Reporting Adverse Events Following Immunization (AEFI) in Canada

USER GUIDE TO COMPLETION AND SUBMISSION OF THE **AEFI** REPORTS

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

Canada

TO PROMOTE AND PROTECT THE HEALTH OF CANADIANS THROUGH LEADERSHIP, PARTNERSHIP, INNOVATION AND ACTION IN PUBLIC HEALTH.

— Public Health Agency of Canada

This guide was developed by the **Vaccine Vigilance Working Group** and the **Public Health Agency of Canada**

Également disponible en français sous le titre :
Déclaration de manifestations cliniques inhabituelles (MCI) à la suite de l'immunisation au Canada

To obtain additional information, please contact:

Public Health Agency of Canada
Address Locator 0900C2 Ottawa,
ON K1A 0K9
E-mail: aefi-essi@phac-aspc.gc.ca

Publication date: February 2025

CAT# HP40-249/2025E-PDF
ISBN# 978-0-660-74044-7
PUB# 240580

Table of Contents

ACKNOWLEDGEMENTS

This adverse events following immunization (AEFI) user guide was developed by the Vaccine Vigilance Working Group (VVWG), with the support of the Vaccine Safety Surveillance Division within the Public Health Agency of Canada (PHAC).

The VVWG is comprised of federal/provincial/territorial (F/P/T) partners across Canada. The working group involves key representatives from all provinces and territories, alongside federal liaison members which include Health Canada's (HC) regulators [(Biologic and Radiopharmaceutical Drugs Directorate (BRDD), and the Marketed Health Products Directorate (MHPD)], the First Nations and Inuit Health Branch (FNIHB) of Indigenous Services Canada (ISC), Correctional Service Canada (CSC), the Department of National Defence (DND), the Royal Canadian Mounted Police (RCMP), the Canadian National Vaccine Safety Network (CANVAS), and the lead for the active pediatric hospital surveillance network funded by the Public Health Agency of Canada. The VVWG reports to the Canadian Immunization Committee (CIC).

The VVWG was created in keeping with the National Immunization Strategy (NIS), which highlighted the significance of strengthening and expanding vaccine safety surveillance activities and improving the system of public health response within Canada. The working group reports to the Canadian Immunization Committee and it functions as a long-term task group that facilitates the development of guidelines, standards, protocols and best practices to improve F/P/T public health post-market vaccine safety surveillance in Canada.

In 2004, as part of the effort to further improve and harmonize the reporting of AEFIs in Canada, VVWG took on the task of revising the national AEFI reporting form. The working group developed this user guide as a technical reference to provide assistance on accurate completion of the new national AEFI reporting form.

The VVWG representatives and the liaison members from the following jurisdictions and organizations contributed to the development of this user guide:

Alberta	Liaison members:
British Columbia	BRDD – HC
Manitoba	MHPD – HC
New Brunswick	FNIHB – ISC
Newfoundland and Labrador	CSC
Northwest Territories	DND
Nova Scotia	RCMP
Nunavut	CANVAS
Ontario	Lead for the active pediatric hospital surveillance network
Prince Edward Island	PHAC – Vaccine Safety Surveillance Division
Quebec	
Saskatchewan	
Yukon	

ACRONYMS AND ABBREVIATIONS

AEFI	Adverse Events Following Immunization
BRDD	Biologic and Radiopharmaceutical Drugs Directorate
BCCD	Brighton Collaboration Case Definition
CAEFISS	Canadian Adverse Events Following Immunization Surveillance System
CANVAS	Canadian National Vaccine Safety Network
CIC	Canadian Immunization Committee
CIG	Canadian Immunization Guide
CISSS	Centre intégré de santé et de services sociaux
CIUSSS	Centre intégré universitaires de santé et de services sociaux
CSC	Correctional Service Canada
CVP	Canada Vigilance Program
DND	Department of National Defence
F/P/T	Federal, provincial and territorial
FNIHB	First Nations and Inuit Health Branch
HC	Health Canada
ICH	International Conference on Harmonization
LCDC	Laboratory Centre for Disease Control
MedDRA	Medical Dictionary for Regulatory Activities
MHPD	Marketed Health Products Directorate
NACI	National Advisory Committee on Immunization
NIS	National Immunization Strategy
P/T	Province and Territory
PHAC	Public Health Agency of Canada
RCMP	Royal Canadian Mounted Police
SAP	Special Access Program
VVWG	Vaccine Vigilance Working Group
WHO	World Health Organization

A} BACKGROUND

When did National Vaccine Post Marketing Surveillance begin in Canada?

National monitoring of adverse events dates back to the 1960s when it was the responsibility of the Laboratory Centre for Disease Control (LCDC) for vaccines as well as for drugs. LCDC's responsibility was limited to human preventive vaccines in 1987. That same year, a computerized database was created to collate adverse event reports from all sources. The current Canadian Adverse Event Following Immunization Surveillance System (CAEFISS) is managed by the Vaccine Safety Surveillance Division of the Public Health Agency of Canada (PHAC).

What is an Adverse Event Following Immunization (AEFI)?

An AEFI is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

Learn more about AEFIs:

World Health Organization. *Global manual on surveillance of adverse events following immunization, 2016 update*. https://iris.who.int/handle/10665/206144

Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO). *Definition and Application of Terms for Vaccine Pharmacovigilance*. Report of CIOMS/WHO Working group on Vaccine Pharmacovigilance. Geneva: CIOMS and WHO; 2012 [cited 2018 Aug 23]. https://cioms.ch/wp-content/uploads/2017/01/report_working_group_on_vaccine_LR.pdf

How is vaccine safety monitored in Canada?

Vaccine safety assessment and monitoring is a continuum that spans all phases of the vaccine product's 'life cycle' from discovery through market authorization and beyond. The Federal government (HC regulators and PHAC) and other stakeholders including the F/P/T public health authorities, vaccine industry, health professionals and consumers are involved and contribute at various levels to the safety monitoring of vaccines marketed in Canada. For additional information regarding vaccine safety monitoring in Canada, please refer to the Canadian Immunization Guide: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-2-vaccine-safety/page-2-vaccine-safety.html

HC and PHAC share the monitoring of the quality, safety and effectiveness of vaccines marketed in Canada. The Canada Vigilance Program (CVP) managed by HC receives serious AEFI reports from manufacturers, Canadian hospitals, healthcare professionals and consumers. Similarly, CAEFISS, managed by PHAC, receives AEFI reports from all P/T public health authorities and from federal departments including Department of National Defence, Correctional Service Canada, Indigenous Services Canada and Royal Canadian Mounted Police. CAEFISS includes both passive surveillance (spontaneous reports from F/P/Ts) and active vaccine safety surveillance in pediatric hospitals.

Both HC and PHAC regularly review AEFI reports submitted to their respective databases and monitor scientific literature, activities of other regulatory agencies, as well as the World Health Organization Global Advisory Committee on Vaccine Safety (WHO GACVS). In addition, HC routinely receives and reviews Periodic Safety Update Reports (PSURs)/Periodic Benefit-Risk Evaluation Reports (PBRERs), Risk Management Plans (RMPs) and other safety assessments for vaccines submitted by manufacturers. Potential safety signals arising from any of the above sources are assessed collaboratively by HC and PHAC. The source of the identified safety signal determines the lead investigating agency. HC generally leads on signals arising from the review of AEFIs from the CVP, PBRERs, the literature, and international regulatory sources, while PHAC leads on signals arising from CAEFISS, the provincial network of vaccine safety focal

points forming the Vaccine Vigilance Working Group (VVWG) and the Public Health Network and its committees. HC and PHAC will take appropriate action if any new public health risks are identified.

Should all AEFIs be reported?

No. During their development, vaccines undergo rigorous testing for safety, quality and efficacy. During these "pre-licensure trials" efforts are made to capture every single adverse event that follows immunization. By the time a vaccine is authorized for marketing, the safety profile for common adverse events such as vaccination site reactions or mild fever is well known. It is always important to counsel vaccinees or their guardians regarding the possible occurrence of such reactions, but there is no need to report such expected events unless they are more severe or more frequent than expected.

What type of AEFI should be reported?

AEFIs should be reported when the event:

- **Has a temporal association with a vaccine** (i.e., occurs following receipt of vaccine)**;**

  AND

- **Has no other clear cause at the time of reporting:** A causal relationship between immunization and the event that follows does not need to be proven and submitting a report does not imply or establish causality. Sometimes the vaccinee's medical history, recent disease, concurrent illness/condition and/or concomitant medication(s) can explain the event(s).

Of particular interest are those AEFIs which:

- **Meet one or more of the seriousness criteria:** An adverse event that results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/ incapacity, or is a congenital anomaly/birth defect should be considered serious. Any medical event that requires intervention to prevent one of the outcomes above may also be considered as serious. For additional information regarding serious events, please refer to the WHO Global Manual on Surveillance of Adverse Events Following Immunization (2016 update): https://www.who.int/publications/i/item/9789241507769.
- **Are unexpected regardless of seriousness:** An adverse event whose nature, severity, or outcome is not consistent with the term or description used in the local/regional product labeling (e.g., Package Insert or Summary of Product Characteristics), or any adverse event that was previously observed but is occurring more frequently, should be considered unexpected. For additional information regarding unexpected events, please refer to the ICH Harmonised Tripartite Guideline (E2D 2003): https://database.ich.org/sites/default/files/E2D_Guideline.pdf.

The timeline between vaccination and occurrence of an AEFI is very important as it aids in the assessment of the temporal association. AEFIs which occur outside of these timelines can still be submitted at the reporter's clinical discretion as this may indicate a possible safety signal. For guidance on assessing onset timelines for selected AEFIs, refer to the VVWG Resource Document: Temporal criteria for selected AEFIs table, Annex 4. If there is any doubt as to whether or not an event should be reported, a conservative approach should be taken and the event should be reported.

Who reports AEFIs?

AEFI reports originate from multiple sources in Canada. Most of the P/Ts have now enacted mandatory AEFI reporting requirements. However, overall, reports are generally submitted on a voluntary basis by health care professionals.

The usual and preferred reporting flow of AEFI reports to CAEFISS is from local or regional health units to central P/T immunization programs. Reports are forwarded to PHAC electronically, or in hard copy by the P/Ts after all personal identifying information has been removed. On occasion, reports may be submitted

directly to PHAC by travel health clinics, pharmacists, physicians or the public. These reports are entered into the national database and a copy and/or the reporter's information are redirected to the P/T health authorities of the reporter through the Vaccine Vigilance Working Group (VVWG) representative.

To enhance timely detection and assessment of serious adverse events following immunization involving children, PHAC funds the conduct of active vaccine safety surveillance in pediatric hospitals in Canada: Immunization Monitoring Program ACTive (IMPACT) from 1991 to 2023, and Surveillance Program for Rapid Identification and Tracking of Infectious Diseases in Kids (SPRINT-KIDS) from 2023 to present. The current active pediatric hospital surveillance network includes the participation of 15 pediatric hospitals across Canada. The 15 hospitals identify cases and collate them into the surveillance network's database. The information from this database is submitted to PHAC on a regular basis, ensuring timely identification of serious adverse events. When an AEFI report is generated from one of these hospitals, the same report is sent to public health at the P/T or local public health unit level depending on the standard practice for a given jurisdiction. As each report has a unique Pediatric Surveillance Reference Number, it is only entered once into CAEFISS. Special numbering of reports is done to avoid duplication.

CVP on the other hand receives serious AEFI reports, from the market authorization holders (i.e., the sponsors or manufacturers that have the legal authority to market their drug including vaccine in Canada), health care professionals and consumers as mandated by the *Food and Drugs Act and Regulations*. In addition, as of December 2019, the hospitals are required to report all serious adverse drug reactions according to the *Food and Drug Regulations for adverse drug reactions* requirements. The mandatory reporting requirements for hospitals excludes serious adverse reactions to vaccines administered under a routine immunization program of a P/T to CVP.

The information collected enables both HC and PHAC to monitor the safety profile of vaccines to determine if their benefits continue to outweigh their risks in accordance with the requirements of the *Food and Drugs Act and Regulations.*

What is done with AEFI reports at the provincial/territorial level?

AEFI reports are received at the local/regional level from multiple sources: physicians, nurses, pharmacists, public health, the active pediatric hospital surveillance network, and the public. Recommendations for future immunizations are usually made at the local/regional level. In P/Ts with electronic systems, the data are entered at the local health unit or regional health authority level and are then shared with the P/T. The AEFI data are analyzed and disseminated at the P/T level to their stakeholders. Data are then sent electronically to PHAC.

Of Note: For health products and vaccines that are co-administered during routine vaccination, but which are not monitored by CAEFISS, P/Ts are responsible for reporting adverse events to these products to the correct Health Canada program (where applicable). Reports of adverse events are only collated in CAEFISS if they contain at least one vaccine which is approved in Canada, is part of P/T vaccination schedules (children, adult, travel) and is not distributed through Health Canada's Special Access Program. Reports that do not contain at least one vaccine meeting these criteria should not be forwarded to PHAC. Please see the following instructions for reports that do not meet these criteria:

- If the product reported in the AEFI report is a not a vaccine (e.g., monoclonal antibodies, Botox, immunoglobulins, or diagnostic tests), the information regarding the adverse event should be sent to Health Canada's Canada Vigilance Program (CVP). For additional information please refer to Canada Vigilance Program: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/canada-vigilance-program.html
- If the AEFI report is for a vaccine distributed through Health Canada's Special Access Program (SAP), the information regarding the adverse event should be sent to the SAP. For additional information please refer to Special Access Program: https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs.html

- If the AEFI report is for a vaccine not approved in Canada, the report should be retained at the P/T level.

Examples of products and vaccines for which adverse events should be reported to either SAP or CVP can be found in the table below. Please note that this list is not exhaustive.

Table 1. Examples of products and vaccines monitored by Health Canada Programs.

Product Category	Trade Name	Health Canada Program
Vaccines	FSME-IMMUN (Tick-borne encephalitis vaccine), BCG (Bacillus Calmette–Guérin vaccine)	SAP
Monoclonal antibodies	Palivizumab, Nirsevimab	CVP
Immunoglobulins	HyperHEP, KamRAB, VARIZIG, HyperTET, Cytogam	
Diagnostic test	Tubersol	
Other products	Botox	

What is done with AEFI reports at the national level?

Personnel in the Vaccine Safety Surveillance Division screen all submitted reports, ensure they are entered into the CAEFISS and coded using the international standard Medical Dictionary for Regulatory Activities (MedDRA). Reports are monitored with special attention to serious or unusual events that could signal a concern regarding vaccine safety. Analyses are done regularly to search for vaccine safety signals.

Similarly, personnel from HC process and review serious AEFI reports submitted to CVP. Both HC and PHAC regularly publish vaccine safety summaries and reports received by their respective surveillance systems.

In addition, on a monthly basis HC and PHAC meet through the Vaccine Safety Review Working Group (VSR WG). The working group provides a (horizontal) linkage/forum between the two departments to enable regular sharing of information pertaining to vaccine quality, safety and effectiveness issues as well as timely identification and review of vaccine safety concerns when they arise.

When, why and how was a national AEFI reporting form first developed?

Critical groundwork for the current CAEFISS system was done at the Post Marketing Surveillance of Vaccine Associated Adverse Events workshop in 1990, sponsored by Health Canada's Bureau of Communicable Disease (CDWR 1991; Vol. 17–19:97–98) and attended by F/P/T stakeholders as well as vaccine manufacturers, key non-governmental organizations and expert scientific advisors. The purpose of the workshop was to develop a framework for a coordinated approach to optimize vaccine post marketing surveillance in Canada. At the workshop, post marketing surveillance for vaccines was defined as the coordinated, structured, systematic, ongoing collection of data and their subsequent epidemiologic analysis and dissemination. It was recommended that passive surveillance be centrally aggregated with input by public health and physicians and supplemented by active surveillance activities.

The first national vaccine adverse event reporting form was developed through an F/P/T collaborative process during the year following the 1990 workshop. It was agreed that the form would list several adverse events considered to be of public health importance. Reporters could then check off the specific event and add written detail. An "other" option was also added, so that any adverse event of concern to a reporter could be reported. It was agreed that all P/T AEFI reporting forms would be based on the national AEFI reporting form with nothing deleted. However, items could be added if they were of specific interest to a region. Case definitions were also developed, although many simply specified that a physician diagnosis would be required. In 1996, the AEFI reporting form was revised and it is that version which has been in use until now. A series of F/P/T workshops held from 2000– 2002, led to the development of published functional standards, a minimum core data set and updated data definitions for AEFI reporting (CCDR 2002; 28).

Why has the form been revised?

Priorities to improve vaccine safety surveillance in Canada were established during the development of the National Immunization Strategy (NIS). Revisions to the AEFI reporting form were part of efforts to improve voluntary AEFI reporting in Canada based on surveillance priorities. Other updates to the form were to facilitate application of standardized AEFI case definitions developed by the Brighton Collaboration, which is an international voluntary group whose goal is to facilitate the development, evaluation, and dissemination of high quality information about the safety of human vaccines.

How is privacy and confidentiality of information ensured?

Personal health information is confidential. All P/Ts and PHAC take great care to protect personal health information. Health care workers are encouraged to discuss with clients, or the clients' caregiver, the reason for reporting the AEFI and the confidentiality of all collected information. For further information regarding the protection of personal health information you may contact the privacy representatives at your local public health office. Alternatively, the *Privacy Act* can be accessed online at the following address: https://www.laws-lois.justice.gc.ca/eng/acts/P-21/index.html

Where can copies of the AEFI reporting form be obtained?

The form for completion and submission of an AEFI report is published on the PHAC website at:

https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization.html

In addition, the form is available in the Compendium of Pharmaceuticals and Specialties.

B} GUIDELINES ON HOW TO COMPLETE SECTIONS OF THE AEFI REPORTING FORM

Reports of adverse events following immunization should be made on an AEFI Reporting Form. This guide is intended to be used when completing the AEFI Reporting Form for submission to P/T health authorities as well as to PHAC. Its purpose is to provide assistance on how to accurately complete the AEFI Reporting Form. It is not intended to guide treatment. Treatment of all AEFIs should proceed, as appropriate, prior to completing the AEFI Reporting Form. Following the immediate care of the vaccine recipient, the AEFI Reporting Form can be completed with all available information.

Given the variation in practice between each of the provinces and territories, sections of the AEFI Reporting Form may not be applicable to all settings. If in doubt, please contact your local public health unit.

REPORTING FORM FOR ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

Complete each section of the AEFI Reporting Form as follows:

On the top right hand corner of the first page of the AEFI Reporting Form, check one of the boxes to indicate whether the AEFI report being submitted is an "**Initial report**" or a "**Follow up report**". For all follow up reports, provide the "**Unique episode #**" of the initial report.

SECTION 1. PROVINCIAL AND REGIONAL IDENTIFYING INFORMATION

SECTION 1A) UNIQUE EPISODE NUMBER

A unique episode number is a mandatory case identification number and should be assigned to each AEFI report submitted to PHAC. In P/Ts that use electronic reporting systems, this number may be automatically generated by the system. In P/Ts that do not use electronic reporting systems, this number should only be filled in by those persons who are authorized to assign the number at P/T health authorities (e.g., P/T health professionals and/or officials). The unique episode number should be marked on the top of every page of the AEFI Reporting Form as an identifier to link the pages together. If you are not authorized to assign this number, please leave this field blank.

SECTION 1B) REGION NUMBER

A region number that corresponds to a given health unit should be entered for those regions that have one. The region number (the number that corresponds to a given health unit) should be marked on the top of every page of the AEFI Reporting Form as an identifier to link the pages together. This number should only be filled in by those persons who are authorized to assign it and should be left blank if it does not apply to your region.

SECTION 2. PEDIATRIC SURVEILLANCE REFERENCE NUMBER

A pediatric surveillance reference number is automatically assigned by the active pediatric hospital surveillance network's system when an AEFI report is generated from one of their hospitals. The pediatric surveillance reference number should be marked on the top of every page of the AEFI Reporting Form. Please leave this section blank if it does not apply to you (e.g., if you are not a hospital that is part of the active pediatric hospital surveillance network).

Note: The P/Ts should retain the assigned pediatric surveillance reference numbers when forwarding their reports to PHAC as they are required for the data quality assurance process.

SECTION 3. PATIENT IDENTIFICATION

This section is intended to capture patient information for use by regional and/or provincial/territorial health officials. This information is kept confidential and should **NOT** be forwarded to PHAC.

This section should be completed in keeping with provincial/territorial guidelines.

Patient identification information: Provide the patient's first and last name, health number (if applicable), address of usual residence and community including city/town and postal code (with the understanding that this address might be in a different province/territory than where the vaccine was administered or where the AEFI is being reported) and a telephone number (either residential or business or both), where the patient can be reached.

Information source: If the source of the information for the AEFI report is a parent, or another care provider, provide their name and relation to the patient. If required by your jurisdiction, provide contact information (including their full mailing address and phone number where they can be reached) in Section 10, if it is different from the patient's.

SECTION 4. INFORMATION AT TIME OF IMMUNIZATION AND AEFI ONSET

SECTION 4A) AT TIME OF IMMUNIZATION

Provide all information, as described below, in the space provided on the form:

Province/Territory of immunization: Indicate the P/T where the immunization was received. This may be different from the patient's P/T of residence and/or where the AEFI is being reported. If the vaccine was administered outside of Canada, indicate the country in which the vaccine was administered in the space to capture P/T and also comment if it was received at a Canadian operated clinic in that country. Reports of vaccines not approved in Canada should be kept at the P/T level and not forwarded to PHAC.

Date vaccine administered (DVA): Indicate the date and time of vaccine administration, remembering to specify if the vaccine was administrated in the "**am**" or "**pm**" by selecting the appropriate descriptor. If the complete date and time is unknown, please provide as much information as possible (e.g., month and/or year) as this is now a mandatory field in CAEFISS. All dates should be captured in ISO 8601 format: yyyy/mm/dd.

Date of birth: Indicate the patient's date of birth in the space provided. If the complete date is unknown, please provide as much information as possible (e.g., month and/or year). All dates should be captured in ISO 8601 format: yyyy/mm/dd.

Age: Indicate the patient's age at the time of immunization, including the age units. Use days for infants aged less than 1 week; weeks for infants aged less than 1 month; months for infants aged less than 1 year; and years thereafter. If the patient's exact age is unknown, please estimate the patient's age.

Sex at birth: Refers to the patient's sex assigned at birth. Sex is typically assigned based on a person's reproductive system and other physical characteristics (e.g., male or female). Indicate by selecting "**Male**", "**Female**", or "**Other**", if unknown or ambiguous.

Gender: Refers to the patient's personal and/or social identity. Patients should be asked which gender identity they self-identify as. Indicate by entering one of the following categories: "**Woman/Girl**", "**Trans woman**", "**Man/Boy**", "**Trans man**", "**Non-binary**", "**Or please specify this patient's gender**", "**Unknown**", or "**Not asked**". If "**Or please specify this patient's gender**", please specify gender identity using the term given by the patient.

Pregnant at time of immunization: Indicate by selecting the tick box if the patient is/was pregnant at time of immunization.

Gestation age in weeks/days: Indicate in weeks/days how far along the pregnancy is/was at time of immunization.

Breastfeeding at time of immunization: Indicate by selecting the tick box if the patient was breastfeeding a child at the time of immunization.

Race: We know that people of different races do not have significantly different genetics, but our race still has important consequences, including how we are treated by different individuals and institutions. The collection of standardized race-based data, such as that included on the AEFI Reporting Form can help uncover inequalities and identify opportunities for health care quality improvement. The primary purpose of measuring race-based health inequalities is to identify, monitor and address inequities that potentially stem from bias and racism — including at systemic, interpersonal and internal levels. Patients should be asked to identify which race category (or categories) best describes themselves. Indicate by entering one or more of the following categories: "**Black**", "**East/Southeast Asian**", "**Indigenous**", "**Latino**", "**Middle Eastern**", "**South Asian**", "**White**", "**Another race category**", "**Prefer not to answer**", "**Do not know**", or "**Not asked**". If "**Another race category**", please specify. Note that the option "**Indigenous**" refers to Indigenous origin outside of Canada.

Indigenous status: Refers to whether the patient identifies with the Indigenous peoples of Canada. Patients should be asked which Indigenous identity they self-identify as. Indicate by entering one or more of the following categories: "**First Nations**", "**Métis**", "**Inuk/Inuit**", "**Other Indigenous**", "**Prefer not to answer**", or "**Not asked**". If "**Other Indigenous**", please specify.

SECTION 4B) VACCINES

Provide all information pertaining to the immunizing agent(s) administered on the "date vaccine administered" in Section 4a. There is space to record six (6) immunizing agents in Section 4b; however, if more than six (6) were administered simultaneously, record the additional vaccines in Section 10.

When completing Section 4b, provide all information as outlined below:

Immunizing agent(s): Record the proper name or accepted abbreviation as outlined in Annex 2 for all immunizing agents on separate lines. If the immunizing agent is not listed in Annex 2, record the name of the immunizing agent as accurately as possible, and ensure to specify the trade name and manufacturer for the vaccine in the proceeding columns.

Trade name: Specify the trade name of each vaccine administered.

Manufacturer: Specify the name of the Market Authorization Holder, as indicated on the product label, for each vaccine administered.

Lot number: Document the complete lot number, including all letters and numbers, for each vaccine administered. This information is essential for conducting signal detection or future risk assessments.

Expiry date: Indicate the expiration date for each vaccine administered. All dates should be captured in ISO 8601 format: yyyy/mm/dd.

Dose number: Provide the dose number in the series (1, 2, 3, 4, 5, etc. or booster) for each vaccine administered. For the Influenza vaccine, unless a patient receives two doses in one season, the "**Dose #**"

should be recorded as “1”.

Dosage/unit: Indicate the dose strength (e.g., 0.5) and unit (e.g., mL) for each vaccine administered.

Route: Specify the route of administration for each vaccine administered. Abbreviations (as described below) are acceptable:

- **Intradermal:** ID
- **Intramuscular:** IM
- **Subcutaneous:** SC
- **Intranasal:** IN
- **Oral:** PO
- **Other:** please specify (no abbreviations)

Site: Indicate the site of injection for each vaccine administered. Abbreviations (as described below) are acceptable:

- **Left arm:** LA
- **Right arm:** RA
- **Arm:** Arm
- **Left leg:** LL
- **Right leg:** RL
- **Leg:** Leg
- **Left gluteal:** LG
- **Right gluteal:** RG
- **Gluteal:** Glut
- **Mouth:** Mo
- **Nose:** Nose
- **Multiple sites:** MS
- **Other:** please specify (no abbreviations)

SECTION 4C) MEDICAL HISTORY (UP TO THE TIME OF AEFI ONSET)

Indicate the patient’s medical history prior to the time of AEFI onset by checking all that apply from the list provided below. Provide all additional details and descriptions, including medical investigations, dates, and timing prior to time of AEFI onset, when available, in Section 10.

Concomitant medication(s): Provide the name of all medications, including prescription, over the counter and herbal supplements, which the patient had been taking immediately prior to the time of AEFI onset, including those taken only as needed, in Section 10. When available, provide the dose, frequency, route of administration and reason for taking each concomitant medication.

Known medical condition(s): Indicate all known medical conditions that the patient experienced prior to the time of AEFI onset with a corresponding date of onset in Section 10. If an exact date of onset is unknown, please provide the greatest amount of detail that is available (e.g., year of onset). Include any conditions for which the patient is taking a concomitant medication including chronic conditions and those with intermittent symptoms such as migraine headaches.

Allergies and reactions: Indicate all allergies and details of previous anaphylactic reactions that the patient was known to have at the time of AEFI onset, including allergies to vaccinations, medications and/or foods in Section 10. Please provide the greatest amount of detail that is available (e.g., year of onset) and previous reactions.

Acute illness/injury: Indicate if the patient had an acute illness and/or injury immediately prior to the time of AEFI onset and specify a corresponding date of onset in Section 10 if known. If an exact date of onset is unknown, provide the greatest amount of detail that is available (e.g., month and/or year of onset). Include only acute illnesses or injuries, such as animal bites or skin puncture injuries.

Recent immunization history: Indicate any other vaccine(s) received within 30 days prior to the "date vaccine administered" in Section 4a. Indicate the immunizing agent, trade name, manufacturer, lot number, dose number in the series, and date of vaccine administration (DVA) for each immunization (if known). All dates should be captured in ISO 8601 format: yyyy/mm/dd.

SECTION 5. PREVIOUS AEFI

Indicate whether the patient had ever experienced an AEFI following a previous dose of any of the immunizing agents listed in Section 4b. Choose only one of the answers provided in Section 5, as described below:

Yes: The patient had previously received immunization with at least one of the immunizing agents listed in Section 4b and had subsequently experienced an AEFI.

No: The patient had previously received immunization with one or more of the immunizing agents listed in Section 4b and had not experienced a subsequent AEFI.

Unknown: It is unknown if the patient had previously received immunization with any of the immunizing agents listed in Section 4b **and/or**, if an AEFI followed.

Not applicable (no prior doses): The patient had never previously received immunization with any of the immunizing agents listed Section 4b.

If the answer is "**Yes**", the patient had previously experienced an AEFI following a previous dose of one or more of the immunizing agents listed in Section 4b, provide all details of the previous AEFI in Section 10, including the corresponding time to onset and duration, when known. Also, when possible, provide information regarding the severity of the AEFI and if the previous AEFI was less or more severe than the currently reported AEFI.

If there is uncertainty regarding which option to choose, or if there is additional information to provide (e.g., multiple vaccines were administered and not all of the information regarding the patient's past AEFI experience can be captured in Section 5), please provide additional details in Section 10.

SECTION 6. IMMUNIZATION ERRORS

Indicate whether the AEFI has followed an incorrect immunization (an immunization error, program error including cold chain issues, etc.) by choosing "**Yes**", "**No**", or "**Unknown**". If "**Yes**", please indicate all that apply in Section 6 by checking the box next to the situation that most closely reflects the error (as described below) and provide all known details in Section 10.

Vaccine administered at inappropriate site: The vaccine was administered at a site not recommended for its administration (e.g., arm) or higher/lower than recommended.

Inappropriate route of vaccination: The vaccine was administered via a route not recommended for its

administration (e.g., subcutaneous vs. intramuscular).

Inappropriate age at vaccine administration: The vaccine was administered to an individual who was not within the recommended age limits for that specific vaccine.

Wrong vaccine administered: An unintended vaccine was administered.

Other, specify: If an error has occurred that is not accurately reflected in the list of provided errors, please choose "**Other**" and specify in the space provided. Provide all details in Section 10. Examples of other immunization errors include the following:

Expired vaccine used: The vaccine was administered after the expiry date as indicated on the vaccine label by the manufacturer.

Extra dose administered: An extra dose of the vaccine was administered.

Inappropriate dose of vaccine administered: A larger or smaller dose of vaccine was administered than that recommended for the patient's age group.

Inappropriate schedule of vaccine administered: The vaccine administration did not follow an appropriate schedule (e.g., the dose was administered too soon after the previous dose in the series had been administered).

Incorrect product storage: Any excursion from conditions recommended during the transport, storage and handling of vaccines (e.g. the use of a vaccine exposed to light or temperatures outside those recommended for the product; the use of multi-dose vials outside the specified time after initial puncturing or after reconstitution; etc.).

Product preparation error: Any errors in the preparation of vaccines prior to administration. This may include inappropriate processes used for mixing or reconstituting vaccines, and/or the use of an incorrect diluent type or volume.

SECTION 7. IMPACT OF AEFI, OUTCOME, AND LEVEL OF CARE OBTAINED

SECTION 7A) HIGHEST IMPACT OF AEFI

Indicate the highest perceived impact of the AEFI on the patient's daily activities (as assessed by the patient or the parent/caregiver) by choosing one of the provided responses in Section 7a:

Did not interfere with daily activities: No change, or only minimal change is reported by the patient in relation to their daily activities (e.g., work, exercise, social commitments, etc.).

Prevented daily activities: Significant change is reported by the patient in relation to their daily activities (e.g., prevented work, exercise and/or social commitments).

Interfered with but did not prevent daily activities: Moderate change is reported by the patient in relation to their daily activities (e.g., interfered with work, exercise and/or social commitments).

Unknown: The perceived impact of the AEFI on the patient's daily activities is unknown.

For young children (e.g., infants and toddlers), indicate the highest perceived impact of the AEFI on their daily activities as assessed by the child's parent/caregiver according to the following:

Did not interfere with daily activities: No change or only minimal change, is observed in the child's daily patterns and/or habits (e.g., eating, sleeping, playing, etc.).

Prevented daily activities: Significant change is observed in the child's daily patterns and/or habits (e.g., not eating, not sleeping, not playing, etc.).

Interfered with but did not prevent daily activities: Moderate change is observed in the child's daily patterns and/or habits (e.g., reduced appetite, disrupted sleep, disrupted play, etc.).

SECTION 7B) OUTCOME AT TIME OF REPORT

Indicate the outcome of the AEFI at the time of completion of the report by choosing one of the provided responses in Section 7b. If the patient is not yet recovered, provide all available details in Section 10 and provide updates as they become available. Similarly, should the event result in persistent or significant disability and/or incapacity or death, provide all available details in Section 10.

When completing Section 7b, provide the information as outlined below:

Death: Patient died. Record the corresponding date of death in the space provided. All dates should be captured in ISO 8601 format: yyyy/mm/dd.

Persistent or significant disability/incapacity: An injury, which impairs the physical and/or mental ability of a person to perform their normal work or non-occupational activities supposedly in a significant manner or for the remainder of their life.

Congenital anomaly/birth defect: Structural or functional abnormalities of prenatal origin that are present at birth.

Not yet recovered: Residual signs and/or symptoms remain (at the time of the report).

Fully recovered: All signs and symptoms have resolved.

Unknown: The outcome of the AEFI is unknown or unclear.

SECTION 7C) HIGHEST LEVEL OF CARE OBTAINED

Indicate the highest level of care obtained for the reported AEFI by choosing one of the provided options in Section 7c, described in detail below.

None: No care was received for the reported AEFI.

Telephone/virtual consultation with Health Care Provider: The patient had a telephone or virtual consultation with a health care provider (e.g., nurse, nurse practitioner, physician, etc.) regarding the reported AEFI.

Non-urgent visit: The patient was seen by a health care professional (e.g., at a physician's office or walk in clinic) for the assessment and/or treatment of the reported AEFI. Document all investigations conducted and treatments received in Section 10.

Emergency visit (no hospitalization): The patient was seen by a health care professional for an emergency visit for the assessment and/or treatment of the reported AEFI. Please note that emergency visits are not considered admission to hospital and therefore, admission and discharge dates are not required. Document all investigations conducted and treatments received in Section 10.

Unknown: It is unknown if the patient received care for the reported AEFI.

Required hospitalization: The patient was hospitalized for the assessment and/or treatment of the reported AEFI. Indicate the number of days the patient was hospitalized (including days spent in intensive care unit), the date of admission and the date of discharge in the spaces provided. All dates should be captured in ISO 8601 format: yyyy/mm/dd. Document all investigations conducted and treatments received in Section 10.

Resulted in prolongation of existing hospitalization: If the patient was already in hospital at the time of immunization and the AEFI resulted in a longer hospital stay, please check "**Resulted in prolongation of existing hospitalization**" and indicate the number of additional days stayed in hospital as a result of the AEFI. Also indicate the date of hospital admission and discharge for the entire period of hospitalization

(if known) in the spaces provided. All dates should be captured in ISO 8601 format: yyyy/mm/dd. Document all investigations conducted and treatments received in Section 10.

SECTION 7D) TREATMENT RECEIVED

Indicate whether the patient received any treatment, including self-treatment, for the reported AEFI by choosing "**Yes**", "**No**", or "**Unknown**". Provide details of all treatments received, following the onset of the AEFI, in Section 10 when applicable.

SECTION 8. REPORTER INFORMATION

Complete the reporter information section in full including the reporter's first and last names, a phone and fax contact number (including extensions when applicable) and the full mailing address of the institution/setting/centre. Indicate the work setting in which the reporter is located by selecting one of the following: "**Long-term care home**", "**Physician office**", "**Community nursing station**", "**Public health**", "**Pharmacy**", "**School/student clinic**", "**Hospital**", "**Workplace clinic**", "**Local vaccination campaign clinic**", "**CISSS/CIUSSS**", "**CANVAS**", or "**Other, specify**". If "**Other, specify**", specify the setting in the space provided. Sign and date the AEFI Reporting Form in the space provided and specify your professional status or affiliation by selecting one of the following: "**MD: Medical Doctor**", "**RN: Registered Nurse**", "**Active Pediatric Surveillance Hospital**", "**Pharmacist**", "**CANVAS**", or "**Other, specify**". If "**Other, specify**", specify your professional status or affiliation in the space provided. All dates should be captured in ISO 8601 format: yyyy/mm/dd.

SECTION 9. AEFI DETAILS

Indicate the details of the AEFI being reported by checking all that apply. All additional pertinent details, including clinical details, types of treatment, test results, and prior infections with the pathogen(s) being vaccinated against in Section 4b, should be provided in Section 10. For convenience and consistency, high level definitions have been provided for most events listed in Section 9. **However, if an asterisk (‡) is present beside an AEFI term, this specific event should be diagnosed by a physician or nurse practitioner, except in the case of anaphylaxis where objective signs can be reported by any health care practitioner (e.g., nurse, emergency medical technician, etc.).** If not, sufficient information should be provided in Section 10 to support the selection(s). For each AEFI where a Brighton Collaboration Case Definition (BCCD) exists, the most current published version of the case definition has been cited.

Time to onset and duration of signs and symptoms: For all AEFIs, indicate the time to onset (time from immunization to onset of first sign/symptom), and the duration (time from onset of first sign/symptom to resolution of all of signs and symptoms). The time to onset and the duration of the signs and symptoms of the specified AEFI should be documented according to the following guidelines for all AEFIs:

- If the time to onset or the duration is less than one (1) hour, record in minutes (m).
- If the time to onset or the duration is greater than or equal to one (1) hour, but less than one (1) day, record in hours (h).
- If the time to onset or the duration is greater than or equal to one (1) day, record in days (d).

SECTION 9A) LOCAL REACTION AT OR NEAR VACCINATION SITE

Any description of morphological or physiological change at or near the vaccination site (BCCD: Vaccine 26 (2008) 6800–6813).

Indicate, by choosing all that apply, any local reactions at or near the vaccination site, as described below. For the indicated local reaction, please specify the time to onset and duration in the table provided.

Infected abscess: A localized collection of pus in a cavity formed by the disintegration of tissue, usually caused by microorganisms that invade the tissues (BCCD: Vaccine 25 (2007) 5821–5838). Note the presence of any of the following by ticking the appropriate box on the form: erythema, pain, tenderness, warmth, spontaneous/surgical drainage, palpable fluctuance, fluid collection shown by imaging technique, lymphangitic streaking, regional lymphadenopathy and microbial results. If fever present, check box in Section 9d. Use Section 10 for additional details. If treated with antibiotics, indicate if resolution/improvement was temporally related to treatment.

Lymphadenitis: Inflammation of one or more lymph nodes, usually caused by a primary focus of infection elsewhere in the body (Current Infectious Disease Reports, 2009) 183-189: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7089441/pdf/11908_2009_Article_28.pdf).

Sterile abscess: An abscess whose contents are not caused by pyogenic bacteria (BCCD: Vaccine 25 (2007) 5821–5838). Note the presence of any of the following by ticking the appropriate box on the form: erythema, pain, tenderness, warmth, spontaneous/surgical drainage, palpable fluctuance, fluid collection shown by imaging technique, lymphangitic streaking, regional lymphadenopathy and microbial results. If fever present, check box in Section 9d. Use Section 10 for additional details. If treated with antibiotics, indicate if resolution/improvement was temporally related to treatment.

Cellulitis: A diffuse inflammatory process within solid tissues, characterized by edema, redness, pain, and interference with function, usually caused by infection with streptococci, staphylococci, or similar organisms (BCCD: Vaccine 25 (2007) 5803–5820). Note the presence of any of the following by ticking the appropriate box on the form: swelling, pain, tenderness, erythema, warmth, induration, lymphangitic streaking, regional lymphadenopathy and microbial results. If fever present, check box in Section 9d. Use Section 10 for additional details.

Nodule: Discrete, well demarcated soft tissue mass or lump at the vaccination site that has a firm texture and is not accompanied by erythema, warmth or abscess formation (BCCD: Vaccine 22 (2004) 575–585).

Reaction joint-to-joint/crosses joint(s), specify:

Reaction stretches joint-to-joint: Reaction extending between two joints but not past either adjacent joint (National Centre for Immunisation Research and Surveillance (NCIRS) Injection Site Reactions, 2019) https://ncirs.org.au/sites/default/files/2019-07/NCIRS%20Information%20sheet%20-%20Injection%20site%20reactions_July%202019.pdf. Specify which joints in the space provided.

Reaction crosses joint: Reaction extending past at least one joint adjacent to the site of vaccine administration (NCIRS Injection Site Reactions, 2019) https://ncirs.org.au/sites/default/files/2019-07/NCIRS%20Information%20sheet%20-%20Injection%20site%20reactions_July%202019.pdf. Specify which joint(s) is/are crossed in the space provided.

Specify: Specify which joints in the space provided. Specify all details of the reaction in Section 10 that are not already captured in Section 9a.

Other, specify: Specify in the space provided. Provide all details of the vaccination site reaction in Section 10 that are not already captured in Section 9a above. Examples of "**Other**" local reactions that may be reported here include necrosis, papule, etc.

For all local reactions at or near the vaccination site, describe the signs and symptoms by checking all that apply from the list below. Provide any additional details in Section 10.

Swelling: Visible enlargement of the vaccinated limb that is assessed by any person, with or without objective measurement (BCCD: Vaccine 25 (2007) 5858–5874).

Pain: An unpleasant sensation occurring in varying degrees of severity that could be described as discomfort, distress or agony (BCCD: Vaccine 30 (2012) 4558–4577).

Tenderness: Abnormal sensitivity to touch or release of pressure.

Erythema: Abnormal redness of the skin.

Warmth: A tactile sensation/perception of an increase in temperature.

Induration: Palpable thickening, firmness or hardening of soft tissue (subcutaneous tissue, fat, fascia or muscle) that is assessed by a health care provider (BCCD: Vaccine 25 (2007) 5839–5857).

Rash: A morphologically described change in the appearance of the skin or mucosa at or near vaccination site that consists of one or more clearly identified primary lesion(s) (macule, papule, vesicle, nodule, bulla, cyst, plaque, pustule), and/or secondary skin change(s) (scaling, atrophy, ulcer, fissure, excoriation) (BCCD: Vaccine 25 (2007) 5697–5706).

Largest diameter of vaccination site reaction: Indicate the diameter (in centimetres) of the largest vaccination site reaction that is present.

Site(s) of reaction: Site(s) of the local reaction being reported, if known. (Left arm: LA, Right arm: RA, Arm: Arm, Left leg: LL, Right leg: RL, Leg: Leg, Left gluteal: LG, Right gluteal: RG, Gluteal: Glut, Mouth: Mo, Nose: Nose, Multiple sites: MS; if "Other", please specify.)

Palpable fluctuance: Wavelike motion on palpation due to presence of liquid content (BCCD: Vaccine 25 (2007) 5821–5838).

Fluid collection shown by imaging technique: An imaging device is used in the detection of fluid collection (e.g., ultrasound, magnetic resonance imaging (MRI) and/or X-ray).

Spontaneous/surgical drainage:

> **Spontaneous drainage:** Draining of fluid from a site without intervention (BCCD: Vaccine 25 (2007) 5821–5838). When available, describe drainage material (purulent or non-purulent, bloody, etc.) and provide all Gram stain/culture results.
>
> **Surgical drainage:** Withdrawal of fluids from the site through needle aspiration or incision which could be complete or partial (BCCD: Vaccine 25 (2007) 5821–5838). When available, describe drainage material (purulent or non-purulent, bloody, etc.) and provide all Gram stain/culture results.

Microbial results: Tests that are carried out to identify organisms that can cause disease or infection.

Lymphangitic streaking: Red streaks below the skin's surface that follows the path of lymph draining from the site of infection via lymphatic vessels to regional lymph nodes.

Regional lymphadenopathy: Abnormal enlargement of the lymph nodes closest to the vaccination site (e.g., inguinal adenopathy when associated with an intramuscular vaccination in the thigh, axillary adenopathy associated with an intramuscular vaccination in the deltoid, etc.).

SECTION 9B) ALLERGIC AND ALLERGIC-LIKE EVENTS

Choose one of the following events below. For the indicated allergic event, please specify the time to onset and duration in the table provided.

Anaphylaxis: An acute hypersensitivity reaction with multi-organ-system involvement that can present as, or rapidly progress to, a severe life-threatening reaction (BCCD: Vaccine 41 (2023) 2605-2614). Check all applicable signs/symptoms referable to skin/mucosal, cardiovascular, respiratory and/or gastrointestinal systems that were observed during the course of the event and use Section 10 for additional details. Provide specific measurements, where available, for pulse, respiratory rate and blood pressure. For each, indicate if the measurement was taken before or after treatment with epinephrine, if applicable.

Oculo-Respiratory Syndrome (ORS): The presence of bilateral "red eyes" plus one or more respiratory

symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness or sore throat) that starts within 24 hours of vaccination, with or without facial oedema (Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine for 2018-2019: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2018-2019.html).

Other allergic events: An event considered by the reporter to be allergic in nature but not anaphylaxis or ORS. Check all signs and symptoms in Section 9b that were present and use Section 10 for any additional details.

For any allergic and allergic-like event selected above, check all that apply below.

Epinephrine administered: Indicate whether Epinephrine was used to treat the allergic event by choosing "**Yes**" or "**No**". If "**Yes**", please provide details in Section 10.

Mast cell tryptase measured: Indicate whether mast cell tryptase was measured by choosing "**Yes**" or "**No**". If "**Yes**", indicate whether the mast cell tryptase was elevated (>upper normal limit OR 1.2 X baseline + 2 ng/L) by checking the proceeding tickbox. Provide the measurement and reference range in the spaces provided. Provide any additional details in Section 10.

For cases of suspected anaphylaxis, was more than one body system (skin/mucosal, cardiovascular, respiratory, gastrointestinal) involved within the first hour after onset of signs or symptoms?: Indicate by choosing "**Yes**", "**No**", or "**Unknown**". If "**Yes**", please provide details in Section 10.

For a chosen event, describe the signs and symptoms by checking all that apply from the list below. Provide all additional details in Section 10.

SKIN/MUCOSAL

Choose all that apply from the list provided below.

Urticaria (hives) (not at vaccination site): Localized redness of superficial layers of skin that is itchy, raised, sharply demarcated and transient (that is, skin changes at any location are usually present for less than 12 hours) at a site other than the vaccination site (BCCD: Vaccine 28 (2010) 4487–4498). Specify site of reaction in Section 10.

Generalized erythema with pruritus: Abnormal redness of the skin without any raised skin lesions involving more than one body site (i.e., each limb is counted separately, as is the abdomen, back, head and neck) and accompanied by a sensation that provokes the desire to rub and/or scratch to obtain relief (BCCD: Vaccine 28 (2010) 4487–4498). Specify sites of reaction in Section 10.

Generalized erythema without pruritus: Abnormal redness of the skin without any raised skin lesions involving more than one body site (i.e., each limb is counted separately, as is the abdomen, back, head and neck) *without* any sensation that provokes the desire to rub and/or scratch to obtain relief (BCCD: Vaccine 28 (2010) 4487–4498). Specify sites of reaction in Section 10.

Bilateral red itchy eyes (new onset): Redness of the whites of the eyes (sclera) accompanied by a sensation that provokes the desire to rub and/or scratch to obtain relief (BCCD: Vaccine 28 (2010) 4487–4498).

Bilateral red eyes without itching: Redness of the whites of the eyes (sclera) *without* any sensation that provokes the desire to rub and/or scratch to obtain relief (BCCD: Vaccine 28 (2010) 4487–4498).

Angioedema of skin at a site other than vaccination site (may include lip swelling): Areas of deeper swelling of the skin and/or mucosal tissues in either single or multiple sites (other than the vaccination site) which may not be well circumscribed and are usually not itchy (BCCD: Vaccine 28 (2010) 4487–4498). Angioedema should only be reported if there was visible skin or mucosal swelling; sensation of 'swelling of the lip' or 'swelling of the tongue or throat' in the absence of visible swelling should not be

documented as angioedema. Specify site of reaction in Section 10.

CARDIOVASCULAR

Choose all that apply from the list provided below.

Measured hypotension‡: An abnormally low blood pressure and documented by appropriate measurement. Infants and children: age specific systolic blood pressure of less than the 3rd to 5th percentile or greater than a 30% decrease from that person's baseline; Adults: systolic blood pressure of less than 90 mmHg or greater than 30% decrease from that person's baseline (BCCD: Vaccine 28 (2010) 4487–4498). This manifestation should be documented by a healthcare professional. Report measured blood pressure (in mmHg) in the space provided.

Loss of consciousness (excluding vasovagal syncope): Total suspension of conscious relationship with the outside world as demonstrated by the inability to perceive and to respond to verbal, visual, or painful stimulus (BCCD: Vaccine 28 (2010) 4487–4498). Indicate duration of the event in Section 10.

RESPIRATORY

Choose all that apply from the list provided below.

Expiratory wheezing‡: A whistling, squeaking, musical, or puffing sound made by breathing out (BCCD: Vaccine 28 (2010) 4487–4498). This manifestation should be documented by a healthcare professional, which could be with/without a stethoscope.

Inspiratory stridor‡: A harsh and continuous sound made on breathing in (BCCD: Vaccine 28 (2010) 4487–4498). This manifestation should be documented by a healthcare professional, which could be with/without a stethoscope.

Upper airway swelling‡: Indicate the observed location by checking "tongue", "pharynx", "uvula", and/or "larynx". This manifestation should be documented by a healthcare professional.

Tachypnea‡: Rapid breathing which is abnormally high for age and circumstance (younger than 1 year: more than 60 breaths per minute; 1–2 years: more than 40 breaths per minute; 2–5 years: more than 35 breaths per minute; 5–12 years: more than 30 breaths per minute; older than 12 years: more than 16 breaths per minute) (same source as tachycardia) (BCCD: Vaccine 28 (2010) 4487–4498). This manifestation should be documented by a healthcare professional.

Cyanosis‡: A dark bluish or purplish discolouration of the skin and/or mucous membranes due to lack of oxygen in the blood (BCCD: Vaccine 28 (2010) 4487–4498). This manifestation should be documented by a healthcare professional.

Grunting‡: A sudden and short noise with each breath when breathing out (BCCD: Vaccine 28 (2010) 4487–4498). This manifestation should be documented by a healthcare professional.

Measured hypoxia with O2 saturation <90%‡: (BCCD: Vaccine 41 (2023) 2605-2614). This manifestation should be documented by a healthcare professional.

Chest wall retractions‡: Inward movement of the muscles between the ribs (intercostal), in the lower part of the neck (supra-clavicular or tracheal tug) or below the chest (subcostal) (BCCD: Vaccine 28 (2010) 4487–4498). These movements are usually a sign of difficulty breathing. This manifestation should be documented by a healthcare professional.

Increased use of accessory respiratory muscles‡: Accessory respiratory muscles can include muscles in the neck (scalenes, sternocleidomastoids), muscles in the chest (pectoralis major and minor), and abdominal muscles (Mechanics of respiratory muscles, Respiratory Physiology & Neurobiology, 2008) https://www.sciencedirect.com/science/article/pii/S1569904808001134?via%3Dihub. This manifestation should be documented by a healthcare professional.

Sore throat: Discomfort or pain in the throat.

Difficulty swallowing: Sensation or feeling of difficulty in the passage of solids and liquids down to the stomach.

Chest tightness: Inability or perception of not being able to move air in or out of the lungs.

Hoarse voice: An unnaturally harsh cry of infant or vocalization in a child or adult (BCCD: Vaccine 28 (2010) 4487–4498).

New onset and persistent (recurring or lasting more than 5 minutes):

Dry cough: Rapid expulsion of air from the lungs to clear the lung airways and not accompanied by expectoration (a non-productive cough) (BCCD: Vaccine 28 (2010) 4487–4498).

Sneezing: An involuntary (reflex), sudden, violent, and audible expulsion of air through the mouth and nose (BCCD: Vaccine 28 (2010) 4487–4498).

Runny nose: Discharge of thin nasal mucus (BCCD: Vaccine 28 (2010) 4487–4498).

GASTROINTESTINAL

Choose all that apply from the list provided below.

New onset (≥2 episodes if <12 months old; otherwise ≥1 episode):

Vomiting: The reflex act of ejecting the contents of the stomach through the mouth (BCCD: Vaccine 28 (2010) 4487–4498). Provide details in Section 10.

Diarrhea: Loose or watery stools which may occur more frequently than usual (BCCD: Vaccine 28 (2011) 4487–4498). Provide details in Section 10.

SECTION 9C) NEUROLOGICAL EVENTS

Indicate any neurological events as described below. Check all applicable boxes in Section 9c, and use Section 10 to record all additional pertinent clinical details and test results. For each selected neurological event, please specify the time to onset and duration in the table provided.

Meningitis‡: Commonly defined as a syndrome characterized by acute onset of signs and symptoms of meningeal inflammation and cerebrospinal fluid (CSF) pleocytosis, independent of the presence or absence of microorganisms on Gram stain and/or routine culture (BCCD: Vaccine 25 (2007) 5793–5802). Must be diagnosed by a physician or nurse practitioner. Please provide lumbar puncture (LP) results with cerebrospinal fluid analysis and blood cultures in Section 10.

Aseptic Meningitis: Meningitis as described above, in the absence of microorganisms on Gram stain and/or on routine culture (BCCD: Vaccine 25 (2007) 5793-5802). Must be diagnosed by a physician or nurse practitioner. Please provide lumbar puncture results with cerebrospinal fluid analysis in Section 10.

Encephalopathy‡: Refers to a state of being, in which consciousness or mental status is altered (BCCD: Vaccine 25 (2007) 5771–5792). Should be diagnosed by a physician or nurse practitioner.

Encephalitis‡: Defined as inflammation of the parenchyma of the brain (BCCD: Vaccine 25 (2007) 5771–5792). Should be diagnosed by a physician or nurse practitioner. Use Section 10 to record all additional pertinent clinical details and test results, especially results of CT or MRI brain, EEG and/or lumbar puncture with cerebrospinal fluid analysis.

Meningoencephalitis‡: Meningoencephalitis is acceptable terminology when both encephalitis and meningitis are present (BCCD: Vaccine 25 (2007) 5771–5792). Must be diagnosed by a physician or nurse practitioner. Use Section 10 to record all additional pertinent clinical details and test results, including computed tomography (CT) or MRI brain, electroencephalography (EEG), and/or lumbar

puncture with cerebrospinal fluid analysis.

Guillain-Barré Syndrome (GBS)‡: A condition characterized by various degrees of weakness, sensory abnormalities, and autonomic dysfunction due to damage to peripheral nerves and nerve roots (BCCD: Vaccine 29 (2011) 599–612). Should be diagnosed by a physician or nurse practitioner. Use Section 10 to record all additional pertinent clinical details and test results, especially hyporeflexia/areflexia (weak or absent reflexes), electromyography (EMG) and/or lumbar puncture (LP) with results of cerebrospinal fluid analysis.

Bell's palsy‡: A subset of peripheral facial nerve palsy with unknown cause. Inability to wrinkle the forehead or raise the eyebrows on the affected side should be specified (BCCD: Vaccine 35 (2017) 1972–1983). Should be diagnosed by a physician or nurse practitioner. Use Section 10 to record all additional pertinent clinical details and test results, including blood work and brain imaging where available.

Other paralysis‡: Loss of ability to move. Should be diagnosed by a physician or nurse practitioner.

Seizure(s): Episodes of neuronal hyperactivity most commonly resulting in sudden, involuntary muscular contractions. They may also manifest as sensory disturbances, autonomic dysfunction and behavioral abnormalities, and impairment or loss of consciousness (BCCD: Vaccine 22 (2004) 557–562). Indicate the type of seizure and seizure details in the designated area at the bottom of Section 9c.

Acute disseminated encephalomyelitis‡: Described as a uniphasic syndrome of brain inflammation and demyelination, occurring in temporal association with an antecedent immunologic challenge, such as infection or an immunization (BCCD: Vaccine 25 (2007) 5771–5792). Should be diagnosed by a physician or nurse practitioner. Use Section 10 to record all additional pertinent clinical details and test results, including MRI brain and/or spine and/or lumbar puncture with cerebrospinal fluid analysis.

Myelitis/Transverse myelitis‡: Defined as inflammation of the parenchyma of the spinal cord (BCCD: Vaccine 25 (2007) 5771-5792). Should be diagnosed by a physician or nurse practitioner. Use Section 10 to record all additional pertinent clinical details and test results, including MRI spine and/or lumbar puncture with cerebrospinal fluid analysis.

Other neurologic diagnosis, specify‡: Specify in the space provided. Should be diagnosed by a physician or nurse practitioner. Use Section 10 to record all additional pertinent clinical details and test results.

For all neurological events selected above, describe the signs, symptoms and test results relating to the reported event(s) by checking all that apply from the list below. Provide any additional details in Section 10.

Depressed/altered level of consciousness: Impairment of the ability to maintain awareness of self and environment combined with markedly reduced responsiveness to environmental stimuli.

Lethargy: A general state of sluggishness, listlessness, or lack of interest, combined with being tired, and having difficulty concentrating or doing simple tasks.

Personality change lasting ≥ 24 hours: Change in personal behaviour-response patterns.

Fever (≥ 38.0°C): Endogenous elevation of at least one body temperature, regardless of measurement device, anatomic site, age or environmental conditions (BCCD: Vaccine 22 (2004) 551–556).

Focal or multifocal neurologic sign(s): Neurological impairment which is caused by a lesion somewhere in the nervous system.

Formication: Sensation of insects crawling over or within the skin. Indicate site of reaction in Section 10.

Anaesthesia (numbness)/Paraesthesia (prickling or tingling)/Burning:

Anaesthesia: Loss of sensation resulting from pharmacologic depression of nerve function or from neurogenic dysfunction (Stedman's Medical Dictionary (2016)). Indicate site of reaction in Section

10.

Paraesthesia: A spontaneous abnormal usually nonpainful sensation (e.g., tingling, pricking); may be due to lesions of both the central and peripheral nervous systems (Stedman's Medical Dictionary (2016)). Indicate site of reaction in Section 10. Brief tingling immediately following immunization should be included under Section 9b. Allergic and Allergic-like Events.

Burning: Sensation of stinging or heat not necessarily accompanied by redness, or physical signs of skin irritation. Indicate site of reaction in Section 10.

Other, specify: Specify and provide any additional details in Section 10.

CSF abnormality: Alteration in normal cerebrospinal fluid (CSF) visual appearance, measured hydrostatic pressure, chemistry (protein, sugar) and/or cellular content (white blood cells, red blood cells) as well as Gram stain/routine bacterial culture results or other tests for presence of microbes.

EEG abnormality: Abnormal electroencephalography (EEG) as interpreted by a qualified health professional.

EMG abnormality: Abnormal skeletal electromyography (EMG) as interpreted by a qualified health professional.

Neuroimaging abnormality: Abnormal results of any test used to detect anomalies or trace pathways of nerve activity in the central nervous system; includes Computed Tomography (CT) scans, Magnetic Resonance Imaging (MRI), and Positron Emission Tomography (PET) scans.

Brain/spinal cord histopathologic abnormality: Microscopic changes of the diseased brain/ spinal cord tissues. Abnormalities seen on routine and/or electron microscopy by qualified health professionals using appropriately prepared (e.g., using special stains) tissue samples from brain and/or spinal cord.

Decreased or absent reflexes: Please document any additional details in Section 10 as to whether physical examination revealed hyporeflexia or areflexia.

TYPES OF SEIZURES

Type of seizure: Indicate the type of seizure by selecting either "**Partial**" or "**Generalized**".

Partial seizure: Seizure that originates from a localized area of the cerebral cortex and involves neurologic symptoms specific to the affected area of the brain.

Generalized seizure: A seizure with loss of consciousness and generalized motor movements due to generalized hyperactivity in the cerebral cortex.

Specify further by selecting one of the following:

Tonic: Sustained increase in muscle contraction lasting a few seconds to minutes.

Clonic: Sudden, brief (less than 100 milliseconds) involuntary contractions of the same muscle groups, regularly repetitive at a frequency of about 2 to 3 contractions per second.

Tonic-Clonic: A sequence consisting of a tonic phase followed by a clonic phase.

Atonic: Sudden loss of tone in postural muscles, often preceded by a myoclonic jerk, and may be precipitated by hyperventilation (in the absence of Hypotonic-Hyporesponsive Episode, syncope, or myoclonic jerks).

Absence: The occurrence of an abrupt, transient loss or impairment of consciousness (which may not be remembered), sometimes with light twitching, fluttering eyelids, etc.

Myoclonic: Involuntary shock-like contractions, irregular in rhythm and amplitude, followed by relaxation, of a muscle or a group of muscles.

Seizure details: Select the appropriate option for each of the following and record additional details in Section 10.

Sudden loss of consciousness: Sudden total unresponsiveness (suspension of conscious relationship with the outside world, inability to perceive and respond). Indicate by choosing "**Yes**", "**No**" or "**Unknown**". If "**Yes**", provide additional details in Section 10.

Witnessed by healthcare professional: Indicate if the event was witnessed by a healthcare professional (e.g., doctor, nurse, etc.) by choosing "**Yes**", "**No**" or "**Unknown**". If "**Yes**", provide additional details in Section 10.

Previous history of seizures: For individuals who have had seizures at any time prior to this immunization, indicate the type by choosing "**Febrile**", "**Afebrile**" or "**Unknown**". Provide any additional details in Section 10.

Febrile: With fever of at least 38.0°C.

Afebrile: Without fever.

Unknown: It is unknown if the seizure was febrile or afebrile. Provide all known details in Section 10.

SECTION 9D) OTHER EVENTS

For a selected event, describe the signs and symptoms by checking all that apply. Provide all additional details in Section 10. For each selected event, please specify the time to onset and duration in the table provided.

Hypotonic-Hyporesponsive Episode (age <2 years): Characterized by sudden onset of limpness (reduced muscle tone), change in skin colour (pallor or cyanosis) and reduced responsiveness (i.e., less responsive than usual to verbal or other sensorial stimuli) (BCCD: Vaccine 25 (2007) 5875-5881). Check each appropriate box in Section 9d and use Section 10 to indicate if muscle tone, responsiveness or skin colour is known to be normal. **Do not use the Hypotonic-Hyporesponsive Episode checkbox if the patient is two (2) years of age or older**; instead, please check "**Other serious or unexpected event(s) not listed in the form**" and describe in Section 10.

Choose all that apply to the reported AEFI from the list provided below:

Limpness: Lacking firmness and strength; no muscle tone.

Pallor: Unnatural lack of colour in the skin (abnormal loss of colour from normal skin).

Cyanosis: A dark bluish or purplish discolouration of the skin and mucous membrane due to lack of oxygen of the blood (BCCD: Vaccine 28 (2010) 4487–4498).

Decreased (↓) responsiveness/Unresponsiveness: Change in usual responsiveness to sensory stimuli or lack of responsiveness to sensory stimuli.

Persistent crying (continuous and unaltered crying for ≥3 hours): Crying which is continuous, unaltered and lasts for 3 or more hours among young children (BCCD: Vaccine 22 (2004) 586-591).

Intussusception‡: The prolapse of one part of the intestine into the lumen of an immediately adjacent part, causing partial or complete intestinal obstruction (BCCD: Vaccine 22 (2004) 569–574). Should be diagnosed by a physician or nurse practitioner. Provide all pertinent details in Section 10.

Arthritis: Inflammation of the joint(s). Choose all that apply to the reported AEFI from the list provided below:

Joint redness: Redness of the skin at the joint(s).

Joint warm to touch: Sensation of increase in temperature, above body temperature, at the joint(s) to touch.

Joint pain: Discomfort, pain or inflammation arising from any part of the joint. (Mayo Clinic)

Joint swelling: An abnormal increase in the size of the joint(s).

Inflammatory changes in synovial fluid: Laboratory synovial or joint fluid analysis indicative of inflammatory response.

Parotitis: Swelling with pain and/or tenderness of parotid gland(s) (Previous Cdn def'n—CCDR 1995; 21–13: page F–8).

Multisystem inflammatory syndrome in children (MIS-C)‡: A severe illness requiring hospitalization in a person aged less than 21 years, with laboratory evidence of current or previous (within 12 weeks) SARS-CoV-2 infection or prior SARS-CoV-2 immunization. Features of MIS-C include severe extrapulmonary organ dysfunction (including thrombosis), laboratory evidence of severe inflammation, and absence of severe respiratory disease (BCCD: Vaccine 39 (2021) 3037-3049). Should be diagnosed by a physician or nurse practitioner.

Please include the following information in Section 10, if available:

1) If fever (38°C) was present and, if so, for how many consecutive days.
2) Clinical features:
    a. Mucocutaneous (rash, erythema or cracking of the lips/mouth/pharynx, bilateral nonexudative conjunctivitis, erythema/edema of the hands and feet)
    b. Gastrointestinal (abdominal pain, vomiting, diarrhea)
    c. Shock/hypotension
    d. Neurological (altered mental status, headache, weakness, paraesthesia, lethargy)
3) Laboratory evidence of inflammation:
    a. Elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), ferritin or procalcitonin
4) Measures of disease activity:
    a. Elevated brain natriuretic peptide (BNP) or N-terminal pro b-type natriuretic peptide (NT-proBNP) or troponin
    b. Neutrophilia, lymphopenia, or thrombocytopenia
    c. Evidence of cardiac involvement by echocardiography or physical stigmata of heart failure
    d. Electrocardiogram (ECG) changes consistent with myocarditis or myopericarditis

Multisystem inflammatory syndrome in adults (MIS-A)‡: A severe illness requiring hospitalization in a person aged at least 21 years, with laboratory evidence of current or previous (within 12 weeks) SARS-CoV-2 infection or prior SARS-CoV-2 immunization. Features of MIS-A include severe extrapulmonary organ dysfunction (including thrombosis), laboratory evidence of severe inflammation, and absence of severe respiratory disease (BCCD: Vaccine 39 (2021) 3037-3049). Should be diagnosed by a physician or nurse practitioner.

Please include the following information in Section 10, if available:

1) If fever was present and, if so, for how many consecutive days.
2) Clinical features:
    a. Mucocutaneous (rash, erythema or cracking of the lips/mouth/pharynx, bilateral nonexudative conjunctivitis, erythema/edema of the hands and feet)
    b. Gastrointestinal (abdominal pain, vomiting, diarrhea)

c. Shock/hypotension

d. Neurological (altered mental status, headache, weakness, paraesthesia, lethargy)

3) Laboratory evidence of inflammation:

a. Elevated CRP, ESR, ferritin or procalcitonin

4) Measures of disease activity:

a. Elevated BNP or NT-proBNP or troponin

b. Neutrophilia, lymphopenia, or thrombocytopenia

c. Evidence of cardiac involvement by echocardiography or physical stigmata of heart failure

d. ECG changes consistent with myocarditis or myopericarditis

Thrombosis/Thromboembolism‡: Thrombosis occurs when a thrombus (localized hemostatic plug or blood clot) forms in a blood vessel. This can lead to a blockage either at the site of origin, or the clot can become dislodged and cause a blockage in a different blood vessel (thromboembolism) (BCCD: Vaccine 40 (2022) 6431-6444). Should be diagnosed by a physician or nurse practitioner.

Please include the following information in Section 10, if available:

1) Pathological findings, surgical findings, and/or imaging studies that **confirm** the presence of a thrombus.

2) Clinical presentation, signs and/or symptoms consistent with thrombosis or thromboembolism.

3) Elevated D-dimer level.

4) Imaging studies **suggestive** of thrombosis or thromboembolism.

Thrombosis with Thrombocytopenia syndrome (TTS)‡: A syndrome of concurrent thrombosis or thromboembolism and thrombocytopenia. TTS is a term that encompasses many different entities with varying pathogenesis. One of those entities is vaccine-induced immune thrombocytopenia and thrombosis (VITT), which is now understood to be a clearly defined syndrome associated with anti-PF4 antibodies (BCCD: Vaccine 42 (2024) 1799-1811). Should be diagnosed by a physician or nurse practitioner.

Please include the following information in Section 10, if available:

1) Platelet count less than 150 X 10^9/L, that is new onset AND with no heparin exposure within the last 30 days.

2) Evidence of confirmed thrombosis in any location.

3) History of severe, persistent headache with an onset of at least 5 days post immunization.

4) D-dimer results (ideally with reference range provided).

5) Anti-PF4 results by enzyme-linked immunosorbent assay (ELISA) or by functional assay.

Single organ cutaneous vasculitis‡: Refers to small vessel vasculitis of the skin where systemic involvement has been excluded (BCCD: Vaccine 34 (2016) 6561-6571). Should be diagnosed by a physician or nurse practitioner.

Please include the following information in Section 10, if available:

1) Clinical: presence of hemorrhagic papules or urticarial lesions lasting more than 24 hours leaving bruising or hyperpigmentation or purpuric targetoid plaques on face, ears, extremities with edema and low grade fever.

2) Evidence of other organ involvement.

3) Skin biopsy results.

Syncope with injury: Details of the injury resulting from syncope should be reported in Section 10.

Rash (elsewhere than at vaccination site): A skin or mucosal change (either new or an exacerbation of a previous condition) following immunization that consists of clearly identified primary lesion(s) (bulla, cyst, macule, nodule, papule, plaque, pustule, vesicle, wheal), and/or secondary skin change(s) (scaling, atrophy, excoriation, fissure ulcer) at site(s) other than the injection site (BCCD: Vaccine 25 (2007) 5697–5706). Refer to Annex 3 for definitions. When possible, provide a written description of the rash, using the terminology provided.

Kawasaki disease‡: A systemic vasculitis of infancy and childhood affecting medium-sized muscular arteries (BCCD: Vaccine 34 (2016) 6582- 6596). Should be diagnosed by a physician or nurse practitioner. Provide all pertinent details in Section 10.

Thrombocytopenia‡: Platelets count of less than 150 X 10^9/L; accompanied by petechial rash or other clinical signs and/or symptoms of spontaneous bleeding (epistaxis, hematoma, hematemesis, hematochezia, hematuria, hemoptysis, petechia, purpura, ecchymosis) (BCCD: Vaccine 25 (2007) 5717-5724). Should be diagnosed by a physician or nurse practitioner. Indicate the lowest platelet count and the clinical evidence for spontaneous bleeding in the designated space at the end of Section 9d. Provide all additional details in Section 10.

Severe vomiting: The reflex act of ejecting the contents of the stomach through the mouth (severe enough to interfere with daily routine).

Severe diarrhea: An increase by three or more loose or liquid stools (above normal or baseline) occurring within a 24 hour period (BCCD: Vaccine 28 (2011) 4487–4498).

Erythema multiforme‡: An acute, immune-mediated condition characterized by the appearance of distinctive target-like lesions on the skin. These lesions are often accompanied by erosions or bullae involving the oral, genital, and/or ocular mucosae (Journal of American Academy of Dermatology 8 (1983) 763-775). Should be diagnosed by a physician or nurse practitioner.

Myocarditis‡: Inflammation of the myocardium of the heart (BCCD: Vaccine 40 (2022) 1499-1511). Should be diagnosed by a physician or nurse practitioner.

Please include the following information in Section 10, if available:

1) Clinical presentation.

2) Histopathological examination of myocardial tissue either from autopsy or biopsy.

3) Elevated myocardial biomarker (troponin T or troponin I or CK myocardial band).

4) Cardiac MRI, echocardiogram and/or ECG results.

5) Elevated biomarker of inflammation (i.e., CRP, ESR, d-dimer).

Pericarditis‡: Inflammation of the pericardial sac surrounding the heart (BCCD: Vaccine 40 (2022) 1499-1511). Should be diagnosed by a physician or nurse practitioner.

Please include the following information in Section 10, if available:

1) Clinical presentation.

2) Histopathological examination of pericardial tissue either from autopsy or biopsy.

3) Evidence of abnormal fluid collection or pericardial inflammation (echo, cardiac MRI, MRI/CT chest).

4) Specific ECG abnormalities (diffuse concave up ST segment elevation, ST segment depression in aVR, PR depression throughout the leads without reciprocal ST segment depressions).

5) Physical exam findings (pericardial friction rub, pulsus paradoxus, distant heart sounds).

Fever (≥ 38.0°C): Endogenous elevation of at least one body temperature measurement, regardless of measurement device, anatomic site, age or environmental conditions (BCCD: Vaccine 22 (2004) 551–556). Report only if fever occurs in conjunction with a reportable event. For fever in a neurological event, indicate fever in Section 9c only.

Shoulder injury related to vaccine administration (SIRVA): Pain in the ipsilateral shoulder starting less than 48 hours after vaccination and lasting more than 7 days. This is a result of vaccination administered into or too close to underlying joint structures (BCCD: Vaccine 38 (2020) 1137-1143).

Other serious or unexpected event(s) not listed in the form: Provide all details in Section 10.

Other serious adverse event: An adverse event that results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/ incapacity, or is a congenital anomaly/birth defect should be considered serious. Any medical event that requires intervention to prevent one of the outcomes above may also be considered as serious. For additional information regarding serious events, please refer to the WHO Global Manual on Surveillance of Adverse Events Following Immunization (2016 update): https://www.who.int/publications/i/item/9789241507769

Unexpected adverse event: An adverse event whose nature, severity, or outcome is not consistent with the term or description used in the local/regional product labeling (e.g., Package Insert or Summary of Product Characteristics), or any adverse event that was previously observed but is occurring more frequently, should be considered unexpected. For additional information regarding unexpected events, please refer to the ICH Harmonised Tripartite Guideline (E2D 2003): https://database.ich.org/sites/default/files/E2D_Guideline.pdf

SECTION 10. SUPPLEMENTARY INFORMATION

Section 10 should be used to capture all information that is pertinent to the AEFI but that has not been fully captured elsewhere or that needs further explanation. Document all known details of any investigations or treatments for the recorded AEFI. This can include clinical details, types of treatment, test results, and prior infections with the pathogen(s) being vaccinated against in Section 4b. If additional space is required, please attach a separate sheet. Indicate the section of the AEFI Reporting Form that the information applies to, if applicable, when recording information in Section 10.

SECTION 11. RECOMMENDATIONS FOR FUTURE IMMUNIZATION(S) ACCORDING TO THE FEDERAL, PROVINCIAL AND TERRITORIAL BEST PRACTICES

This section is to be completed by the Medical Officer of Health/Medical Health Officer (MOH/MHO), Medical Doctor (MD), Registered Nurse (RN) or their designate who are assigned to provide public health recommendations according to the F/P/T best practices. In some provinces and territories, only the MOH or MD can provide recommendations for future immunizations. In others, RNs have been trained to provide the recommendations as well.

Indicate your recommendations for the patient with regard to future immunizations by selecting all that apply from the following: "**No change to immunization schedule**", "**Determine protective antibody level**", "**No further immunizations with, specify**", "**Expert referral, specify**", "**Active follow up for AEFI recurrence after next vaccine**", "**Controlled setting for next immunization**", or "**Other, specify**". If "**No further immunizations with, specify**", please specify which vaccine(s) this recommendation is referring to in the space provided. If "**Expert referral, specify**" or "**Other, specify**", please provide details in the space provided. A "**Comments**" section has been added for your convenience; however, should you require additional space for your recommendation(s), please capture this information in Section 10.

Complete the reporter information section in full providing your full name. Indicate your professional status by selecting one of the following: "**MOH/ MHO: Medical Officer of Health/Medical Health Officer**", "**MD: Medical Doctor**", or "**RN: Registered Nurse**". If your professional status is not listed, select "**Other, specify**" and specify in the space provided. In addition, indicate a phone number where you can be reached and sign and date the AEFI Reporting Form in the space provided. All dates should be captured in ISO 8601 format: yyyy/mm/dd.

SECTION 12. FOLLOW UP INFORMATION FOR A SUBSEQUENT DOSE OF SAME VACCINE(S)

Note: The information in this section is not collected by all provinces/territories.

Complete Section 12 when an individual who has previously experienced an AEFI following administration of a vaccine receives a subsequent dose of the same vaccine (i.e., vaccines given in series).

Choose one of the options as defined below to describe the outcome following the administration of the subsequent dose of vaccine and provide all pertinent details in Section 10.

Vaccine not administered: A subsequent dose of the vaccine was not administered.

Vaccine administered with recurrence of AEFI: A subsequent dose of vaccine was administered and followed by the occurrence of the same adverse event that was previously experienced by the patient. Fill out a new AEFI Reporting Form for the subsequent AEFI.

Vaccine administered without AEFI: A subsequent dose of vaccine was administered without the occurrence of any AEFI.

Vaccine administered, other AEFI observed: A subsequent dose of vaccine was administered and followed by the occurrence of a different adverse event than was previously experienced by the patient. Fill out a new AEFI Reporting Form for the subsequent AEFI.

Vaccine administered without information on AEFI: A subsequent dose of vaccine was administered and it is unknown if it was followed by the occurrence of any AEFI.

ANNEX 1. WHERE TO SEND A COMPLETED AEFI REPORT

For submitting a completed AEFI report and for any AEFI-related questions please consult the information provided by your federal, provincial or territorial local health unit/health services. Their contact information is available here: https://www.canada.ca/en/public-health/services/immunization/federal-provincial-territorial-contact-information-aefi-related- questions.html

ANNEX 2. LIST OF CURRENT APPROVED VACCINES

Access the list of approved vaccines in Canada: www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/user-guide-completion-submission-aefi-reports/approved-vaccines.html

ANNEX 3. DEFINITIONS OF MUCOCUTANEOUS LESIONS

The information in this section is taken from BCCD: Vaccine 25 (2007) 5697–5706.

Primary mucocutaneous lesions (morphology):

Bulla: A fluid-filled cavity or elevation ≥1 cm in diameter. Fluid can be clear, serous, hemorrhagic, or pus-filled.

Cyst: A closed cavity or sac containing fluid or semisolid material. A cyst may have an epithelial, endothelial, or membranous lining.

Macule: A flat, generally <0.5 cm area of skin or mucous membranes with different color or texture from surrounding tissue.

Nodule: A dermal or subcutaneous, firm, well-defined lesion.

Papule: A discrete, solid, elevated body usually <0.5 cm in diameter. Papules are further classified by shape, size, color, and surface change.

Plaque: A discrete, solid, elevated body usually broader than it is thick measuring >0.5 cm in diameter. Plaques may be further classified by shape, size, color, and surface change.

Pustule: A superficial vesicle containing a cloudy or purulent fluid. Pustules are usually <0.5 cm in diameter.

Vesicle: Fluid filled cavity or elevation <1 cm in diameter. Fluid may be clear, serous, or hemorrhagic.

Wheal (hive): An edematous, transitory papule or plaque.

Secondary mucocutaneous changes:

Erosion: A localized loss of the epidermal or mucosal epithelium.

Crusting: Dried exudates of plasma.

Scaling: Whitish scales or flakes are present on the skin.

Atrophy: Thinning or absence of the dermis or subcutaneous fat.

Excoriations: Oval or linear depressions in the skin with complete removal of the epidermis, exposing a broad section of red dermis.

Fissures: Linear, wedge-shaped cracks in the epidermis which may extend down to the dermis.

Ulcer: A circumscribed loss of the epidermis or mucosa extending to dermis.

ANNEX 4. RESOURCE DOCUMENT: TEMPORAL CRITERIA FOR SELECTED ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFIS)

Notes:

- These onset timelines (Table 2) are for guidance only, and are not considered a mandatory requirement for AEFI reporting.
- The intended use of this document is to provide a tool to support health professionals when reviewing/assessing potential AEFI for reporting.
- Provinces/territories (P/Ts) can adopt the proposed onset timelines or use them as a reference document when reviewing/updating their own guidance document.
- The temporal criteria in this document are not intended for causality assessment. For guidance on causality assessment please refer to the World Health Organization (WHO) document: https://www.who.int/publications/i/item/9789241516990

Table 2. List of selected AEFIs and temporal criteria by vaccine type.

AEFI	TEMPORAL CRITERIA BY VACCINE TYPE	
	NON-LIVE VACCINES	LIVE VACCINES
LOCAL REACTION AT OR NEAR VACCINATION SITE		
Injection site abscess	0-14 days	BCG: Any Other: 0-14 days
Injection site cellulitis	0-7 days	BCG: Any Other: 0-7 days
Other severe or unusual local reactions (including pain, erythema, swelling, pruritus, etc.)	0-11 days	
Lymphadenitis and/or regional lymphadenopathy	0-7 days	BCG: Any Other: 0-42 days
ALLERGIC AND ALLERGIC-LIKE EVENTS		
Anaphylaxis	0-4 hours	
Oculo-Respiratory Syndrome (ORS)	0-24 hours	
Other allergic (IgE-mediated) events	0-4 hours	
NEUROLOGICAL EVENTS		
Meningitis	0-42 days	
Encephalopathy		
Meningoencephalitis		
Guillain-Barré Syndrome (GBS)		
Acute disseminated encephalomyelitis (ADEM)		
Bell's Palsy		
Encephalitis		
Febrile seizure/Non-febrile seizure		
Other paralytic syndrome (including acute flaccid paralysis)		
Myelitis/Transverse myelitis		
Other neurologic diagnosis		
VASCULITIDES		
Single organ cutaneous vasculitis	0-28 days	
Kawasaki disease		
IgA Vasculitis/Henoch-Schönlein Purpura (HSP)		

AEFI	TEMPORAL CRITERIA BY VACCINE TYPE	
	NON-LIVE VACCINES	LIVE VACCINES
SKIN EVENTS		
Rash elsewhere than at vaccination site (excluding rash due to disseminated vaccine-strain infection)	0-28 days	
Erythema multiforme	0-28 days	
Severe skin reactions: Stevens Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN)	0-28 days	
Severe skin reactions: drug rash with eosinophilia and systemic symptoms (DRESS)	0-56 days	
Severe skin reactions: acute generalized exanthematous pustulosis (AGEP)	0-21 days	
OTHER EVENTS		
Fever >38°C	0-3 days	0-28 days
Hypotonic-Hyporesponsive Episode (HHE)	0-2 days	
Persistent crying (>3 hours)	0-2 days	
Intussusception in infants (<1 year)	N/A	0-21 days
Arthritis/Arthralgia	0-30 days	
Parotitis	N/A	0-30 days
Multisystem inflammatory syndrome in children (MIS-C)	0-90 days	
Multisystem inflammatory syndrome in adults (MIS-A)	0-90 days	
Thrombosis and/or thromboembolism	1-28 days	
Thrombosis with thrombocytopenia syndrome (TTS)	4-42 days	N/A
Thrombocytopenia (platelet count <150 x 10^9/L)	0-42 days	
Syncope with injury	0-1 hour	
Vomiting, severe	0-7 days	
Diarrhea, severe	0-7 days	
Myocarditis	0-28 days	
Pericarditis	0-28 days	
Shoulder injury related to vaccine administration (SIRVA)	0-2 days	
Disseminated vaccine strain infection following vaccination	N/A	Any
Other serious or unexpected event(s) not listed in the form, that are thought by health professionals to be possibly related to vaccination	Any	

ANNEX 5. CONTACT INFORMATION FOR THE HEALTH CANADA PROGRAMS

Canada Vigilance Program: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/canada-vigilance-program.html

Special Access Program: https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs.html