, while some reporteding using it for various uses such as stakeholder engagement, policy development, and receiving timely updates on emerging safety signals. For future reports, ~~they~~ many suggested a need for a dashboard covering~~for~~ all vaccine products approved by Health Canada for transparency. Others were interested in seeing messaging to address vaccine hesitancy, statistical testing, ~~more lay terms for the public, s~~and infographics. An importance on the use of lay terms for the public was also highlighted.

Operational lessons learned from reporting during the COVID-19 pandemic

What worked:

- Having dedicated staff members who worked full-time on online reporting.
- Having coordinated communications staff who prioritized online reporting and streamlined the process for us
    - It was agreed upon that COVID-19 AEFI reporting was on their work plans.
    - Streamline between digital comms, strategic comms, program, and greenlights Infobase web coding.
- Having timely doses administered data on a routine basis.

What didn't work:

- Short approval turnaround time.
- Incorporating feedback from so many groups was often conflicting. Most notably, feedback from comms about plain language that changed the technical meanings at times.
- Data often delayed from Health Canada.

Commenté [SS(3]: Potentially we can just say: Internationally, we found not all countries are providing public-facing AEFI reports.

Commenté [SS(4]: Should we specify if these are still COVID-19 focused or if they have transitions to all vaccines?

- Having to rely on doses administered data for report scheduling.
- Manual entry of data into Google Sheets and Word document for approvals.
- Manual process invites data entry errors.
- Very time consuming.
- Evolving methodologies resulted in retracted statements which may have caused public confusion/distrust

Reporting infrastructure

Infobase, a web coding team within PHAC, is recommended as the web platform by communications and SDAR staff given the versatility in posting various national health data visualizations in a cohesive web format. Other Infobase dashboards and reports from PHAC are all similar in format to what we plan on reporting. This platform and working relationships really excelled during the COVID-19 pandemic, and Infobase is knowledgeable in advising the appropriate Government of Canada accessibility requirements in addition to being able to help coordinate reviews and approvals with the various communications groups. Lastly, Infobase also learned web coding lessons during the COVID-19 vaccination rollout and now have certain technologies which will help aide the process of future web postings.

SDAR is meeting with strategic comms, digital comms, and Infobase to discuss further on April 8, 2024.

Timelines

PHAC senior management would like to see a first product launch prior to the 2024-2025 influenza vaccination campaign, so September/October 2024 could be a reasonable goal to post the first iteration of the online report. That being said, all of the proposed timelines are highly subject to SDAR and Infobase workloads (to be discussed on April 8). We can also consider updating on November 10th, World Immunization Day.

Quarterly reporting is proposed:

- Users have been expecting regular routine reporting over COVID-10 pandemic, and when this was discontinued it was at a quarterly report period.
- In the past, quarterly reports were used to supplement larger reports, so it's a frequency that was used between 2018 and 2019 before the pandemic.
- Can always aim for quarterly, then re-evaluate if not operationally feasible.

Note on doses distributed

The timeline of updating rates will depend on when the doses distributed are updated for each vaccine as some vaccines have different timelines (depending on vaccine supply receives data from manufacturers). The doses distributed database currently has some other limitations worth exploring, and the data management team is working to improve these with the development of a new database. [*can spend time over next weeks looking into availability of doses distributed data*?].

Commenté [AW5]: I'd like to see something simple go out in september/october but then we can consider adding in more more info each update? But will require Mirna, Susanna, and Infobase's input to see what's possible, especially given the SDAR staffing considerations.
I'm also acknowledging that quarterly might be too ambitious so super opened to other intervals if not operationally feasible.

Analysis plan

Inclusion criteria

All AEFI reports submitted to CAEFISS within the past 10 years that meet the data cutoff date, are complete, and are active will be included in the online report.

Analysis

Data will be presented as numbers and potentially rates per 100,000 doses distributed (given that SDAR deems the doses distributed an appropriate measurement given the data nuances). Should doses distributed not be available as a denominator, we will consider instead using the proportion of one vaccine compared to all vaccines as a way to give the public a comparison group to work off of.

Data elements

Table 1. Minimum key variables to include for online reporting.

Variable	Rationale	Considerations
Seriousness	• To demonstrate the level of severity that the adverse event had on the individual. • Aim to communicate that the majority of CAEFISS reports are non-serious to increase confidence in the vaccine. • Will increase knowledge and transparency about serious reports by showing what could be expected.	Changes to definition/coding practices over time may impact numbers over time.
Date vaccine administered (DVA)	• Used to derive the year of vaccine administration in order to provide temporal chart. • Aim to communicate that reports have been analysed consistently over time and the numbers have remained stable (i.e. no major increased with the exception of COVID-19). • Emphasize that the increase of reports since 2021 is a successful use of the CAEFISS reporting system to capture adverse events of a novel vaccine during the pandemic.	Can also use date report received (DRR) to PHAC, but DVA may be more meaningful to audience since not subjected to surveillance system/reporting nuances. We used DRR during COVID-19 but was a limitation.
Reporter	• To demonstrate to the audience how reports are typically submitted in the public health system in Canada. • Aim to communicate to the public to seek these individuals if they want to submit reports.	Although this wasn't in the COVID-19 report, we received questions about how to report so might be nice to highlight this to provide insight into how reporting works. This was also provided in historical CAEFISS annual reports.
Vaccine	• To demonstrate differences among vaccines. • Audience may be interested in finding specific information. about a vaccine they received/are considering receiving.	

Commenté [AW6]: Will need to discuss with Helen and Nooshin

Commenté [AW7]: I think this is acceptable though as a regular part of maintaining a surveillance system

Commenté [SS8R7]: I agree, although I think we can improve the seriousness definition a bit if we incorperate the IME list into the serious definition. https://www.ema.europa.eu/en/human-regulatory-overview/research-development/pharmacovigilance-research-development/eudravigilance/eudravigilance-system-overview

It could be interesting to create a new seriousness definition and see if there are any reports MAE deem serious which are not picked up in the new definition.

Commenté [AW9]: Happy to discuss this further! 😊 Depends on the story we're trying to tell, whether it's a) This is when people who submitted AEFI reports were vaccinated or b) This is when PHAC received and processed reports submitted to us.

I think the first may be more interesting for the audience, whereas the second is a bit more technically nuanced and more for "surveillance" audience. I don't think the public will care about reporting lags and processing time as much as knowing when the vaccines were administered.

Note can also depend on the denominator we have.

Commenté [SS10R9]: I think I am leaning towards DVA as well. Although note: If we use DVA we will have to note that the data in the most recent ~ month is likely underestimated as not all events have occurred, been, reported, and been entered into CAEFISS.

Commenté [SS11]: I really like this idea! I think we may just have to do some digging into this variable a bit. It may be confusing to publish that consumers can report to CAEFISS. I am still a bit confused as to how they can as well

Commenté [SS12]: I think it would be a good idea to elaborate a bit more here: Trade name, abbreviation? Grouped how? I know we chatted about it a bit but may be good to have it somewhere in the document

Age	• Used to derive age groups. • To demonstrate to the audience how safety profiles differ across age groups. • Good opportunity to communicate differences in reporting behaviours.	Can expect parents to report more on behalf of their children/enhanced scrutiny versus adults who may be less likely to seek care on behalf of themselves.
Sex	• To demonstrate to the audience how AEFI reporting differs by biological sex. • May be good opportunity to communicate differences in reporting behaviours and biological differences, and encourage men to report too.	Women may be more likely to report and have biological predispositions to certain responses.
Adverse event following immunization	• To be transparent in the types of adverse events that are reported so individuals have a better idea of what to expect after vaccinations.	Can use either MedDRA PT or SOC

Commenté [SS13]: Suggest adding the age groups you plan on reporting. I think COVID-19 age groups were kind of unique so may be worth looking at some of the routine vaccines Canadians receive and see the age groups eligible. I think it would be best to have one standard age group used for everything

Commenté [AW14]: This is talked about a bit in the COVID report, can use similar messaging

Commenté [SS15]: Added MedDRA to try and distinguish between the MedDRA term variables in CAEFISS and the MAE Primary MedDRA terms in CAEFISS

Commenté [SS16R15]: Could also use HLT or HLGT depending on how granular you would like to go.

Future variables to consider adding in

- Time to onset, to demonstrate that individuals can expect that most adverse events would be experienced within a certain time frame.
    - Note that this will have to be per AEFI, not report
- Highest level of care (risks of misinterpretation?)
- Rates
- Can add a tab for background rates~~observed/expected analyses~~ (can be updated from Sarah's team once a year rather than publish)
    - Publish yearly rates of events which are typically monitored following vaccination using hospital and emergency department data. These rates could then act as background rates for newly approved vaccines.
- Can add tab for infographic and/or factsheets called "Explore the data stories"

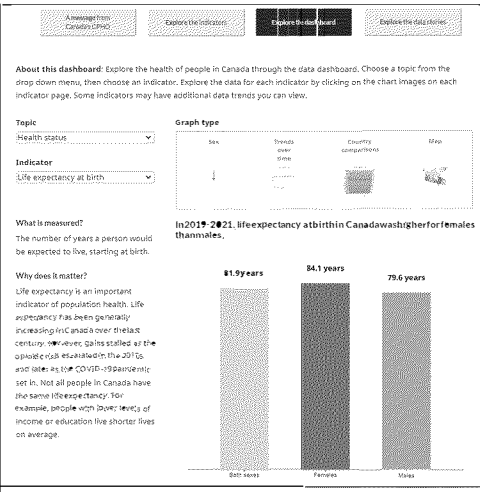
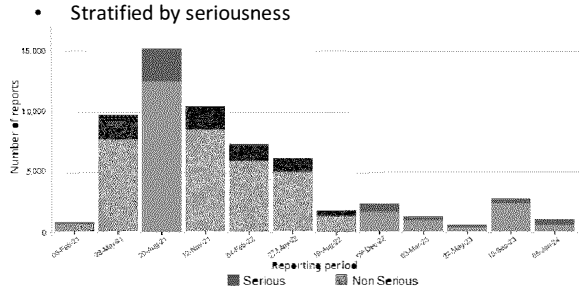
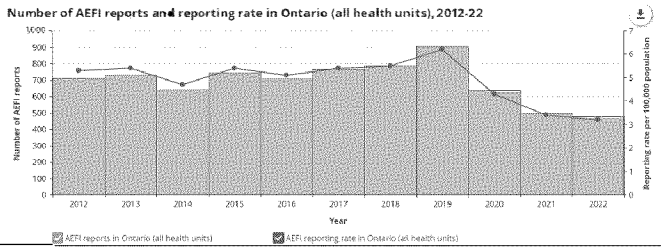
Commenté [SS17]: What if we just put out the time to the first symptom the report had? I think reports typically have multiple symptoms related to one event (e.g. redness, hives, trouble breathing all related to Anaphylaxis) so could treat the first TTO as the start of the events.

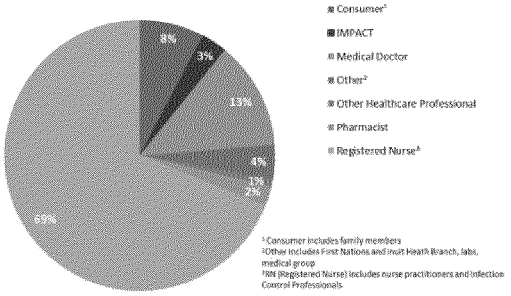
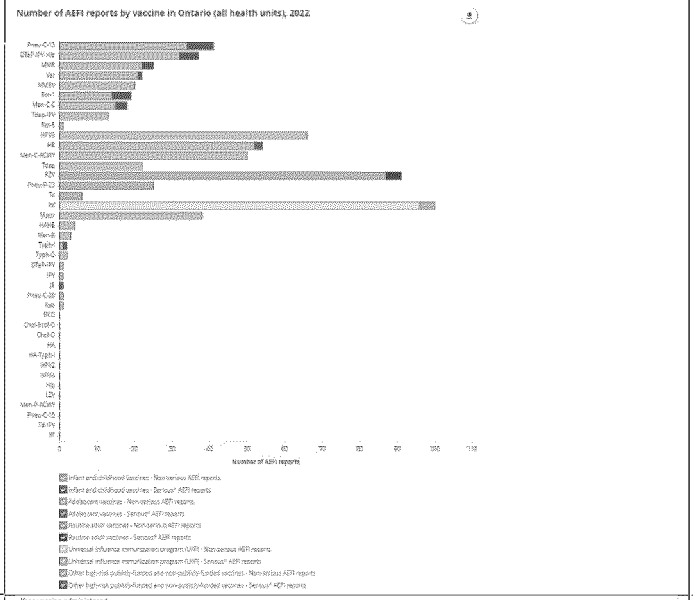
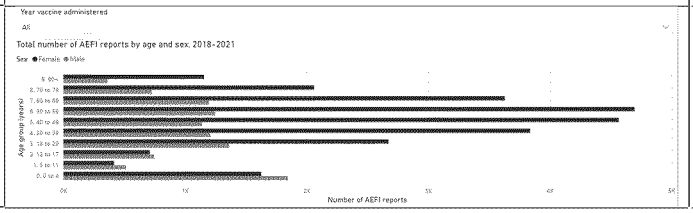
a mis en forme

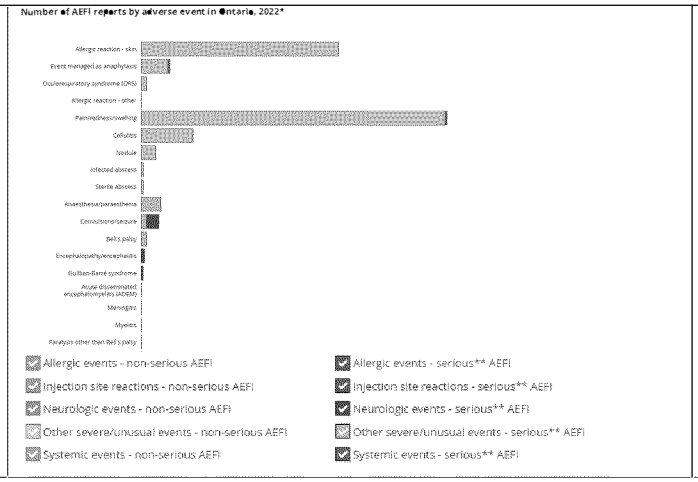
Webpage mock-up

Table 2. Mock-up of web report using dummy data and screenshots of other web products.

Section	Demonstration	Notes
Overall format	• Similar to CPHO dashboard, with interpretation text on one side and interactive chart on the other. • Two tabs to start: one for Technical data notes and one for dashboard.	• Can expand to more tabs for additional information in future releases

		
Interpretation note	• An interpretation note at the top regarding important data explanation as a “check to continue” or at the top of page before user can scroll down. Can be called “Essential context to understand the data”	
	•	
AEFI reports over time	• Stratified by seriousness  	Can filter by vaccine

Reporter		
Vaccine		Colour coated by vaccine grouping
Demographics		Can filter by vaccine

AEFI		Can filter by vaccine

Appendix

Appendix 1. Reporting of CAEFISS AEFIs between 2000 and 2024 as per the current CAEFISS website.

Title of report on CAEFISS webpage	Timeframe	Data included	Reporting mechanism	Frequency of reporting
Annual report	• 2013-2016 data was all published in one report in September 2018 • 2017 data was published in one report in December 2018 • 2018-2021 data published in one report in February 2024	• Inconsistencies in the years of data that was included in the summaries • Full-length intro, methods, discussion • All vaccines combined • Number and rate of serious/non-serious reports over time, age/sex distribution, reason for reporting, healthcare utilization, outcome, serious analysis	CCDR pee-reviewed article	Various
Biannual report	Posted online regularly from 2018 to 2018	Same as above, includes analysis by vaccine type	Webpage	Two times a year
Quarterly report	Posted online regularly from 2018 to 2018	Same as above, but shorter summary	Webpage	Four times a year
"Other" report	• 1990 to 2014: ad hoc analyses, some archived • Reports on specific vaccines: 2002, 2005, IMPACT (2019), Influenza (2021-2022) • Select reports on specific adverse events: ORS 2000, 2005, both archived	Various	Webpage and select CCDR peer-reviewed journal articles	Various/ad hoc

Commenté [SS18]: I think there is an error here?

Commenté [SS19]: I think there is an error here?

Online AEFI Surveillance Planning

Created by: Ashley Weeks
Reviewed by: Sarah Spruin, Joy Pader, Nimesh Patel
Last updated: 2024-02-29

Objective

This document aims to describe a plan to streamline the reporting of adverse events following immunization (AEFIs) submitted to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) to the public via an interactive web data platform. We aim to leverage lessons learned from the COVID-19 pandemic vaccination rollout and past CAEFISS reporting mechanisms to improve on current practices and create a modern data tool that ~~is~~ facilitates informative, transparent, and ~~-~~timely dissemination of data, enabling~~for helping~~ Canadians to make informed vaccination decisions.

Background

CAEFISS is a provincial, territorial, and federal public health post-market vaccine safety surveillance system. The database is managed by the Public Health Agency of Canada (PHAC) and includes both passive and active surveillance components; passive from spontaneous reports submitted by public health jurisdictions, and active through a sentinel network of pediatric hospital sites from the Immunization Monitoring Program ACTive (IMPACT). Reports may also be sent from the market authorization holders to Health Canada via their Canada Vigilence database. ~~Despite being a robust surveillance system for over twenty years, there have been several inconsistencies in national public reporting of the AEFIs submitted to CAEFISS over time.~~

During the COVID-19 pandemic, the Public Health Agency of Canada (PHAC) published ~~the~~a detailed online report of side effects following COVID-19 vaccination in Canada in collaboration with Health Canada from 2021 to 2024. The production of the online COVID-19 report contained AEFI report data from CAEFISS, the Canada Vigilance Database (Health Canada), and dose administered data from Canadian COVID-19 Vaccination Coverage Surveillance System (CCVSS). Given the transition from pandemic to endemic and the decrease in COVID-19 vaccine uptake, the regular COVID-19 AEFI report no longer serves its initially conceived purpose of providing regular updates on emerging safety issues for a pandemic vaccination campaign and was therefore discontinued on January 19, 2024.

Despite being a robust surveillance system for over twenty years, there have been several inconsistencies in national public reporting of the AEFIs submitted to CAEFISS over time. Prior to the COVID-19 pandemic and for other vaccines, there have been various inconsistencies for public-facing AEFI reports, in terms of: how they were published (website versus journal article); what information was included; and how frequently the reports were produced. More information on past CAEFISS reporting can be found in the Appendix.

a mis en forme : Police :Non Gras

Commenté [NP1]: I think this is the mandate of the branch? May be we could align our language to the branch mandate.

Commenté [AW2R1]: Love it, thanks Nimesh!

Commenté [SS3]: Should we mention that the majority of the database is passive surveillance?

Commenté [NP4]: Seems an incomplete sentence.

Commenté [SS5]: Not sure how formal you need to be here but it may be worth a little paragraph on CVD above this before you mention it? Kind of like you have for CAEFISS

Current status of AEFI reporting

PHAC has discontinued the routine COVID-19 online report as of January 19, 2024, while aiming to transition to a new webpage inclusive to all vaccines approved by Health Canada. The Signal Detection, Analysis and Reporting (SDAR) team aims to complete planning and approvals by May 1, 2024, with a launch of new web product in the fall of 2024 (subject to SDAR and Infobase team workloads) prior to the 2024-2025 influenza season.

Reporting from other jurisdictions

An environmental scan was conducted in order to determine trends among public health agencies with regards to reporting vaccine safety data. More details may be found here.

Internationally, it appears that many countries are providing public-facing AEFI reports, but others do not. New Zealand and South Africa are no longer providing recent or frequent AEFI reports. The United States does not provide recent or frequent AEFI reports but may publish related journal articles intermittently. Japan only reports on the total number of vaccines administered and does not provide AEFI information. However, Australia, Singapore, Sweden, the Netherlands, the European Medicines Agency, and the United Kingdom are still providing public-facing AEFI reports.

The majority of Canadian provinces and territories have discontinued their public-facing COVID-19 AEFI safety reports. Ontario, Alberta and Saskatchewan are the only provinces frequently providing vaccine safety reports and/or updating their online website for COVID-19 and other vaccines.

Feedback from Vaccine Vigilance Working group (VVWG)

A VVWG member survey was sent out on February 26, 2024, in order to enrich our learnings with how the relevance of the Online COVID-19 AEFI report applied to the work of our provincial/territorial/departmental surveillance partners. We sought feedback on how frequently they accessed the report, for what purpose, and for suggestions as to what they're interested in seeing in the future. A full summary of results can be found here ~~[*input summary from Joy when complete*]~~.

We received responses from 15 individuals who primarily worked in the provincial/territorial public health units. Most respondents (73%) used the report for information only, while some reporteding using it for various uses such as stakeholder engagement (27%), policy development (27%), and receiving timely updates on emerging safety signals (described narratively). For future reports, ~~they~~ many (60%) suggested a need for a dashboard coveringfor all vaccine products approved by Health Canada for transparency. Others were interested in seeing messaging to address vaccine hesitancy, statistical testing, ~~more lay terms for the public, s~~and infographics. An importance on the use of lay terms for the public was also highlighted.

Commenté [PN(6]: Need to assess feasibility considering a small staff. Do we have foundation to develop programs in R or do we need to start from scratch? We could also launch it in phases and slowly expand the dashboard to cover all HC approved vaccines.

Commenté [AW7R6]: Yes, I also agree with starting in phases: stick with the most important aspects (age/sex, severity, vaccine, AEFI) at the start and then build upon for future releases. There is SAS code that exists and just needs to be updated. There are also sections of R code for certain analyses that we can also utilize.

Commenté [PN(8]: I like this!

Code de champ modifié

Commenté [SS(9]: Potentially we can just say: Internationally, we found not all countries are providing public-facing AEFI reports.

Commenté [SS(10]: Should we specify if these are still COVID-19 focused or if they have transitions to all vaccines?

Commenté [PN(11]: What is the response rate?

Commenté [AW12R11]: It's hard to say the response rate as it was sent to all VVWG members, and they may have forwarded it to their team members so I can't give an exact estimate of how many people it was sent to, other than at minimum VVWG. I can see it was sent to 57 VVWG members if that helps?

Commenté [PN(13]: Could include some numbers and proportions to better understand the magnitude.

Commenté [PN(14]: What proportion of the total respondents?

Operational lessons learned from reporting during the COVID-19 pandemic

What worked:

- Having dedicated staff members who worked full-time on online reporting.
- Having coordinated communications staff who prioritized online reporting and streamlined the process for us
    - It was agreed upon that COVID-19 AEFI reporting was on their work plans.
    - Streamline between digital comms, strategic comms, program, and greenlights Infobase web coding.
- Having timely doses administered data on a routine basis.

What didn't work:

- Short approval turnaround time.
- Incorporating feedback from so many groups was often conflicting. Most notably, feedback from comms about plain language that changed the technical meanings at times.
- Data often delayed from Health Canada.
- Having to rely on doses administered data for report scheduling.
- Manual entry of data into Google Sheets and Word document for approvals.
- Manual process invites data entry errors.
- Very time consuming.
- Evolving methodologies resulted in retracted statements which may have caused public confusion/distrust

Reporting infrastructure

Infobase, a web coding team within PHAC, is recommended as the web platform by communications and SDAR staff given the versatility in posting various national health data visualizations in a cohesive web format. Other Infobase dashboards and reports from PHAC are all similar in format to what we plan on reporting. This platform and working relationships really excelled during the COVID-19 pandemic, and Infobase is knowledgeable in advising the appropriate Government of Canada accessibility requirements in addition to being able to help coordinate reviews and approvals with the various communications groups. Lastly, Infobase also learned web coding lessons during the COVID-19 vaccination rollout and now have certain technologies which will help aide the process of future web postings.

SDAR is meeting with strategic comms, digital comms, and Infobase to discuss further on April 8, 2024.

Timelines

PHAC senior management would like to see a first product launch prior to the 2024-2025 influenza vaccination campaign, so September/October 2024 could be a reasonable goal to post the first iteration of the online report. That being said, all of the proposed timelines are highly subject to SDAR and Infobase workloads (to be discussed on April 8). We can also consider updating on November 10th, World Immunization Day.

Quarterly reporting is proposed:

- Users have been expecting regular routine reporting over COVID-10 pandemic, and when this was discontinued it was at a quarterly report period.
- In the past, quarterly reports were used to supplement larger reports, so it's a frequency that was used between 2018 and 2019 before the pandemic.
- Can always aim for quarterly, then re-evaluate if not operationally feasible.

Note on doses distributed

The timeline of updating rates will depend on when the doses distributed are updated for each vaccine as some vaccines have different timelines (depending on vaccine supply receives data from manufacturers). The doses distributed database currently has some other limitations worth exploring, and the data management team is working to improve these with the development of a new database. [*can spend time over next weeks looking into availability of doses distributed data*?].

Analysis plan

Inclusion criteria

All AEFI reports submitted to CAEFISS within the past 10 years that meet the data cutoff date, are complete, and are active will be included in the online report.

Analysis

Data will be presented as numbers and potentially rates per 100,000 doses distributed (given that SDAR deems the doses distributed an appropriate measurement given the data nuances). Should doses distributed not be available as a denominator, we will consider instead using the proportion of a variable of interest from one vaccine compared to all vaccines as a way to give the public a comparison group to work off of.

Data elements

Table 1. Minimum key variables to include for online reporting.

Variable	Rationale	Considerations

Commenté [AW15]: I'd like to see something simple go out in september/october but then we can consider adding in more more info each update? But will require Mirna, Susanna, and Infobase's input to see what's possible, especially given the SDAR staffing considerations.
I'm also acknowledging that quarterly might be too ambitious so super opened to other intervals if not operationally feasible.

Commenté [AW16]: Will need to discuss with Helen and Nooshin

Commenté [PN(17]: Did you mean proportion of an AEFI for a vaccine of interest?

Seriousness	• To demonstrate the level of severity that the adverse event had on the individual. • Aim to communicate that the majority of CAEFISS reports are non-serious to increase confidence in the vaccine. • Will increase knowledge and transparency about serious reports by showing what could be expected.	Changes to definition/coding practices over time may impact numbers over time.
Date vaccine administered (DVA)	• Used to derive the year of vaccine administration in order to provide temporal chart. • Aim to communicate that ~~reports have been analysed consistently over time~~trend in number of reports over time and the numbers have remained stable (i.e. no major increased with the exception of COVID-19). • Emphasize that the increase of reports since 2021 is a successful use of the CAEFISS reporting system to capture adverse events of a novel vaccine during the pandemic.	Can also use date report received (DRR) to PHAC, but DVA may be more meaningful to audience since not subjected to surveillance system/reporting nuances. We used DRR during COVID-19 but was a limitation.
Reporter	• To demonstrate to the audience how reports are typically submitted in the public health system in Canada. • Aim to communicate to the public to seek these individuals if they want to submit reports. • International online COVID-19 AEFI reports or webpages from the United Kingdom, Sweden and the Netherlands include reporter as a variable. •	Although this wasn't in the COVID-19 report, we received questions about how to report so might be nice to highlight this to provide insight into how reporting works. This was also provided in historical CAEFISS annual reports. Note: may not need to be priority for first iteration of report.
Vaccine / vaccine type	• To demonstrate differences among vaccines.	Need to look into how to group together.

Commenté [AW18]: I think this is acceptable though as a regular part of maintaining a surveillance system

Commenté [SS19R18]: I agree, although I think we can improve the seriousness definition a bit if we incorperate the IME list into the serious definition. https://www.ema.europa.eu/en/human-regulatory-overview/research-development/pharmacovigilance-research-development/eudravigilance/eudravigilance-system-overview

It could be interesting to create a new seriousness definition and see if there are any reports MAE deem serious which are not picked up in the new definition.

Commenté [AW21]: Happy to discuss this further! Depends on the story we're trying to tell, whether it's a) This is when people who submitted AEFI reports were vacci ... [1]

Commenté [SS22R21]: I think I am leaning towards DVA as well. Although note: If we use DVA we will have to n ... [2]

Commenté [NP23R21]: I also agree that DVA is more meaningful. And I think we could delay the reporting to ... [3]

Commenté [NP20]: Should we say to communicate trend in number of reports over time?

Commenté [SS24]: I really like this idea! I think we may just have to do some digging into this variable a bit. It n ... [4]

Commenté [NP2SR24]: I do not feel strongly about including this variable in the first phase of the online ... [5]

Commenté [AW26R24]: We can do a preliminary investigation over the summer and if too nuanced then ... [6]

Commenté [JP27]: Though this extra bullet might be helpful.

a mis en forme : Sans numérotation ni puces

Commenté [SS28]: I think it would be a good idea to elaborate a bit more here: Trade name, abbreviation? ... [7]

Commenté [AW29R28]: For Dalsy's input

	• Audience may be interested in finding specific information. about a vaccine they received/are considering receiving.	
Age	• Used to derive age groups: 0-4, 5-11, 12-17, 18-29, 30-39, 40-49, 50-59, 60-69, 70-79, 80+. • To demonstrate to the audience how safety profiles differ across age groups. • Good opportunity to communicate differences in reporting behaviours.	Can expect parents to report more on behalf of their children/enhanced scrutiny versus adults who may be less likely to seek care on behalf of themselves.
Sex	• To demonstrate to the audience how AEFI reporting differs by biological sex. • May be good opportunity to communicate differences in reporting behaviours and biological differences, and encourage men to report too.	Women may be more likely to report and have biological predispositions to certain responses.
Adverse event following immunization	• To be transparent in the types of adverse events that are reported so individuals have a better idea of what to expect after vaccinations.	Can use either MedDRA PT, HLT, and/or SOC

Future variables to consider adding in

- Time to onset, to demonstrate that individuals can expect that most adverse events would be experienced within a certain time frame.
  - Note that this will have to be per AEFI, not report or just put in the first TTO of the first symptom of the report.
- Highest level of care (risks of misinterpretation?)
- Rates per doses distributed (given that no doses administered will be provided).
- Can add a tab for background rates~~observed/expected analyses~~ (can be updated from Sarah's team once a year rather than publish)
  - Publish yearly rates of events which are typically monitored following vaccination using hospital and emergency department data. These rates could then act as background rates for newly approved vaccines.
- Can add tab for infographic and/or factsheets called "Explore the data stories"

Commenté [SS30]: Suggest adding the age groups you plan on reporting. I think COVID-19 age groups were kind of unique so may be worth looking at some of the routine vaccines Canadians receive and see the age groups eligible. I think it would be best to have one standard age group used for everything.

Commenté [AW31R30]: We can also tweak the age groups as necessary

Commenté [AW32]: This is talked about a bit in the COVID report, can use similar messaging

Commenté [SS33]: Added MedDRA to try and distinguish between the MedDRA term variables in CAEFISS and the MAE Primary MedDRA terms in CAEFISS

Commenté [SS34R33]: Could also use HLT or HLGT depending on how granular you would like to go.

Commenté [AW35R33]: Thanks. Sarah!

Commenté [SS36]: What if we just put out the time to the first symptom the report had? I think reports typically have multiple symptoms related to one event (e.g. redness, hives, trouble breathing all related to Anaphylaxis) so could treat the first TTO as the start of the events.

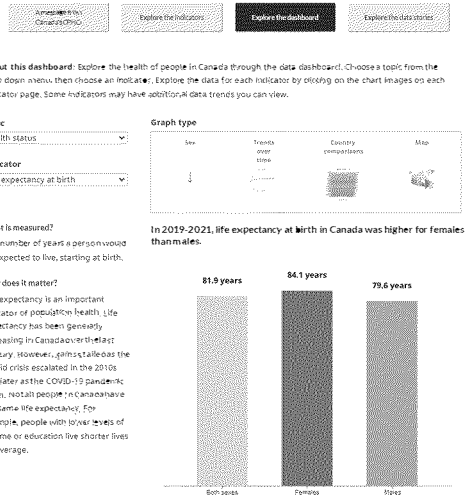
Commenté [AW37R36]: I like that suggestion! Added

Commenté [NP38]: Should we specify since we do not receive doses administered data.

~~a mis en forme~~

Webpage mock-up

Table 2. Mock-up of web report using dummy data and screenshots of other web products.

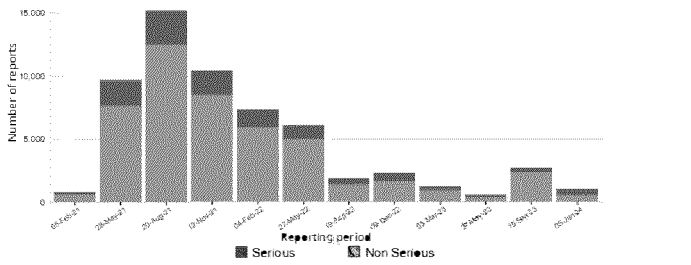
Section	Demonstration	Notes
Overall format	• Similar to CPHO dashboard or the CCDSS dashboard, with interpretation text on one side and interactive chart on the other. • Two tabs to start: one for Technical data notes and one for dashboard. 	
Interpretation note	• An interpretation note at the top regarding important data explanation as a “check to continue” or at the top of page before user can scroll down. Can be called “Essential context to understand the data”	
AEFI reports over time	• Stratified by seriousness	Can filter by vaccine

Commenté [NP39]: Should we use this instead as a template?

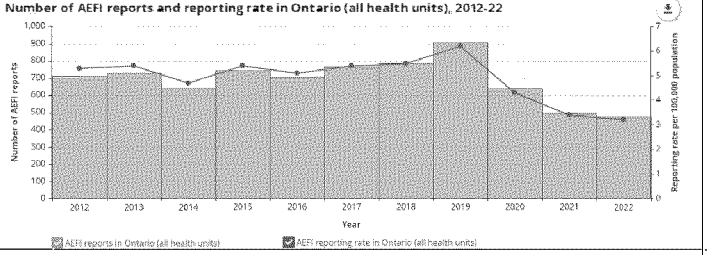
https://health-infobase.canada.ca/ccdss/data-tool/

Both look good though.

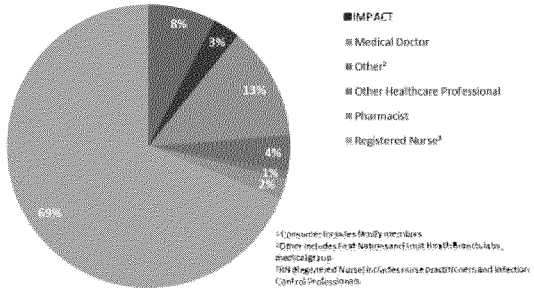
Commenté [AW40R39]: Added this in too 😊

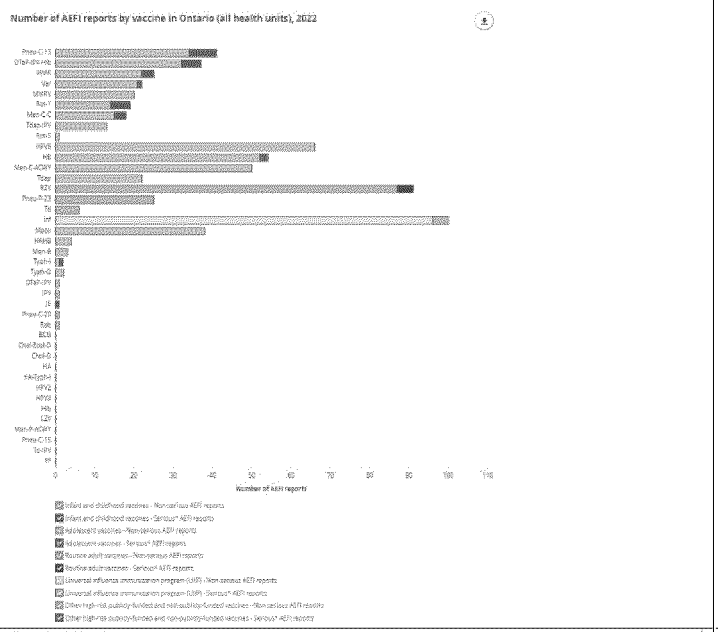
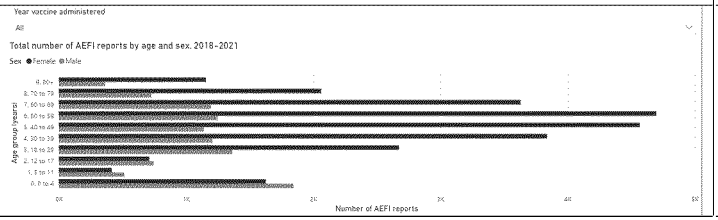


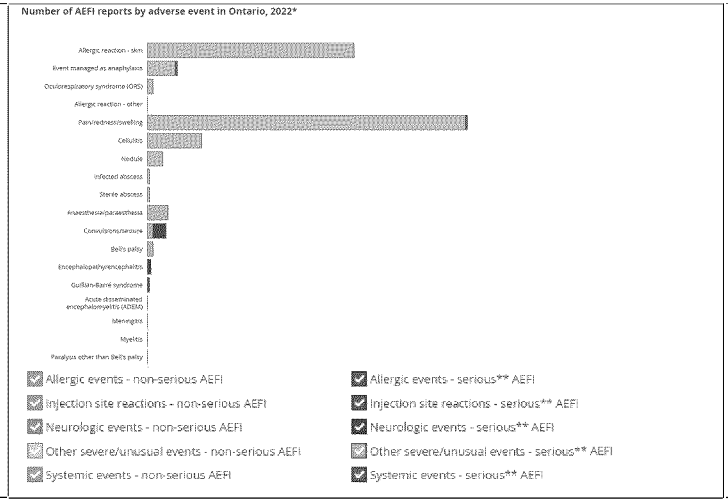
Number of AEFI reports and reporting rate in Ontario (all health units), 2012-22



Reporter



Vaccine		Colour coated by vaccine grouping
Demographics		Can filter by vaccine

AEFI		Can filter by vaccine

Appendix

Appendix 1. Reporting of CAEFISS AEFIs between 2000 and 2024 as per the current CAEFISS website.

Title of report on CAEFISS webpage	Timeframe	Data included	Reporting mechanism	Frequency of reporting
Annual report	• 2013-2016 data was all published in one report in September 2018 • 2017 data was published in one report in December 2018 • 2018-2021 data published in one report in February 2024	• Inconsistencies in the years of data that was included in the summaries • Full-length intro, methods, discussion • All vaccines combined • Number and rate of serious/non-serious reports over time, age/sex distribution, reason for reporting,	CCDR pee-reviewed article	Various

		healthcare utilization, outcome, serious analysis		
Biannual report	Posted online regularly from 20186 to 2018	Same as above, includes analysis by vaccine type	Webpage	Two times a year
Quarterly report	Posted online regularly from ~~2018~~ 2016 to 2018	Same as above, but shorter summary	Webpage	Four times a year
"Other" report	• 1990 to 2014: ad hoc analyses, some archived • Reports on specific vaccines: 2002, 2005, IMPACT (2019), Influenza (2021-2022) • Select reports on specific adverse events: ORS 2000, 2005, both archived	Various	Webpage and select CCDR peer-reviewed journal articles	Various/ad hoc

Commenté [SS41]: I think there is an error here?

Commenté [SS42]: I think there is an error here?

Page 5 : [1] Commenté [AW21] Weeks, Ashley (PHAC/ASPC) 2024-03-15 10:21:00

Happy to discuss this further! Depends on the story we're trying to tell, whether it's a) This is when people who submitted AEFI reports were vaccinated or b) This is when PHAC received and processed reports submitted to us.

I think the first may be more interesting for the audience, whereas the second is a bit more technically nuanced and more for "surveillance" audience. I don't think the public will care about reporting lags and processing time as much as knowing when the vaccines were administered.

Note can also depend on the denominator we have.

Page 5 : [2] Commenté [SS22R21] Spruin, Sarah (PHAC/ASPC) 2024-03-25 09:14:00

I think I am leaning towards DVA as well. Although note: If we use DVA we will have to note that the data in the most recent ~ month is likely underestimated as not all events have occurred, been, reported, and been entered into CAEFISS.

Page 5 : [3] Commenté [NP23R21] Patel, Nimeshkumar (PHAC/ASPC) 2024-03-28 06:12:00

I also agree that DVA is more meaningful. And I think we could delay the reporting to the dashboard by a month, for instance, to allow AEFIs to be reported in the CAEFISS to address Sarah's comment.

Page 5 : [4] Commenté [SS24] Spruin, Sarah (PHAC/ASPC) 2024-03-25 09:25:00

I really like this idea! I think we may just have to do some digging into this variable a bit. It may be confusing to publish that consumers can report to CAEFISS. I am still a bit confused as to how they can as well

Page 5 : [5] Commenté [NP25R24] Patel, Nimeshkumar (PHAC/ASPC) 2024-03-28 06:20:00

I do not feel strongly about including this variable in the first phase of the online reporting without investigating this variable a bit.

Page 5 : [6] Commenté [AW26R24] Weeks, Ashley (PHAC/ASPC) 2024-03-28 10:12:00

We can do a preliminary investigation over the summer and if too nuanced then include it as a lesser priority for future reporting (not for first iteration).

Page 5 : [7] Commenté [SS28] Spruin, Sarah (PHAC/ASPC) 2024-03-25 09:34:00

I think it would be a good idea to elaborate a bit more here: Trade name, abbreviation? Grouped how? I know we chatted about it a bit but may be good to have it somewhere in the document

Online AEFI Surveillance Planning

Created by: Ashley Weeks
Reviewed by: Sarah Spruin, Joy Pader, Nimesh Patel, Mirna Panic
Last updated: 2024-~~02-29~~-04-22

Objective

This document aims to describe a plan to streamline the reporting of adverse events following immunization (AEFIs) submitted to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) to the public via an interactive web data platform. We aim to leverage lessons learned from the COVID-19 pandemic vaccination rollout and past CAEFISS reporting mechanisms to improve on current practices and create a modern data tool that ~~is~~ facilitates informative, transparent, and ~~-~~timely dissemination of data, enabling~~for helping~~ Canadians to make informed vaccination decisions.

Background

CAEFISS is a provincial, territorial, and federal public health post-market vaccine safety surveillance system. The database is managed by the Public Health Agency of Canada (PHAC) and includes both passive and active surveillance components; passive from spontaneous reports submitted by public health jurisdictions, and active through a sentinel network of pediatric hospital sites from the Immunization Monitoring Program ACTive (IMPACT). Reports may also be sent from the market authorization holders to Health Canada via their Canada Vigilence database. ~~Despite being a robust surveillance system for over twenty years, there have been several inconsistencies in national public reporting of the AEFIs submitted to CAEFISS over time.~~

During the COVID-19 pandemic, the Public Health Agency of Canada (PHAC) published the~~a~~ detailed online report of side effects following COVID-19 vaccination in Canada in collaboration with Health Canada from 2021 to 2024. The production of the online COVID-19 report contained AEFI report data from CAEFISS, the Canada Vigilance Database (Health Canada), and dose administered data from Canadian COVID-19 Vaccination Coverage Surveillance System (CCVSS). Given the transition from pandemic to endemic and the decrease in COVID-19 vaccine uptake, the regular COVID-19 AEFI report no longer serves its initially conceived purpose of providing regular updates on emerging safety issues for a pandemic vaccination campaign and was therefore discontinued on January 19, 2024.

Despite being a robust surveillance system for over twenty years, there have been several inconsistencies in national public reporting of the AEFIs submitted to CAEFISS over time. Prior to the COVID-19 pandemic and for other vaccines, there have been various inconsistencies for public-facing AEFI reports, in terms of: how they were published (website versus journal article); what information was included; and how frequently the reports were produced. More information on past CAEFISS reporting can be found in the Appendix.

Current status of AEFI reporting

PHAC has discontinued the routine COVID-19 online report as of January 19, 2024, while aiming to transition to a new webpage inclusive to all vaccines approved by Health Canada. The Signal Detection, Analysis and Reporting (SDAR) team aims to complete planning and approvals by May ~~1~~10, 2024, with a

a mis en forme : Police :Non Gras

Commenté [NP1]: I think this is the mandate of the branch? May be we could align our language to the branch mandate.

Commenté [AW2R1]: Love it, thanks Nimesh!

Commenté [SS3]: Should we mention that the majority of the database is passive surveillance?

Commenté [NP4]: Seems an incomplete sentence

Commenté [SS5]: Not sure how formal you need to be here but it may be worth a little paragraph on CVD above this before you mention it? Kind of like you have for CAEFISS

launch of new web product in the fall of 2024 (subject to SDAR and Infobase team workloads) prior to the 2024-2025 influenza season.

Reporting from other jurisdictions

An environmental scan was conducted in order to determine trends among public health agencies with regards to reporting vaccine safety data. More details may be found here.

Internationally, it appears that many countries are providing public-facing AEFI reports, but others do not. New Zealand and South Africa are no longer providing recent or frequent AEFI reports. The United States does not provide recent or frequent AEFI reports but may publish related journal articles intermittently. Japan only reports on the total number of vaccines administered and does not provide AEFI information. However, Australia, Singapore, Sweden, the Netherlands, the European Medicines Agency, and the United Kingdom are still providing public-facing AEFI reports.

The majority of Canadian provinces and territories have discontinued their public-facing COVID-19 AEFI safety reports. Ontario, Alberta and Saskatchewan are the only provinces frequently providing vaccine safety reports and/or updating their online website for COVID-19 and other vaccines.

Feedback from Vaccine Vigilance Working group (VVWG)

A VVWG member survey was sent out on February 26, 2024, in order to enrich our learnings with how the relevance of the Online COVID-19 AEFI report applied to the work of our provincial/territorial/departmental surveillance partners. We sought feedback on how frequently they accessed the report, for what purpose, and for suggestions as to what they're interested in seeing in the future. A full summary of results can be found here ~~*[input summary from Joy when complete*~~].

~~W~~e Of approximately 57 participants that the survey was sent to, we received responses from 15 individuals who primarily worked in the provincial/territorial public health units. Most respondents (73%) used the report for information only, while some reported~~ed~~ing using it for various uses such as stakeholder engagement (27%), policy development (27%), and receiving timely updates on emerging safety signals (described narratively). For future reports, ~~they~~ many (60%) suggested a need for a dashboard coveringfor all vaccine products approved by Health Canada for transparency. Others were interested in seeing messaging to address vaccine hesitancy, statistical testing, ~~more layterms for the public, s~~and infographics. An importance on the use of lay terms for the public was also highlighted.

Operational lessons learned from reporting during the COVID-19 pandemic

What worked:

- Having dedicated staff members who worked full-time on online reporting.
- Having coordinated communications staff who prioritized online reporting and streamlined the process for us
    - It was agreed upon that COVID-19 AEFI reporting was on their work plans.
    - Streamline between digital comms, strategic comms, program, and greenlights Infobase web coding.
- Having timely doses administered data on a routine basis.

What didn't work:

- Short approval turnaround time.

Commenté [PN(6]: Need to assess feasibility considering a small staff. Do we have foundation to develop programs in R or do we need to start from scratch? We could also launch it in phases and slowly expand the dashboard to cover all HC approved vaccines.

Commenté [AW7R6]: Yes, I also agree with starting in phases: stick with the most important aspects (age/sex, severity, vaccine, AEFI) at the start and then build upon for future releases. There is SAS code that exists and just needs to be updated. There are also sections of R code for certain analyses that we can also utilize.

Commenté [PN(8]: I like this!

Code de champ modifié

Commenté [SS(9]: Potentially we can just say: Internationally, we found not all countries are providing public-facing AEFI reports.

Commenté [SS(10]: Should we specify if these are still COVID-19 focused or if they have transitions to all vaccines?

Commenté [PN(11]: What is the response rate?

Commenté [AW12R11]: It's hard to say the response rate as it was sent to all VVWG members, and they may have forwarded it to their team members so I can't give an exact estimate of how many people it was sent to, other than at minimum VVWG. I can see it was sent to 57 VVWG members if that helps?

Commenté [PN(13]: Could include some numbers and proportions to better understand the magnitude.

Commenté [PN(14]: What proportion of the total respondents?

- Incorporating feedback from so many groups was often conflicting. Most notably, feedback from comms about plain language that changed the technical meanings at times.
- Data often delayed from Health Canada.
- Having to rely on doses administered data for report scheduling.
- Manual entry of data into Google Sheets and Word document for approvals.
- Manual process invites data entry errors.
- Very time consuming.
- Evolving methodologies resulted in retracted statements which may have caused public confusion/distrust

Reporting infrastructure

Infobase, a web coding team within PHAC, is recommended as the web platform by communications and SDAR staff given the versatility in posting various national health data visualizations in a cohesive web format. Other Infobase dashboards and reports from PHAC are all similar in format to what we plan on reporting. This platform and working relationships really excelled during the COVID-19 pandemic, and Infobase is knowledgeable in advising the appropriate Government of Canada accessibility requirements in addition to being able to help coordinate reviews and approvals with the various communications groups. Lastly, Infobase also learned web coding lessons during the COVID-19 vaccination rollout and now have certain technologies which will help aide the process of future web postings.

SDAR is meeting with strategic comms, digital comms, and Infobase to discuss further on April 8, 2024.

Timelines

PHAC senior management would like to see a first product launch prior to the 2024-2025 influenza vaccination campaign, so September/~~October~~ 2024 could be a reasonable goal to post the first iteration of the online report. That being said, all of the proposed timelines are highly subject to SDAR ~~and Infobase~~ workloads ~~(to be discussed on April 8)~~. We can also consider updating on November 10th, World Immunization Day.

Quarterly reporting is proposed:

- Users have been expecting regular routine reporting over COVID-10 pandemic, and when this was discontinued it was at a quarterly report period.
- In the past, quarterly reports were used to supplement larger reports, so it's a frequency that was used between 2018 and 2019 before the pandemic.
- Can always aim for quarterly, then re-evaluate if not operationally feasible.

Note on doses distributed

The timeline of updating rates will depend on when the doses distributed are updated for each vaccine as some vaccines have different timelines (depending on vaccine supply receives data from manufacturers). The doses distributed database currently has some other limitations worth exploring, and the data management team is working to improve these with the development of a new database. [*can spend time over next weeks looking into availability of doses distributed data*?].

Commenté [AW15]: I'd like to see something simple go out in september/october but then we can consider adding in more more info each update? But will require Mirna, Susanna, and Infobase's input to see what's possible, especially given the SDAR staffing considerations.
I'm also acknowledging that quarterly might be too ambitious so super opened to other intervals if not operationally feasible.

Analysis plan

Inclusion criteria

All AEFI reports submitted to CAEFISS within the past 10 years that meet the data cutoff date, are complete, and are active will be included in the online report.

Analysis

Data by seriousness, date vaccine administered, vaccine, age, sex, and AEFI will be presented as numbers and potentially rates per 100,000 doses distributed. ~~(g~~Given limitations with doses distributed (e.g. overestimating the doses that were administered, no age/sex breakdowns, and different data update schedules), ~~that~~ SDAR will investigate the usefulness of this data, along with population data, as rate denominators~~deems the doses distributed an appropriate measurement given the data nuances~~). Should doses distributed not be ~~available~~ appropriate as a denominator, we will consider instead using the proportion of a variable of interest from one vaccine compared to all vaccines as a way to give the public a comparison group to work off of.

~~Data elements~~

~~**Table 1.** Minimum key variables to include for online reporting.~~

~~**Variable**~~	~~**Rationale**~~	~~**Considerations**~~
~~Seriousness~~	~~• To demonstrate the level of severity that the adverse event had on the individual.~~ ~~• Aim to communicate that the majority of CAEFISS reports are non-serious to increase confidence in the vaccine.~~ ~~• Will increase knowledge and transparency about serious reports by showing what could be expected.~~	~~Changes to definition/coding practices over time may impact numbers over time.~~
~~Date vaccine administered (DVA)~~	~~• Used to derive the year of vaccine administration in order to provide temporal chart.~~ ~~• Aim to communicate that reports have been analysed consistently over time and the numbers have remained stable (i.e. no major increased with the exception of COVID-19).~~ ~~• Emphasize that the increase of reports since 2021 is a successful use of the CAEFISS reporting system to capture adverse events of a novel vaccine during the pandemic.~~	~~Can also use date report received (DRR) to PHAC, but DVA may be more meaningful to audience since not subjected to surveillance system/reporting nuances. We used DRR during COVID-19 but was a limitation.~~
~~Reporter~~	~~• To demonstrate to the audience how reports are typically submitted in the public health system in Canada.~~ ~~• Aim to communicate to the public to seek these individuals if they want to submit reports.~~	~~Although this wasn't in the COVID-19 report, we received questions about how to report so might be nice to highlight this to provide insight into how reporting works. This~~

Commenté [PN(16]: Did you mean proportion of an AEFI for a vaccine of interest?

Commenté [AW17]: I think this is acceptable though as a regular part of maintaining a surveillance system

Commenté [SS18R17]: I agree, although I think we can improve the seriousness definition a bit if we incorperate the IME list into the serious definition: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/pharmacovigilance-research-development/eudravigilance/eudravigilance-system-overview

It could be interesting to create a new seriousness definition and see if there are any reports MAE deem serious which are not picked up in the new definition.

Commenté [NP19]: Should we say to communicate trend in number of reports over time?

Commenté [AW20]: Happy to discuss this further! 😊 Depends on the story we're trying to tell, whether it's a) This is when people who submitted AEFI reports were vaccinated or b) This is when PHAC received and processed reports submitted to us.

I think the first may be more interesting for the audience, whereas the second is a bit more technically nuanced and more for "surveillance" audience. I don't think the public will care about reporting lags and processing time as much as knowing when the vaccines were administered.

Note can also depend on the denominator we have.

Commenté [SS21R20]: I think I am leaning towards DVA as well. Although note: If we use DVA we will have to note that the data in the most recent ~ month is likely underestimated as not all events have occurred, been reported, and been entered into CAEFISS.

Commenté [NP22R20]: I also agree that DVA is more meaningful. And I think we could delay the reporting to the dashboard by a month, for instance, to allow AEFIs to be reported in the CAEFISS to address Sarah's comment.

a mis en forme : Sans numérotation ni puces

Commenté [SS23]: I really like this idea! I think we may just have to do some digging into this variable a bit. It may be confusing to publish that consumers can report to CAEFISS. I am still a bit confused as to how they can as well

Commenté [NP24R23]: I do not feel strongly about including this variable in the first phase of the online reporting without investigating this variable a bit.

Commenté [AW25R23]: We can do a preliminary investigation over the summer and if too nuanced then include it as a lesser priority for future reporting (not for first iteration).

		was also provided in historical CAEFISS annual reports.
Vaccine	• To demonstrate differences among vaccines. • Audience may be interested in finding specific information about a vaccine they received/are considering receiving.	
Age	• Used to derive age groups. • To demonstrate to the audience how safety profiles differ across age groups. • Good opportunity to communicate differences in reporting behaviours.	Can expect parents to report more on behalf of their children/enhanced scrutiny versus adults who may be less likely to seek care on behalf of themselves.
Sex	• To demonstrate to the audience how AEFI reporting differs by biological sex. • May be good opportunity to communicate differences in reporting behaviours and biological differences, and encourage men to report too.	Women may be more likely to report and have biological predispositions to certain responses.
Adverse event following immunization	• To be transparent in the types of adverse events that are reported so individuals have a better idea of what to expect after vaccinations.	Can use either MedDRA PT, HLT, and/or SOC

Future variables to consider adding in

- Time to onset, to demonstrate that individuals can expect that most adverse events would be experienced within a certain time frame.
    - Note that this will have to be per AEFI, not report or just put in the first TTO of the first symptom of the report.
- Highest level of care (risks of misinterpretation?)
- Rates per doses distributed (given that no doses administered will be provided).
- Can add a tab for background rates observed/expected analyses (can be updated from Sarah's team once a year rather than publish)
    - Publish yearly rates of events which are typically monitored following vaccination using hospital and emergency department data. These rates could then act as background rates for newly approved vaccines.
- Can add tab for infographic and/or factsheets called "Explore the data stories"
- Reporter
    - To demonstrate to the audience how reports are typically submitted in the public health system in Canada.
    - Aim to communicate to the public to seek these individuals if they want to submit reports.
    - International online COVID-19 AEFI reports or webpages from the United Kingdom, Sweden and the Netherlands include reporter as a variable.

Commenté [SS26]: I think it would be a good idea to elaborate a bit more here: Trade name, abbreviation? Grouped how? I know we chatted about it a bit but may be good to have it somewhere in the document

Commenté [AW27R26]: For Dalsy's input

Commenté [SS28]: Suggest adding the age groups you plan on reporting. I think COVID-19 age groups were kind of unique so may be worth looking at some of the routine vaccines Canadians receive and see the age groups eligible. I think it would be best to have one standard age group used for everything

Commenté [AW29R28]: We can also tweak the age groups as necessary

Commenté [AW30]: This is talked about a bit in the COVID report, can use similar messaging

Commenté [SS31]: Added MedDRA to try and distinguish between the MedDRA term variables in CAEFISS and the MAE Primary MedDRA terms in CAEFISS

Commenté [SS32R31]: Could also use HLT or HLGT depending on how granular you would like to go.

Commenté [AW33R31]: Thanks. Sarah!

Commenté [SS34]: What if we just put out the time to the first symptom the report had? I think reports typically have multiple symptoms related to one event (e.g. redness, hives, trouble breathing all related to Anaphylaxis) so could treat the first TTO as the start of the events.

Commenté [AW35R34]: I like that suggestion! Added

Commenté [NP36]: Should we specify since we do not receive doses administered data.

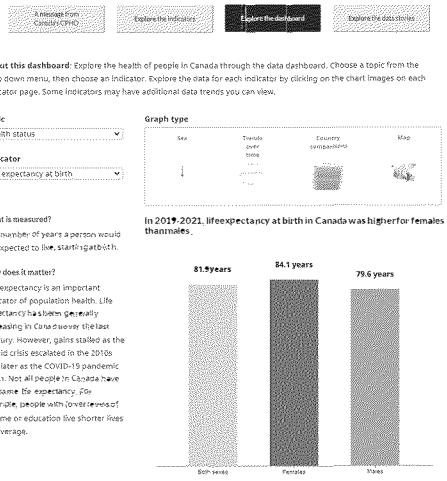
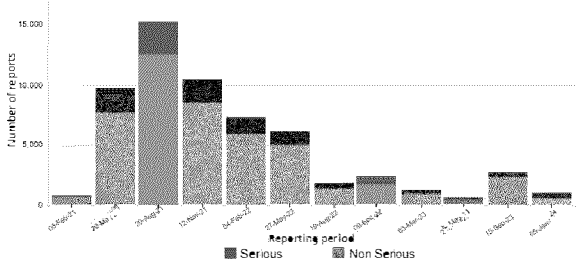
a mis en forme

a mis en forme

- Although this wasn't in the COVID-19 report, we received questions about how to report so might be nice to highlight this to provide insight into how reporting works. This was also provided in historical CAEFISS annual reports.

Webpage mock-up

Table 2. Mock-up of web report using dummy data and screenshots of other web products.

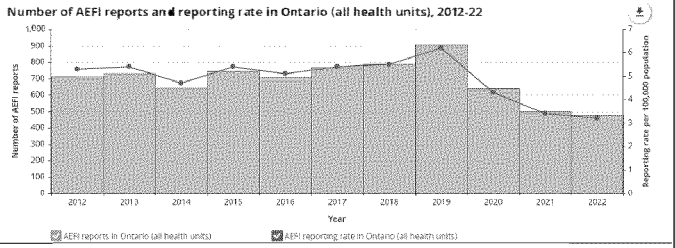
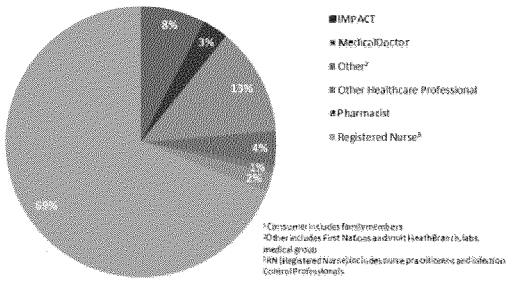
Section	Demonstration	Notes
Overall format	• Similar to CPHO dashboard or the CCDSS dashboard, with interpretation text on one side and interactive chart on the other. • Two tabs to start: one for Technical data notes and one for dashboard. 	• Can expand to m tabs for addition information in future releases
Interpretation note	• An interpretation note at the top regarding important data explanation as a "check to continue" or at the top of page before user can scroll down. Can be called "Essential context to understand the data"	
AEFI reports over time	• Stratified by seriousness 	Can filter by vaccine

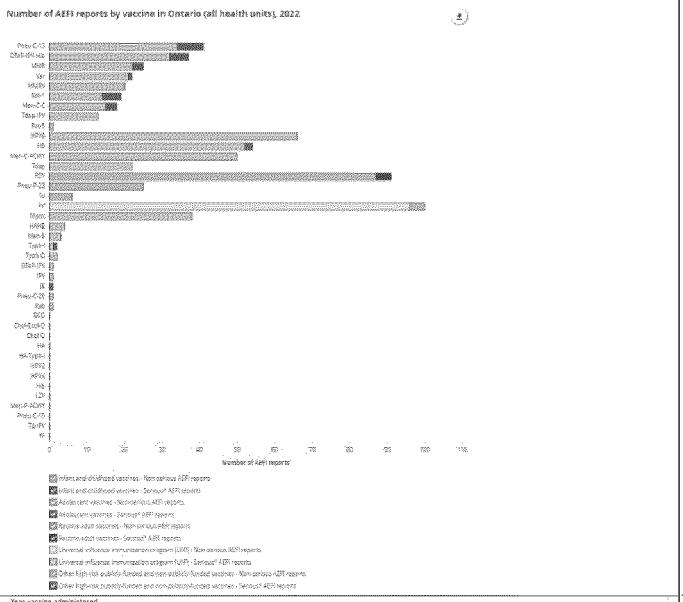
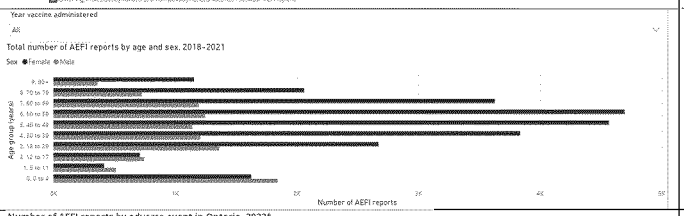
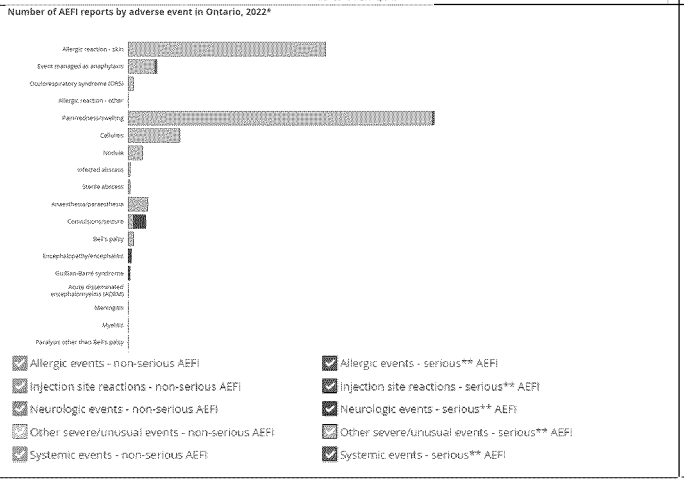
Commenté [NP37]: Should we use this instead as a template?

https://health-infobase.canada.ca/ccdss/data-tool/

Both look good though.

Commenté [AW38R37]: Added this in too 😉

		
Reporter		To consider adding

Vaccine		Colour coated by vaccine grouping
Demographics		Can filter by vaccine
AEFI		Can filter by vaccine

Appendix

Appendix 1. Reporting of CAEFISS AEFIs between 2000 and 2024 as per the current CAEFISS website.

Title of report on CAEFISS webpage	Timeframe	Data included	Reporting mechanism	Frequency of reporting
Annual report	• 2013-2016 data was all published in one report in September 2018 • 2017 data was published in one report in December 2018 • 2018-2021 data published in one report in February 2024	• Inconsistencies in the years of data that was included in the summaries • Full-length intro, methods, discussion • All vaccines combined • Number and rate of serious/non-serious reports over time, age/sex distribution, reason for reporting, healthcare utilization, outcome, serious analysis	CCDR pee-reviewed article	Various
Biannual report	Posted online regularly from 20186 to 2018	Same as above, includes analysis by vaccine type	Webpage	Two times a year
Quarterly report	Posted online regularly from ~~2018~~ 2016 to 2018	Same as above, but shorter summary	Webpage	Four times a year
"Other" report	• 1990 to 2014: ad hoc analyses, some archived • Reports on specific vaccines: 2002, 2005, IMPACT (2019), Influenza (2021-2022) • Select reports on specific adverse events: ORS 2000, 2005, both archived	Various	Webpage and select CCDR peer-reviewed journal articles	Various/ad hoc

Commenté [SS39]: I think there is an error here?

Commenté [SS40]: I think there is an error here?

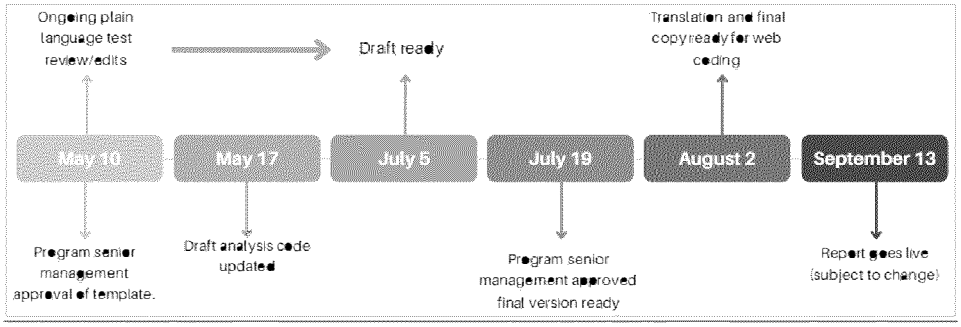
Appendix 2. Critical path of developmental steps to achieve fall web deliverable.

a mis en forme : Police :11 pt

Task/deliverable	Involved staff	Date	Note(s)
Finalize internal proposal framework for senior management.	• VSS (Ashley, Mirna)	April 29, 2024.	• Seek senior management approval on template before moving forward with technical coding.
Senior management signoff on template.	• VSS (Ashley, Mirna)	May 10, 2024.	
Draft of interpretation text by VSS team sent to comms for plain language.	• VSS (Ashey, Mirna) • Digital comms (Quenby, Andrea) • Strategic comms (Sheila)	Send initial draft to comms by May 10, 2024.	• Ashley to set up meeting to discuss the week of May 13-17. • Can set up biweekly check-in meetings if necessary to keep on track. • First iteration will be generic surveillance descriptive text; this will be updated as necessary with more

			specific results as data analysis is confirmed.
Ongoing: modifications to text based on plain language and updated analysis results.	• All	May 10 to July 5, 2024.	• Include Infobase as an FYI in case they have suggestions or need VSS eyes to make technical formatting tweaks.
Updated code for data pull/analysis.	• VSS (Ashley, Joy) • Infobase (Scott, Benoit, student?)	Draft code corresponding to original proposal by May 17, 2024.	• Will touch base with Infobase team to confirm technical requirements/formatting for the tentative framework that was approved by senior management.
Final draft of online report ready with updated data.	• VSS (Mirna, Ashley, Nimesh, Joy)	July 5, 2024.	• Including updated data and plain language text.
Approvals/revisions with program senior management.	• VSS (Mirna, Nimesh)	July 5 to July 19, 2024.	
Translation	• Digital comms (Quenby, Andrea) • VSS (Mirna, Ashley)	July 19 to August 2, 2024.	• Will need to confirm translation timeline. • Can also send Infobase the English report first and translate in parallel to initial web coding?
Send final copy to Infobase for web coding.	• VSS (Mirna, Nimesh)	July 29 to September 13, 2024.	Infobase, please let us know if this is feasible; if not, we will tweak the date we go live.
Developmental link greenlights.	• VSS senior management	September 9 to 12, 2024.	Will need to confirm level of who signs off (DGO? VP?).
Report live on Canada.ca.	• **Infobase (Benoit, Scott, student)**	**September 13, 2024.**	**To be confirmed with Infobase depending on workloads.**

Appendix 3. Timeline of main milestones



Online AEFI Surveillance Planning

Created by: Ashley Weeks
Reviewed by: Sarah Spruin, Joy Pader, Nimesh Patel, Mirna Panic
Last updated: 2024-04-22

Objective

This document aims to describe a plan to streamline the reporting of adverse events following immunization (AEFIs) submitted to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) to the public via an interactive web data platform. We aim to leverage lessons learned from the COVID-19 pandemic vaccination rollout and past CAEFISS reporting mechanisms to improve on current practices and create a modern data tool that facilitates informative, transparent, and timely dissemination of data, enabling Canadians to make informed vaccination decisions.

Background

CAEFISS is a provincial, territorial, and federal public health post-market vaccine safety surveillance system. The database is managed by the Public Health Agency of Canada (PHAC) and includes both passive and active surveillance components; passive from spontaneous reports submitted by public health jurisdictions, and active through a sentinel network of pediatric hospital sites from the Immunization Monitoring Program ACTive (IMPACT). Reports may also be sent from the market authorization holders to Health Canada via their Canada Vigilence database.

During the COVID-19 pandemic, the Public Health Agency of Canada (PHAC) published the detailed online report of side effects following COVID-19 vaccination in Canada in collaboration with Health Canada from 2021 to 2024. The production of the online COVID-19 report contained AEFI report data from CAEFISS, the Canada Vigilance Database (Health Canada), and dose administered data from Canadian COVID-19 Vaccination Coverage Surveillance System (CCVSS). Given the transition from pandemic to endemic and the decrease in COVID-19 vaccine uptake, the regular COVID-19 AEFI report no longer serves its initially conceived purpose of providing regular updates on emerging safety issues for a pandemic vaccination campaign and was therefore discontinued on January 19, 2024.

Despite being a robust surveillance system for over twenty years, there have been several inconsistencies in national public reporting of the AEFIs submitted to CAEFISS over time. Prior to the COVID-19 pandemic and for other vaccines, there have been various inconsistencies for public-facing AEFI reports, in terms of: how they were published (website versus journal article); what information was included; and how frequently the reports were produced. More information on past CAEFISS reporting can be found in the Appendix.

Current status of AEFI reporting

PHAC has discontinued the routine COVID-19 online report as of January 19, 2024, while aiming to transition to a new webpage inclusive to all vaccines approved by Health Canada. The Signal Detection, Analysis and Reporting (SDAR) team aims to complete planning and approvals by May 10, 2024, with a launch of new web product in the fall of 2024 (subject to SDAR and Infobase team workloads) prior to the 2024-2025 influenza season.

Commenté [NP1]: I think this is the mandate of the branch? May be we could align our language to the branch mandate.

Commenté [AW2R1]: Love it, thanks Nimesh!

Commenté [SS3]: Should we mention that the majority of the database is passive surveillance?

Commenté [NP4]: Seems an incomplete sentence

Commenté [SS5]: Not sure how formal you need to be here but it may be worth a little paragraph on CVD above this before you mention it? Kind of like you have for CAEFISS

Commenté [PN(6]: Need to assess feasibility considering a small staff. Do we have foundation to develop programs in R or do we need to start from scratch? We could also launch it in phases and slowly expand the dashboard to cover all HC approved vaccines.

Commenté [AW7R6]: Yes, I also agree with starting in phases; stick with the most important aspects (age/sex, severity, vaccine, AEFI) at the start and then build upon for future releases. There is SAS code that exists and just needs to be updated. There are also sections of R code for certain analyses that we can also utilize.

Commenté [PN(8]: I like this!

Reporting from other jurisdictions

An environmental scan was conducted in order to determine trends among public health agencies with regards to reporting vaccine safety data. More details may be found here.

Internationally, it appears that many countries are providing public-facing AEFI reports, but others do not. New Zealand and South Africa are no longer providing recent or frequent AEFI reports. The United States does not provide recent or frequent AEFI reports but may publish related journal articles intermittently. Japan only reports on the total number of vaccines administered and does not provide AEFI information. However, Australia, Singapore, Sweden, the Netherlands, the European Medicines Agency, and the United Kingdom are still providing public-facing AEFI reports.

The majority of Canadian provinces and territories have discontinued their public-facing COVID-19 AEFI safety reports. Ontario, Alberta and Saskatchewan are the only provinces frequently providing vaccine safety reports and/or updating their online website for COVID-19 and other vaccines.

Feedback from Vaccine Vigilance Working group (VVWG)

A VVWG member survey was sent out on February 26, 2024, in order to enrich our learnings with how the relevance of the Online COVID-19 AEFI report applied to the work of our provincial/territorial/departmental surveillance partners. We sought feedback on how frequently they accessed the report, for what purpose, and for suggestions as to what they're interested in seeing in the future. A full summary of results can be found here.

Of approximately 57 participants that the survey was sent to, we received responses from 15 individuals who primarily worked in the provincial/territorial public health units. Most respondents (73%) used the report for information only, while some reported using it for various uses such as stakeholder engagement (27%), policy development (27%), and receiving timely updates on emerging safety signals (described narratively). For future reports, many (60%) suggested a need for a dashboard covering all vaccine products approved by Health Canada for transparency. Others were interested in seeing messaging to address vaccine hesitancy, statistical testing, and infographics. An importance on the use of lay terms for the public was also highlighted.

Operational lessons learned from reporting during the COVID-19 pandemic

What worked:

- Having dedicated staff members who worked full-time on online reporting.
- Having coordinated communications staff who prioritized online reporting and streamlined the process for us
    - It was agreed upon that COVID-19 AEFI reporting was on their work plans.
    - Streamline between digital comms, strategic comms, program, and greenlights Infobase web coding.
- Having timely doses administered data on a routine basis.

What didn't work:

- Short approval turnaround time.
- Incorporating feedback from so many groups was often conflicting. Most notably, feedback from comms about plain language that changed the technical meanings at times.

Commenté [SS(9]: Potentially we can just say: Internationally, we found not all countries are providing public-facing AEFI reports.

Commenté [SS(10]: Should we specify if these are still COVID-19 focused or if they have transitions to all vaccines?

Commenté [PN(11]: What is the response rate?

Commenté [AW12R11]: It's hard to say the response rate as it was sent to all VVWG members, and they may have forwarded it to their team members so I can't give an exact estimate of how many people it was sent to, other than at minimum VVWG. I can see it was sent to 57 VVWG members if that helps?

Commenté [PN(13]: Could include some numbers and proportions to better understand the magnitude.

Commenté [PN(14]: What proportion of the total respondents?

- Data often delayed from Health Canada.
- Having to rely on doses administered data for report scheduling.
- Manual entry of data into Google Sheets and Word document for approvals.
- Manual process invites data entry errors.
- Very time consuming.
- Evolving methodologies resulted in retracted statements which may have caused public confusion/distrust

Reporting infrastructure

Infobase, a web coding team within PHAC, is recommended as the web platform by communications and SDAR staff given the versatility in posting various national health data visualizations in a cohesive web format. Other Infobase dashboards and reports from PHAC are all similar in format to what we plan on reporting. This platform and working relationships really excelled during the COVID-19 pandemic, and Infobase is knowledgeable in advising the appropriate Government of Canada accessibility requirements in addition to being able to help coordinate reviews and approvals with the various communications groups. Lastly, Infobase also learned web coding lessons during the COVID-19 vaccination rollout and now have certain technologies which will help aide the process of future web postings.

SDAR is meeting with strategic comms, digital comms, and Infobase to discuss further on April 8, 2024.

Timelines

PHAC senior management would like to see a first product launch prior to the 2024-2025 influenza vaccination campaign, so September 2024 could be a reasonable goal to post the first iteration of the online report. That being said, all of the proposed timelines are highly subject to SDAR workloads. We can also consider updating on November 10th, World Immunization Day.

Bi-yearly (twice a year) reporting is proposed:

- Users have been expecting regular routine reporting over COVID-10 pandemic, and when this was discontinued it was at a quarterly report period.
- Can always aim for bi-yearly, then re-evaluate if not operationally feasible.

Note on doses distributed

The timeline of updating rates will depend on when the doses distributed are updated for each vaccine as some vaccines have different timelines (depending on vaccine supply receives data from manufacturers). The doses distributed database currently has some other limitations worth exploring, and the data management team is working to improve these with the development of a new database.

Analysis plan

Inclusion criteria

All AEFI reports submitted to CAEFISS within the past 10 years that meet the data cutoff date, are complete, and are active will be included in the online report.

Commenté [AW15]: I'd like to see something simple go out in september/october but then we can consider adding in more more info each update? But will require Mirna, Susanna, and Infobase's input to see what's possible, especially given the SDAR staffing considerations. I'm also acknowledging that quarterly might be too ambitious so super opened to other intervals if not operationally feasible.

Analysis

Data by seriousness, date vaccine administered, vaccine, age, sex, and AEFI will be presented as numbers and potentially rates per 100,000 doses distributed. Given limitations with doses distributed (e.g. overestimating the doses that were administered, no age/sex breakdowns, and different data update schedules), SDAR will investigate the usefulness of this data, along with population data, as rate denominators. Should doses distributed not be appropriate as a denominator, we will consider instead using the proportion of a variable of interest from one vaccine compared to all vaccines as a way to give the public a comparison group to work off of.

Future variables to consider adding in

- Time to onset, to demonstrate that individuals can expect that most adverse events would be experienced within a certain time frame.
    - Note that this will have to be per AEFI, not report or just put in the first TTO of the first symptom of the report.
- Highest level of care (risks of misinterpretation?)
- Rates per doses distributed (given that no doses administered will be provided).
- Can add a tab for background rates (can be updated from Sarah's team once a year rather than publish)
    - Publish yearly rates of events which are typically monitored following vaccination using hospital and emergency department data. These rates could then act as background rates for newly approved vaccines.
- Can add tab for infographic and/or factsheets called "Explore the data stories"
- Reporter
    - To demonstrate to the audience how reports are typically submitted in the public health system in Canada.
    - Aim to communicate to the public to seek these individuals if they want to submit reports.
    - International online COVID-19 AEFI reports or webpages from the United Kingdom, Sweden and the Netherlands include reporter as a variable.
    - Although this wasn't in the COVID-19 report, we received questions about how to report so might be nice to highlight this to provide insight into how reporting works. This was also provided in historical CAEFISS annual reports.

Webpage mock-up

Table 2. Mock-up of web report using dummy data and screenshots of other web products.

Section	Demonstration	Notes
Overall format	• Similar to CPHO dashboard or Public Health Ontario dashboard, with interpretation text on one side and interactive chart on the other. • Two tabs to start: one for Technical data notes and one for dashboard.	• Can expand to m tabs for addition information in future releases

Commenté [PN(16]: Did you mean proportion of an AEFI for a vaccine of interest?

Commenté [SS17]: What if we just put out the time to the first symptom the report had? I think reports typically have multiple symptoms related to one event (e.g. redness, hives, trouble breathing all related to Anaphylaxis) so could treat the first TTO as the start of the events.

Commenté [AW18R17]: I like that suggestion! Added

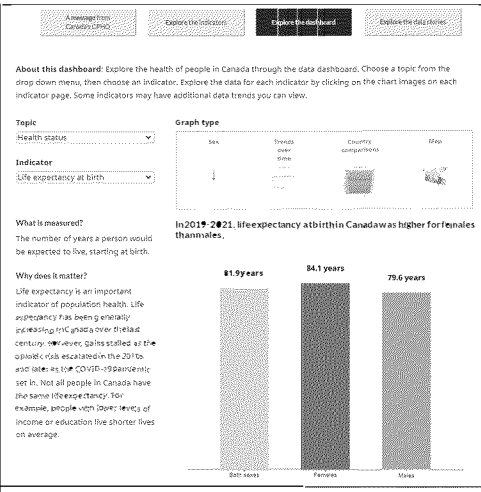
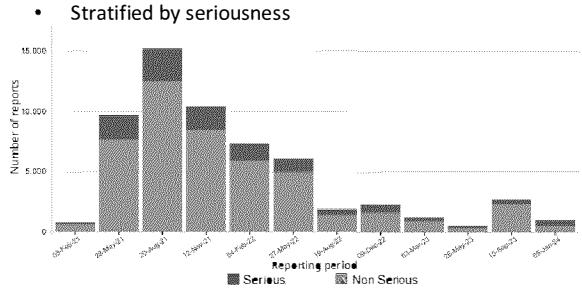
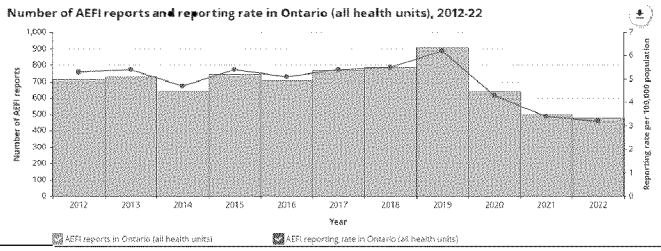
Commenté [NP19]: Should we specify since we do not receive doses administered data.

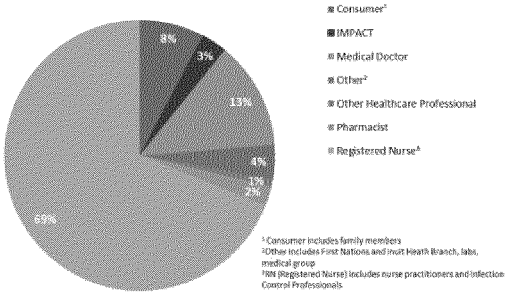
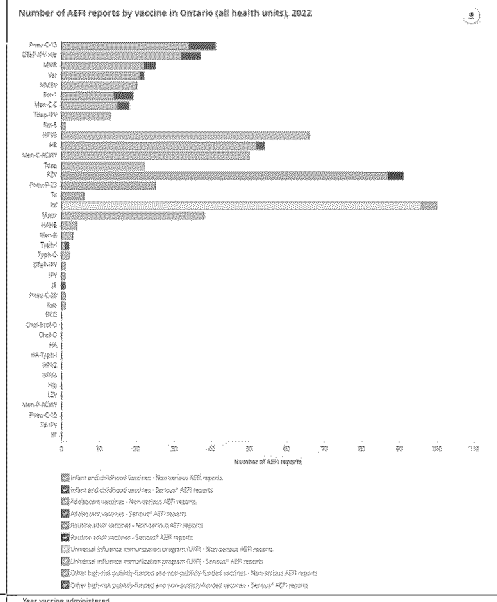
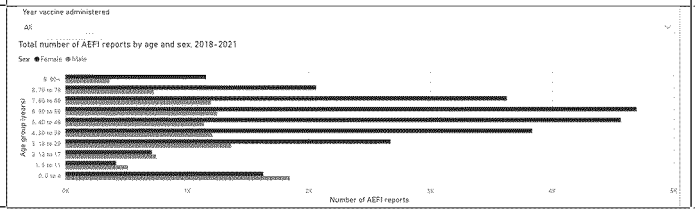
Commenté [NP20]: Should we use this instead as a template?

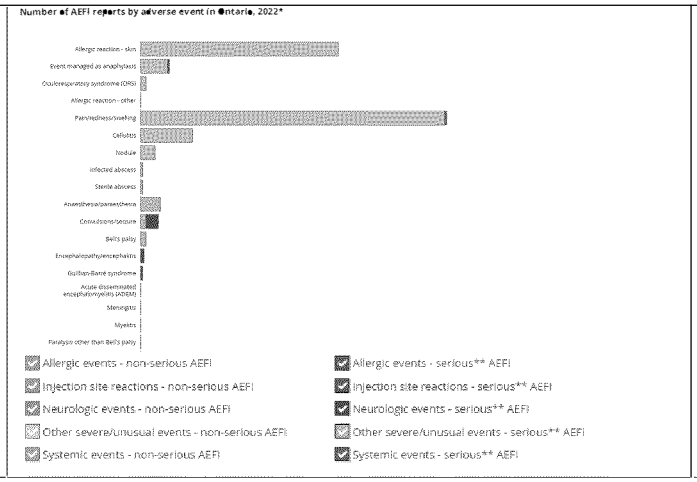
https://health-infobase.canada.ca/ccdss/data-tool/

Both look good though.

Commenté [AW21R20]: Added this in too ☺

		
Interpretation note	• An interpretation note at the top regarding important data explanation as a “check to continue” or at the top of page before user can scroll down. Can be called “Essential context to understand the data”	
AEFI reports over time	• Stratified by seriousness  	Can filter by vaccine

Reporter		To consider adding
Vaccine		Colour coated by vaccine grouping
Demographics		Can filter by vaccine

AEFI		Can filter by vaccine

Appendix

Appendix 1. Reporting of CAEFISS AEFIs between 2000 and 2024 as per the current CAEFISS website.

Title of report on CAEFISS webpage	Timeframe	Data included	Reporting mechanism	Frequency of reporting
Annual report	• 2013-2016 data was all published in one report in September 2018 • 2017 data was published in one report in December 2018 • 2018-2021 data published in one report in February 2024	• Inconsistencies in the years of data that was included in the summaries • Full-length intro, methods, discussion • All vaccines combined • Number and rate of serious/non-serious reports over time, age/sex distribution, reason for reporting, healthcare utilization, outcome, serious analysis	CCDR pee-reviewed article	Various
Biannual report	Posted online regularly from 2016 to 2018	Same as above, includes analysis by vaccine type	Webpage	Two times a year
Quarterly report	Posted online regularly from 2016 to 2018	Same as above, but shorter summary	Webpage	Four times a year
"Other" report	• 1990 to 2014: ad hoc analyses, some archived • Reports on specific vaccines: 2002, 2005, IMPACT (2019), Influenza (2021-2022) • Select reports on specific adverse events: ORS 2000, 2005, both archived	Various	Webpage and select CCDR peer-reviewed journal articles	Various/ad hoc

Commenté [SS22]: I think there is an error here?

Commenté [SS23]: I think there is an error here?

Appendix 2. Critical path of developmental steps to achieve fall web deliverable.

Task/deliverable	Involved staff	Date	Note(s)
Finalize internal proposal framework for senior management.	• VSS (Ashley, Mirna)	April 29, 2024.	• Seek senior management approval on template before moving forward with technical coding.
Senior management signoff on template.	• VSS (Ashley, Mirna)	May 10, 2024.	
Draft of interpretation text by VSS team sent to comms for plain language.	• VSS (Ashey, Mirna) • Digital comms (Quenby, Andrea) • Strategic comms (Sheila)	Send initial draft to comms by May 10, 2024.	• Ashley to set up meeting to discuss the week of May 13-17. • Can set up biweekly check-in meetings if necessary to keep on track. • First iteration will be generic surveillance descriptive text; this will be updated as necessary with more specific results as data analysis is confirmed.
Ongoing: modifications to text based on plain language and updated analysis results.	• All	May 10 to July 5, 2024.	• Plain language review will go back and forth between program and web comms until final product is reached. At which point web comms will send to infobase. • Include Infobase as an FYI in case they have suggestions or need VSS epis to make technical formatting tweaks.
Updated code for data pull/analysis.	• VSS (Ashley, Joy) • Infobase (Scott, Benoit, student?)	Draft code corresponding to original proposal by May 17, 2024.	• Will touch base with Infobase team to confirm technical requirements/formatting for the tentative framework that was approved by senior management.
Final draft of online report ready with updated data.	• VSS (Mirna, Ashley, Nimesh, Joy)	July 5, 2024.	• Web comms will coordinate final plain language text with health infobase.
Approvals/revisions with program senior management.	• VSS (Mirna, Nimesh)	July 5 to July 19, 2024.	
Translation	• Digital comms (Quenby, Andrea) • VSS (Mirna, Ashley)	July 19 to August 2, 2024.	• Web comms will coordinate translation once final English has management approvals (this will happen concurrently to infobase coding the EN text) • Can also send Infobase the English report first and translate in parallel to initial web coding?
Send final copy to Infobase for web coding.	• VSS (Mirna, Nimesh)	July 29 to September 13, 2024.	Infobase to let us know if this is feasible; if not, we will tweak the date we go live.

Developmental link greenlights.	• VSS senior management	September 9 to 12, 2024.	Will need to confirm level of who signs off (DGO? VP?).
Report live on Canada.ca.	• **Infobase (Benoit, Scott, student)**	**September 13, 2024.**	**To be confirmed with Infobase depending on workloads.**

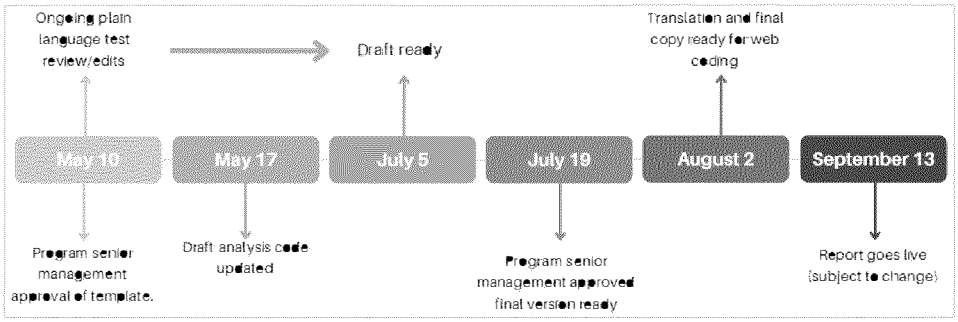
***Add in table of requested changes from Comms

Commenté [AW24]: @ashley

a mis en forme : Surlignage

a mis en forme : Surlignage

Appendix 3. Timeline of main milestones



Online AEFI Surveillance Planning

Created by: Ashley Weeks
Reviewed by:
Last updated: 2024-02-29

Objective

This document aims to describe a plan to streamline the reporting of adverse events following immunization (AEFIs) submitted to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) to the public via an interactive web data platform. We aim to leverage lessons learned from the COVID-19 pandemic vaccination rollout and past CAEFISS reporting mechanisms to improve on current practices and create a modern data tool that is informative for helping Canadians make informed vaccination decisions.

Background

CAEFISS is a provincial, territorial, and federal public health post-market vaccine safety surveillance system. The database is managed by PHAC and includes both passive and active surveillance components. Despite being a robust surveillance system for over twenty years, there have been several inconsistencies in national public reporting of the AEFIs submitted to CAEFISS over time.

During the COVID-19 pandemic, the Public Health Agency of Canada (PHAC) published a detailed online report of side effects following COVID-19 vaccination in Canada in collaboration with Health Canada from 2021 to 2024. The production of the online COVID-19 report contained AEFI report data from CAEFISS, the Canada Vigilance Database (Health Canada), and dose administered data from Canadian COVID-19 Vaccination Coverage Surveillance System (CCVSS). Given the transition from pandemic to endemic and the decrease in COVID-19 vaccine uptake, the regular COVID-19 AEFI report no longer serves its initially conceived purpose of providing regular updates on emerging safety issues for a pandemic vaccination campaign and was therefore discontinued on January 19, 2024.

Prior to the COVID-19 pandemic and for other vaccines, there have been various inconsistencies for public-facing AEFI reports, in terms of: how they were published (website versus journal article); what information was included; and how frequently the reports were produced. More information on past CAEFISS reporting can be found in the Appendix.

Current status of AEFI reporting

PHAC has discontinued the routine COVID-19 online report as of January 19, 2024, while aiming to transition to a new webpage inclusive to all vaccines. The Signal Detection, Analysis and Reporting (SDAR) team aims to complete planning and approvals by May 1, 2024, with launch of new web product in the fall of 2024 (subject to SDAR and Infobase team workloads) prior to the 2024-2025 influenza season.

Reporting from other jurisdictions

An environmental scan was conducted in order to determine trends among public health agencies with regards to reporting vaccine safety data. More details may be found here.

Internationally, it appears that many countries are providing public-facing AEFI reports, but others do not. New Zealand and South Africa are no longer providing recent or frequent AEFI reports. The United States does not provide recent or frequent AEFI reports but may publish related journal articles intermittently. Japan only reports on the total number of vaccines administered and does not provide AEFI information. However, Australia, Singapore, Sweden, the Netherlands, the European Medicines Agency, and the United Kingdom are still providing AEFI reports.

The majority of Canadian provinces and territories have discontinued their COVID-19 AEFI safety reports. Ontario, Alberta and Saskatchewan are the only provinces frequently providing vaccine safety reports and/or updating their online website.

Feedback from Vaccine Vigilance Working group (VVWG)

A VVWG member survey was sent out on February 26, 2024, in order to enrich our learnings with how the relevance of the Online COVID-19 AEFI report applied to the work of our provincial/territorial/departmental surveillance partners. We sought feedback on frequently they accessed the report, for what purpose, and for suggestions as to what they're interested in seeing in the future. A full summary of results can be found here ~~*[input summary from Joy when complete]*~~.

We received responses from ~~15~~ 14 individuals who primarily worked in the provincial/territorial public health units. Most respondents used the report for information only, while some reporting using it for various uses such as stakeholder engagement, policy development, and receiving timely updates on emerging safety signals. For future reports, ~~they~~ many suggested a dashboard for all vaccine products for transparency. Others were interested in seeing messaging to address vaccine hesitancy, statistical testing, more lay terms for the public, ~~s~~and infographics.

Commenté [JP1]: I could be wrong please let me know. When I did the summary I only got 14. I'm not sure what happened to the 1

Operational lessons learned from reporting during the COVID-19 pandemic

What worked:

- Having dedicated staff members who worked full-time on online reporting.
- Having coordinated communications staff who prioritized online reporting and streamlined the process for us
    - It was agreed upon that COVID-19 AEFI reporting was on their work plans.
    - Streamline between digital comms, strategic comms, program, and greenlights Infobase web coding.
- Having timely doses administered data on a routine basis.

What didn't work:

- Short approval turnaround time.
- Incorporating feedback from so many groups was often conflicting. Most notably, feedback from comms about plain language that changed the technical meanings at times.
- Data often delayed from Health Canada.
- Having to rely on doses administered data for report scheduling.
- Manual entry of data into Google Sheets and Word document for approvals.
- Manual process invites data entry errors.
- Very time consuming.

Reporting infrastructure

Infobase, a web coding team within PHAC, is recommended as the web platform by communications and SDAR staff given the versatility in posting various national health data visualizations in a cohesive web format. Other Infobase dashboards and reports from PHAC are all similar in format to what we plan on reporting. This platform and working relationships really excelled during the COVID-19 pandemic, and Infobase is knowledgeable in advising the appropriate Government of Canada accessibility requirements in addition to being able to help coordinate reviews and approvals with the various communications groups. Lastly, Infobase also learned web coding lessons during the COVID-19 vaccination rollout and now have certain technologies which will help aide the process of future web postings.

SDAR is meeting with strategic comms, digital comms, and Infobase to discuss further on April 8, 2024.

Timelines

PHAC senior management would like to see a first product launch prior to the 2024-2025 influenza vaccination campaign, so September/October 2024 could be a reasonable goal to post the first iteration of the online report. That being said, all of the proposed timelines are highly subject to SDAR and Infobase workloads (to be discussed on April 8). We can also consider updating on November 10th, World Immunization Day.

Quarterly reporting is proposed:

- Users have been expecting regular routine reporting over COVID-10 pandemic, and when this was discontinued it was at a quarterly report period.
- In the past, quarterly reports were used to supplement larger reports, so it's a frequency that was used between 2018 and 2019 before the pandemic.
- Can always aim for quarterly, then re-evaluate if not operationally feasible.

Note on doses distributed

The timeline of updating rates will depend on when the doses distributed are updated for each vaccine as some vaccines have different timelines (depending on vaccine supply receives data from manufacturers). The doses distributed database currently has some other limitations worth exploring, and the data management team is working to improve these with the development of a new database. [*can spend time over next weeks looking into availability of doses distributed data*?].

Analysis plan

Inclusion criteria

All AEFI reports submitted to CAEFISS within the past 10 years that meet the data cutoff date, are complete, and are active will be included in the online report.

Analysis

Data will be presented as numbers and potentially rates per 100,000 doses distributed (given that SDAR deems the doses distributed an appropriate measurement given the data nuances). Should doses distributed not be available as a denominator, consider instead using the proportion of one vaccine compared to all vaccines as a way to give the public a comparison group to work off of.

Commenté [AW2]: I'd like to see something simple go out in september/october but then we can consider adding in more more info each update? But will require Mirna, Susanna, and Infobase's input to see what's possible, especially given the SDAR staffing considerations. I'm also acknowledging that quarterly might be too ambitious so super opened to other intervals if not operationally feasible.

Commenté [AW3]: Will need to discuss with Helen and Nooshin

Data elements

Table 1. Minimum key variables to include for online reporting.

Variable	Rationale	Considerations
Seriousness	• To demonstrate the level of severity that the adverse event had on the individual. • Aim to communicate that the majority of CAEFISS reports are non-serious to increase confidence in the vaccine. • Will increase knowledge and transparency about serious reports by showing what could be expected.	Changes to definition/coding practices over time may impact numbers over time.
Date vaccine administered (DVA)	• Used to derive the year of vaccine administration in order to provide temporal chart. • Aim to communicate that reports have been analysed consistently over time and the numbers have remained stable (i.e. no major increased with the exception of COVID-19). • Emphasize that the increase of reports since 2021 is a successful use of the CAEFISS reporting system to capture adverse events of a novel vaccine during the pandemic.	Can also use date report received (DRR) to PHAC, but DVA may be more meaningful to audience since not subjected to surveillance system/reporting nuances. We used DRR during COVID-19 but was a limitation.
Reporter	• To demonstrate to the audience how reports are typically submitted in the public health system in Canada. • Aim to communicate to the public to seek these individuals if they want to submit reports. • International online COVID-19 AEFI reports or webpages from the United Kingdom, Sweden and the Netherlands include reporter as a variable.	Although this wasn't in the COVID-19 report, we received questions about how to report so might be nice to highlight this to provide insight into how reporting works. This was also provided in historical CAEFISS annual reports.
Vaccine type	• To demonstrate differences among vaccines. • Audience may be interested in finding specific information. about a vaccine they received/are considering receiving.	
Age	• Used to derive age groups. • To demonstrate to the audience how safety profiles differ across age groups. • Good opportunity to communicate differences in reporting behaviours.	Can expect parents to report more on behalf of their children/enhanced scrutiny versus adults who may be less likely to seek care on behalf of themselves.
Sex	• To demonstrate to the audience how AEFI reporting differs by biological sex. • May be good opportunity to communicate differences in reporting behaviours and biological differences, and encourage men to report too.	Women may be more likely to report and have biological predispositions to certain responses.

Commenté [AW4]: I think this is acceptable though as a regular part of maintaining a surveillance system

Commenté [AW5]: Happy to discuss this further! Depends on the story we're trying to tell, whether it's a) This is when people who submitted AEFI reports were vaccinated or b) This is when PHAC received and processed reports submitted to us.

I think the first may be more interesting for the audience, whereas the second is a bit more technically nuanced and more for "surveillance" audience. I don't think the public will care about reporting lags and processing time as much as knowing when the vaccines were administered.

Note can also depend on the denominator we have.

Commenté [JP6]: Though this extra bullet might be helpful.

Commenté [JP7]: Just a suggestion to add type

Commenté [AW8]: This is talked about a bit in the COVID report, can use similar messaging

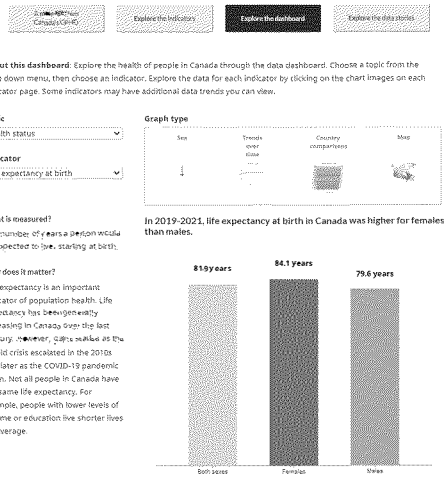
Adverse event following immunization	• To be transparent in the types of adverse events that are reported so individuals have a better idea of what to expect after vaccinations.	Can use either PT or SOC

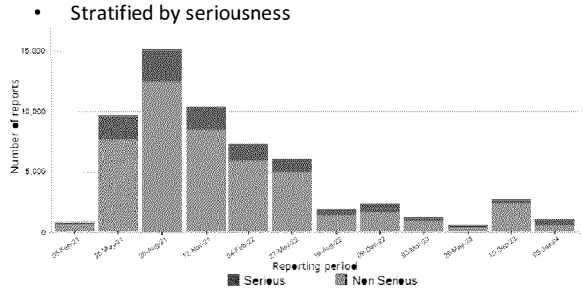
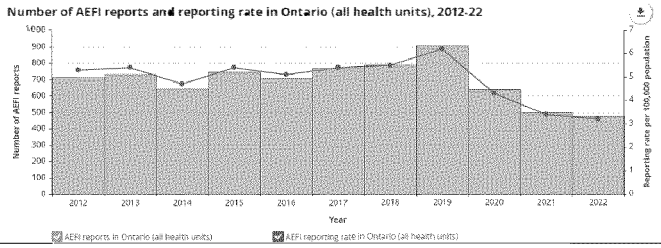
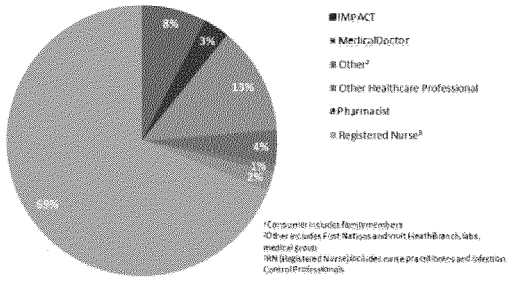
Future variables to consider adding in

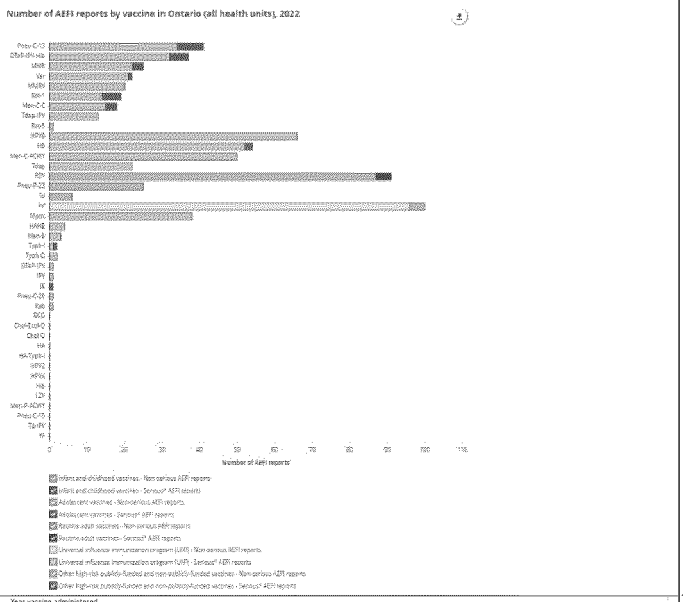
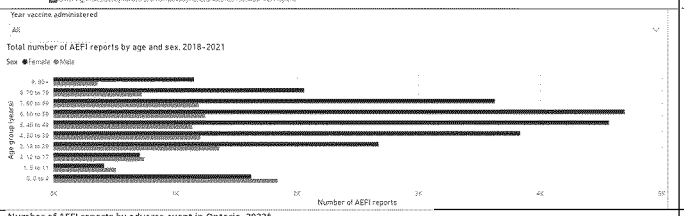
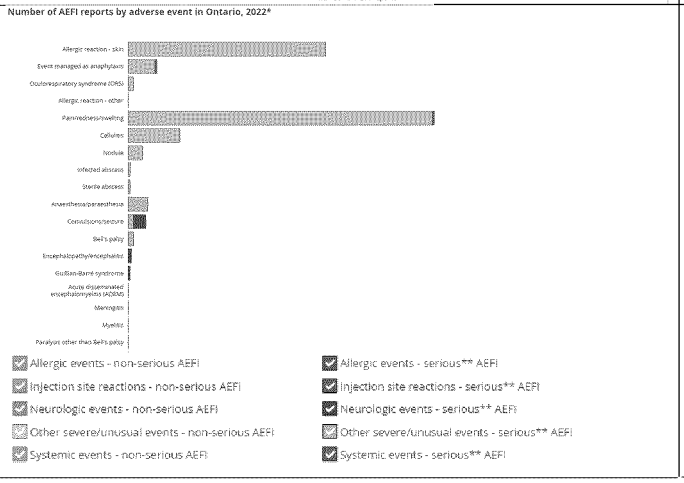
- Time to onset, to demonstrate that individuals can expect that most adverse events would be experienced within a certain time frame.
    - Note that this will have to be per AEFI, not report
- Highest level of care (risks of misinterpretation?)
- Rates
- Can add a tab for observed/expected analyses (can be updated from Sarah's team once a year rather than publish)
- Can add tab for infographic and/or factsheets called "Explore the data stories"

Webpage mock-up

Table 2. Mock-up of web report using dummy data and screenshots of other web products.

Section	Demonstration	Notes
Overall format	• Similar to CPHO dashboard, with interpretation text on one side and interactive chart on the other. • Two tabs to start: one for Technical data notes and one for dashboard. 	• Can expand to more tabs for additional information in future releases
Interpretation note	• An interpretation note at the top regarding important data explanation as a "check to continue" or at the top of page before user can scroll down. Can be called "Essential context to understand the data"	
	•	

AEFI reports over time	• Stratified by seriousness  	Can filter by vaccine
Reporter	 [1]Consumer includes family members [2]Other includes First Nations and Inuit Health Branch, labs, medical group [3]RN (Registered Nurse) includes nurse practitioners and Infection Control Professionals.	

Vaccine		Colour coated by vaccine grouping
Demographics		Can filter by vaccine
AEFI		Can filter by vaccine

Appendix

Appendix 1. Reporting of CAEFISS AEFIs between 2000 and 2024 as per the current CAEFISS website.

Title of report on CAEFISS webpage	Timeframe	Data included	Reporting mechanism	Frequency of reporting
Annual report	• 2013-2016 data was all published in one report in September 2018 • 2017 data was published in one report in December 2018 • 2018-2021 data published in one report in February 2024	• Inconsistencies in the years of data that was included in the summaries • Full-length intro, methods, discussion • All vaccines combined • Number and rate of serious/non-serious reports over time, age/sex distribution, reason for reporting, healthcare utilization, outcome, serious analysis	CCDR pee-reviewed article	Various
Biannual report	Posted online regularly from 2018 to 2018	Same as above, includes analysis by vaccine type	Webpage	Two times a year
Quarterly report	Posted online regularly from 2018 to 2018	Same as above, but shorter summary	Webpage	Four times a year
"Other" report	• 1990 to 2014: ad hoc analyses, some archived • Reports on specific vaccines: 2002, 2005, IMPACT (2019), Influenza (2021-2022) • Select reports on specific adverse events: ORS 2000, 2005, both archived	Various	Webpage and select CCDR peer-reviewed journal articles	Various/ad hoc

Online AEFI Surveillance Planning

Created by: Ashley Weeks
Reviewed by:
Last updated: 2024-02-29

Objective

This document aims to describe a plan to streamline the reporting of adverse events following immunization (AEFIs) submitted to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) to the public via an interactive web data platform. We aim to leverage lessons learned from the COVID-19 pandemic vaccination rollout and past CAEFISS reporting mechanisms to improve on current practices and create a modern data tool that is informative for helping Canadians make informed vaccination decisions.

Background

CAEFISS is a provincial, territorial, and federal public health post-market vaccine safety surveillance system. The database is managed by PHAC and includes both passive and active surveillance components. Despite being a robust surveillance system for over twenty years, there have been several inconsistencies in national public reporting of the AEFIs submitted to CAEFISS over time.

During the COVID-19 pandemic, the Public Health Agency of Canada (PHAC) published a detailed online report of side effects following COVID-19 vaccination in Canada in collaboration with Health Canada from 2021 to 2024. The production of the online COVID-19 report contained AEFI report data from CAEFISS, the Canada Vigilance Database (Health Canada), and dose administered data from Canadian COVID-19 Vaccination Coverage Surveillance System (CCVSS). Given the transition from pandemic to endemic and the decrease in COVID-19 vaccine uptake, the regular COVID-19 AEFI report no longer serves its initially conceived purpose of providing regular updates on emerging safety issues for a pandemic vaccination campaign and was therefore discontinued on January 19, 2024.

Prior to the COVID-19 pandemic and for other vaccines, there have been various inconsistencies for public-facing AEFI reports, in terms of: how they were published (website versus journal article); what information was included; and how frequently the reports were produced. More information on past CAEFISS reporting can be found in the Appendix.

Current status of AEFI reporting

PHAC has discontinued the routine COVID-19 online report as of January 19, 2024, while aiming to transition to a new webpage inclusive to all vaccines. The Signal Detection, Analysis and Reporting (SDAR) team aims to complete planning and approvals by May 1, 2024, with launch of new web product in the fall of 2024 (subject to SDAR and Infobase team workloads) prior to the 2024-2025 influenza season.

Reporting from other jurisdictions

An environmental scan was conducted in order to determine trends among public health agencies with regards to reporting vaccine safety data. More details may be found here.

Internationally, it appears that many countries are providing public-facing AEFI reports, but others do not. New Zealand and South Africa are no longer providing recent or frequent AEFI reports. The United States does not provide recent or frequent AEFI reports but may publish related journal articles intermittently. Japan only reports on the total number of vaccines administered and does not provide AEFI information. However, Australia, Singapore, Sweden, the Netherlands, the European Medicines Agency, and the United Kingdom are still providing AEFI reports.

The majority of Canadian provinces and territories have discontinued their COVID-19 AEFI safety reports. Ontario, Alberta and Saskatchewan are the only provinces frequently providing vaccine safety reports and/or updating their online website.

Feedback from Vaccine Vigilance Working group (VVWG)

A VVWG member survey was sent out on February 26, 2024, in order to enrich our learnings with how the relevance of the Online COVID-19 AEFI report applied to the work of our provincial/territorial/departmental surveillance partners. We sought feedback on frequently they accessed the report, for what purpose, and for suggestions as to what they're interested in seeing in the future. A full summary of results can be found here [*input summary from Joy when complete*].

We received responses from 15 individuals who primarily worked in the provincial/territorial public health units. Most respondents used the report for information only, while some reporting using it for various uses such as stakeholder engagement, policy development, and receiving timely updates on emerging safety signals. For future reports, they many suggested a dashboard for all vaccine products for transparency. Others were interested in seeing messaging to address vaccine hesitancy, statistical testing, more lay terms for the public, sand infographics.

Operational lessons learned from reporting during the COVID-19 pandemic

What worked:

- Having dedicated staff members who worked full-time on online reporting.
- Having coordinated communications staff who prioritized online reporting and streamlined the process for us
    - It was agreed upon that COVID-19 AEFI reporting was on their work plans.
    - Streamline between digital comms, strategic comms, program, and greenlights Infobase web coding.
- Having timely doses administered data on a routine basis.

What didn't work:

- Short approval turnaround time.
- Incorporating feedback from so many groups was often conflicting. Most notably, feedback from comms about plain language that changed the technical meanings at times.
- Data often delayed from Health Canada.
- Having to rely on doses administered data for report scheduling.
- Manual entry of data into Google Sheets and Word document for approvals.
- Manual process invites data entry errors.
- Very time consuming.

Reporting infrastructure

Infobase, a web coding team within PHAC, is recommended as the web platform by communications and SDAR staff given the versatility in posting various national health data visualizations in a cohesive web format. Other Infobase dashboards and reports from PHAC are all similar in format to what we plan on reporting. This platform and working relationships really excelled during the COVID-19 pandemic, and Infobase is knowledgeable in advising the appropriate Government of Canada accessibility requirements in addition to being able to help coordinate reviews and approvals with the various communications groups. Lastly, Infobase also learned web coding lessons during the COVID-19 vaccination rollout and now have certain technologies which will help aide the process of future web postings.

SDAR is meeting with strategic comms, digital comms, and Infobase to discuss further on April 8, 2024.

Timelines

PHAC senior management would like to see a first product launch prior to the 2024-2025 influenza vaccination campaign, so September/October 2024 could be a reasonable goal to post the first iteration of the online report. That being said, all of the proposed timelines are highly subject to SDAR and Infobase workloads (to be discussed on April 8). We can also consider updating on November 10th, World Immunization Day.

Quarterly reporting is proposed:

- Users have been expecting regular routine reporting over COVID-10 pandemic, and when this was discontinued it was at a quarterly report period.
- In the past, quarterly reports were used to supplement larger reports, so it's a frequency that was used between 2018 and 2019 before the pandemic.
- Can always aim for quarterly, then re-evaluate if not operationally feasible.

Note on doses distributed

The timeline of updating rates will depend on when the doses distributed are updated for each vaccine as some vaccines have different timelines (depending on vaccine supply receives data from manufacturers). The doses distributed database currently has some other limitations worth exploring, and the data management team is working to improve these with the development of a new database. [*can spend time over next weeks looking into availability of doses distributed data*?].

Analysis plan

Inclusion criteria

All AEFI reports submitted to CAEFISS within the past 10 years that meet the data cutoff date, are complete, and are active will be included in the online report.

Analysis

Data will be presented as numbers and potentially rates per 100,000 doses distributed (given that SDAR deems the doses distributed an appropriate measurement given the data nuances). Should doses distributed not be available as a denominator, consider instead using the proportion of one vaccine compared to all vaccines as a way to give the public a comparison group to work off of.

Commenté [AW1]: I'd like to see something simple go out in september/october but then we can consider adding in more more info each update? But will require Mirna, Susanna, and Infobase's input to see what's possible, especially given the SDAR staffing considerations.
I'm also acknowledging that quarterly might be too ambitious so super opened to other intervals if not operationally feasible.

Commenté [AW2]: Will need to discuss with Helen and Nooshin

Commenté [P(3]: For our own purposes, I would elaborate here

Data elements

Table 1. Minimum key variables to include for online reporting.

Variable	Rationale	Considerations
Seriousness	• To demonstrate the level of severity that the adverse event had on the individual. • Aim to communicate that the majority of CAEFISS reports are non-serious to increase confidence in the vaccine. • Will increase knowledge and transparency about serious reports by showing what could be expected.	Changes to definition/coding practices over time may impact numbers over time.
Date vaccine administered (DVA)	• Used to derive the year of vaccine administration in order to provide temporal chart. • Aim to communicate that reports have been analysed consistently over time and the numbers have remained stable (i.e. no major increased with the exception of COVID-19). • Emphasize that the increase of reports since 2021 is a successful use of the CAEFISS reporting system to capture adverse events of a novel vaccine during the pandemic.	Can also use date report received (DRR) to PHAC, but DVA may be more meaningful to audience since not subjected to surveillance system/reporting nuances. We used DRR during COVID-19 but was a limitation.
Reporter	• To demonstrate to the audience how reports are typically submitted in the public health system in Canada. • Aim to communicate to the public to seek these individuals if they want to submit reports.	Although this wasn't in the COVID-19 report, we received questions about how to report so might be nice to highlight this to provide insight into how reporting works. This was also provided in historical CAEFISS annual reports.
Vaccine	• To ~~demonstrate~~investigate differences in the severity of AEFI reporting and the types of AEFIs reported among vaccines and vaccine types. • Audience may be interested in finding specific information. about a vaccine they received/are considering receiving.	
Age	• Used to derive age groups. • To ~~demonstrate~~ investigate to the audience how safety profiles differ across age groups. • Good opportunity to communicate differences in reporting behaviours.	Can expect parents to report more on behalf of their children/enhanced scrutiny versus adults who may be less likely to seek care on behalf of themselves.
Sex	• To demonstrate to the audience how AEFI reporting differs by biological sex.	Women may be more likely to report and have biological

Commenté [P(4]: We cannot "demonstrate" anything in a passive surveillance system. I think a more appropriate term would be : to report on the proportion of adverse events which are considered serious.

Commenté [AW6]: I think this is acceptable though as a regular part of maintaining a surveillance system

Commenté [P(S]: I understand that this statement is based on your knowledge of the evidence accumulated so far, however, we cannot aim to communicate a finding before we have verified it. What I mean to say is: our role is to determine whether the majority of reports are non-serious and whether the proportion of serious to non serious reports remains stable through time.

Commenté [AW8]: Happy to discuss this further! 😊 Depends on the story we're trying to tell, whether it's a) This is when people who submitted AEFI reports were vaccinated or b) This is when PHAC received and processed reports submitted to us.

I think the first may be more interesting for the audience, whereas the second is a bit more technically nuanced and more for "surveillance" audience. I don't think the public will care about reporting lags and processing time as much as knowing when the vaccines were administered.

Note can also depend on the denominator we have.

Commenté [P(7]: again, I would rephrase these statements in relation to the analysis objective: our role is to investigate whether changes in reporting rates have impacted the number of AEFI reports we have received

Commenté [P(9]: I would suggest: to investigate the primary reporting sources for AEFIS in Canada and track how the relative proportions change over time.

One type of reporter suddenly under or over reporting can impact the types of reports we receive (ex: we can hypothesize that reports coming from physicians will be more severe. If the relative proportion of these reports decreases due to an increase in consumer reporting, it may artificially deflate the proportion of serious reports. This also is likely to have impacts on SDA analyses)

Commenté [P(10]: I would say it is an opportunity to investigate shifts in reporting rates and reporting behaviors. Reporting rates should be looked at in relation to vaccine hesitancy/resistance statistics (and doses administered, if we had such data) by age group.

	• May be good opportunity to communicate differences in reporting behaviours and biological differences, and encourage men to report too.	predispositions to certain responses.
Adverse event following immunization	• To be transparent in the types of adverse events that are reported so individuals have a better idea of what to expect after vaccinations.	Can use either PT or SOC

Commenté [AW11]: This is talked about a bit in the COVID report, can use similar messaging

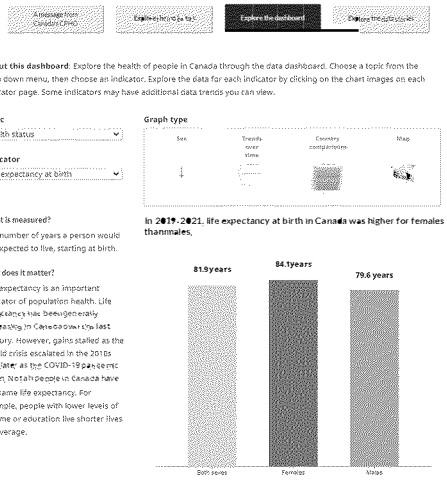
Commenté [P(12]: I would suggest removing this table for now. We can flush this out in a new version and I will share templates that may help us structure our thinking a bit better :)

Future variables to consider adding in

- Time to onset, to demonstrate that individuals can expect that most adverse events would be experienced within a certain time frame.
    - Note that this will have to be per AEFI, not report
- Highest level of care (risks of misinterpretation?)
- Rates
- Can add a tab for observed/expected analyses (can be updated from Sarah's team once a year rather than publish)
- Can add tab for infographic and/or factsheets called "Explore the data stories"

Webpage mock-up

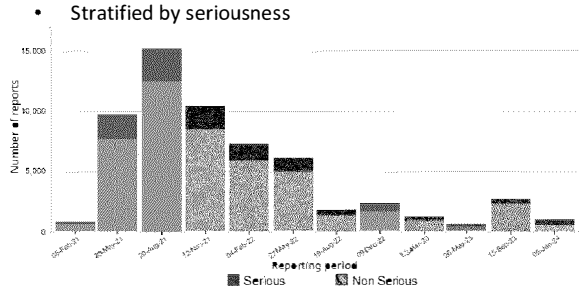
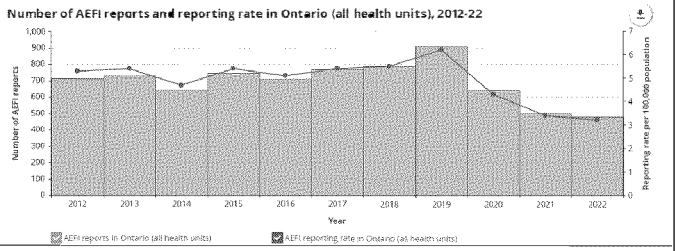
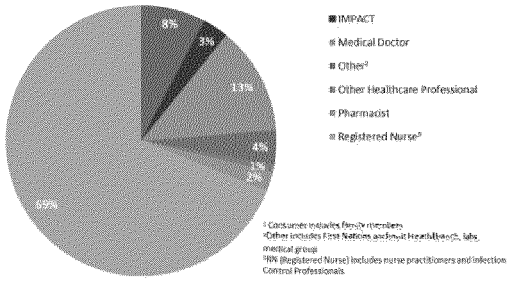
Table 2. Mock-up of web report using dummy data and screenshots of other web products.

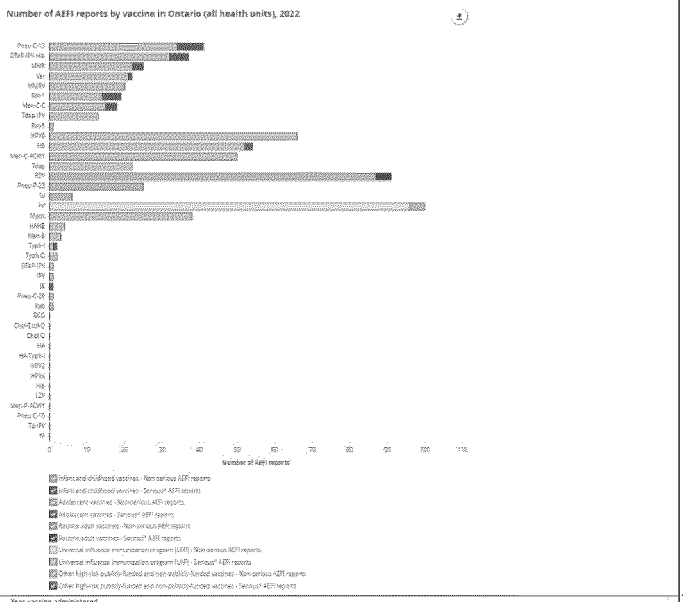
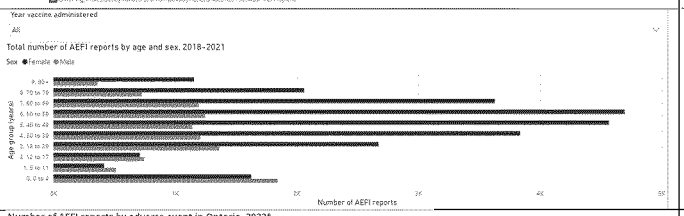
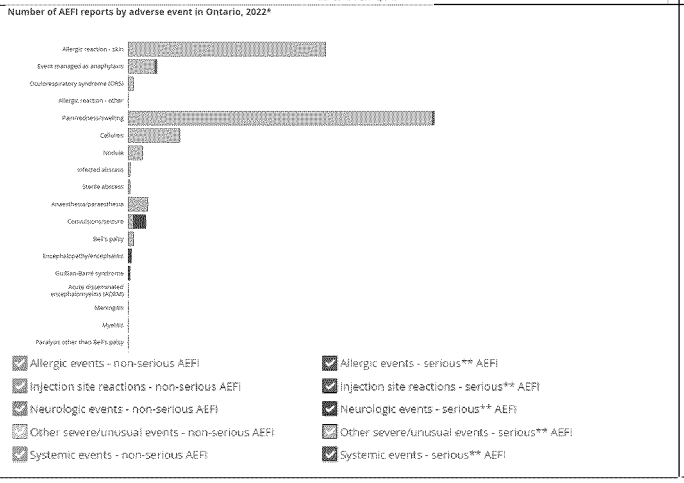
Section	Demonstration	Notes
Overall format	• Similar to CPHO dashboard, with interpretation text on one side and interactive chart on the other. • Two tabs to start: one for Technical data notes and one for dashboard. 	• Can expand to m tabs for addition information in future releases
Interpretation note	• An interpretation note at the top regarding important data explanation as a "check to continue" or at the top of page before	

Commenté [P(13]: This is sufficient for our discussion with infobase.

As a next step, I think I would like us to hash out a surveillance analysis plan where we describe
1. Our analysis objectives
2. The indicators we will present in relation to this objective
3. The data elements and variables that will be used to calculate said indicator.
4. Any relevant notes on the factors that pertain to data collection or data quality that may introduce bias in our results.

We may have desired indicators where we have no data . We should have a track record of this to bring back to Kim's team. We should also be documenting limitations in our denominators and what may be a more appropriate alternative

	user can scroll down. Can be called “Essential context to understand the data”	
	•	
AEFI reports over time	• Stratified by seriousness  	Can filter by vaccine
Reporter		

Vaccine		Colour coated by vaccine grouping
Demographics		Can filter by vaccine
AEFI		Can filter by vaccine

Appendix

Appendix 1. Reporting of CAEFISS AEFIs between 2000 and 2024 as per the current CAEFISS website.

Title of report on CAEFISS webpage	Timeframe	Data included	Reporting mechanism	Frequency of reporting
Annual report	• 2013-2016 data was all published in one report in September 2018 • 2017 data was published in one report in December 2018 • 2018-2021 data published in one report in February 2024	• Inconsistencies in the years of data that was included in the summaries • Full-length intro, methods, discussion • All vaccines combined • Number and rate of serious/non-serious reports over time, age/sex distribution, reason for reporting, healthcare utilization, outcome, serious analysis	CCDR pee-reviewed article	Various
Biannual report	Posted online regularly from 2018 to 2018	Same as above, includes analysis by vaccine type	Webpage	Two times a year
Quarterly report	Posted online regularly from 2018 to 2018	Same as above, but shorter summary	Webpage	Four times a year
"Other" report	• 1990 to 2014: ad hoc analyses, some archived • Reports on specific vaccines: 2002, 2005, IMPACT (2019), Influenza (2021-2022) • Select reports on specific adverse events: ORS 2000, 2005, both archived	Various	Webpage and select CCDR peer-reviewed journal articles	Various/ad hoc

De :	Patel, Nimeshkumar (PHAC/ASPC)
À :	Joanette, Quenby (HC/SC)
Cc :	Weeks, Ashley (PHAC/ASPC); Spruin, Sarah (PHAC/ASPC); Ingraham, Erin (HC/SC); Hipson, Erika (HC/SC); Privé, Jonathan (HC/SC)
Objet :	RE: Blurb For the Vaccine Safety Website
Date :	2024-06-25 07:26:31

Hi Quenby,

Thank you for your response. Could you please send us the language that Comms translated (the most recent version)?

Thanks,

Nimesh

Nimesh Patel (He/his)
Acting Senior Epidemiologist | Épidémiologiste principale
Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada | Agence de la santé publique du Canada
nimeshkumar.patel@phac-aspc.gc.ca / Tel: 343-574-8609

From: Joanette, Quenby (HC/SC)
Sent: Monday, June 24, 2024 10:33 AM
To: Patel, Nimeshkumar (PHAC/ASPC)
Cc: Weeks, Ashley (PHAC/ASPC) ; Spruin, Sarah (PHAC/ASPC) ; Ingraham, Erin (HC/SC) ; Hipson, Erika (HC/SC) ; Privé, Jonathan (HC/SC)
Subject: RE: Blurb For the Vaccine Safety Website

Hi Nimesh,

Thanks for reaching out so we can finalize this request. Unfortunately, below isn't what Comms agreed to in terms of plain language (we had already translated the blurb when we thought we had received approval). Given the delays and the change in messaging, we ask that program send the ENG for translation. As soon as we have that, we'll connect up with InfoBase to post.

Thanks for understanding.

Regards,

Quenby

Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>

Sent: Friday, June 21, 2024 3:13 PM

To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>

Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>

Subject: Blurb For the Vaccine Safety Website

Hello Sheila and Quenby,

Please see the below blurb, approved by our VP, that we intend to put on one of our webpage. I know Mirna was in touch with you about the blurb, but she is out of the office until end of the next week. Hence, I am reaching out with the request. Apologies if the request needs to be directed somewhere else (InfoBase) indeed!

The VP approved blurb:

> This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada*. We will no longer be updating this online report. Instead, COVID-19 vaccine safety data will be shared in a surveillance report that will include data on all vaccines approved in Canada. We will provide a link to this new report as soon as it is available. In the meantime, recent reports and technical publications on vaccine safety are available.
>
> This decision was made because the COVID-19 response has evolved from a global pandemic to an ongoing health issue and extensive evidence on COVID-19 vaccine safety has been gathered globally.
>
> Rest assured that robust vaccine safety monitoring efforts continue: if any COVID-19 vaccine safety concerns are detected, we will communicate them promptly.

**

Context:

As you know, we are no longer going to be reporting on COVID-19 vaccine AEFIs in an independent web report. Our reporting team have been working on developing a surveillance analysis plan and associated knowledge translation plan for all vaccine AEFIs, which will also cover the COVID-19 vaccines from now on. In the meantime, we would like to advise the public that we will no longer be updating the COVID-19 web report. We have developed a blurb, that we hope to have posted on the existing report page advising the public that the January report was the last report.

Where it will be:

At the top of these pages

https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html

https://health-infobase.canada.ca/covid-19/vaccine-safety/

Thank you for all your assistance on this.

Nimesh

Nimesh Patel (He/his)

Acting Senior Epidemiologist | Épidémiologiste principale

Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins

Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation

Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)

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

nimeshkumar.patel@phac-aspc.gc.ca / Tel: 343-574-8609

De : Panic, Mirna (PHAC/ASPC)
À : Weeks, Ashley (PHAC/ASPC); Patel, Nimeshkumar (PHAC/ASPC)
Cc : Spruin, Sarah (PHAC/ASPC)
Objet : RE: Blurb For the Vaccine Safety Website
Date : 2024-07-04 14:07:59

Hi Nimesh and team
Here are my corrections to the French blurb. I also made a correction to the En blurb (highlighted in yellow). Please go ahead and push this for coding:

> *Il s'agit de la dernière publication régulière des manifestations cliniques inhabituelles à la suite de l'immunisation contre la COVID-19 au Canada. Nous ne mettrons plus à jour ce rapport en ligne. Les données sur la sécurité des vaccins contre la COVID-19 seront plutôt partagées dans un rapport de surveillance qui inclura des données sur tous les vaccins approuvés au Canada. Nous fournirons un lien vers ce nouveau rapport dès qu'il sera disponible. Entre-temps, des rapports récents et des publications techniques sur la sécurité des vaccins sont disponibles.*
> *Cette décision a été prise parce que la réponse à la COVID-19 est passée de la gestion d'une pandémie mondiale à celle d'un problème de santé établi et à caractère persistant, et que de nombreuses données probantes sur la sécurité des vaccins contre la COVID-19 ont été recueillies à l'échelle mondiale.*
> *Des efforts rigoureux de surveillance de la sécurité des vaccins se poursuivent. Si des enjeux liés à sécurité des vaccins contre la COVID-19 sont détectés, nous vous les communiquerons rapidement.*

From: Weeks, Ashley (PHAC/ASPC)
Sent: Friday, June 28, 2024 10:54 AM
To: Patel, Nimeshkumar (PHAC/ASPC) ; Panic, Mirna (PHAC/ASPC)
Cc: Spruin, Sarah (PHAC/ASPC)
Subject: FW: Blurb For the Vaccine Safety Website
Hi both,
Just looping you in on a conversation that Sarah and I had with Andrew this morning so that you can follow the latest when you're back on Tuesday!
Andrew has confirmed that the below blurb has been approved by VP, and both Andrew and Susanna agreed with the minor edits Shiela proposed and said it didn't re-require VP approved since it was so minor. I also proposed some small tweaks to the French given the usual comms people didn't translate it this time so I updated some of the technical text to match the current online language (e.g. "securité des vaccines" instead of "innocuité, and matched the title of the webpage).
As such, **these blurbs are ready to go for Infobase web coding next week** – woohoo!! I was originally going to send it today, but 1) the coder is off today and 2) I wanted to give you an opportunity to agree or disagree with this on Tuesday, especially since I think Mirna had been working with comms on a slightly different version. Please let me know if you see any red flags and if not. Nimesh, should Mirna need to extend her leave, I'm thinking that we should still proceed with web posting to help get it off all of our plates and seeing that sr management is good with this too.

> *This is the last regular posting of Reported side effects following COVID-19 vaccination in Canada. We will no longer be updating this online report. Instead, COVID-19 vaccine*

safety data will be shared in a surveillance report that will include data on all vaccines approved in Canada. We will provide a link to this new report as soon as it is available. In the meantime, recent reports and technical publications on vaccine safety are available.

This decision was made because the COVID-19 response has evolved from managing a global pandemic to an ongoing health issue and extensive evidence on COVID-19 vaccine safety has been gathered globally.

Robust vaccine safety monitoring efforts continue. If any COVID-19 vaccine safety concerns are detected, we will communicate them promptly.

//

Il s'agit de la dernière publication régulière des manifestations cliniques inhabituelles à la suite de l'immunisation contre la COVID-19 au Canada. Nous ne mettrons plus à jour ce rapport en ligne. Au lieu de cela, les données sur la sécurité des vaccins contre la COVID-19 seront partagées dans un rapport de surveillance qui inclura des données sur tous les vaccins approuvés au Canada. Nous fournirons un lien vers ce nouveau rapport dès qu'il sera disponible. Entre-temps, des rapports récents et des publications techniques sur la sécurité des vaccins sont disponibles.

Cette décision a été prise parce que la réponse à la COVID-19 est passée d'une pandémie mondiale à un problème de santé continu et que de nombreuses données probantes sur la sécurité des vaccins contre la COVID-19 ont été recueillies à l'échelle mondiale.

De solides efforts de surveillance de la sécurité des vaccins se poursuivent. Si des problèmes de la sécurité des vaccins contre la COVID-19 sont détectés, nous les communiquerons rapidement.

Best,
Ashley

From: Lalonde, Danielle (PHAC/ASPC) <Danielle.Lalonde@phac-aspc.gc.ca>
Sent: Wednesday, June 26, 2024 2:12 PM
To: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>
Cc: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>
Subject: FW: Blurb For the Vaccine Safety Website

Hi Ashley,
Seeing Nimesh is away I'd figure to send this to you as well as this is urgent
Thank you,
Danielle

From: Lalonde, Danielle (PHAC/ASPC)
Sent: Wednesday, June 26, 2024 2:09 PM
To: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>
Subject: RE: Blurb For the Vaccine Safety Website

Hi Nimesh,
As requested here is the French blurb translation.
Let me know if you need anything else

Cheers,
Danielle

From: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>
Sent: Tuesday, June 25, 2024 1:29 PM
To: Lalonde, Danielle (PHAC/ASPC) <Danielle.Lalonde@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>
Subject: FW: Blurb For the Vaccine Safety Website

Hi Danielle,

Please see the below blurb for the translation:

The VP approved blurb:

> This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada*. We will no longer be updating this online report. Instead, COVID-19 vaccine safety data will be shared in a surveillance report that will include data on all vaccines approved in Canada. We will provide a link to this new report as soon as it is available. In the meantime, recent reports and technical publications on vaccine safety are available.
>
> This decision was made because the COVID-19 response has evolved from a global pandemic to an ongoing health issue and extensive evidence on COVID-19 vaccine safety has been gathered globally.
>
> Robust vaccine safety monitoring efforts continue. If any COVID-19 vaccine safety concerns are detected, we will communicate them promptly.

Thanks,
Nimesh

Nimesh Patel (He/his)
Acting Senior Epidemiologist | Épidémiologiste principale
Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada | Agence de la santé publique du Canada
nimeshkumar.patel@phac-aspc.gc.ca / Tel: 343-574-8609

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Tuesday, June 25, 2024 11:10 AM
To: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>; MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>
Subject: RE: Blurb For the Vaccine Safety Website

Hi Nimesh,

I'm not sure if Quenby (web) will take care of translation. Web usually only translates when they do a plain language review of the web content. She can let us know when returns Thursday.

If you'd prefer to go ahead with translation, your admin would likely have a contact for a translation service your directorate uses.

Take care,

Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205
Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>
Sent: Tuesday, June 25, 2024 12:06 PM
To: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>; MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>
Subject: RE: Blurb For the Vaccine Safety Website

Hi Sheila,

Thank you for your response. This is super helpful! The proposed changes look fine with us. Here is the revised blurb:

The VP approved blurb:

> This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada*. We will no longer be updating this online report. Instead, COVID-19 vaccine safety data will be shared in a surveillance report that will include data on all vaccines approved in Canada. We will provide a link to this new report as soon as it is available. In the meantime, recent reports and technical publications on vaccine safety are available.
>
> This decision was made because the COVID-19 response has evolved from a global pandemic to an ongoing health issue and extensive evidence on COVID-19 vaccine safety has been gathered globally.
>
> Robust vaccine safety monitoring efforts continue. If any COVID-19 vaccine safety concerns are detected, we will communicate them promptly.

I am wondering if Comms could please help us with French Translation, and have this posted on the InfoBase. If you would like us to reach out for the translation, it would be great if you could share a contact for that. I sincerely appreciate all the assistance we have received on this, and your patience! We look forward to having this posted on our webpage soon.

Thanks,

Nimesh

Nimesh Patel (He/his)
Acting Senior Epidemiologist | Épidémiologiste principale
Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada | Agence de la santé publique du Canada
nimeshkumar.patel@phac-aspc.gc.ca / Tel: 343-574-8609

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Tuesday, June 25, 2024 8:07 AM
To: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>
Subject: RE: Blurb For the Vaccine Safety Website

Hi Nimesh!

Thank you so much for getting back to us. I have proposed a small change below. Please let me know if you are ok with this and Quenby can move ahead with getting it posted.

Thanks,

Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205
Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>
Sent: Friday, June 21, 2024 3:13 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>
Subject: Blurb For the Vaccine Safety Website

Hello Sheila and Quenby,

Please see the below blurb, approved by our VP, that we intend to put on one of our webpage. I know Mirna was in touch with you about the blurb, but she is out of the office until end of the next week. Hence, I am reaching out with the request. Apologies if the request needs to be directed somewhere else (InfoBase) indeed!

The VP approved blurb:

> This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada*. We will no longer be updating this online report. Instead, COVID-19 vaccine safety data will be shared in a surveillance report that will include data on all vaccines approved in Canada. We will provide a link to this new report as soon as it is available. In the meantime, recent reports and technical publications on vaccine safety are available.
>
> This decision was made because the COVID-19 response has evolved from a global pandemic to an ongoing health issue and extensive evidence on COVID-19 vaccine safety has been gathered globally.
>
> ~~Rest assured that~~ Robust vaccine safety monitoring efforts continue. If any COVID-19 vaccine safety concerns are detected, we will communicate them promptly.

**

Context:

As you know, we are no longer going to be reporting on COVID-19 vaccine AEFIs in an independent web report. Our reporting team have been working on developing a surveillance analysis plan and associated knowledge translation plan for all vaccine AEFIs, which will also cover the COVID-19 vaccines from now on. In the meantime, we would like to advise the public that we will no longer be updating the COVID-19 web report. We have developed a blurb, that we hope to have posted on the existing report page advising the public that the January report was the last report.

Where it will be:

At the top of these pages

https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html

https://health-infobase.canada.ca/covid-19/vaccine-safety/

Thank you for all your assistance on this.

Nimesh

Nimesh Patel (He/his)

Acting Senior Epidemiologist | Épidémiologiste principale

Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins

Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation

Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)

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

nimeshkumar.patel@phac-aspc.gc.ca / Tel: 343-574-8609

De :	Patel, Nimeshkumar (PHAC/ASPC)
À :	Joanette, Quenby (HC/SC)
Cc :	Weeks, Ashley (PHAC/ASPC); Spruin, Sarah (PHAC/ASPC); MacKenzie, Andrew (PHAC/ASPC); Ingraham, Erin (HC/SC); Panic, Mirna (PHAC/ASPC)
Objet :	RE: Blurb For the Vaccine Safety Website
Date :	2024-07-08 16:17:50

Sounds good, thank you!

Nimesh

Nimesh Patel (He/his)
Acting Senior Epidemiologist | Épidémiologiste principale
Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada | Agence de la santé publique du Canada
nimeshkumar.patel@phac-aspc.gc.ca / Tel: 343-574-8609

From: Joanette, Quenby (HC/SC)
Sent: Monday, July 8, 2024 9:08 AM
To: Patel, Nimeshkumar (PHAC/ASPC)
Cc: Weeks, Ashley (PHAC/ASPC) ; Spruin, Sarah (PHAC/ASPC) ; MacKenzie, Andrew (PHAC/ASPC) ; Ingraham, Erin (HC/SC) ; Panic, Mirna (PHAC/ASPC)
Subject: RE: Blurb For the Vaccine Safety Website

Good morning, all!

The alert boxes are now live at the top of the Summary and Detailed report pages. If you can't see them, please press CTRL F5.

https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html
https://sante-infobase.canada.ca/covid-19/securite-vaccins/sommaire.html
https://health-infobase.canada.ca/covid-19/vaccine-safety/
https://sante-infobase.canada.ca/covid-19/securite-vaccins/

When you're ready to do the consolidation of pages in Sept, please poke me.

Cheers,

Quenby

Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>
Sent: Friday, July 5, 2024 1:55 PM

To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Ingraham, Erin (HC/SC) <erin.ingraham@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>; MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Subject: RE: Blurb For the Vaccine Safety Website

Perfect, thank you for your prompt response!

Have a wonderful weekend!

Cheers,

Nimesh

Nimesh Patel (He/his)
Acting Senior Epidemiologist | Épidémiologiste principale
Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada | Agence de la santé publique du Canada
nimeshkumar.patel@phac-aspc.gc.ca / Tel: 343-574-8609

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Friday, July 5, 2024 11:53 AM
To: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>; Ingraham, Erin (HC/SC) <erin.ingraham@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>; MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>
Subject: RE: Blurb For the Vaccine Safety Website

Fantastic! Thanks for this. I'll send this to InfoBase. It may not go live until Monday, but we're almost at the finish line! I'll loop back around once live.

Cheers,

Quenby

Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>
Sent: Friday, July 5, 2024 1:52 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Manhire, Sheila (HC/SC)

<sheila.manhire@hc-sc.gc.ca>

Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>; MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>

Subject: RE: Blurb For the Vaccine Safety Website

Hi Quenby,

We have the translation now, and the blurb is ready to be published. Thank you for your patience and assistance with this. Please let us know if you need anything else. We look forward to having this blurb on the webpages soon!

This is the last regular posting of Reported side effects following COVID-19 vaccination in Canada. We will no longer be updating this online report. Instead, COVID-19 vaccine safety data will be shared in a surveillance report that will include data on all vaccines approved in Canada. We will provide a link to this new report as soon as it is available. In the meantime, recent reports and technical publications on vaccine safety are available.

This decision was made because the COVID-19 response has evolved from managing a global pandemic to an ongoing health issue and extensive evidence on COVID-19 vaccine safety has been gathered globally.

Robust vaccine safety monitoring efforts continue. If any COVID-19 vaccine safety concerns are detected, we will communicate them promptly.

//

Il s'agit de la dernière publication régulière des manifestations cliniques inhabituelles à la suite de l'immunisation contre la COVID-19 au Canada. Nous ne mettrons plus à jour ce rapport en ligne. Les données sur la sécurité des vaccins contre la COVID-19 seront plutôt partagées dans un rapport de surveillance qui inclura des données sur tous les vaccins approuvés au Canada. Nous fournirons un lien vers ce nouveau rapport dès qu'il sera disponible. Entre-temps, des rapports récents et des publications techniques sur la sécurité des vaccins sont disponibles.

Cette décision a été prise parce que la réponse à la COVID-19 est passée de la gestion d'une pandémie mondiale à celle d'un problème de santé établi et à caractère persistant, et que de nombreuses données probantes sur la sécurité des vaccins contre la COVID-19 ont été recueillies à l'échelle mondiale.

Des efforts rigoureux de surveillance de la sécurité des vaccins se poursuivent. Si des enjeux liés à sécurité des vaccins contre la COVID-19 sont détectés, nous vous les communiquerons rapidement.

Where it will be:

At the top of these pages

https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html

https://health-infobase.canada.ca/covid-19/vaccine-safety/

Thanks,

Nimesh

Nimesh Patel (He/his)

Acting Senior Epidemiologist | Épidémiologiste principale
Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada | Agence de la santé publique du Canada
nimeshkumar.patel@phac-aspc.gc.ca / Tel: 343-574-8609

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Thursday, June 27, 2024 7:42 AM
To: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>; MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>
Subject: RE: Blurb For the Vaccine Safety Website

Thanks so much!
I'll be here to flip to InfoBase once ready.
Cheers,

Quenby

Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>
Sent: Tuesday, June 25, 2024 1:56 PM
To: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>; MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>
Subject: RE: Blurb For the Vaccine Safety Website

Hi Sheila,
Thank you for your prompt response. Our admin is helping us with the translation so we are good there now. We will reach out as soon as we have the translation.
Regards,
Nimesh
Nimesh Patel (He/his)

Acting Senior Epidemiologist | Épidémiologiste principale
Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada | Agence de la santé publique du Canada
nimeshkumar.patel@phac-aspc.gc.ca / Tel: 343-574-8609

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Tuesday, June 25, 2024 11:10 AM
To: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>; MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>
Subject: RE: Blurb For the Vaccine Safety Website

Hi Nimesh,

I'm not sure if Quenby (web) will take care of translation. Web usually only translates when they do a plain language review of the web content. She can let us know when returns Thursday.

If you'd prefer to go ahead with translation, your admin would likely have a contact for a translation service your directorate uses.

Take care,

Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205
Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>
Sent: Tuesday, June 25, 2024 12:06 PM
To: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>; MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>
Subject: RE: Blurb For the Vaccine Safety Website

Hi Sheila,

Thank you for your response. This is super helpful! The proposed changes look fine with us. Here is the revised blurb:

The VP approved blurb:

> This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada*. We will no longer be updating this online report. Instead, COVID-19 vaccine safety data will be shared in a surveillance report that will include data on all vaccines approved in

Canada. We will provide a link to this new report as soon as it is available. In the meantime, recent reports and technical publications on vaccine safety are available.

This decision was made because the COVID-19 response has evolved from a global pandemic to an ongoing health issue and extensive evidence on COVID-19 vaccine safety has been gathered globally.

Robust vaccine safety monitoring efforts continue. If any COVID-19 vaccine safety concerns are detected, we will communicate them promptly.

I am wondering if Comms could please help us with French Translation, and have this posted on the InfoBase. If you would like us to reach out for the translation, it would be great if you could share a contact for that. I sincerely appreciate all the assistance we have received on this, and your patience! We look forward to having this posted on our webpage soon.

Thanks,

Nimesh

Nimesh Patel (He/his)
Acting Senior Epidemiologist | Épidémiologiste principale
Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada | Agence de la santé publique du Canada
nimeshkumar.patel@phac-aspc.gc.ca / Tel: 343-574-8609

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Tuesday, June 25, 2024 8:07 AM
To: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>
Subject: RE: Blurb For the Vaccine Safety Website

Hi Nimesh!

Thank you so much for getting back to us. I have proposed a small change below. Please let me know if you are ok with this and Quenby can move ahead with getting it posted.

Thanks,

Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205
Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>
Sent: Friday, June 21, 2024 3:13 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>

Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>

Subject: Blurb For the Vaccine Safety Website

Hello Sheila and Quenby,

Please see the below blurb, approved by our VP, that we intend to put on one of our webpage. I know Mirna was in touch with you about the blurb, but she is out of the office until end of the next week. Hence, I am reaching out with the request. Apologies if the request needs to be directed somewhere else (InfoBase) indeed!

The VP approved blurb:

> This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada*. We will no longer be updating this online report. Instead, COVID-19 vaccine safety data will be shared in a surveillance report that will include data on all vaccines approved in Canada. We will provide a link to this new report as soon as it is available. In the meantime, recent reports and technical publications on vaccine safety are available.
>
> This decision was made because the COVID-19 response has evolved from a global pandemic to an ongoing health issue and extensive evidence on COVID-19 vaccine safety has been gathered globally.
>
> ~~Rest assured that~~ Robust vaccine safety monitoring efforts continue. If any COVID-19 vaccine safety concerns are detected, we will communicate them promptly.

**

Context:

As you know, we are no longer going to be reporting on COVID-19 vaccine AEFIs in an independent web report. Our reporting team have been working on developing a surveillance analysis plan and associated knowledge translation plan for all vaccine AEFIs, which will also cover the COVID-19 vaccines from now on. In the meantime, we would like to advise the public that we will no longer be updating the COVID-19 web report. We have developed a blurb, that we hope to have posted on the existing report page advising the public that the January report was the last report.

Where it will be:

At the top of these pages

https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html

https://health-infobase.canada.ca/covid-19/vaccine-safety/

Thank you for all your assistance on this.

Nimesh

Nimesh Patel (He/his)

Acting Senior Epidemiologist | Épidémiologiste principale

Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins

Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation

Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)

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

nimeshkumar.patel@phac-aspc.gc.ca / Tel: 343-574-8609

De : El Jaouhari, Maryem (PHAC/ASPC)
À : Weeks, Ashley (PHAC/ASPC)
Objet : RE: Communication for online report discontinuation
Date : 2024-01-25 10:31:30

Okay great, that sounds good! Agreed, she can always cut out what isn't necessary.
Thanks!
Maryem

From: Weeks, Ashley (PHAC/ASPC)
Sent: Thursday, January 25, 2024 10:06 AM
To: El Jaouhari, Maryem (PHAC/ASPC)
Subject: RE: Communication for online report discontinuation

Hey Maryem,
Thanks so much for taking a look at this so quickly! I agree with all your comments so I'll accept your changes and pass along to Susanna! Hehe yeah it's wild to thing we survived 84 web postings LOL! It's wild to reflect back!
Good point about the additional yellow highlighted information; it doesn't hurt to add it in for additional information, and we can let Susanna cut it out if she doesn't feel it's necessary.
Best,
Ashley

From: El Jaouhari, Maryem (PHAC/ASPC) <maryem.eljaouhari@phac-aspc.gc.ca>
Sent: Thursday, January 25, 2024 9:47 AM
To: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>
Subject: RE: Communication for online report discontinuation

Morning Ashley I hope you are too!
This looks great and this is so exciting! I was so surprised when I saw the number 84, props to you for leading this so effortlessly over the years. I left a few edits/comments but please feel free to decline any.
Thanks,
Maryem

From: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>
Sent: Thursday, January 25, 2024 9:33 AM
To: El Jaouhari, Maryem (PHAC/ASPC) <maryem.eljaouhari@phac-aspc.gc.ca>
Subject: Communication for online report discontinuation

Good morning Maryem,
I hope you're doing well and also having a nice comfy morning at home!
Susanna asked me to prepare a communiqué to our partners (HC, Infobase, Comms, VVWG) about our report being discontinued. I just wanted to check in with you to see if you have any suggestions to my proposed text? I mostly stole it from language that Susanna had already sent out for approvals but I shortened her piece a bit and added in a thank you and some stats on our accomplishments. Please let me know if you think I've missed anything or you think I can remove any text!
Thanks so much,
Ashley

Ashley Weeks (she / elle)
Epidemiologist | Épidémiologiste
Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins

Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada | Agence de la santé publique du Canada
ashley.weeks@phac-aspc.gc.ca | +1-613-286-1328

De :	Laroche, Julie A (PHAC/ASPC)
À :	Ogunnaike-Cooke, Susanna (PHAC/ASPC); COVID-19 Vaccine Surveillance / Surveillance Du Vaccin de la COVID-19 (PHAC/ASPC)
Cc :	Wan, Natalie (PHAC/ASPC); Yome, Julie (PHAC/ASPC); Weeks, Ashley (PHAC/ASPC)
Objet :	RE: DG-VP bilat bullets - Jan 15
Date :	2024-01-16 11:45:34

Thanks Susanna. No edits to the bullet below (from my perspective).
We did have the provision of COVID-19 coverage data from the p/ts on the DG VP bilat agenda last week where we provided an update on some of the upcoming changes to reporting and p/t participation.
Julie

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC)
Sent: Tuesday, January 16, 2024 8:49 AM
To: COVID-19 Vaccine Surveillance / Surveillance Du Vaccin de la COVID-19 (PHAC/ASPC) ; Laroche, Julie A (PHAC/ASPC)
Cc: Wan, Natalie (PHAC/ASPC) ; Yome, Julie (PHAC/ASPC) ; Weeks, Ashley (PHAC/ASPC)
Subject: RE: DG-VP bilat bullets - Jan 15
Hi DGO,
Here is the second item for the CG/VP bilat.
@Laroche, Julie A (PHAC/ASPC) I've highlighted a bullet related to data on doses administered, as this is your area. Please advise if you would recommend any edits to that bullet or if you have any new information to add on this issue. Also, this may trigger questions on what the changes are that PTs are making to the data they provide, so we'll need to provide an update on CIRC discussions to Anne-Marie.
++++++++++++++
For decision: Discontinuation of the COVID-19 online AEFI report
Issue: VSS is proposing a discontinuation of the COVID-19-specific online AEFI report
Rationale: Given the transition from pandemic to endemic and the decrease in COVID-19 vaccine uptake, the regular COVID-19 AEFI report no longer serves its initially conceived purpose of providing regular updates on emerging safety issues for a pandemic vaccine campaign.
Considerations:

- Over 100,000 million doses of vaccines have been administered in Canada alone, with billions administered internationally. The general safety profile of the vaccines is now well characterized, with any new knowledge emerging from other sources e.g. enhanced surveillance or research.
- Going forward, the online report is less informative on new safety issues given that COVID-19 vaccine uptake has decreased significantly (and therefore identification of rare safety issues would occur over longer timelines)
- PTs are making changes to their provision of doses administered data, which will impact the data quality and required format for the AEFI report, e.g. without data on doses administered, the AEFI report would need to shift to using doses distributed data, after which sex and age analysis for AEFI rates will no longer be possible.
- International counterparts with COVID-specific AEFI reporting have discontinued their reports
- Web analytics indicates that interest in the online report in 2023 was low for most of the year, with a slight increase during the flu season (when COVID-19 vaccine campaigns were co-occurring)
- HC colleagues are supportive of regularizing the reporting of COVID-19 AEFI into a more routine report (frequency to be determined) due to decrease in their COVID-19-specific resources

Next steps:

- PHAC will work with HC to discuss plans and options for AEFI reporting (all vaccines) going forward
- In consultation with Comms and the IDVPB Immunization Support and Knowledge Mobilization Teams, lessons learned from the pandemic will be leveraged to provide information tailored to specific audiences

Thanks,
Susanna

==========

Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

*Note I am sending this message at a time that suits me and which may not be part of your regular working hours. Please do not feel as though you need to respond right away
*Notez que j'envoie ce message à un moment qui me convient et qui peut ne pas faire partie de vos heures de travail habituelles. Ne vous sentez pas obligé de répondre tout de suite.

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC)
Sent: Monday, January 15, 2024 2:33 PM
To: COVID-19 Vaccine Surveillance / Surveillance Du Vaccin de la COVID-19 (PHAC/ASPC) <phac.vaccinesurveillance-surveillanceduvaccin.aspc@canada.ca>
Cc: Wan, Natalie (PHAC/ASPC) <natalie.wan@phac-aspc.gc.ca>; Yome, Julie (PHAC/ASPC) <julie.yome@phac-aspc.gc.ca>
Subject: FW: DG-VP bilat bullets - Jan 15

Hi DGO,
Here are some bullets re the Data Sharing MRAP items.
I'll need to develop some additional bullets for another item: COVID-19online report.
Thanks,
Susanna

==========

Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

From: Yome, Julie (PHAC/ASPC) <julie.yome@phac-aspc.gc.ca>
Sent: Monday, January 15, 2024 10:32 AM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Cc: Henry, Minoo (PHAC/ASPC) <minoo.henry@phac-aspc.gc.ca>
Subject: DG-VP bilat bullets - Jan 15

Hi Susanna,
Here is a draft of the DG-VP bilat update on the MRAP:
Subject: OAG Audit (COVID-19 vaccines) MRAP item on data sharing
For information.
Update: A proposal for HC read-only access to CAEFISS has been sent to FPTs for consideration, an important step in the PHAC-led consultation on the data sharing MRAP item.
Background:

- PHAC launched consultation sessions in spring 2023 with FPT partners on a proposal for HC

staff to have access to the PHAC-led CAEFISS database.

- After some delays, a proposal summary for read-only access for HC to CAEFISS was sent to PTs for review and decision by February 22.
- Data sharing discussions with PTs will continue in March to discuss outcomes and next steps for consultation on data sharing with manufacturers and the WHO.
- While there are several interdependent components to data sharing, making progress on this first item will maintain momentum and engagement with FPT immunization partners.
- Discussing PT issues in this step-wise manner will allow incremental progress to be made and targeted solutions to be identified for outstanding issues.

Considerations:

- Stakeholder relations risk: PHAC has received numerous requests from FPT partners for clarity on the HC parameters for access to CAEFISS and have cited frustration/impatience at the delays and the resultant impact on them re postponing their internal consultation discussions.
- Portfolio risk: If successful, this initiative would represent a significant and positive incremental step to resolve a longstanding challenge in vaccine safety surveillance. Given this decade-plus challenge, it is critical that PHAC and HC build on previous discussions and make progress on the long standing issues that have been identified.
- Portfolio risk: PHAC has sought an extension for this MRAP item due to the delays in obtaining information from HC. ln addition, extensions have also been sought for the subsequent two MRAP items as these also involve discussions with the same FPT lmmunization program partners on data sharing with manufacturers and with WHO.

De :	Joanette, Quenby (HC/SC)
À :	Ogunnaike-Cooke, Susanna (PHAC/ASPC)
Cc :	Manhire, Sheila (HC/SC); Panic, Mirna (PHAC/ASPC); Privé, Jonathan (HC/SC)
Objet :	RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website
Date :	2024-03-27 12:35:50

Hi Susanna,

Certainly, we can have a meeting to discuss plain language for AEFIs in relation to future gen pop pages. I think we can come to an agreement that works for the gen pop audience while also being accurate if we do a bit more digging on key terms. There's always going to be an issue with search engine optimization if we don't use terms users are querying for—then we'd be accused of hiding information, so that balance needs to be considered.

Also noted about your issues for the litigation holds, and a novel perspective I wouldn't have anticipated at the beginning of the pandemic. I can imagine the additional burden this has placed on your small team.

That said, I don't know if the vitriol you experienced would have been reduced by applying the technical term to the process given how divided the country became during the pandemic regarding vaccination. People were going to find a way to tell us their thoughts as evidenced by all our feedback widgets and contact us queries of the same nature, regardless of which part of the COVID content block it related to. That's certainly been our experience, anyway.

When the next opportunity presents itself to collaborate, we'll be better prepared.

Kind regards,

Quenby

Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Sent: Wednesday, March 27, 2024 10:23 AM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

ATIA - 23

Thanks Quenby.

I'll move it up for approvals and let you know when we get DG and VP sign-off.

To note, from my perspective, there is a big lesson learned for the future: We need to figure out language that's accurate AND plain language. Using 'side effect' for our online report was inaccurate and likely fueled a fair bit of vaccine hesitancy (judging from all the webmail and hate mail we got on this issue). [redacted] This is because 'side effect' means a causal association has been established between the vaccine and the health issue.

Thanks,

Susanna

==========

Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Tuesday, March 26, 2024 3:06 PM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Thanks, Susanna!

That's fine with me from a plain language perspective. Normally, on gen pop pages, we avoid the 'adverse events' phrase but it's all over this shared audience page, so everyone should be accustomed to it by now.

Is this ready for translation? If so, Web will get on that right away for ideal posting tomorrow. I know we're a day late, but this small hiccup shouldn't warrant OT from InfoBase.

Kind regards,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Sent: Tuesday, March 26, 2024 2:27 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Sorry to be difficult, but we can't/shouldn't say this statement "… COVID-19 vaccines are safe…" given that there have been a few (though rare) causally associated adverse events that caused serious morbidity and even some deaths. Throughout the vaccine rollout, w argued against HC using such language and they eventually stopped doing so in some documents. We shifted to talking about vaccines having a good "safety profile".

That said, recognizing the need to use lay language, I could be ok with this:

This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada* because:

- the COVID-19 response has evolved from a global pandemic to an ongoing health issue
- extensive evidence on adverse events following COVID-19 vaccination has been gathered globally.

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available.

Thanks,

Susanna

==========
Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Tuesday, March 26, 2024 2:01 PM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>

Cc: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: FW: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi Susanna

Quenby kindly reviewed the blurb and made two small changes to your proposal:

- She replaced the word *publication* by posting because an online publication tends to be a formal document (think a report with an ISBN or a manuscript)
- She removed the term "safety profile" as it is not defined and it is not a term an everyday user would be familiar with. I tweaked her suggestion slightly.

New proposed blurb for approval:

This is the last regular posting of reported side effects following COVID-19 vaccination in Canada because:

- the COVID-19 response has evolved from a global pandemic to an ongoing health issue
- extensive scientific evidence has indicated that COVID-19 vaccines are safe.

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available.

**

Context:
As you know, we are no longer going to be reporting on COVID-19 vaccine AEFIs in an independent web report. Ashley and the team have been working on developing a surveillance analysis plan and associated knowledge translation plan for all vaccine AEFIs, which will also cover the COVID-19 vaccines from now on. In the meantime, we would like to advise the public that we will no longer be updating the COVID-19 web report. We have developed a blurb, that we hope to have posted on the existing report page advising the public that the January report was the last report.

Who has reviewed:
The blurb was developed collaboratively by Ashley Weeks (acting senior epidemiologist), Mirna Panic (SDAR manager), Susanna Ogunnaike-cooke, Sheila Manhire (senior communications advisor) and was edited for clarity and use of plain language by Quenby Joanette (senior digital communications advisor). Mirna and Ashley have reviewed the final version.

Where it will be:
At the top of these pages
https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html
https://health-infobase.canada.ca/covid-19/vaccine-safety/

Thank you all for the thoughtful consideration of the wording for this blurb

M
Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Tuesday, March 26, 2024 12:59 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Absolutely! That's perfectly okay. I just wanted to flag that profile doesn't mean anything to gen pop because nowhere on our website (InfoBase or Canada.ca) has it ever been explained. If the statement was inaccurate, 'tis why I ask the subject matter experts to check my work.

Feel free to update that line and seek full approvals. And Web will translate quickly.

Thanks,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Tuesday, March 26, 2024 12:57 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi Quenby

I noted you were away and thank you for the very quick reply! My only concern is with the second bullet; we say the safety of the COVID vaccines is stable. I understand that safety profile is a technical term, but we cannot say that the safety of the vaccine is *stable* ; this is why we continue to do surveillance and monitoring of vaccine safety (ex: there could be a situation where there is something wrong with a specific vaccine lot – granted, these events are very, very rare).

Could we say something like : "extensive scientific research and evidence indicates that vaccines are safe"

Thanks !
M

Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Tuesday, March 26, 2024 12:42 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi Mirna,

I was away yesterday but have just added the edits back into a Word doc and tracked my edits again.

Do you know how long program wants this message up before we do that consolidation I mentioned as phase 2?

Thanks,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)

Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Monday, March 25, 2024 11:15 AM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: FW: For Approval by DG: Draft Blurb For the Vaccine Safety Website
Importance: High

Hi Quenby!

Happy Tuesday – my apologies for the quick turn around on this request (I fully left a message in my drafts and thought I had sent it, which resulted in delays in obtaining approvals). Susanna (my director) reviewed and proposed some edits to our blurb. I quite like her proposal. Sheila recommended that you take a peak for plain language and let us know if you have any concerns. If you could get back to us ASAP, I would be very appreciative and you would be doing me a huge favor in helping me make up for my poor email management these past two weeks. If not, just send me a note on teams.

Susanna's proposed blurb
This is the last regular publication of the *Reported side effects following COVID-19 vaccination in Canada* because:

- the COVID-19 response has evolved from global pandemic to an ongoing health issue
- the safety profile of the COVID-19 vaccines is stable

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available

What do you think? Thank you in advance for your input
Cordialement,
Mirna

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Monday, March 25, 2024 8:51 AM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Lalonde, Danielle (PHAC/ASPC) <Danielle.Lalonde@phac-aspc.gc.ca>; Vaccine Safety / Sécurité Des Vaccins (PHAC/ASPC) <vaccinesafetysurveillance-surveillancedelasecuritedesvaccins@phac-aspc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi all,

The revised text is fine from my perspective.

Mirna, I recommend sharing it with Quenby for a quick plain language check, but I don't anticipate

any concerns with it.

Thanks and happy Monday!
Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205

Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Sent: Friday, March 22, 2024 7:53 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Lalonde, Danielle (PHAC/ASPC) <Danielle.Lalonde@phac-aspc.gc.ca>; Vaccine Safety / Sécurité Des Vaccins (PHAC/ASPC) <vaccinesafetysurveillance-surveillancedelasecuritedesvaccins@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi Mirna,

Thanks for all the work on this.

I'm a bit concerned that the proposed wording does not align with the kind of messaging our VP wanted, as it talks a lot about what we **won't** do rather than just signaling a transition.

I would like to propose some edits:

This is the last regular publication of the *Reported side effects following COVID-19 vaccination in Canada* because:

- the COVID-19 response has evolved from global pandemic to an ongoing health issue
- the safety profile of the COVID-19 vaccines is stable

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available

Let me know if you think I need to talk with Sheila about why I don't think Don would approve the proposed wording below.

Thanks,

Susanna

==========

Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

*Note I am sending this message at a time that suits me and which may not be part of your regular working hours. Please do not feel as though you need to respond right away

*Notez que j'envoie ce message à un moment qui me convient et qui peut ne pas faire partie de vos heures de travail habituelles. Ne vous sentez pas obligé de répondre tout de suite.

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Friday, March 22, 2024 11:19 AM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Cc: Lalonde, Danielle (PHAC/ASPC) <Danielle.Lalonde@phac-aspc.gc.ca>; Vaccine Safety / Sécurité Des Vaccins (PHAC/ASPC) <vaccinesafetysurveillance-surveillancedelasecuritedesvaccins@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: For Approval by DG: Draft Blurb For the Vaccine Safety Website
Importance: High

Hi Susanna,

I am a little mortified, but I was about to follow up with this and I think I am the culprit – I don't think this message made it out of my drafts. My apologies. Could we get Anne-Marie to quickly look this over and provide her approval (or let us know if she has concerns/does not approve)?

Context: As you know, we are no longer going to be reporting on COVID-19 vaccine AEFIs in an independent web report. Ashley and the team have been working on developing a surveillance analysis plan and associated knowledge translation plan for all vaccine AEFIs, which will also cover the COVID-19 vaccines from now on. In the meantime, we would like to advise the public that we will no longer be updating the COVID-19 web report. We have developed a blurb, that we hope to have posted on the existing report page advising the public that the January report was the last report.

Who has reviewed: The blurb was developed collaboratively by Ashley Weeks (acting senior epidemiologist), Mirna Panic (SDAR manager), Susanna Ogunnaike-cooke, Sheila Manhire (senior communications advisor) and was edited for clarity and use of plain language by Quenby Joanette (senior digital communications advisor). Mirna and Ashley have reviewed the final version.

For action by Anne-Marie: Review and (hopefully) approval of the blurb below before March 26 (if timeline is unrealistic, please let us know as the delay is my fault).

Blurb (78 words):

This content is no longer being updated because:

- the response to COVID-19 has been downgraded, as it's no longer considered a global health emergency
- frequent reporting on COVID-19 vaccine safety is no longer required, as the safety of the vaccines has been well established following extensive research and monitoring

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available.

Where it will be:
At the top of these pages
https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html
https://health-infobase.canada.ca/covid-19/vaccine-safety/

Thank you for your help and my sincere apologies for the inconvenience
Mirna
Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 2:07 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Mirna and Quenby,

I would recommend DG approval on the blurb, given we are archiving a once very high-profile web page.

Thanks!
Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205

Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 1:59 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Awesome sauce. Level of approval will always depend on the topic and how high-profile the request is. If this isn't considered high profile, then I'm coolio with just your approval to proceed with translation.

Sheila, thoughts on level on your end?

I'm happy to connect up with InfoBase and share our approach with them and to get some info on how long they think the first phase will take to code (the blurb) followed by the consolidation/redirects.

Thanks,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Monday, March 11, 2024 1:56 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Quenby

I would consider them approved for translation (unless you require director-level sign off in writing, in which case I will poke Susanna to send you a note). I am relieved that you have a FRE concurrence editor and don't feel the need to review the translation if you already have in-house capacity to ensure the translation aligns with the terminology used in francophone media/science discourse in Canada.

Regarding archiving, both suggestions make sense to me. We are ok to add the blurb to the summary/detailed report page now for a limited time, decide what that timeframe on one of our upcoming calls, and then delete those pages (setting up a redirect to the consolidated page for anyone with a bookmark or direct link to our pages).

Thanks

Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 1:22 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Mirna,

Glad you like the edits. Would you consider them approved for translation?

And if you'd like to look at the FRE translation, then I'll send to you before I send it to our FRE concurrence editor. We have 2 editors who check the content we plain language to ensure it resonates in the same way with a Francophone audience.

In terms of archiving pages, what I mean is that you have several pages in this content block:

https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html

https://health-infobase.canada.ca/covid-19/vaccine-safety/

https://health-infobase.canada.ca/covid-19/vaccine-safety/utd.html

https://health-infobase.canada.ca/covid-19/vaccine-safety/archive/

While you do have archived reports, that's not what I meant. The whole content block will no longer be 'current' and so we don't usually leave pieces like this without a notification that they too are archived as a package. We add archive banners to archived content—for example, this NACI publication: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-guidance-additional-covid-19-booster-dose-spring-2023-individuals-high-risk-severe-illness-due-covid-19.html. This is what I mean when I ask how many pages are getting archived.

In looking at all the pages, we could avoid an archive banner if we consolidate the 'Understanding the data' and the 'Archived reports' page. Since the former page explains the offerings of the latter page. So, in the interim, we add the blurb to the summary/detailed report page now for a limited time (we can decide what that timeframe is), and then delete those pages (setting up a redirect to the consolidated page for anyone with a bookmark or direct link to our pages). Those pages will soon no longer serve a purpose.

Let me know if this jives with you.

Thanks,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Monday, March 11, 2024 1:08 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Quenby and Sheila

Thanks so much for your quick turn around on this.

Quenby : We quite like your edits and appreciate the notes on your editorial changes. I appreciate your willingness to coordinate translation. I am francophone so I would be happy to look the final blurb over to make sure the technical translation is correct.

Regarding Archiving: We are a bit confused because we were under the impression that the older reports were already archived on Canada.ca (via these links: Public Health Infobase - Public Health Agency of Canada).

As such, the note would need to be put on the summary + detailed report pages of the January 19 editions:

a. COVID-19 vaccine safety: Summary of weekly report on side effects following immunization - Canada.ca
b. COVID-19 vaccine safety: Report on side effects following immunization - Canada.ca

If your question is: "Yes, Mirna, I am wondering if you want the summary+detailed report+understanding the data pages of the Jan 19 report archived"; I would say that I am happy to take your guidance here. Intuitively, I would leave them up until May, in case people are searching the website to see if a new report will be posted.

Thanks again, everyone

Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 12:05 PM
To: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Sheila,

That question would need to be directed at InfoBase, so they code their own stuff.

The blurb is easy enough to code. InfoBase will also need to know if the whole content block is being archived. They're generally pretty quick if identified as an

urgency.

Please confirm the archiving question and then I'll loop them in.

Thanks,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 12:03 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Thanks for everyone edits!

Quenby, are you able to answer Mirna's question of whether it can be up by March 26 as they have received a question on when the next report will be published?

Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205

Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 10:25 AM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna

(PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Good morning, all!

I took Mirna's blurb and edited it with tracked changes. Please let me know if this still gets your message across. Since Web reviewed for plain language, I can get the translation sorted.

Also, are you looking to archive each page in the content block, and therefore put this blurb on each page? When we archive pages, we ask Google to de-index them from searches so users don't find old data. You can keep it linked from your various report pages, but it will be removed as a crosslink across Canada.ca outside your specific CAEFISS pages.

We can certainly discuss this at our meeting.

Cheers,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Friday, March 8, 2024 5:04 PM
To: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Sheila

Thank you so much for this update – I appreciate the work you have done to make it more "straight to the point" and succinct. I have made some small tweaks,. I moved the last sentence to the first paragraph, as I think it helps with flow (personal preference – feel free to ignore it). We have also added a bit of nuance in the text as we just think it is important to highlight that we are not just stopping the reporting because the response is getting downgraded. There has been a shift in the disease epidemiology, in vaccine uptake AND in

the amount of data we have to establish the vaccine's safety profile. Our suggestion is below:

**

This page is no longer being updated. *With transmission becoming endemic, as opposed to being a global health emergency, the response to COVID-19 is being downgraded. Frequent reporting on COVID-19 vaccine safety is no longer required as the safety profile of COVID-19 vaccines has been well established following extensive research and monitoring.*

COVID-19 vaccine safety monitoring will continue as part of routine safety monitoring of all authorized vaccines in Canada. Recent reports and publications on vaccine safety are available: https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html

**

Sheila and Quenby; we have also received an info request from the public asking when the next report will be. We are asked to respond before March 26. Is it realistic to hope that this blurb (or a modified version of it, following Quenby's magic) could be put online before that date? Thanks for your advice and guidance

Have a lovely and restful weekend!
Mirna

Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Wednesday, March 6, 2024 3:15 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Mirna,

Thanks for meeting with me yesterday! I like the text you've provided; and think it will be very useful for developing MLQAs on the discontinuation of this tool for COVID vaccine safety reporting.

However, for web, I recommend keeping it shorter and more plain language. I've attached a revised

version that Quenby can send for plain language review if you are comfortable with the main points.

Thanks again,
Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205

Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Tuesday, March 5, 2024 5:58 PM
To: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: Draft Blurb For the Vaccine Safety Website

Hi Sheila,

Thank you for taking the time to meet with us today. Based on our discussion, I have modified our initial draft blurb to indicate the transition of the COVID-19 reporting. I did not have time to run this by the lovely Ashley before she wrapped up her work for the day, so I hope I am doing her proud

As a reminder, we were hoping to put the disclaimer on this page: COVID-19 vaccine safety: Report on side effects following immunization - Canada.ca

Given the transition of COVID-19 epidemiology from a pandemic to an endemic state, and the fact that the safety profile of COVID-19 vaccines has been well established following extensive research and monitoring in Canada and globally, the Public Health Agency of Canada and Health Canada will be transitioning back towards routine surveillance data publication and communication of vaccine safety concerns. As such, this is the last web update of the quarterly report on adverse events following immunization with a COVID-19 vaccine. This change aligns with national and international shifts in practice, which recognize that rapid reporting is no longer needed to gather and share new or emerging evidence on potential vaccine safety issues specific to the COVID-19 pandemic vaccination campaign.

Though no new safety signals have appeared since June 2021, robust routine safety monitoring of COVID-19 vaccines administered in Canada will continue, along with prompt communication on any updated safety advice when needed. In the coming months, we will be transitioning to new vaccine safety communication and reporting tools aiming to support individuals and families across Canada in making evidence-informed decisions to protect their health. Our most recent reports and publications on vaccine safety can be accessed on the following page:

https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html .

We are looking forward to your feedback and insights
M

Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

De :	Joanette, Quenby (HC/SC)
À :	Panic, Mirna (PHAC/ASPC)
Cc :	Manhire, Sheila (HC/SC)
Objet :	RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website
Date :	2024-03-26 16:54:11

Hi Mirna,

Once approved, please just let Sheila and I know. I will communicate with InfoBase in terms of directions for the alert box. It's just cleaner since I have a Word doc with the translation and instructions already.

I did get it pre-emptively translated, and concurrence will be done by tomorrow. If your DG doesn't make any edits, I'll send on the trail to InfoBase. If there are edits, our FRE editor will need to relook at it.

Merci,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Tuesday, March 26, 2024 4:34 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; Tremblay, Benoit (PHAC/ASPC) <benoit.tremblay@phac-aspc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi Quenby

No OT needed, indeed! Thank you all for working so quickly on this. We will route this to our DG for approval and let you know when we have it so that it can be posted. Thank you all for your high response speed here.

M

Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Tuesday, March 26, 2024 3:06 PM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Thanks, Susanna!

That's fine with me from a plain language perspective. Normally, on gen pop pages, we avoid the 'adverse events' phrase but it's all over this shared audience page, so everyone should be accustomed to it by now.

Is this ready for translation? If so, Web will get on that right away for ideal posting tomorrow. I know we're a day late, but this small hiccup shouldn't warrant OT from InfoBase.

Kind regards,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Sent: Tuesday, March 26, 2024 2:27 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Sorry to be difficult, but we can't/shouldn't say this statement "… COVID-19 vaccines are safe…" given that there have been a few (though rare) causally associated adverse events that caused serious morbidity and even some deaths. Throughout the vaccine rollout, w argued against HC using such language and they eventually stopped doing so in some documents. We shifted to talking about vaccines having a good "safety profile".

That said, recognizing the need to use lay language, I could be ok with this:

This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada* because:

- the COVID-19 response has evolved from a global pandemic to an ongoing health issue
- extensive evidence on adverse events following COVID-19 vaccination has been gathered globally.

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available.

Thanks,

Susanna

==========

Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Tuesday, March 26, 2024 2:01 PM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Cc: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: FW: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi Susanna

Quenby kindly reviewed the blurb and made two small changes to your proposal:

- She replaced the word *publication* by posting because an online publication tends to be a formal document (think a report with an ISBN or a manuscript)
- She removed the term "safety profile" as it is not defined and it is not a term an everyday user would be familiar with. I tweaked her suggestion slightly.

New proposed blurb for approval:

This is the last regular posting of reported side effects following COVID-19 vaccination in Canada because:

- the COVID-19 response has evolved from a global pandemic to an ongoing health issue
- extensive scientific evidence has indicated that COVID-19 vaccines are safe.

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available.

**

Context:
As you know, we are no longer going to be reporting on COVID-19 vaccine AEFIs in an independent web report. Ashley and the team have been working on developing a surveillance analysis plan and associated knowledge translation plan for all vaccine AEFIs, which will also cover the COVID-19 vaccines from now on. In the meantime, we would like to advise the public that we will no longer be updating the COVID-19 web report. We have developed a blurb, that we hope to have posted on the existing report page advising the public that the January report was the last report.

Who has reviewed:
The blurb was developed collaboratively by Ashley Weeks (acting senior epidemiologist), Mirna Panic (SDAR manager), Susanna Ogunnaike-cooke, Sheila Manhire (senior communications advisor) and was edited for clarity and use of plain language by Quenby Joanette (senior digital communications advisor). Mirna and Ashley have reviewed the final version.

Where it will be:
At the top of these pages
https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html
https://health-infobase.canada.ca/covid-19/vaccine-safety/

Thank you all for the thoughtful consideration of the wording for this blurb

M
Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Tuesday, March 26, 2024 12:59 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Absolutely! That's perfectly okay. I just wanted to flag that profile doesn't mean anything to gen pop because nowhere on our website (InfoBase or Canada.ca) has it ever been explained. If the statement was inaccurate, 'tis why I ask the subject matter experts to check my work.

Feel free to update that line and seek full approvals. And Web will translate quickly.

Thanks,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Tuesday, March 26, 2024 12:57 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi Quenby

I noted you were away and thank you for the very quick reply! My only concern is with the second bullet; we say the safety of the COVID vaccines is stable. I understand that safety profile is a technical term, but we cannot say that the safety of the vaccine is *stable* ; this is why we continue to do surveillance and monitoring of vaccine safety (ex: there could be a situation where there is something wrong with a specific vaccine lot – granted, these events are very, very rare).

Could we say something like : "extensive scientific research and evidence indicates that vaccines are safe"

Thanks !

M

Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Tuesday, March 26, 2024 12:42 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi Mirna,

I was away yesterday but have just added the edits back into a Word doc and tracked my edits again.

Do you know how long program wants this message up before we do that consolidation I mentioned as phase 2?

Thanks,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Monday, March 25, 2024 11:15 AM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: FW: For Approval by DG: Draft Blurb For the Vaccine Safety Website
Importance: High

Hi Quenby!

Happy Tuesday – my apologies for the quick turn around on this request (I fully left a message in my drafts and thought I had sent it, which resulted in delays in obtaining approvals). Susanna (my director) reviewed and proposed some edits to our blurb. I quite like her proposal. Sheila recommended that you take a peak for plain language and let us know if you have any concerns. If you could get back to us ASAP, I would be very appreciative and you would be doing me a huge favor in helping me make up for my poor email management these past two weeks. If not, just send me a note on teams.

Susanna's proposed blurb
This is the last regular publication of the *Reported side effects following COVID-19 vaccination in Canada* because:

- the COVID-19 response has evolved from global pandemic to an ongoing health issue
- the safety profile of the COVID-19 vaccines is stable

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available

What do you think? Thank you in advance for your input
Cordialement,
Mirna

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Monday, March 25, 2024 8:51 AM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Lalonde, Danielle (PHAC/ASPC) <Danielle.Lalonde@phac-aspc.gc.ca>; Vaccine Safety / Sécurité Des Vaccins (PHAC/ASPC) <vaccinesafetysurveillance-surveillancedelasecuritedesvaccins@phac-aspc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi all,

The revised text is fine from my perspective.

Mirna, I recommend sharing it with Quenby for a quick plain language check, but I don't anticipate any concerns with it.

Thanks and happy Monday!
Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205

Conseillère principale en communications, Communications en santé publique

Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Sent: Friday, March 22, 2024 7:53 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Lalonde, Danielle (PHAC/ASPC) <Danielle.Lalonde@phac-aspc.gc.ca>; Vaccine Safety / Sécurité Des Vaccins (PHAC/ASPC) <vaccinesafetysurveillance-surveillancedelasecuritedesvaccins@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For Approval by DG: Draft Blurb For the Vaccine Safety Website

Hi Mirna,

Thanks for all the work on this.

I'm a bit concerned that the proposed wording does not align with the kind of messaging our VP wanted, as it talks a lot about what we **won't** do rather than just signaling a transition.

I would like to propose some edits:

This is the last regular publication of the *Reported side effects following COVID-19 vaccination in Canada* because:

- the COVID-19 response has evolved from global pandemic to an ongoing health issue
- the safety profile of the COVID-19 vaccines is stable

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available

Let me know if you think I need to talk with Sheila about why I don't think Don would approve the proposed wording below.

Thanks,

Susanna

==========

Susanna Ogunnaike-Cooke (She/Elle)
613-608-0339
susanna.ogunnaike-cooke@phac-aspc.gc.ca

*Note I am sending this message at a time that suits me and which may not be part of your regular working hours. Please do not feel as though you need to respond right away

*Notez que j'envoie ce message à un moment qui me convient et qui peut ne pas faire partie de vos heures de travail habituelles. Ne vous sentez pas obligé de répondre tout de suite.

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Friday, March 22, 2024 11:19 AM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Cc: Lalonde, Danielle (PHAC/ASPC) <Danielle.Lalonde@phac-aspc.gc.ca>; Vaccine Safety / Sécurité Des Vaccins (PHAC/ASPC) <vaccinesafetysurveillance-surveillancedelasecuritedesvaccins@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: For Approval by DG: Draft Blurb For the Vaccine Safety Website
Importance: High

Hi Susanna,

I am a little mortified, but I was about to follow up with this and I think I am the culprit – I don't think this message made it out of my drafts. My apologies. Could we get Anne-Marie to quickly look this over and provide her approval (or let us know if she has concerns/does not approve)?

Context: As you know, we are no longer going to be reporting on COVID-19 vaccine AEFIs in an independent web report. Ashley and the team have been working on developing a surveillance analysis plan and associated knowledge translation plan for all vaccine AEFIs, which will also cover the COVID-19 vaccines from now on. In the meantime, we would like to advise the public that we will no longer be updating the COVID-19 web report. We have developed a blurb, that we hope to have posted on the existing report page advising the public that the January report was the last report.

Who has reviewed: The blurb was developed collaboratively by Ashley Weeks (acting senior epidemiologist), Mirna Panic (SDAR manager), Susanna Ogunnaike-cooke, Sheila Manhire (senior communications advisor) and was edited for clarity and use of plain language by Quenby Joanette (senior digital communications advisor). Mirna and Ashley have reviewed the final version.

For action by Anne-Marie: Review and (hopefully) approval of the blurb below before March 26 (if timeline is unrealistic, please let us know as the delay is my fault).

Blurb (78 words):
This content is no longer being updated because:

- the response to COVID-19 has been downgraded, as it's no longer considered a global health emergency
- frequent reporting on COVID-19 vaccine safety is no longer required, as the safety of the vaccines has been well established following extensive research and monitoring

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available.

Where it will be:

At the top of these pages
https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html
https://health-infobase.canada.ca/covid-19/vaccine-safety/

Thank you for your help and my sincere apologies for the inconvenience
Mirna
Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 2:07 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Mirna and Quenby,

I would recommend DG approval on the blurb, given we are archiving a once very high-profile web page.

Thanks!
Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205

Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 1:59 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>

Subject: RE: Draft Blurb For the Vaccine Safety Website

Awesome sauce. Level of approval will always depend on the topic and how high-profile the request is. If this isn't considered high profile, then I'm coolio with just your approval to proceed with translation.

Sheila, thoughts on level on your end?

I'm happy to connect up with InfoBase and share our approach with them and to get some info on how long they think the first phase will take to code (the blurb) followed by the consolidation/redirects.

Thanks,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Monday, March 11, 2024 1:56 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Quenby

I would consider them approved for translation (unless you require director-level sign off in writing, in which case I will poke Susanna to send you a note). I am relieved that you have a FRE concurrence editor and don't feel the need to review the translation if you already have in-house capacity to ensure the translation aligns with the terminology used in francophone media/science discourse in Canada.

Regarding archiving, both suggestions make sense to me. We are ok to add the blurb to the summary/detailed report page now for a limited time, decide what that timeframe on one of our upcoming calls, and then delete those pages (setting up a redirect to the consolidated page for anyone with a bookmark or direct link to our pages).

Thanks

Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 1:22 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Mirna,

Glad you like the edits. Would you consider them approved for translation?

And if you'd like to look at the FRE translation, then I'll send to you before I send it to our FRE concurrence editor. We have 2 editors who check the content we plain language to ensure it resonates in the same way with a Francophone audience.

In terms of archiving pages, what I mean is that you have several pages in this content block:

https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html

https://health-infobase.canada.ca/covid-19/vaccine-safety/

https://health-infobase.canada.ca/covid-19/vaccine-safety/utd.html

https://health-infobase.canada.ca/covid-19/vaccine-safety/archive/

While you do have archived reports, that's not what I meant. The whole content block will no longer be 'current' and so we don't usually leave pieces like this without a notification that they too are archived as a package. We add archive banners to archived content—for example, this NACI publication: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-guidance-additional-covid-19-booster-dose-spring-2023-individuals-high-risk-severe-illness-due-covid-19.html. This is what I mean when I ask how many pages are getting archived.

In looking at all the pages, we could avoid an archive banner if we consolidate the 'Understanding the data' and the 'Archived reports' page. Since the former page explains the offerings of the latter page. So, in the interim, we add the blurb to the summary/detailed report page now for a limited time (we can decide what that timeframe is), and then delete those pages (setting up a redirect to the consolidated page for anyone with a bookmark or direct link to our pages). Those pages will soon no longer serve a purpose.

Let me know if this jives with you.

Thanks,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Monday, March 11, 2024 1:08 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Quenby and Sheila

Thanks so much for your quick turn around on this.

Quenby : We quite like your edits and appreciate the notes on your editorial changes. I appreciate your willingness to coordinate translation. I am francophone so I would be happy to look the final blurb over to make sure the technical translation is correct.

Regarding Archiving: We are a bit confused because we were under the impression that the older reports were already archived on Canada.ca (via these links: Public Health Infobase - Public Health Agency of Canada).

As such, the note would need to be put on the summary + detailed report pages of the January 19 editions:

a. COVID-19 vaccine safety: Summary of weekly report on side effects following immunization -

Canada.ca

b. COVID-19 vaccine safety: Report on side effects following immunization - Canada.ca

If your question is: "Yes, Mirna, I am wondering if you want the summary+detailed report+understanding the data pages of the Jan 19 report archived"; I would say that I am happy to take your guidance here. Intuitively, I would leave them up until May, in case people are searching the website to see if a new report will be posted.

Thanks again, everyone

Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 12:05 PM
To: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Sheila,

That question would need to be directed at InfoBase, so they code their own stuff.

The blurb is easy enough to code. InfoBase will also need to know if the whole content block is being archived. They're generally pretty quick if identified as an urgency.

Please confirm the archiving question and then I'll loop them in.

Thanks,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 12:03 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Thanks for everyone edits!

Quenby, are you able to answer Mirna's question of whether it can be up by March 26 as they have received a question on when the next report will be published?

Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205

Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Monday, March 11, 2024 10:25 AM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Good morning, all!

I took Mirna's blurb and edited it with tracked changes. Please let me know if this still gets your message across. Since Web reviewed for plain language, I can get the translation sorted.

Also, are you looking to archive each page in the content block, and therefore put this blurb on each page? When we archive pages, we ask Google to de-index them from searches so users don't find old data. You can keep it linked from your various report pages, but it will be removed as a crosslink across

Canada.ca outside your specific CAEFISS pages.

We can certainly discuss this at our meeting.

Cheers,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Friday, March 8, 2024 5:04 PM
To: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Sheila

Thank you so much for this update – I appreciate the work you have done to make it more "straight to the point" and succinct. I have made some small tweaks,. I moved the last sentence to the first paragraph, as I think it helps with flow (personal preference – feel free to ignore it). We have also added a bit of nuance in the text as we just think it is important to highlight that we are not just stopping the reporting because the response is getting downgraded. There has been a shift in the disease epidemiology, in vaccine uptake AND in the amount of data we have to establish the vaccine's safety profile. Our suggestion is below:

**

This page is no longer being updated. *With transmission becoming endemic, as opposed to being a global health emergency, the response to COVID-19 is being downgraded. Frequent reporting on COVID-19 vaccine safety is no longer required as the safety profile of COVID-19 vaccines has been well established following extensive research and monitoring.*

COVID-19 vaccine safety monitoring will continue as part of routine safety monitoring of all authorized vaccines in Canada. Recent reports and publications on vaccine safety are available: https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html

**

Sheila and Quenby; we have also received an info request from the public asking when the next report will be. We are asked to respond before March 26. Is it realistic to hope that this blurb (or a modified version of it, following Quenby's magic) could be put online before that date? Thanks for your advice and guidance

Have a lovely and restful weekend!
Mirna

Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Wednesday, March 6, 2024 3:15 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: Draft Blurb For the Vaccine Safety Website

Hi Mirna,

Thanks for meeting with me yesterday! I like the text you've provided; and think it will be very useful for developing MLQAs on the discontinuation of this tool for COVID vaccine safety reporting.

However, for web, I recommend keeping it shorter and more plain language. I've attached a revised version that Quenby can send for plain language review if you are comfortable with the main points.

Thanks again,
Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205

Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Tuesday, March 5, 2024 5:58 PM
To: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: Draft Blurb For the Vaccine Safety Website

Hi Sheila,

Thank you for taking the time to meet with us today. Based on our discussion, I have modified our initial draft blurb to indicate the transition of the COVID-19 reporting. I did not have time to run this by the lovely Ashley before she wrapped up her work for the day, so I hope I am doing her proud

As a reminder, we were hoping to put the disclaimer on this page: COVID-19 vaccine safety: Report on side effects following immunization - Canada.ca

Given the transition of COVID-19 epidemiology from a pandemic to an endemic state, and the fact that the safety profile of COVID-19 vaccines has been well established following extensive research and monitoring in Canada and globally, the Public Health Agency of Canada and Health Canada will be transitioning back towards routine surveillance data publication and communication of vaccine safety concerns. As such, this is the last web update of the quarterly report on adverse events following immunization with a COVID-19 vaccine. This change aligns with national and international shifts in practice, which recognize that rapid reporting is no longer needed to gather and share new or emerging evidence on potential vaccine safety issues specific to the COVID-19 pandemic vaccination campaign.

Though no new safety signals have appeared since June 2021, robust routine safety monitoring of COVID-19 vaccines administered in Canada will continue, along with prompt communication on any updated safety advice when needed. In the coming months, we will be transitioning to new vaccine safety communication and reporting tools aiming to support individuals and families across Canada in making evidence-informed decisions to protect their health. Our most recent reports and publications on vaccine safety can be accessed on the following page: https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html .

We are looking forward to your feedback and insights
M

Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

De : MacKenzie, Andrew (PHAC/ASPC)
À : Panic, Mirna (PHAC/ASPC)
Objet : RE: For VP approval: Language to add to AEFI online report page re transition to routine reporting
Date : 2024-05-09 11:30:22

Hi Mirna,

I'm just learning about the struggles for this blurb but I agree that writing short, plain language text is often difficult. I think this looks like a great compromise and don't have any comments. I'll route it up to Susanna for review and approval.

Thank you!

Andrew

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Thursday, May 9, 2024 9:42 AM
To: MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>
Subject: FW: For VP approval: Language to add to AEFI online report page re transition to routine reporting
Importance: High

Hi Andrew

I am routing for your review and subsequent routing to DGO of an updated blurb that explains the fact that our reporting of COVID-19 vaccine safety data will no longer be a standalone item and will be integrated into our regular, all vaccine, surveillance reporting efforts (Ashley and I are working on an online report plan for your review shortly).

This blurb has had several iterations, initially with our colleagues at comms, who provided advice on plain language, myself and Susanna. Susanna and I had proposed a paragraph to explain our decision and our communications colleagues advised that shorter blurbs are more appropriate for webpage updates and worked with us to get it down to an 80-word update notice.This short blurb was sent up for approval by our VP, who commented that it was too cryptic, did not provide enough detail and that the language could be even plainer. I have done my best to combine the insights from our communications colleagues, Susanna's lessons learned from the pandemic, existing language from our other web pages and Dr Sheppard's comments into a new version. I hope this is a satisfactory compromise.

My apologies for the delay – I have to admit that I struggled a little bit to come up with a plain language blurb that is short, but not too parsimonious and which incorporates our communications lessons-learned from the pandemic.

Proposed blurb

> This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada*. We will no longer be updating this online report. Instead, COVID-19 vaccine safety

data will be shared in a surveillance report that will include data on all vaccines approved in Canada. We will provide a link to this new report as soon as it is available. In the meantime, recent reports and technical publications on vaccine safety are available.

This decision was made because the COVID-19 response has evolved from a global pandemic to an ongoing health issue and extensive evidence on COVID-19 vaccine safety has been gathered globally.

Rest assured that robust vaccine safety monitoring efforts continue: if any COVID-19 vaccine safety concerns are detected, we will communicate them promptly.

Thank you
Mirna

Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Yome, Julie (PHAC/ASPC) <julie.yome@phac-aspc.gc.ca>
Sent: Monday, April 8, 2024 10:06 AM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Vaccine Safety / Sécurité Des Vaccins (PHAC/ASPC) <vaccinesafetysurveillance-surveillancedelasecuritedesvaccins@phac-aspc.gc.ca>
Subject: FW: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Hi Mirna,

I assume your team was working with Susanna on this? See the suggestion from VP below.

In case it's helpful (feel free to ignore!) – some suggestions:

This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada*.

Going forward, reporting on COVID-19 vaccine safety will be integrated with the routine safety monitoring and reporting of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available.

This decision was made because the COVID-19 response has evolved from a global pandemic to an ongoing health issue and extensive evidence on adverse events following COVID-19 vaccination has been gathered globally.

From: Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>
Sent: Monday, April 8, 2024 9:23 AM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Yome, Julie (PHAC/ASPC) <julie.yome@phac-aspc.gc.ca>
Cc: Vaccine Safety / Sécurité Des Vaccins (PHAC/ASPC) <vaccinesafetysurveillance-surveillancedelasecuritedesvaccins@phac-aspc.gc.ca>; Leinan, Valerie (PHAC/ASPC) <valerie.leinan@phac-aspc.gc.ca>; Holmes, Nathalie (PHAC/ASPC) <nathalie.holmes@phac-aspc.gc.ca>; Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>
Subject: FW: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Good morning,

Please see the comment below from the VP for revisions.

Thanks,
Caroline

From: Infectious Disease and Vaccination Programs Branch / Direction générale des programmes sur les maladies infectieuses et de la vaccination (PHAC/ASPC) <idvp-pmiv@phac-aspc.gc.ca>
Sent: Monday, April 8, 2024 6:48 AM
To: Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>; Infectious Disease and Vaccination Programs Branch / Direction générale des programmes sur les maladies infectieuses et de la vaccination (PHAC/ASPC) <idvp-pmiv@phac-aspc.gc.ca>
Subject: RE: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Good morning. Please see below comment from VP. Tks, Nicky

VP has revied the proposed text and has provided the following feedback to the team

I find it too cryptic and short. Could use a better plain language introduction. As of x we will be moving to integration of ….. This decision has been made because…..

Infectious Diseases and Vaccination Programs Branch

Public Health Agency of Canada

Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada

From: Holmes, Nathalie (PHAC/ASPC) <nathalie.holmes@phac-aspc.gc.ca> **On Behalf Of** Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC)
Sent: Friday, April 5, 2024 10:56 AM
To: Infectious Disease and Vaccination Programs Branch / Direction générale des programmes sur les maladies infectieuses et de la vaccination (PHAC/ASPC) <idvp-pmiv@phac-aspc.gc.ca>
Cc: Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>
Subject: FW: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Hello VPO, I am sending the following DG-approved request for VP approval. Thank you.

Per the decision taken in January 2024 to transition from a COVID-only online AEFI report to regular reporting, the CIS has worked with Comms to develop some language that will be added to the web page for the last posted report.

Context: As you know, we are no longer going to be reporting on COVID-19 vaccine AEFIs in an independent web report. Instead, we will be reporting on COVID vaccine safety as part of our routine reporting for all vaccines. We are working on developing a surveillance analysis plan and associated knowledge translation plan for all vaccine AEFIs, which will also cover the COVID-19 vaccines. In the meantime, we are proposing to add the wording below to the COVID-19 online report webpages to advise the public that we will no longer be updating that report.

Who has reviewed: The proposed language was developed by the CIS in collaboration with Sheila Manhire (senior communications advisor) and Quenby Joanette (senior digital communications advisor).

++++++++++

> This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada* because:
>
> - the COVID-19 response has evolved from a global pandemic to an ongoing health issue
> - extensive evidence on adverse events following COVID-19 vaccination has been gathered globally.
>
> Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available.

++++++++++

Nathalie Holmes
(Elle | She) on behalf of

Single Window - Director General's Office / Guichet Unique - Bureau de la Directrion générale
Centre for Immunization Surveillance / Centre de surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch / Direction générale des programmes sur les maladies infectieuses et de la vaccination
Public Health Agency of Canada / Agence de la santé publique du Canada
vaccinesurveillance-surveillanceduvaccin@phac-aspc.gc.ca

This Single Window is monitored Mon-Fri 0800-1600 hrs.
Note that the Single Window is not monitored during weekends or public holidays

Le guichet unique est surveillé du lundi au vendredi de 8 h à 16 h.
Notez que le guichet unique n'est pas surveillé pendant les week-ends et les jours fériés

De :	Hunter, Josee (HC/SC)
À :	Panic, Mirna (PHAC/ASPC); Joanette, Quenby (HC/SC)
Cc :	Manhire, Sheila (HC/SC); Ogunnaike-Cooke, Susanna (PHAC/ASPC)
Objet :	RE: For VP approval: Language to add to AEFI online report page re transition to routine reporting
Date :	2024-05-06 11:51:49
Pièces jointes :	image001.png image002.png
Importance :	Haute

Hello Mirna,

I will be attending a Director-level meeting this afternoon to discuss the status of upcoming web postings.

This one is listed as being posted this week, but I see it has been in VPO for quite some time. Could we please get a status update?

Week of May 6 TBC – Alert boxes on COVID AEFI InfoBase pages that indicate updates will no longer be posted as part of COVID-specific monitoring (alert box text with VP for approval)

Thank you!

Josee

Josée Hunter (She, her / elle)
Communications Executive | Chef des communications
Communications and Public Affairs Branch | Direction générale des affaires publiques et des communications
Centre for Foodborne & Zoonotic Infectious Disease, Therapeutics and Vaccine Preventable Diseases |
Centre des maladies infectieuses d'origine alimentaire, environnementale et zoonotique, produits thérapeutiques et maladies évitables par la vaccination
Health Canada & Public Health Agency of Canada | Santé Canada & l'Agence de la santé publique du Canada
josee.hunter@hc-sc.gc.ca| Tel: 343-550-3011

M/L	T/M	W/M	T/J	F/V

Please do not hesitate to reply in the official language of your choice. / N'hésitez pas à répondre dans la langue officielle de votre choix.

From: Manhire, Sheila (HC/SC)
Sent: Monday, April 29, 2024 2:07 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC)

<quenby.joanette@hc-sc.gc.ca>
Cc: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Hi Mirna and Susanna,

Time for my weekly follow up . Please let me know if I can help address VPO's comments on the proposed web text.

Thanks,
Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205

Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Manhire, Sheila (HC/SC)
Sent: Monday, April 22, 2024 1:45 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: RE: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Hi Mirna,

Just following up to see if there has been any movement on this. Could you also please remind me when the next AEFI report would have been posted and when people may come to the site looking for it?

Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205

Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>

Sent: Thursday, April 11, 2024 3:19 PM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Cc: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Coucou

I think created confusion by rushing though this, again. Re-reading the chain, I just realised that I read Julie's feedback as the VP's feedback, which in fact was contained in the email below.

Please do not action anything today. I want to re-validate with Susanna about whether we want to go back up the chain again to have the changes Julie proposed (which I really like), approved. It seems like the VP also finds our text "too short", so I am not sure how we resolve the conflicting feedback we have from our communications colleagues with their feedback. All that to say, no action. Let me just touch base with Susanna.

M

Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Sent: Thursday, April 11, 2024 12:47 PM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: RE: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Hi Mirna,

Can you confirm this is the change?

If so, I'll send to Benoit, and he'll put it on DEV, then you tell him to post when ready.

Merci,

Quenby
Quenby Joanette
Senior Digital Communications Advisor
Digital Communications, Communications and Public Affairs Branch
Health Canada | Government of Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

Conseillère en communications numériques (principale)
Communications numériques, Direction générale des affaires publiques et des communications
Santé Canada | Gouvernement du Canada
Quenby.Joanette@hc-sc.gc.ca | 613-297-5783

From: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Sent: Thursday, April 11, 2024 11:50 AM
To: Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Cc: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>
Subject: FW: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Hi amazing colleagues!

The blurb has finally been approved by our VP. I can confirm they simply moved the order of the sentences around (please flag this to your translator, Quenby, it will save them time!) We can proceed with putting it on the website ! Quenby ; let me know if you are ok to coordinate with Infobase. Thank you all for your help and extensive discussions on this!

M

Mirna Panić (elle/she/her)

Gestionnaire – Division de surveillance de la sécurité des vaccins
Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada / Gouvernement du Canada
mirna.panic@phac-aspc.gc.ca / Tél. cell. : 514-299-6871

Manager – Vaccine Safety Surveillance Division
Infectious Disease and Vaccination Programs Branch
Public Health Agency of Canada / Government of Canada
mirna.panic@phac-aspc.gc.ca / Cel: 514-299-6871

From: Yome, Julie (PHAC/ASPC) <julie.yome@phac-aspc.gc.ca>
Sent: Monday, April 8, 2024 10:06 AM
To: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Cc: Vaccine Safety / Sécurité Des Vaccins (PHAC/ASPC) <vaccinesafetysurveillance-surveillancedelasecuritedesvaccins@phac-aspc.gc.ca>

Subject: FW: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Hi Mirna,

I assume your team was working with Susanna on this? See the suggestion from VP below.

In case it's helpful (feel free to ignore!) – some suggestions:

> This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada*.
>
> Going forward, reporting on COVID-19 vaccine safety will be integrated with the routine safety monitoring and reporting of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available.
>
> This decision was made because the COVID-19 response has evolved from a global pandemic to an ongoing health issue and extensive evidence on adverse events following COVID-19 vaccination has been gathered globally.

From: Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>
Sent: Monday, April 8, 2024 9:23 AM
To: Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@phac-aspc.gc.ca>; Yome, Julie (PHAC/ASPC) <julie.yome@phac-aspc.gc.ca>
Cc: Vaccine Safety / Sécurité Des Vaccins (PHAC/ASPC) <vaccinesafetysurveillance-surveillancedelasecuritedesvaccins@phac-aspc.gc.ca>; Leinan, Valerie (PHAC/ASPC) <valerie.leinan@phac-aspc.gc.ca>; Holmes, Nathalie (PHAC/ASPC) <nathalie.holmes@phac-aspc.gc.ca>; Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>
Subject: FW: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Good morning,

Please see the comment below from the VP for revisions.

Thanks,
Caroline

From: Infectious Disease and Vaccination Programs Branch / Direction générale des programmes sur les maladies infectieuses et de la vaccination (PHAC/ASPC) <idvp-pmiv@phac-aspc.gc.ca>
Sent: Monday, April 8, 2024 6:48 AM

To: Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>; Infectious Disease and Vaccination Programs Branch / Direction générale des programmes sur les maladies infectieuses et de la vaccination (PHAC/ASPC) <idvp-pmiv@phac-aspc.gc.ca>
Subject: RE: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Good morning. Please see below comment from VP. Tks, Nicky

VP has revied the proposed text and has provided the following feedback to the team

I find it too cryptic and short. Could use a better plain language introduction. As of x we will be moving to integration of ….. This decision has been made because…..

Infectious Diseases and Vaccination Programs Branch
Public Health Agency of Canada

Direction générale des programmes sur les maladies infectieuses et de la vaccination
Agence de la santé publique du Canada

From: Holmes, Nathalie (PHAC/ASPC) <nathalie.holmes@phac-aspc.gc.ca> **On Behalf Of** Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC)
Sent: Friday, April 5, 2024 10:56 AM
To: Infectious Disease and Vaccination Programs Branch / Direction générale des programmes sur les maladies infectieuses et de la vaccination (PHAC/ASPC) <idvp-pmiv@phac-aspc.gc.ca>
Cc: Centre for Immunization Surveillance - CIS / Centre de surveillance de l'immunisation - CSI(PHAC/ASPC) <immunization.surveillance-immunisation@phac-aspc.gc.ca>
Subject: FW: For VP approval: Language to add to AEFI online report page re transition to routine reporting

Hello VPO, I am sending the following DG-approved request for VP approval. Thank you.

Per the decision taken in January 2024 to transition from a COVID-only online AEFI report to regular reporting, the CIS has worked with Comms to develop some language that will be added to the web page for the last posted report.

Context: As you know, we are no longer going to be reporting on COVID-19 vaccine AEFIs in an independent web report. Instead, we will be reporting on COVID vaccine safety as part of our routine reporting for all vaccines. We are working on developing a surveillance analysis plan and associated knowledge translation plan for all vaccine AEFIs, which will also cover the COVID-19 vaccines. In the meantime, we are proposing to add the wording below to the COVID-19 online report webpages to advise the public that we will no longer be updating that report.

Who has reviewed: The proposed language was developed by the CIS in collaboration with Sheila Manhire (senior communications advisor) and Quenby Joanette (senior digital communications

advisor).

++++++++++

This is the last regular posting of *Reported side effects following COVID-19 vaccination in Canada* because:

- the COVID-19 response has evolved from a global pandemic to an ongoing health issue
- extensive evidence on adverse events following COVID-19 vaccination has been gathered globally.

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. Recent reports and technical publications on vaccine safety are available.

++++++++++

Nathalie Holmes
(Elle | She) on behalf of

Single Window - Director General's Office / Guichet Unique - Bureau de la Directrion générale
Centre for Immunization Surveillance / Centre de surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch / Direction générale des programmes sur les maladies infectieuses et de la vaccination
Public Health Agency of Canada / Agence de la santé publique du Canada
vaccinesurveillance-surveillanceduvaccin@phac-aspc.gc.ca

This Single Window is monitored Mon-Fri 0800-1600 hrs.
Note that the Single Window is not monitored during weekends or public holidays

Le guichet unique est surveillé du lundi au vendredi de 8 h à 16 h.
Notez que le guichet unique n'est pas surveillé pendant les week-ends et les jours fériés

De : MacKenzie, Andrew (PHAC/ASPC)
À : Patel, Nimeshkumar (PHAC/ASPC)
Cc : Spruin, Sarah (PHAC/ASPC)
Objet : RE: Marc - FW: FOR GUIDANCE FW: PUB-002614- URGENT FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Date : 2024-06-20 16:29:08
Pièces jointes : image001.png
image002.png

Hi Nimesh,
Thank you for clarifying! I will modify the highlighted passage slightly to indicate that we are "planning" to launch a new webpage in the fall in case we need to change the plan. "PHAC is planning to launch a new webpage in Fall 2024 that will include information on reported side effects for a broader range of vaccines, including authorized COVID-19 vaccines" I'll ask the Correspondence team to send the response from the generic account.
Thanks,
Andrew

From: Patel, Nimeshkumar (PHAC/ASPC)
Sent: Thursday, June 20, 2024 3:35 PM
To: MacKenzie, Andrew (PHAC/ASPC)
Cc: Spruin, Sarah (PHAC/ASPC)
Subject: RE: Marc - FW: FOR GUIDANCE FW: PUB-002614- URGENT FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Hi Andrew,
Thank you for the email. Mirna's plan was to first put some language on the webpage and then respond to the inquirer. She was in touch with comms (may be Joanette, Quenby) to put a blurb on the dashboard/webpage that this content is no longer being updated. That last we know, the comms is currently reviewing the language. No one from our team has access to the most latest revisions, but I can reach out to them to see where things are right now.
I think we could take either of the following approaches:

1. I can check in with comms and InfoBase, and expedite to have the approved language on the webpage. Once it is posted, we can use the exact language to respond to the inquirer.
2. As it has taken long to have the approved language posted on the webpage, we can respond to the correspondent with the below blurb and continue to work with comms to have it posted on our webpage as earliest as possible. That way the inquirer is not waiting too long to have a response from us. The risk is that our response may not 100% align with what will be posted on the webpage.

"The content on *Reported side effects following COVID-19 vaccination in Canada* is no longer being updated because:

- the response to COVID-19 has been downgraded, as it's no longer considered a global health emergency
- frequent reporting on COVID-19 vaccine safety is no longer required, as the safety of the vaccines has been well established following extensive research and monitoring

Reporting on COVID-19 vaccine safety will continue as part of routine safety monitoring of all approved vaccines in Canada. PHAC will launch a new webpage in Fall 2024 that will include information on reported side effects for a broader range of vaccines, including authorized COVID-19 vaccines." –
We could include the highlighted sentence or remove it considering we are still in planning phase.
If it is easier, we could chat more in our trilateral meeting tomorrow.
Thanks,
Nimesh

Nimesh Patel (He/his)
Acting Senior Epidemiologist ¦ Épidémiologiste principale
Vaccine Safety Surveillance Division ¦ Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance ¦ Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) ¦ Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada ¦ Agence de la santé publique du Canada
nimeshkumar.patel@phac-aspc.gc.ca / Tel: 343-574-8609

From: MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>
Sent: Thursday, June 20, 2024 10:09 AM
To: Patel, Nimeshkumar (PHAC/ASPC) <nimeshkumar.patel@phac-aspc.gc.ca>
Cc: Spruin, Sarah (PHAC/ASPC) <sarah.spruin@phac-aspc.gc.ca>
Subject: FW: Marc - FW: FOR GUIDANCE FW: PUB-002614- URGENT FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Hi Nimesh,
Do you have some standard language that you are using for people that want to know when the next AEFI report will be?
Thanks,
Andrew

From: Crain, Jennifer (PHAC/ASPC) <jennifer.crain@phac-aspc.gc.ca>
Sent: Thursday, June 20, 2024 11:23 AM
To: MacKenzie, Andrew (PHAC/ASPC) <andrew.mackenzie@phac-aspc.gc.ca>
Cc: infobase (PHAC/ASPC) <infobase@phac-aspc.gc.ca>; INFO (PHAC/ASPC) <info@phac-aspc.gc.ca>; Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Subject: FW: Marc - FW: FOR GUIDANCE FW: PUB-002614- URGENT FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Hi Andrew,
It was nice to see you at Anne-Marie's retirement recently!
On another note, I just learned that Mirna Panic is currently away, and we have (Infobase via Comms) recently been trying to connect with her team regarding a public request for information (RFI) initially received by Health Canada in early April, and that has since been redirected several times (see thread below) in an effort to land on the responsible program team for response.
The requester is seeking information on "When will the next update take place for the "Reported side effects following COVID-19 vaccination in Canada REPORT?".
I've looped in Comms (Sheila), the infobase@phac, and info@phac generic account as well, so that we will all be aware of any movement of this request,

for response tracking purposes.
Grateful for your assistance in responding to the requester as promptly as workload allows.
As far as process, I would recommend sending the approved reply to the PHAC generic inbox info@phac-aspc.gc.ca for response (with a cc to the rest of us), unless you are comfortable with a direct reply from your Division's generic inbox, if one is available.
Hope this helps, and thanks very much!

Jennifer Crain, MA
(she | elle)
Business Manager, Health Infobase | Gestionnaire d'affaires, Infobase Santé
Centre for Surveillance and Applied Research | Centre de surveillance et de recherche appliquée
Tel. | Tél.: (613) 799-4096
Email | Courriel: Jennifer.Crain@phac-aspc.gc.ca

L/M	M/T	M/W	J/T	V/F
Télétravail/Telework	785 Carling	785 Carling	Télétravail/Telework	Télétravail/Telework

I acknowledge that my place of work is within the ancestral, traditional and unceded territory of the Algonquin Nation | Je tiens à reconnaître que les terres sur lesquelles mon bureau est situé font partie du territoire traditionnel non cédé du peuple Algonquin.

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Wednesday, June 12, 2024 1:09 PM
To: INFO (PHAC/ASPC) <info@phac-aspc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>; Xu, Yuhui (PHAC/ASPC) <yuhui.xu@phac-aspc.gc.ca>; Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>
Cc: Crain, Jennifer (PHAC/ASPC) <jennifer.crain@phac-aspc.gc.ca>; infobase (PHAC/ASPC) <infobase@phac-aspc.gc.ca>; Tremblay, Benoit (PHAC/ASPC) <benoit.tremblay@phac-aspc.gc.ca>; Millingen, Scott Van (PHAC/ASPC) <Scott.VanMillingen@phac-aspc.gc.ca>
Subject: RE: Marc - FW: FOR GUIDANCE FW: PUB-002614- URGENT FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Mirna and Ashley,
Did someone from your team respond to the inquiry?
Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205
Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: INFO (PHAC/ASPC) <info@phac-aspc.gc.ca>
Sent: Wednesday, June 12, 2024 12:58 PM
To: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; infobase (PHAC/ASPC) <infobase@phac-aspc.gc.ca>; Xu, Yuhui (PHAC/ASPC) <yuhui.xu@phac-aspc.gc.ca>; Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>
Cc: Crain, Jennifer (PHAC/ASPC) <jennifer.crain@phac-aspc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>; Tremblay, Benoit (PHAC/ASPC) <benoit.tremblay@phac-aspc.gc.ca>; Millingen, Scott Van (PHAC/ASPC) <Scott.VanMillingen@phac-aspc.gc.ca>; INFO (PHAC/ASPC) <info@phac-aspc.gc.ca>
Subject: RE: Marc - FW: FOR GUIDANCE FW: PUB-002614- URGENT FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Good afternoon all,
Just sending a gentle nudge on this one. Can you please confirm that a response was sent to this correspondent? We will close this one off in our tracker once you are able to confirm for us.
Thank you,
Ben

From: Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>
Sent: Wednesday, May 15, 2024 3:19 PM
To: infobase (PHAC/ASPC) <infobase@phac-aspc.gc.ca>; Xu, Yuhui (PHAC/ASPC) <yuhui.xu@phac-aspc.gc.ca>; Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>
Cc: Crain, Jennifer (PHAC/ASPC) <jennifer.crain@phac-aspc.gc.ca>; Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>; Tremblay, Benoit (PHAC/ASPC) <benoit.tremblay@phac-aspc.gc.ca>; Millingen, Scott Van (PHAC/ASPC) <Scott.VanMillingen@phac-aspc.gc.ca>; INFO (PHAC/ASPC) <info@phac-aspc.gc.ca>
Subject: RE: Marc - FW: FOR GUIDANCE FW: PUB-002614- URGENT FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Good afternoon,
Looping in the manager in vaccine safety, Mirna, who is leading on the transition of this reporting. Mirna, can you please respond directly to the public inquiry? The draft web blurb is probably sufficient for the response.
Thanks,
Sheila

Sheila Manhire
Senior Communications Advisor, Public Health Comms
Health Canada and the Public Health Agency of Canada / Government of Canada
Sheila.Manhire@hc-sc.gc.ca / Tel: 343-550-6205
Conseillère principale en communications, Communications en santé publique
Santé Canada et l'Agence de la santé publique du Canada / Gouvernement du Canada
Sheila.Manhire@hc-sc.gc.ca / Tél: 343-550-6205

From: infobase (PHAC/ASPC) <infobase@phac-aspc.gc.ca>
Sent: Wednesday, May 15, 2024 3:04 PM
To: Xu, Yuhui (PHAC/ASPC) <yuhui.xu@phac-aspc.gc.ca>; Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>

Cc: Crain, Jennifer (PHAC/ASPC) <jennifer.crain@phac-aspc.gc.ca>; Tremblay, Benoit (PHAC/ASPC) <benoit.tremblay@phac-aspc.gc.ca>; Manhire, Sheila (HC/SC) <sheila.manhire@hc-sc.gc.ca>; Millingen, Scott Van (PHAC/ASPC) <Scott.VanMillingen@phac-aspc.gc.ca>; infobase (PHAC/ASPC) <infobase@phac-aspc.gc.ca>; INFO (PHAC/ASPC) <info@phac-aspc.gc.ca>
Subject: FW: Marc - FW: FOR GUIDANCE FW: PUB-002614- URGENT FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Good Afternoon,
The request below was received in the generic inbox for the Health Infobase team (infobase@phac-aspc.gc.ca), redirected from the info@phac-aspc.gc.ca generic inbox.
The requester appears to be a member of the public who initially reached out on April 9th 2024.
The requester (see highlights in the thread below) is enquiring about the next planned update to this product: https://health-infobase.canada.ca/covid-19/vaccine-safety/? It is our understanding that it's the program's intention to discontinue public updates to this product in the near future.
Grateful if your team could promptly respond directly to the requester, considering the appropriate approvals and level of information for public consumption, and cc to info@phac-aspc.gc.ca and infobase@phac-aspc.gc.ca.
With thanks,
Health Infobase Team / Équipe Infobase de la santé
Centre for Surveillance and Applied Research / Centre de surveillance et de recherche appliquée
Public Health Agency of Canada / Agence de la santé publique du Canada

From: INFO (PHAC/ASPC) <info@phac-aspc.gc.ca>
Sent: Wednesday, May 15, 2024 8:49 AM
To: infobase (PHAC/ASPC) <infobase@phac-aspc.gc.ca>
Subject: FW: Marc - FW: FOR GUIDANCE FW: PUB-002614- URGENT FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Good morning team,
Please see the thread below that was bounced over to us from HC. As I understand it, this page is managed by your team – would you be able to help us craft a reply?
We are happy to dispatch the final product from our end, with whatever input you may be able to provide.
Cheers,
Ben

From: Executive Correspondence (PHAC/ASPC) <*executive.correspondence@phac-aspc.gc.ca*>
Sent: Wednesday, May 15, 2024 8:43 AM
To: INFO (PHAC/ASPC) <info@phac-aspc.gc.ca>
Subject: FW: Marc - FW: FOR GUIDANCE FW: PUB-002614- URGENT FW: Reported side effects following COVID-19 vaccination in Canada REPORTS

From: MHPD / DPSC (HC/SC) <mhpd-dpsc@hc-sc.gc.ca>
Sent: Wednesday, May 15, 2024 7:25 AM
To: Executive Correspondence (PHAC/ASPC) <executive.correspondence@phac-aspc.gc.ca>
Subject: FW: Marc - FW: FOR GUIDANCE FW: PUB-002614- URGENT FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Hello PHAC,
For Direct reply. Please bcc this account on your response.
Thank you,
Marc Lapointe
Director General's Office
Marketed Health Products Directorate

From: Thin, Sophea (HC/SC) <sophea.thin@hc-sc.gc.ca>
Sent: Monday, May 6, 2024 10:20 AM
To: Lapointe, Marc (HC/SC) <marc.lapointe@hc-sc.gc.ca>
Cc: MHPD / DPSC (HC/SC) <mhpd-dpsc@hc-sc.gc.ca>; Leblanc, Vanessa (HC/SC) <vanessa.leblanc@hc-sc.gc.ca>; Gasinzigwa, Sarah (HC/SC) <sarah.gasinzigwa@hc-sc.gc.ca>
Subject: Marc - FW: FOR GUIDANCE FW: PUB-002614- URGENT FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Hi Marc,
For your action as MHPD generic account coordinator.
Many thanks, Sophea.

From: Gasinzigwa, Sarah (HC/SC) <sarah.gasinzigwa@hc-sc.gc.ca>
Sent: Monday, May 6, 2024 10:15 AM
To: Thin, Sophea (HC/SC) <sophea.thin@hc-sc.gc.ca>
Cc: Matar, Nour (HC/SC) <nour.matar@hc-sc.gc.ca>; Giannios, Spiros (HC/SC) <Spiros.Giannios@hc-sc.gc.ca>; MHPD / DPSC (HC/SC) <mhpd-dpsc@hc-sc.gc.ca>
Subject: FW: FOR GUIDANCE FW: PUB-002614- URGENT FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Good morning Sophea,
Would you be able to help with this request for DGO to redirect the inquiry below to PHAC with a cc to InfoHC? CV will be able to close this correspondence once this is done.
Thanks,
Sarah

Sarah Gasinzigwa
(she | elle)
Senior Regulatory Affairs Officer
Health Products Surveillance and Epidemiology Bureau (HPSEB)
Marketed Health Products Directorate (MHPD) - Health Canada
sarah.gasinzigwa@hc-sc.gc.ca / Tel: 613-558-3570
Agente principale aux affaires règlementaires
Bureau de la surveillance des produits de santé et de l'épidémiologie (BSPSE)

Direction des produits de santé commercialisés (DPSC) - Santé Canada
sarah.gasinzigwa@hc-sc.gc.ca / Tél. : 613-558-3570

From: Giannios, Spiros (HC/SC) <Spiros.Giannios@hc-sc.gc.ca>
Sent: Monday, May 6, 2024 10:02 AM
To: Gasinzigwa, Sarah (HC/SC) <sarah.gasinzigwa@hc-sc.gc.ca>
Subject: FOR GUIDANCE FW: PUB-002614- URGENT FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Hi Sarah,
I'm bringing this correspondence to your attention because I have sent DGO 2 reminders for them to redirect this inquiry to PHAC and confirm back with CV when it was sent out. Is there any other way to have this redirected to PHAC in a timely manner?
Thank you!
Spiros

From: Giannios, Spiros (HC/SC)
Sent: Friday, May 3, 2024 3:15 PM
To: Matar, Nour (HC/SC) <nour.matar@hc-sc.gc.ca>
Subject: FW: URGENT FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Hi Nour,
This correspondence needs to be redirected to PHAC (it is tracked as PUB-002614 and is backlogged for the time being).
Thank you!
Spiros

From: Giannios, Spiros (HC/SC)
Sent: Friday, April 26, 2024 2:24 PM
To: MHPD / DPSC (HC/SC) <mhpd-dpsc@hc-sc.gc.ca>
Subject: URGENT FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Hi DGO,
This is a second reminder from 2 weeks ago to please confirm redirection of the initial inquiry to PHAC with Info HC as CC so that CV can close the case on our end.
Thank you,
Spiros

From: Giannios, Spiros (HC/SC)
Sent: Friday, April 19, 2024 2:31 PM
To: MHPD / DPSC (HC/SC) <mhpd-dpsc@hc-sc.gc.ca>
Subject: FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Hi DGO,
A friendly reminder to please confirm the redirection of this inquiry to PHAC.
Thank you,
Spiros

From: Giannios, Spiros (HC/SC)
Sent: Thursday, April 11, 2024 11:34 AM
To: MHPD / DPSC (HC/SC) <mhpd-dpsc@hc-sc.gc.ca>
Subject: FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Hi DGO,
Can you please confirm once this inquiry has been redirected to PHAC?
Thanks again,
Spiros

From: Giannios, Spiros (HC/SC)
Sent: Thursday, April 11, 2024 9:38 AM
To: MHPD / DPSC (HC/SC) <mhpd-dpsc@hc-sc.gc.ca>
Cc: Gasinzigwa, Sarah (HC/SC) <sarah.gasinzigwa@hc-sc.gc.ca>; Info (HC/SC) <info@hc-sc.gc.ca>
Subject: FW: Reported side effects following COVID-19 vaccination in Canada REPORTS
Hi DGO,
Could you please redirect this inquiry to the Public Health Agency of Canada (PHAC)?
Thank you,
Spiros

From: Gasinzigwa, Sarah (HC/SC) <sarah.gasinzigwa@hc-sc.gc.ca>
Sent: Thursday, April 11, 2024 9:13 AM
To: Raymond, Joel (HC/SC) <joel.raymond@hc-sc.gc.ca>; Giannios, Spiros (HC/SC) <Spiros.Giannios@hc-sc.gc.ca>
Subject: RE: PUB-002614-Reported side effects following COVID-19 vaccination in Canada REPORTS
Thanks Joël!
@Giannios, Spiros (HC/SC), this means you don't need to draft a response for this, and PUB-002614 can be marked as closed in the tracking sheet once this inquiry has been redirected to PHAC with Info HC in copy.
Thank you,
Sarah

From: Raymond, Joel (HC/SC) <joel.raymond@hc-sc.gc.ca>
Sent: Thursday, April 11, 2024 9:07 AM
To: Gasinzigwa, Sarah (HC/SC) <sarah.gasinzigwa@hc-sc.gc.ca>; Giannios, Spiros (HC/SC) <Spiros.Giannios@hc-sc.gc.ca>
Subject: RE: PUB-002614-Reported side effects following COVID-19 vaccination in Canada REPORTS
Hi Sarah,

I agree with your proposal, no need to respond to inquirer, should be PHAC
Thank you both
Joël

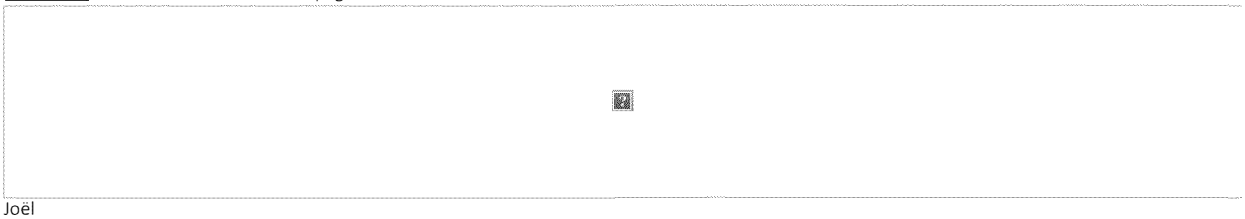
From: Gasinzigwa, Sarah (HC/SC) <sarah.gasinzigwa@hc-sc.gc.ca>
Sent: Wednesday, April 10, 2024 1:42 PM
To: Giannios, Spiros (HC/SC) <Spiros.Giannios@hc-sc.gc.ca>; Raymond, Joel (HC/SC) <joel.raymond@hc-sc.gc.ca>
Subject: RE: PUB-002614-Reported side effects following COVID-19 vaccination in Canada REPORTS
No problem Spiros and thank you Joël! @Raymond, Joel (HC/SC), could you let me know what you think about my comment in red?
We will:

1. Redirect to PHAC for direct response with InfoHC in copy, and
2. Prepare a response informing the inquirer that their email was redirected to PHAC and providing them with PHAC's contact info for follow-up. Alternatively, I suggest not responding to the inquirer and simply redirecting this question internally to PHAC with InfoHC in copy (step 1 above). I say this because the inquirer has already received a notice of redirection from InfoHC where they were told that their inquiry was being redirected to the "appropriate" area. So, sending a second notice of redirection from CV saying we are also redirecting to the appropriate area may come off a bit unorganized. Given that CV was not mentioned or copied in InfoHC's email, I don't believe that there's a need for CV to respond. Let us know!

Thanks!
Sarah

From: Giannios, Spiros (HC/SC) <Spiros.Giannios@hc-sc.gc.ca>
Sent: Wednesday, April 10, 2024 1:38 PM
To: Raymond, Joel (HC/SC) <joel.raymond@hc-sc.gc.ca>; Gasinzigwa, Sarah (HC/SC) <sarah.gasinzigwa@hc-sc.gc.ca>
Subject: RE: PUB-002614-Reported side effects following COVID-19 vaccination in Canada REPORTS
Hi Joël and Sarah,
Thank you for clarifying.
Spiros

From: Raymond, Joel (HC/SC) <joel.raymond@hc-sc.gc.ca>
Sent: Wednesday, April 10, 2024 12:27 PM
To: Gasinzigwa, Sarah (HC/SC) <sarah.gasinzigwa@hc-sc.gc.ca>; Giannios, Spiros (HC/SC) <Spiros.Giannios@hc-sc.gc.ca>
Subject: RE: PUB-002614-Reported side effects following COVID-19 vaccination in Canada REPORTS
Hi Sarah, Spiros: This page indeed belongs to PHAC, therefore they should be answering, not us. I have sent feedback on the website to ask that they indicate who is responsible for this page so that Canadians with questions may contact them. I also got a survey pop up asking me what I thought of PHAC's webpage (see snapshot below), so it's definitely theirs, not HC's. I found a contact form for them Contact the Public Health Agency of Canada - Canada.ca, there's also a 1800# on the page Toll-free: 1-844-280-5020



Joël

From: Gasinzigwa, Sarah (HC/SC) <sarah.gasinzigwa@hc-sc.gc.ca>
Sent: Wednesday, April 10, 2024 10:57 AM
To: Giannios, Spiros (HC/SC) <Spiros.Giannios@hc-sc.gc.ca>; Raymond, Joel (HC/SC) <joel.raymond@hc-sc.gc.ca>
Subject: RE: PUB-002614-Reported side effects following COVID-19 vaccination in Canada REPORTS
Hi Spiros,
No, I don't know. I'm guessing the inquirer is asking about this online report, last updated January 19, 2024: https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html. Some archived standard lines we have say that this page is updated on a monthly basis.
@Raymond, Joel (HC/SC), is HPSEB responsible for the maintenance of this webpage? The suggested citation refers to PHAC, so perhaps this should be redirected to them for response?



Thanks,
Sarah

From: Giannios, Spiros (HC/SC) <Spiros.Giannios@hc-sc.gc.ca>
Sent: Wednesday, April 10, 2024 10:43 AM
To: Gasinzigwa, Sarah (HC/SC) <sarah.gasinzigwa@hc-sc.gc.ca>
Subject: FW: PUB-002614-Reported side effects following COVID-19 vaccination in Canada REPORTS
Hi Sarah,
Do you know when the next update will take place for the Reported side effects following COVID-19 vaccination in Canada report?
Thanks,
Spiros

From: Canada Vigilance (HC/SC) <canadavigilance@hc-sc.gc.ca>
Sent: Wednesday, April 10, 2024 9:54 AM
To: Giannios, Spiros (HC/SC) <Spiros.Giannios@hc-sc.gc.ca>

ATIA - 19(1)

Subject: FW: PUB-002614-Reported side effects following COVID-19 vaccination in Canada REPORTS
Hi Spiros,
This correspondence is assigned to you.
\\Ncr-a-irby1s\irby1\HC\HPFB\MHPD\MHPSEIB-PROS\COMMUNICATIONS GC2\ENQUIRIES\Correspondence\Public\2024\PUB-002614-[redacted]
I can't edit the link in the email.
Thanks
Chirine

-----Original Message-----
From: Info (HC/SC) <info@hc-sc.gc.ca>
Sent: Wednesday, April 10, 2024 8:37 AM
To: [redacted]
Subject: RE: Reported side effects following COVID-19 vaccination in Canada REPORTS
Thank you for contacting Health Canada.
Your recent enquiry has been redirected to the appropriate area for a response.
Sincerely,
Health Canada | Santé Canada
Ottawa, Canada K1A 0K9
info@hc-sc.gc.ca
Telephone | Téléphone 613-957-2991 / Toll free | Sans frais 1 866-225-0709 / Facsimile | Télécopieur 613-941-5366 / Teletypewriter | Téléimprimeur 1 800-267-1245 Government of Canada | Gouvernement du Canada
-----Original Message-----
From: [redacted]
Sent: Tuesday, April 9, 2024 6:56 AM
To: hcinfo.infosc@canada.ca
Subject: Reported side effects following COVID-19 vaccination in Canada REPORTS
Warning: This message is from an EXTERNAL SENDER - be CAUTIOUS, particularly with links and attachments.
Attention: Ce message provient d'un EXPÉDITEUR EXTERNE - soyez PRUDENT, en particulier avec les liens et les pièces jointes.
Dear Health Canada,
When will the next update take place for the Reported side effects following COVID-19 vaccination in Canada REPORT?
Regards
[redacted]
Sent from my iPad

Levesque-Dupere, Mathieu (HC/SC)

De: Wu, Karen (HC/SC)
Envoyé: 2024-03-05 10:45
À: Weeks, Ashley (PHAC/ASPC); Data and Dashboards-Données et tableaux de bords (HC/SC); Manhire, Sheila (HC/SC)
Cc: Panic, Mirna (PHAC/ASPC); Joanette, Quenby (HC/SC); Friesen, Andrea (HC/SC); Crain, Jennifer (PHAC/ASPC); Millingen, Scott Van (PHAC/ASPC); infobase (PHAC/ASPC); El Jaouhari, Maryem (PHAC/ASPC); Pader, Joy (PHAC/ASPC)
Objet: RE: Online reporting for vaccine safety surveillance

Hi Ashley,

All is well here. Hope you're having a good week so far too! 😊

Thank you for the helpful context. It's good information to have. Cc'ing @Manhire, Sheila (HC/SC) for her awareness too.

Have a lovely day,

Karen Wu
(she/her, elle)

A/ Senior Digital Communications Advisor, Data and Dashboards
Communications and Public Affairs Branch
Chat with me on Teams | 343-542-4526

Conseillère principale en communications numériques p.i., Données et tableaux de bord
Direction générale des communications et des affaires publiques
Écrivez-moi sur Teams | 343-542-4526

From: Weeks, Ashley (PHAC/ASPC)
Sent: Monday, March 4, 2024 4:25 PM
To: Data and Dashboards-Données et tableaux de bords (HC/SC) ; Wu, Karen (HC/SC)
Cc: Panic, Mirna (PHAC/ASPC) ; Joanette, Quenby (HC/SC) ; Friesen, Andrea (HC/SC) ; Crain, Jennifer (PHAC/ASPC) ; Millingen, Scott Van (PHAC/ASPC) ; infobase (PHAC/ASPC) ; El Jaouhari, Maryem (PHAC/ASPC) ; Pader, Joy (PHAC/ASPC)
Subject: RE: Online reporting for vaccine safety surveillance

Hi Karen,

Thank you for your email, I hope you're also doing well and having a nice start to the week. We had a few various reasons for discontinuing the report but I believe we've captured most of it below.

Given the transition from pandemic to endemic and the decrease in COVID-19 vaccine uptake, the regular COVID-19 AEFI online report no longer serves its initially conceived purpose of providing regular updates on emerging safety issues for a pandemic vaccine campaign.

The general safety profile of the vaccines is now well characterized, with any new knowledge emerging from other sources e.g. enhanced surveillance or research. Going forward, the online report is less informative on new safety issues given that COVID-19 vaccine uptake has decreased significantly (and therefore identification of rare safety issues would occur over longer timelines).

Additionally:

- Jurisdictions are making changes to their provision of doses administered data, which will highly impact the data quality and required format for the current COVID-19 AEFI report;
- International counterparts with COVID-specific AEFI reporting have discontinued their reports;
- Our collaborators are generally supportive of shifting the reporting of COVID-19 AEFIs into a more routine report (frequency to be determined) with focus on all vaccines due to decreases in their COVID-19-specific resources.

Please let us know if you have any questions!

Thank you,
Ashley

From: Wu, Karen (HC/SC) <karen.wu@hc-sc.gc.ca> **On Behalf Of** Data and Dashboards-Données et tableaux de bords (HC/SC)
Sent: Monday, March 4, 2024 2:00 PM
To: Wu, Karen (HC/SC) <karen.wu@hc-sc.gc.ca>; Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Data and Dashboards-Données et tableaux de bords (HC/SC) <DataDashboards-DonneesTableauxBords@hc-sc.gc.ca>
Cc: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>; Friesen, Andrea (HC/SC) <Andrea.Friesen@hc-sc.gc.ca>; Crain, Jennifer (PHAC/ASPC) <jennifer.crain@phac-aspc.gc.ca>; Millingen, Scott Van (PHAC/ASPC) <Scott.VanMillingen@phac-aspc.gc.ca>; infobase (PHAC/ASPC) <infobase@phac-aspc.gc.ca>
Subject: RE: Online reporting for vaccine safety surveillance

Hi Ashley,

Hope all is well.

Wondering if you could provide context behind the reasoning for the discontinuation of Online COVID-19 Adverse Events Following Immunization (AEFI) Report. Is it because jurisdictions have stopped reporting?

Thank you!

Karen Wu
(she/her, elle)

A/ Senior Digital Communications Advisor, Data and Dashboards
Communications and Public Affairs Branch
Chat with me on Teams | 343-542-4526

Conseillère principale en communications numériques p.i., Données et tableaux de bord
Direction générale des communications et des affaires publiques
Écrivez-moi sur Teams | 343-542-4526

From: Wu, Karen (HC/SC) <karen.wu@hc-sc.gc.ca>
Sent: Friday, March 1, 2024 1:15 PM
To: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>; Data and Dashboards-Données et tableaux de bords (HC/SC) <DataDashboards-DonneesTableauxBords@hc-sc.gc.ca>; Friesen, Andrea (HC/SC) <Andrea.Friesen@hc-sc.gc.ca>
Cc: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>; Joanette, Quenby (HC/SC) <quenby.joanette@hc-sc.gc.ca>
Subject: RE: Online reporting for vaccine safety surveillance

Hi Ashley,

First – congrats on the acting and welcome Mirna!

If you could set up a meeting, that'd be great. I'm adding Quenby to be part of the conversations.

Look forward to it!

Karen Wu
(she/her, elle)

A/ Senior Digital Communications Advisor, Data and Dashboards
Communications and Public Affairs Branch
Chat with me on Teams | 343-542-4526

Conseillère principale en communications numériques p.i., Données et tableaux de bord
Direction générale des communications et des affaires publiques
Écrivez-moi sur Teams | 343-542-4526

From: Weeks, Ashley (PHAC/ASPC) <ashley.weeks@phac-aspc.gc.ca>
Sent: Friday, March 1, 2024 12:18 PM
To: Data and Dashboards-Données et tableaux de bords (HC/SC) <DataDashboards-DonneesTableauxBords@hc-sc.gc.ca>; Friesen, Andrea (HC/SC) <Andrea.Friesen@hc-sc.gc.ca>; Wu, Karen (HC/SC) <karen.wu@hc-sc.gc.ca>
Cc: Panic, Mirna (PHAC/ASPC) <mirna.panic@phac-aspc.gc.ca>
Subject: Online reporting for vaccine safety surveillance

Good afternoon Digital Communications team,

Given our recent discontinuation of the Online COVID-19 Adverse Events Following Immunization (AEFI) Report, we are in the process of developing a plan for longer-term public reporting of vaccine adverse events in Canada. We would like to meet with your group to discuss the web format options that exist (e.g. Infobase, dynamic dashboard, hard-coded HTML webpage, etc.) and the inherent limitations and processes associated with each of these options.

I'm happy to set up a meeting in the next week or two, and if you think of any examples or resources to help inform our online report options, please feel free to share them with us for consideration.

Lastly, I am delighted to e-introduce you to Mirna Panić, our new section manager. She joined our team a couple of weeks ago and is going to help us move our strategic planning forward this year.

Thank you and we're looking forward to hearing your expertise!

Best,
Ashley

Ashley Weeks (she / elle)

Acting Senior Epidemiologist | Épidémiologiste principale
Vaccine Safety Surveillance Division | Division de Surveillance de la Sécurité des vaccins
Centre for Immunization Surveillance | Centre de Surveillance de l'immunisation
Infectious Diseases and Vaccination Programs Branch (IDVPB) |Direction générale des programmes sur les maladies infectieuses et de la vaccination (DGPMIV)
Public Health Agency of Canada | Agence de la santé publique du Canada
ashley.weeks@phac-aspc.gc.ca | +1-613-286-1328