

November 2016



REPORTING  
ADVERSE EVENTS  
FOLLOWING  
IMMUNIZATION  
(AEFI) IN  
MANITOBA

## USER GUIDE FOR COMPLETION AND SUBMISSION OF THE AEFI REPORTS

MANITOBA HEALTH, SENIORS & ACTIVE LIVING | Public Health Branch



Adapted with permission by Manitoba Health, Seniors and Active Living from the User Guide originally developed by the Public Health Agency of Canada.

Cover: "The image on the cover page depicts a close view of the distal tip of an empty syringe revealing the metallic needle with its blue plastic proximal end that attached the needle to the syringe barrel. In the bright red background, though out of focus, you can still make out the universal biohazard symbol. The syringe and needle is a very efficient method for delivering... vaccines... in a parenteral manner." (Image credit: Centers for Disease Control and Prevention public domain image and description)

This is up-to-date as of Panorama Release 2.5.7.

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# USING THIS USER GUIDE

This User Guide is intended to be used as a reference mainly by providers of immunization in the Province of Manitoba who may need to report an Adverse Event Following Immunization (AEFI), that is, by users of the form for reporting AEFI. The form refers to both the pdf form found in the Manitoba Health, Seniors and Active Living (MHSAL) website as well as the form in Panorama.

Information contained in the User Guide will provide immunization providers with direction for how to correctly complete and submit either the pdf or Panorama AEFI report form in Manitoba. Knowing how to complete the form correctly and accurately will allow anyone involved in the processing of AEFI reports to train others on how to report an AEFI. Thus, everyone in the Province of Manitoba who is involved in processing AEFI reports is encouraged to read this.

Sections in this User Guide are placed in a specific order according to how the corresponding sections in the report form are arranged, so one can use this document to answer any specific questions that might arise while filling out the form. If further clarifications are needed, one may contact the appropriate health region or MHSAL. (Conversely, the appropriate health region or MHSAL may contact the reporter for clarification on information provided or to provide any missing information.)

Throughout the Guide, acceptable response options are enclosed in single quotation marks. Also, they are in regular (i.e., neither bold nor underscored) font (if in a drop-down menu in Panorama), in **bold** (if a radio button/checkbox in Panorama) or underscored (if a command button in Panorama).

## Special messages:

This User Guide contains special messages to emphasize certain points. These are accompanied by corresponding symbols or icons along the left margin of the page. Please read these special messages carefully to avoid confusion and incorrect completion of the report form.

**MB** These initials pertain to information specific to the Province of Manitoba. Providers in Manitoba should pay particular attention to this.

 This icon pertains to information specific to Panorama. Providers with access to Panorama should pay particular attention to this.

 This icon pertains to information that is commonly overlooked or misunderstood, resulting in poor data quality, and/or to information that if erroneously provided might impact negatively on sensitive issues like client privacy.

If the icon appears next to a section header, it applies to information in that section and all subsections; if it appears next to a paragraph, it applies only to information in that paragraph and any list of items or bullet points under it; if it appears next to an item or bullet point, it applies only to information in that list item or bullet point and any sub-level list of items or bullet points under it. *The pertinent information within the section, paragraph, list item or bullet point is italicized.*

## **ABBREVIATIONS**

AE	Adverse event
AEFI	Adverse event following immunization
CAEFISS	Canadian Adverse Event Following Immunization Surveillance System
FPT	Federal/provincial/territorial
HC	Health Canada
HCP	Health Care Provider
IMPACT	Immunization Monitoring Program ACTive
IP	Immunization Provider
LCDC	Laboratory Centre for Disease Control
LIN	Local Inventory Number
MHSAL	Manitoba Health, Seniors & Active Living
MOH	Medical Officer of Health
PHAC	Public Health Agency of Canada
PHI	Personal health information
PHN	Public Health Nurse
PHO	Public health office
PT	Provincial/territorial
RHA	Regional Health Authority

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## A. BACKGROUND

### When did national vaccine post-marketing surveillance begin in Canada?

National monitoring of adverse events (AE) dates back to 1965 and 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 AE reports from all sources. The Canadian Adverse Event Following Immunization Surveillance System (CAEFISS) is currently overseen by the Vaccine Safety Section in the Surveillance and Epidemiology Division within the Centre for Immunization and Respiratory Infectious Diseases of the Public Health Agency of Canada (PHAC).

### What is an Adverse Event Following Immunization?

An Adverse Event Following Immunization (AEFI) is any untoward medical occurrence in a vaccinee that follows immunization and that does not necessarily have a causal relationship with the administration of the vaccine (based on International Conference on Harmonisation Topic E6 definition). The AE may be any unfavourable and/or unintended sign, abnormal laboratory finding, symptom or disease.

### Should all AEFIs be reported?

No. During their development, vaccines undergo rigorous testing for safety and efficacy. During these “pre-licensure trials” efforts are made to capture every single AE that follows immunization. By the time a vaccine is authorized for marketing, the safety profile for common AEs such as inflammation at the vaccination site or mild fever is well known and available in the product monograph. 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.*



## MB What type of AEFI should be reported?

AEFIs should be reported when the event:

- **Has a temporal association with a vaccine.**
- **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 that:

- **Meet one or more of the seriousness criteria:** An AE that is life threatening or results in death, requires hospitalization or prolongation of an existing hospitalization, results in residual disability, causes congenital malformation or is medically important. A medically important event or reaction is that which might not be immediately life-threatening or result in death or hospitalisation but might jeopardise the patient or might require intervention to prevent one of the other seriousness criteria.
- **Are unexpected regardless of seriousness:** *An event that has either not been identified previously or one that has been identified previously but is, at current, being reported at an increased frequency.*

*Manitoba's Immunization Regulation, 36/2009, defines a "reportable event" as "an adverse event... that is temporally associated with an immunizing agent, cannot be attributed to a co-existing condition, and that meets at least one of the following criteria:*

- (a) *the event is life-threatening, could result in permanent disability, requires hospitalization or urgent medical attention, or for any other reason is considered to be of a serious nature;*
- (b) *the event is unusual or unexpected, including, without limitation,*
  - (i) *an event that has not been previously identified, or*
  - (ii) *an event that has been previously identified but is being reported at an increased frequency;*
- (c) *at the time of the report there is nothing in the patient's medical history – such as a recent disease or illness, or the taking of medication – that could explain the event."*

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.

Of note, PHAC collects AEFI reports following the administration of active immunizing agents (vaccines). In comparison, Health Canada (HC) collects case reports of AEs following the administration of passive immunizing (therapeutic) and diagnostic agents. *When an AE follows the administration of an active immunizing agent (e.g., vaccine) that is administered simultaneously with a passive immunizing agent (e.g., immune globulin) and/or a diagnostic agent (e.g., tuberculin), complete the AEFI report form. Provide the name of the active immunizing agent, in addition to the passive immunizing agent and/or diagnostic agent, and follow the established procedures for reporting an AEFI.* This information will subsequently be forwarded to PHAC and to HC. On the other hand, if no active immunizing agent (vaccine) has been administered, an AEFI report form should not be completed. Instead, please follow the established procedures for reporting an adverse drug reaction to HC (e.g., completion of the Canada Vigilance Reporting Form).

## **Who reports AEFIs?**

- MB** AEFI reports originate from multiple sources in Canada. Vaccine manufacturers are required by law (Food and Drugs Act and Regulations) to report to HC all serious AEFIs with vaccines for which they are the Market Authorization Holder within 15 days of knowledge of their occurrence. No other legal requirement for reporting AEFIs exists nationally.
- Several provinces have enacted mandatory AEFI reporting requirements. *In Manitoba, the Public Health Act, C.C.S.M. c. P210, mandates reporting by a health professional of a reportable AEFI within seven days after becoming aware of it, in accordance with the regulations made under the Act. Furthermore, the province's Immunization Regulation requires vaccine service providers to provide the director responsible for communicable disease control in the province, or the director's designate, with such additional information about the reportable event as may be requested by the director or designate, in the time and form specified by the director or designate.*

*Pursuant to section 59 of The Public Health Act, C.C.S.M. c. P210,  
“Within seven days after becoming aware of a reportable event, a health professional must report it in accordance with the regulations.”*

The usual and preferred reporting flow is from local or regional health units to central provincial/territorial (PT) immunization programs. Reports are forwarded to PHAC electronically, or in hard copy by the provinces and territories after all personal identifying information has been removed.

- To enhance timely detection and assessment of serious AEs involving children, PHAC funds an active pediatric hospital-based surveillance system known as the Immunization Monitoring Program ACTive (IMPACT). AEFI reports completed by the IMPACT nurse monitors are sent to the appropriate PT jurisdiction (*in Manitoba, they are sent to the appropriate health regions, which forwards to Manitoba Health, Seniors and Active Living [MHSAL] with the Medical Officer of Health [MOH] recommendations, just like any other AEFI report*) as well as to PHAC directly. Special numbering of the reports is done to avoid duplication.

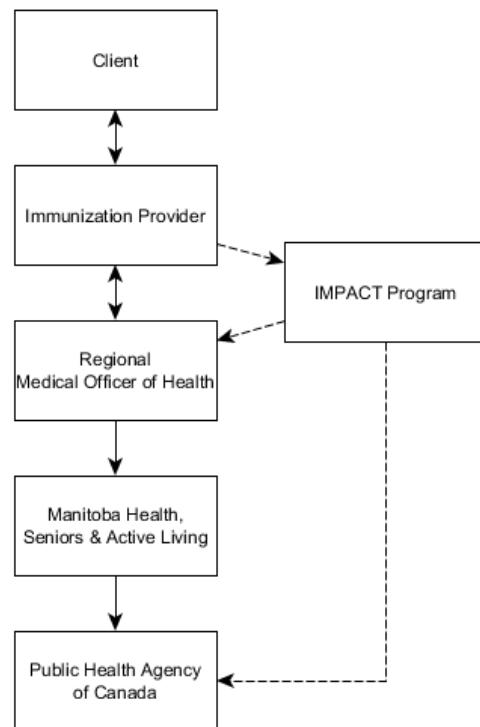
## **What is done with AEFI reports at the provincial/territorial level?**

- MB** AEFI reports are received at the local/regional level from multiple sources: physicians, nurses, pharmacists, public health, IMPACT and the public. Recommendations for future immunizations are usually made at the local/regional level. *In Manitoba, recommendations are made by the regional MOH, who conveys it to the immunization provider (IP). The data are entered at the regional health authority (RHA) level and shared with MHSAL, which checks them for completeness and reviews whether the event is reportable before sending the report on to PHAC. The province may, in coordination with the concerned RHA and in consultation with other local experts as well as with PHAC, perform any further investigation (e.g., causality assessment) that may be required.*

## **What is done with AEFI reports at the national level?**

Personnel in the Vaccine Safety Section screen all submitted reports, ensure they are entered into the CAEFISS database and coded using standard international coding terminology. Reports are monitored with special attention to serious or unusual events that could signal a concern regarding vaccine safety. Canadian data from CAEFISS had been forwarded on to the World Health Organization's International Drug Monitoring Program in Uppsala, Sweden, where global data are analyzed for any evidence of safety concerns. But this was suspended in 2006 for technical reasons and, as of this writing, is on hold pending a review of public health data sharing agreements and considerations for third party data sharing under MLISA.

- MB** *In a nutshell, the process flow of AEFI reporting observed in Manitoba may be viewed simply as illustrated in Figure 1.*



**Figure 1 – AEFI reporting flow in Manitoba**

## **When, why and how was a national AEFI report 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 HC's Bureau of Communicable Disease (CDWR 1991; Vol. 17-19:97-98) and attended by federal/provincial/territorial (FPT) 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 AE report form was developed through an FPT collaborative process during the year following the 1990 workshop. It was agreed that the form would list several AEs considered to be of public health importance. Reporters could check off the specific event and add written detail. There was also an "other" box so that any AE of concern to a reporter could be reported. Case definitions were also developed, although many simply specified that a physician diagnosis would be required. In 1996, the AEFI report form was revised and it is that version which has been in use until now. A series of FPT 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 (Canada Communicable Disease Report 2002; 28).

Priorities to improve vaccine safety surveillance in Canada were established during the development of the National Immunization Strategy. As a part of the efforts to improve voluntary AEFI reporting, it was decided to revise the AEFI report form through members of the Vaccine Vigilance Working Group, which is an FPT group that reports to the Canadian Immunization Committee. Another reason to revise the form was 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.

**MB    *Where and when can copies of the AEFI report form be obtained?***

*The foregoing revised AEFI report form was first introduced in 2009 in Manitoba and other PTs. In 2016, MHSAL developed its own AEFI form to correspond with the electronic system used to capture AEFIs in Manitoba, called Panorama. Links to download Manitoba's AEFI form and user guide can be found at <http://www.gov.mb.ca/health/publichealth/cdc/div/aefi.html> (look under Manitoba Health Resources)*

**How is privacy and confidentiality of information ensured?**

Personal health information (PHI) is confidential. All PTs and PHAC take great care to protect PHI. Health care workers are encouraged to discuss with clients, or the clients' caregivers, the reason for reporting the AEFI and the confidentiality of all collected information. For further information regarding the protection of PHI, you may contact the privacy representatives at your local public health office (PHO).

## **B. GUIDELINES ON HOW TO COMPLETE SECTIONS OF THE AEFI FORM**

This User Guide is intended to be used as a reference mainly by providers of immunization in the Province of Manitoba who may need to report an Adverse Event Following Immunization (AEFI), that is, by users of the form for reporting AEFI. The form refers to both the pdf form found in the MHSAL website as well as the form in Panorama.

The purpose of this User Guide is to provide assistance on how to accurately complete the form. It is not intended to guide treatment. Treatment of all AEFIs should proceed, as appropriate, prior to completing the AEFI form. Following the immediate care of the vaccine recipient, the AEFI form can be completed with all available information.



## **Creating/Updating an AEFI Report in Panorama**

Panorama (<http://www.panoramamanitoba.ca>) is a new electronic system that provides public health professionals with integrated tools that assist in monitoring, managing and reporting on public health. This provincial electronic public health immunization and vaccine inventory management system, will be used for management and surveillance of AEIs beginning Fall 2016. Health care providers (HCP) with access to Panorama can report AEIs occurring in 2016 and onwards using Panorama. Providers without Panorama access should complete the new AEFI Reporting Form, a link to which can be found at <http://www.gov.mb.ca/health/publichealth/cdc/div/aefi.html> (look under Manitoba Health Resources) and submit to the regional MOH. All forms received will also be entered into Panorama for vaccine safety surveillance in Manitoba, and will be included as part of the client immunization record in the provincial immunization registry within Panorama.

The AEFI report is a multi-section electronic record. Each section can be expanded to fill the corresponding information. It does not need to be completed in a specific order. Follow the rest of the guideline to complete the report and review process.

Quick Reference Cards (QRC) are available that illustrate in easy-to-follow diagrams the process for creating, updating, reviewing and following up on AEFI records in Panorama.

**'Save as Draft':** You can save the data you have entered at any point by clicking **Save as Draft**. However, you must first enter at least one associated immunization.

**'Save and Submit':** Before an AEFI report can be submitted for review, the system requires the following information:

- Reporting source
- Source of information
- Information at time of immunization and AEFI onset
- Whether client has history of AEFI following prior dose of the same vaccine
- Whether AEFI was associated with a known immunization incident (error)
- AEFI details
- Reaction's onset and duration values
- Assigned to: Workgroup

**'Save and Resubmit':** Once an AEFI report has been submitted, user can update the AEFI report (change submitted information, submit additional information). To update, select the AEFI report and click **'Update'** in **Adverse Event Summary**.

This will bring the user to the AEFI report with all the boxes editable. Comments and recommendations submitted previously will NOT be editable. Once the updates are done, select the workgroup, and select **'Save and Resubmit'**. A message will pop up prompting the user to enter comments. User should make a note in the space provided of the changes that have been made. This process can be done repeatedly.

**'Update':** Only Panorama users with permissions to write can update the report. Once submitted, select the desired AEFI report to update and click **'Update'** in the **Adverse Event Summary**. After each update, the user needs to record what has been updated in the corresponding comment box.

*'Delete': Only Panorama users with permission to delete can delete the report. Submitted AEFI forms can be deleted by selecting the desired AEFI report and selecting 'Delete' in the **Adverse Event Summary**. User must select reason for deletion ('Altered decision', 'Entered in error', 'Other'). If 'Other' is selected, user needs to specify the other reason in the textbox.*

### **Comment boxes**

*Each section contains one or more section-specific comment boxes. These appear as an empty box with "(4000 characters)" at the bottom right, indicating that the maximum length of text, including spaces, that can be entered into each of these boxes. As you type content, the number of characters remaining will count down. The 'Add' button must be clicked after typing text into the comment box in order to have the comment saved. Once that comment is saved, you can create a second, third, etc. comment in the same section each time using another 4000-character box. Use the box related to the category of the adverse event to record additional comment related to that event type. For example, use the comment box in the **Neurologic events** section to enter additional information related to the neurologic event(s). When 'Add' is clicked, the comment will appear as a "frozen" note in the area immediately below, and the comment cannot be edited or deleted without also deleting the entire report. **Do not enter any client identifiers in the comment boxes, as these comments may be shared non-nominally for vaccine safety surveillance.***



*Additional information should always be added in one of the comment boxes. You should also document the information as per the documentation standards for nurses notes if you are the reporter.*

### **Provincial and Regional Identifying Information**

#### **UNIQUE EPISODE NUMBER – Do not use**



**MB**

A unique episode number is assigned to each AEFI report. Manitoba uses Panorama, an electronic reporting system that automatically generates a unique episode number, labelled the "Adverse Event ID". The unique episode number should be left blank.

#### **IMPACT LIN – For IMPACT use only**

IMPACT is a paediatric, hospital-based, national active surveillance network for AEFI, vaccine failures and select infectious diseases in children. IMPACT is administered by the Canadian Paediatric Society with funding from PHAC. IMPACT reports the more serious hospitalized cases and select outpatient visits for adverse events and vaccine-preventable diseases.

**MB**

An IMPACT Local Inventory Number (LIN) is to be assigned by the IMPACT nurse monitor when an AEFI report is generated from an IMPACT centre. In Manitoba, the IMPACT centre is in the Health Sciences Centre Children's Hospital.

The IMPACT LIN should be marked on the top of the first page of the AEFI form. Please leave this section blank if it does not apply to you (e.g., if you are not an IMPACT hospital/centre).

The IMPACT LIN is used to link the initial provincial/territorial AEFI report to the IMPACT report. Once both reports have been received, the data contained on the AEFI form and the IMPACT forms are merged in the CAEFLSS database.

## **REGION**

The health region should correspond to where the client resides. If you are unsure of the health region, it can be left blank on the form.

 *Enter the health region assigned to the client. If the client's registered address is incorrect, the client should be advised to update their address with MHSAL. An additional address can be added to Panorama by following QRC 1.3.*

 *If the AEFI report is completed by a public health nurse (PHN), they can choose to enter the PHO in which the AEFI occurred. Otherwise they can leave it on the default setting.*

## **Patient Identification**

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

**Patient Identification Information:** Provide the patient's first and last name, health number (if applicable), address of usual residence including postal code (with the understanding that this address might be in a different province/territory than where the vaccine(s) 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. Enter date of birth, age at time of immunization and gender.

## **Reporter Information**

Complete the reporter information section in full including the date reported, 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 setting in which the reporter is located (i.e., 'Physician Office', 'Public Health Office', 'Hospital', 'Pharmacy') or specify if 'Other'. Sign and date the AEFI form in the space provided and specify your professional status (i.e., 'MD' for Medical Doctor; 'RN' for Registered Nurse) or your affiliation (i.e., 'IMPACT') by choosing one of the options provided. If your professional status or affiliation is not listed, specify beside other.

Reporter is the HCP (e.g., nurse, physician) who received and reported the AEFI. This person may or may not be the same person as the IP.

 *In Panorama, do not use indexed reporters, as Panorama does not capture the address and phone number for indexed providers. Enter reporter information under '**Enter information for a non-indexed provider**'. Complete last name, first name, phone number, address and professional status.*

## ***Source of Information***

Source of information can be the reporter, the client or a secondary source such as parent of a child recipient. Indicate if the source of the information is the ‘**Same as Reporter**’, the ‘**Client**’, or ‘**Other**’. If the source of the information is ‘**Other**’, provide their name, relation to the patient and contact information (including their full mailing address and phone number where they can be reached).

## ***Information at Time of Immunization and AEFI Onset***

### **Immunization details**

Provide all information pertaining to the vaccine(s) (and, if applicable, any concomitant passive immunizing and/or diagnostic agent[s]) administered just prior to the onset of the reported AEFI(s). There is space to record five agents. If more than five were administered at the same visit, record the active agents first, then any additional agents in a separate sheet.

When completing this section, provide all information as outlined below:

**Immunizing agent(s):** Please record the proper name or accepted abbreviation as outlined in the Canadian Immunization Guide (<http://healthycanadians.gc.ca/healthy-living-vie-saine/immunization-immunisation/canadian-immunization-guide-canadien-immunisation/index-eng.php>).

**Trade name:** Indicate the trade name of all vaccine(s) received.

**Manufacturer:** Specify the name of the manufacturer as indicated on the product label and as referenced in the Canadian Immunization Guide (<http://healthycanadians.gc.ca/healthy-living-vie-saine/immunization-immunisation/canadian-immunization-guide-canadien-immunisation/index-eng.php>).

**Lot number:** Document the complete lot number including all letters and numbers. This information is essential for conducting future risk assessments.

**Dose number:** Provide the number in series (1, 2, 3, 4, or 5), if known. *For example, a child would receive DTaP-IPV-Hib dose #4 at 18 months and Tdap-IPV dose #5 in pre-school (per infant/pre-school schedule). The same child would receive Tdap dose #1 in his/her teens (per school schedule). For the Influenza vaccine, the Dose Number should ordinarily be recorded as one, unless the client receives more than one dose in one season, which is then recorded accordingly.*

**Dosage/unit:** Indicate the quantity administered for each vaccine, *usually in units of volume (i.e., milliter or ml).*

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

- ‘Intradermal’ (ID)
- ‘Intramuscular’ (IM)
- ‘Intravenous’ (IV)
- ‘Nasal’/Intranasal (IN)
- ‘Oral’/Per orem (PO)

‘Subcutaneous’ (SC)  
‘Topical’ (TOP)  
Other – Need to be specified (no abbreviations)

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

‘Arm: upper left’  
‘Arm: upper right’  
‘Deltoid: left’  
‘Deltoid: right’  
‘Mouth’  
‘Nares: bilateral’  
‘Naris: left’  
‘Naris: right’  
‘Thigh: left’  
‘Thigh: right’  
‘Vastus lateralis: left’  
‘Vastus lateralis: right’  
‘Ventrogluteal: left’  
‘Ventrogluteal: right’  
Other – Need to be specified (no abbreviations)

**Province/Territory of immunization:** Indicate the province or territory where the immunization was received. This may be different from the patient’s province or territory of residence and/or where the AEFI is being reported.



*In Panorama, if the vaccine was administered outside of Manitoba, indicate the PT in which the vaccine(s) was/were administered in a comment box under AEFI Details.*



If the vaccine was administered outside of Canada, indicate the country in which the vaccine(s) was/were administered in the space to capture province/territory. Indicate as well in a comment box under **AEFI Details** if it was received at a Canadian-operated clinic in that country. *In Panorama, the country may also be indicated in that comment box.*

**Date and time vaccine administered:** Indicate the date and time of vaccine administration in 24-hour format (e.g., 10:00 am as 10:00, 2:15 pm as 14:15). If complete information is unknown, provide as much detail as is available (e.g., month and/or year).

This is a multiple response item, and more than one agent can be selected. All of the immunizations given at the same appointment may be associated with the reported event(s). All vaccines given at the time of appointment should be indicated regardless of nature of AEFI.



*Immunizations must first be entered into Panorama to select the immunization(s) associated with the AEFI. View all existing records to determine if the record(s) already exists. If missing, create a new immunization record. If a record exists but additional details on the immunization are provided on the AEFI form that are not recorded in Panorama (e.g., time of immunization, trade name, lot #, dose, route, site), go to the immunization record(s) and update the immunization. If the lot # is not available in the drop-down list, include the lot # in the tradename field.*



Once an agent has been selected from the **Existing Immunizations** list and an AEFI report on that product given on that date created, a second AEFI report on that same agent/date combination cannot be made. All AEFIs associated with that agent/date combination must be entered in the same AEFI report.

### Did an AEFI follow a previous dose of any of the above immunizing agents?

Indicate whether the patient had ever experienced an AEFI following a previous dose of any of the immunizing agents. Choose only one of the answers as described below:

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

**'No prior dose'**: The patient had never previously received immunization with any of the immunizing agents listed in Section IV.

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

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

If the answer is **'Yes'**, provide as much detail as is practicable of the previous AEFI in the corresponding comment box, including the corresponding time to onset and duration, if known. Also, if 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), please provide additional details under **AEFI Details**.



Provide any additional pertinent details in the corresponding comment box. *Remember that in Panorama, once comment is added, it cannot be modified or deleted without having to delete the entire record.*

### Did this AEFI follow an incorrect immunization?

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

**'Given outside the recommended age limits'**: The vaccine was administered to an individual who was not within the recommended age limits for a specific vaccine.

**'Dose exceeded that recommended for age'**: A larger amount of vaccine was administered than is recommended for the patient's age group.

**'Incorrect route'**: The vaccine was administered via a route not recommended for its administration (e.g., subcutaneous vs. intramuscular).

**'Wrong vaccine given'**: An unintended vaccine was administered.

**‘Product expired’:** The vaccine was administered after the expiry date as indicated on the vaccine label by the manufacturer and/or after the recommended amount of time elapsed between the first use of a multi-dose vial and the last use (e.g., as indicated in the product monograph for Fluviral, once entered, the multi-dose vial should be discarded after 28 days).

**‘Other’:** If an error has occurred that is not accurately reflected in the choices above, please choose ‘Other’ and provide all details in the corresponding comment box.



Provide any additional pertinent details in the corresponding comment box. *Remember that in Panorama, once comment is added, it cannot be modified or deleted without having to delete the entire record.*

### Medical history (up to time of AEFI onset)

Indicate the patient’s medical history prior to the time of AEFI onset by choosing all that apply from the list provided below:

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

**‘Known medical conditions/allergies’:** Indicate all known medical conditions and/or allergies that the patient experienced prior to the time of immunization with a corresponding date of onset. 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 with intermittent symptoms such as migraine headaches. Also, specify in this section if the subject was pregnant at the time of immunization.

**‘Acute illness/injury’:** Indicate if the patient had an acute illness and/or injury immediately prior to the time of immunization and specify a corresponding date of onset 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).



Provide any additional pertinent details in the corresponding comment box. *Remember that in Panorama, once comment is added, it cannot be modified or deleted without having to delete the entire record.*

## **AEFI Details**

Indicate the details of the AEFI being reported by checking all that apply. Any additional pertinent details (results of medical investigations, laboratory test, treatment, etc.) should be provided in the corresponding comment box.



For convenience and consistency, high level definitions have been provided for most events listed in this section. *However, if an asterisk (\*) is present beside an AEFI term, this specific event should be diagnosed by a physician. If an event requiring physician diagnosis is not diagnosed by a physician, sufficient information should be provided in the corresponding comment box to support the selection(s). Refer to the Brighton Collaboration website (<https://brightoncollaboration.org/public/what-we-do/setting-standards/case-definitions.html>) for standardized case definitions of the AEIIs.* (Note that some events may not have Brighton diagnostic criteria established yet.)

For all AEIIs, indicate the time to onset (time from immunization to onset of first symptom/sign) and the duration (time from onset of first symptom/sign to resolution of all signs and symptoms).

### **Local reaction at or near vaccination site**

(For non-allergic local reactions only)

**Time to onset and, unless the unresolved checkbox is selected, duration of signs and symptoms are mandatory.** The time to onset and the duration of the signs and symptoms of the specified AEFI should be documented using the appropriate time unit(s) (day, hour, minute).



*If the AEFI is not yet resolved at the time of the report, do not document any duration, and check 'Unresolved' on the right.*

Indicate by choosing all that apply, any local reactions at or near the vaccination site, as described below:

**'Infected abscess'**: A localized collection of pus in a cavity formed by the disintegration of tissue, usually caused by microorganisms that invade the tissues.

**'Sterile abscess'**: An abscess whose contents are not caused by pyogenic bacteria.

**'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.

**'Nodule'**: A firm, small mass of tissue at the vaccination site with discrete or well demarcated borders in the absence of abscess formation, erythema and warmth.

**'Reaction crosses joint'**: Reaction extending past at least one joint adjacent to the site of vaccine administration.

**'Lymphadenitis'**: Inflammation of one or more lymph nodes, usually caused by a primary focus of infection elsewhere in the body.

**'Other'**: Specify all details of the vaccination site reaction that are not already captured above in the corresponding comment box. Examples of '**Other**' local reactions that may be reported here include necrosis, papule, etc.



Provide any additional pertinent details in the corresponding comment box. *Remember that in Panorama, once comment is added, it cannot be modified or deleted without having to delete the entire record.*

**!** For all local reactions at or near the vaccination site, describe the signs and symptoms by selecting all that apply from the list below. *At least one local reaction has to be selected above if a sign/symptom is selected below, otherwise, the local reaction is to be recorded as 'Other', then indicating "Unspecified local reaction" in the corresponding comment box:*

**'Swelling'**: Visible enlargement of the site of vaccination of a vaccinated limb that is assessed by any person.

**'Pain'**: An unpleasant sensation occurring in varying degrees of severity that could be described as discomfort, distress or agony.

**'Tenderness'**: Abnormal sensitivity to touch or release of pressure.

**'Erythema'**: Abnormal redness of the skin.

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

**'Induration'**: Palpable thickening, firmness or hardening of soft tissue that is assessed by a HCP.

**'Rash'**: A temporary eruption on the skin.

**'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.

**'Palpable fluctuance'**: Wavelike motion on palpation due to presence of liquid content.

**'Fluid collection shown by imaging technique'**: An imaging device is used in the detection of fluid collection (e.g., MRI, CT scan and ultrasound).

**'Spontaneous/surgical drainage'**: Draining of fluid from a site. When available, provide all gram stain/culture results.

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

**'Lymphangitic streaking'**: Painful and inflamed red streaks below the skin's surface (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 IM vaccination in the thigh, axillary adenopathy associated with an IM vaccination in the deltoid, etc.).



Provide any additional pertinent details in the corresponding comment box. *Remember that in Panorama, once comment is added, it cannot be modified or deleted without having to delete the entire record.*

## Anaphylaxis or other allergic events

**Time to onset and, unless the unresolved checkbox is selected, duration of signs and symptoms are mandatory.** The time to onset and the duration of the signs and symptoms of the specified AEFI should be documented using the appropriate time unit(s) (day, hour, minute).

**! If the AEFI is not yet resolved at the time of the report, do not document any duration, and check 'Unresolved' on the right.**

Choose one of the following events:

**'Anaphylaxis'**: A clinical syndrome, characterized by the sudden onset and rapid progression of signs and symptoms that affect more than one body system (e.g., skin/mucosal and/or cardio-vascular and/or respiratory and/or gastrointestinal). The form has been designed to capture the major and minor manifestations of anaphylaxis, each of which are defined below. Accurate documentation of signs and symptoms contributes to the diagnostic certainty that an evolving event is indeed anaphylaxis. Refer to the Brighton Collaboration website (<https://brightoncollaboration.org/public/what-we-do/setting-standards/case-definitions.html>) for the case definition. It is not necessary to know the definition prior to completing the AEFI report form nor for there to be a delay in instituting appropriate management.

**'Other allergic events'**: Encompasses all allergic reactions that are neither Anaphylaxis nor a new AEFI first noted during the 2000–2001 influenza immunization campaign in Canada, called Oculo-Respiratory Syndrome (see **Other defined events of interest** below).

**!** For the indicated allergic event, describe the signs and symptoms by selecting all that apply from the list below. *If a sign/symptom is selected and neither 'Anaphylaxis' nor 'Other allergic event' is selected, the event is to be recorded as 'Other allergic event'.*

### 'Skin/Mucosal':

**'Generalized'**: An event occurring in two or more body locations (e.g., both arms) and cannot only affect the injection site. User must select '**Non-injection site**' only or both '**At injection site**' and '**Non-injection site**', but not '**At injection site**' only. If the event occurred only at the injection site, it should be reported as Localized.

**'Localized'**: An event occurring in *only one* body location.

If client has both '**Generalized**' and '**Localized**' skin/mucosal symptoms, select '**Generalized**'.

User must select at least one of the following sub-level items:

- '**At injection site**'
- '**Non-injection site**'

- ‘**Urticaria**’ (**hives**): Circumscribed, intensely itchy weals with erythematous, raised edges and pale, blanched centres. Urticaria may be present at the vaccination site (e.g., within a few centimetres of where immunization was given) and/or may be generalized (involving body sites other than where the vaccine was injected).
- ‘**Erythema**’: Abnormal redness of the skin.
- ‘**Pruritus**’: An unpleasant cutaneous sensation that provokes a desire to rub and/or scratch to obtain relief.
- ‘**Prickle sensation**’: Tingling or smarting (stinging) sensation.

**‘Eyes’:** Select ‘**Red**’ or ‘**Itchy**’ if applicable. If ‘**Red**’ is selected, specify in the comments box whether it was unilateral or bilateral. If unilateral, specify which eye. If bilateral and event is classified as Oculo-Respiratory Syndrome, report the bilateral red eyes in **Other defined events of interest** and not in the **Anaphylaxis or other allergic events** section.

**‘Angioedema’:** Localized edema of the deeper layers of the skin, subcutaneous tissues or mucosa lining the throat, airways and gut. This most often affects the face, near the eyes (‘**Eyelids**’) and mouth or hands and feet (‘**Limbs**’), but may also involve the ‘**Tongue**’, ‘**Throat**’, ‘**Uvula**’, ‘**Larynx**’ or ‘**Lip**’. It is important that the swelling is confirmed by visual inspection by a qualified health care professional rather than rely on patient description alone (“My tongue feels swollen”). Check all of the locations where angioedema is seen on the AEFI report form and if ‘**Other**’ is checked, provide details.

#### ‘Cardio-vascular’:

**‘Measured hypotension’:** An abnormally low blood pressure (systolic pressure <100 mm hg) documented by appropriate measurement.

**‘Decreased central pulse volume’:** Decreased pulse strength as a result of the decrease in volume of blood in the blood vessels.

**‘Capillary refill time >3 sec’:** Capillary refill time is the time required for the normal skin colour to reappear after a blanching pressure is applied. It is usually performed by pressing on the nail bed to cause blanching and then counting the time it takes for the blood to return to the tissue, indicated by a pink colour returning to the nail. Normally it is <3 seconds.

**'Tachycardia'**: An extremely rapid heart rate above an established norm that varies by age. The term is usually applied to a heart rate above 100 beats per minute for adults.

TABLE OF PULSE AND RESPIRATORY RATES		
Age	Heart (pulse) rate per minute, Upper Limit	Respiratory rate per minute, Upper Limit
0-1 mo	180	60
2-12 mo	160	50
12-24 mo	140	40
2-6 y	120	30
6-12 y	110	20
>12y (adult)	100	20

From: Emergency Medicine: A comprehensive study guide. 6th edition. (2004). McGraw Hill.

**'Decreased or loss of consciousness'**: Total unresponsiveness or reduced alertness or awareness of the outside world.

### 'Respiratory':

**'Sneezing'**: An involuntary (reflex), sudden, violent and audible expulsion of air through the mouth and nose.

**'Rhinorrhea'**: Discharge of thin nasal mucus.

**'Hoarse voice'**: An unnaturally rough深深 or noisy quality of voice.

**'Sensation of throat closure'**: Feeling or perception of throat obstruction or occlusion resulting in difficulty breathing.

**'Stridor'**: A harsh, high-pitched breath sound heard on inhalation caused by air passing through a constricted passage.

**'Dry cough'**: Rapid expulsion of air from the lungs to clear the lung airways and not accompanied by expectoration (a non-productive cough).

**'Tachypnea'**: Abnormally rapid and shallow breathing.

**'Wheezing'**: A whistling, squeaking, musical, or puffing sound made on exhalation by air passing through the fauces, glottis, or narrowed tracheobronchial airways (bilateral – both lungs). Wheeze may be audible to the naked ear or may require the use of a stethoscope.

**'Indrawing/retractions'**: Inward movement of the muscles between the ribs. The movements are usually a sign of difficulty with breathing.

**'Grunting'**: A laboured breathing of expiratory effort due to obstruction of the airway.

**'Cyanosis'**: A dark bluish or purplish discolouration of the skin and mucous membrane due to deficient oxygenation of the blood.

## **‘Gastrointestinal’:**

**‘Diarrhea’:** Abnormally frequent discharge of loose and/or watery fecal matter from the bowel. Please provide details.

**‘Abdominal pain’:** Sensation of discomfort, distress or agony in the abdominal region.

**‘Nausea’:** An unpleasant sensation vaguely referred to the epigastric region (upper region of the abdomen) and the abdomen, with a tendency to vomit.

**‘Vomiting’:** The reflex act of ejecting the contents of the stomach through the mouth. Provide details below.



Provide any additional pertinent details in the corresponding comment box. *Remember that in Panorama, once comment is added, it cannot be modified or deleted without having to delete the entire record.*

## **Neurologic events**

**Time to onset and, unless the unresolved checkbox is selected, duration of signs and symptoms are mandatory.** The time to onset and the duration of the signs and symptoms of the specified AEFI should be documented using the appropriate time unit(s) (day, hour, minute).



*If the AEFI is not yet resolved at the time of the report, do not document any duration, and check ‘Unresolved’ on the right.*

Indicate by choosing all that apply, any neurologic events, as described below:

**‘Seizure(s)’:** Episodes of hyperactivity in the brain resulting in sudden, involuntary muscle contractions and abnormal behaviour, loss or impairment of consciousness.



Mandatory sub-level items:

- ‘Witnessed by healthcare professional’ (‘Yes’, ‘No’, ‘Unknown’)
- ‘Sudden loss of consciousness’ (‘Yes’, ‘No’, ‘Unknown’)

Must select either ‘Focal’ or ‘Generalized’, *unless using Panorama AND seizure type is either Myoclonic or Absence:*

- ‘Focal’: Seizure that originates from a localized area of the cerebral cortex and involves neurologic symptoms specific to the affected area of the brain (also called partial seizures, which can be divided into simple and complex partial seizures).



*In Panorama, must select one of ‘Tonic’, ‘Clonic’, ‘Tonic-Clonic’, or ‘Atonic’. These categories are not appropriate responses for focal seizures, but at this time, the system forces selection of one type. Select “atonic” and enter additional details in corresponding comment box.*

- ‘**Generalized**’: Bilateral, with more than minimal muscle involvement.  
Must indicate one of the following:  
 ‘**Tonic**’: Sustained increase in muscle contraction lasting a few seconds to minutes.  
 ‘**Clonic**’: Sudden, brief (<100 milliseconds) involuntary contractions of the same muscle groups, regularly repetitive at a frequency of about two to three contractions/second.  
 ‘**Tonic-Clonic**’: A sequence consisting of a tonic followed by a clonic phase.  
 ‘**Atonic**’: Sudden loss of tone in postural muscles often preceded by a myoclonic jerk and precipitated by hyperventilation (in the absence of Hypotonic-Hyporesponsive Episode, syncope, or myoclonic jerks).



**Myoclonic / Absence:** *At this time, Panorama does not provide the option to select Myoclonic or Absence (formerly called Petit Mal) seizure. For these generalized seizure types, capture by selecting ‘Seizure’, ensuring that the mandatory sub-level items (except ‘Focal’/‘Generalized’<sup>1</sup>) are answered, then indicating “Generalized – Myoclonic” or “Generalized – Absence” (as the case may be) in the corresponding comment box.*

Optional sub-level item:

- ‘**Previous history of seizures**’ (‘**Febrile**’; ‘**Afebrile**’; ‘**Unknown type**’)



*At this time, Panorama does not allow selection of more than one previous seizure type. If previous history of seizures involved both febrile and afebrile, select ‘Unknown type’ and enter additional details in the corresponding comment box.*

‘**Meningitis**’\*: Should be diagnosed by a physician. Document the results of any cerebrospinal fluid (CSF) investigations and any additional pertinent details in the corresponding comment box.

‘**Encephalopathy/Encephalitis**’\*: Should be diagnosed by a physician. Provide any additional pertinent details in the corresponding comment box.

‘**Guillain-Barré Syndrome (GBS)**’\*: Should be diagnosed by a physician. Provide a summary of results in addition to any other relevant investigations including tests to look for possible causes, especially *Campylobacter*.

‘**Bell’s Palsy**’\*: Should be diagnosed by a physician. Provide any additional pertinent details in the corresponding comment box.

‘**Other paralysis**’\*: Should be diagnosed by a physician. Provide any additional pertinent details in the corresponding comment box.

‘**Other neurologic diagnosis**’: Specify in space provided and provide any additional details in the corresponding comment box.

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<sup>1</sup> Although **Myoclonic** and **Absence** are generalized seizure types, selecting **Generalized** will prompt selection of one of the other generalized seizure types.

For all neurologic events, describe the signs, symptoms and test results by selecting all that apply from the list below:

- ‘Depressed/altered level of consciousness, lethargy or personality changes lasting  $\geq$  24 hours’
- ‘Focal or multifocal neurologic sign(s)’
- ‘Fever ( $\geq 38.0^{\circ}\text{C}$ )’
- ‘CSF abnormality’
- ‘EEG<sup>2</sup> abnormality’
- ‘EMG<sup>3</sup> abnormality’
- ‘Neuroimaging abnormality’: Abnormal results in the tests (e.g.: CT scans, MRIs, Pet scans etc) used to detect anomalies or trace pathways of nerve activity in the central nervous system.
- ‘Brain/spinal cord histopathologic abnormality’



Provide any additional pertinent details in the corresponding comment box. *Remember that in Panorama, once comment is added, it cannot be modified or deleted without having to delete the entire record.*

## Other defined events of interest

**Time to onset and, unless the unresolved checkbox is selected, duration of signs and symptoms are mandatory.** The time to onset/interval and the duration of the signs and symptoms of the specified AEFI should be documented using the appropriate time unit(s) (day, hour, minute).



*If the AEFI is not yet resolved at the time of the report, do not document any duration, and check ‘Unresolved’ on the right.*

For a selected event, describe the signs and symptoms by checking all sub-level items that apply. Provide any pertinent additional details in the corresponding comment box.

**‘Hypotonic-Hyporesponsive Episode’** (age <2 years): Sudden onset, in a child aged less than two years, of hypotonia (limpness), reduced responsiveness and either pallor or cyanosis. If the patient is two years of age or older, please check **‘Other serious or unusual events not listed in the form’** and describe the episode.

Choose all that apply from the list provided below:

- ‘Limpness’
- ‘Pallor/cyanosis’
- ‘Reduced responsiveness/unresponsiveness’ – Crying that is continuous, unaltered and lasts for 3 or more hours

**‘Rash’**: A skin or mucosal change (temporary eruption). **This refers to rashes that are neither allergic in nature nor localized at or near vaccination site (e.g., vesicular rash following vaccine-strain viral reactivation).** For non-allergic rash localized to the vaccination site, capture by selecting **‘Rash’ in Local reaction at or near vaccination site**; for rash allergic in nature, capture by selecting

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<sup>2</sup> Electroencephalography

<sup>3</sup> Electromyography

**'Skin/Mucosal'** in **Anaphylaxis or other allergic events**, then selecting either **'Generalized'** or **'Localized'** (as the case may be), then providing description and any other pertinent additional details in the corresponding comment box.

When possible, provide a written description of the primary lesion(s) (bulla, cyst, macule, nodule, papule, plaque, pustule, vesicle, wheal), and/or secondary skin change(s) (scaling, atrophy, excoriation, fissure, ulcer).

Must select one of the following:

- **'Generalized rash'**: Systemic eruption in two or more parts of the body.
- **'Localized at non-injection site'**: Eruption localized at another part of the body, away from the vaccination site. Specify the location in the corresponding comment box.

**'Intussusception'**\*: The prolapse of one part of the intestine into the lumen of an immediately adjacent part, causing partial or complete intestinal obstruction. Should be diagnosed by a physician. Provide any additional pertinent details in the corresponding comment box.

**'Arthritis'**: Inflammation of the joint(s).

Choose all that apply from the list provided below:

- **'Joint redness'**
- **'Joint warm to touch'**
- **'Joint swelling'**
- **'Inflammatory changes in synovial fluid'**

**'Parotitis'**: Inflammation of the parotid gland(s) with pain and/or tenderness.

**'Thrombocytopenia'**\*: Platelet count of less than  $150 \times 10^9/\text{liter}$ , accompanied by petechial rash or other clinical signs and/or symptoms of spontaneous bleeding. Should be diagnosed by a physician. Provide any additional pertinent details in the corresponding comment box.

Choose all that apply from the list provided below. Indicate the lowest platelet count on the AEFI form and provide any additional pertinent details:

- **'Clinical evidence of bleeding'**
- **'Platelet count <150 x 10<sup>9</sup>/liter'**

**'Oculo-Respiratory Syndrome (ORS)'**: A set of signs/symptoms of both the eyes and respiratory system following vaccination with influenza vaccine. Provide any pertinent additional details in the corresponding comment box.

Choose all that apply from the list provided below:

- **'Bilateral red eyes'**
- **'Cough'**
- **'Wheeze'**
- **'Sore Throat'**
- **'Difficulty swallowing'**
- **'Difficulty breathing'**

- ‘Chest tightness’
- ‘Hoarseness’
- ‘Facial swelling’

**‘Fever’ ( $\geq 38.0^{\circ}\text{C}$ ):** This refers to temperature of  $\geq 38.0^{\circ}\text{C}$  in conjunction with any event other than a neurologic event. For fever associated with a neurologic event (e.g., meningitis), capture in **Neurologic events**.



**‘Other serious or unexpected event(s) not listed in the form’:** *This is currently listed in Panorama as ‘Other severe events not listed above’.* Choose this category ONLY if the event cannot be reported using a more appropriate existing category, as these data cannot be readily analyzed or alerted. If selected, must ensure to provide description and any other pertinent additional details in the corresponding comment box that could guide possible classification of the event.



Provide any additional pertinent details in the corresponding comment box. *Remember that in Panorama, once comment is added, it cannot be modified or deleted without having to delete the entire record.*

### ***Impact of AEFI, Outcome and Level of Care***

#### **Highest impact of AEFI**

Indicate the highest perceived impact of the AEFI by selecting one of the provided responses based on the client’s assessment of the impact on their daily activities:

- ‘Did not interfere with daily activities’: No change or only minimal change is reported by the client in relation to their daily activities, such as work, exercise, social commitments.
- ‘Interfered with but did not prevent daily activities’: Moderate change is reported by the client in relation to their daily activities.
- ‘Prevented daily activities’: Significant change is reported by the client in relation to their daily activities.



Provide any additional pertinent details in the corresponding comment box. *Remember that in Panorama, once comment is added, it cannot be modified or deleted without having to delete the entire record.*

#### **Outcome at time of report**

Indicate the outcome of the reported AEFI at the time of completion of the report by choosing one of the provided response options:

- ‘Death’: Patient died (record the corresponding date of death in the space provided).
- ‘Permanent disability/incapacity’: An injury that impairs the physical and/or mental ability of a person to perform his/her normal work or non-occupational activities supposedly for the remainder of his/her life.



- ‘Not yet recovered’: Residual signs and/or symptoms remain (at the time of the report). *This means at least one AEFI category should have no duration information.*
- ‘Fully recovered’: All signs and symptoms have resolved. *This means all AEFI categories should have duration information and none of the ‘Unresolved’ checkboxes should have been checked.*
- ‘Unknown’: The outcome of the AEFI is unknown or unclear.

If the client is not yet recovered, provide any additional pertinent details in the corresponding comment box and provide updates as they become available. Similarly, if the event resulted in permanent disability and/or incapacity or death, provide any additional pertinent details in the corresponding comment box. *Remember that in Panorama, once comment is added, it cannot be modified or deleted without having to delete the entire record.*



## Highest level of care obtained

Indicate the highest level of care obtained for the reported AEFI by selecting one of the provided response options:



- ‘Unknown’: It is unknown if the patient received care for the reported AEFI.
- ‘None’: No care was received for the reported AEFI.
- ‘Telephone advice from a health professional’: The patient received telephone advice from an HCP regarding the reported AEFI.
- ‘Non-urgent visit’: The patient was seen by an HCP in an outpatient setting (e.g., at a physician’s office or walk in clinic) for the assessment and/or treatment of the reported AEFI.
- ‘Emergency visit’: The patient was seen by an HCP in an emergency room setting requiring <24 hours hospital stay based on known date/time of admission and discharge, 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.*
- ‘Required hospitalization’: The patient was hospitalized for ≥24 hours based on known date/time of admission and discharge, for the assessment and/or treatment of the reported AEFI. Indicate the number of days the patient was hospitalized, the date of admission and the date of discharge.
- ‘Resulted in prolongation of existing hospitalization’: The patient was already confined in a hospital at the time of immunization and the AEFI resulted in a longer hospital stay. 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.



Provide any additional pertinent details in the corresponding comment box. *Remember that in Panorama, once comment is added, it cannot be modified or deleted without having to delete the entire record.*

## Treatment received

Indicate whether the patient received any treatment, including self treatment, for the reported AEFI by choosing ‘No’, ‘Unknown’ or ‘Yes’. Provide details of all treatments received following the onset of the AEFI in the comments box when applicable. *Remember that in Panorama, once comment is added, it cannot be modified or deleted without having to delete the entire record.*



## Public Health Recommendations



MB

*In Manitoba, this section is completed by the regional MOH only. Skip this section if you are reporting the AEFI to the regional MOH.*

*In Panorama, this section displays upon saving and submitting the AEFI for review. MOHs or their designate can complete this section after the AEFI is submitted and saved. After completing the review, if the client has contraindication to a vaccine or needs precautionary arrangement before the next immunization visit for a vaccine, the reporter should enter the relevant information in **Special Considerations**.*

### AEFI Status:

- **Draft** – Saved as draft, not submitted
- **Submitted for review** – Submitted but review not complete
- **Review in progress** – Started review but has not completed review, resubmitted, or requested for more info
- **Information required** – Reviewed and requested for more info
- **Consultation requested** – If further consultation required from provincial MOH
- **Review complete** – Reviewed and gave recommendations, report completed

*Note that the foregoing statuses are system-generated values.*

**‘Eligible for reporting to PHAC’:** Whether the event is reportable to the Public Health Agency of Canada. **Leave this box blank.** The vaccine safety coordinator at MHSAL will check this box if the AEFI report is complete and ready for submission to PHAC.

**‘On behalf of Health Service Provider’:** Check this box if the user is entering the recommendations on behalf of another MOH or designate. Click ‘Find’ and enter the name of the MOH or designate providing the recommendations.

**Public Health Recommendations:** Indicate by choosing all that apply, your recommendations for the client with regard to future vaccinations, and specify additional information when requested:

- **‘No change to immunization schedule’**
- **‘Determine protective antibody level’**
- **‘No further immunizations’** – Need to specify the agent in corresponding comment box, including enter information under **Special Considerations** as contraindication
- **‘Expert referral’** – Need to specify the expert in corresponding comment box
- **‘Controlled setting for next immunization’** Need to enter information under **Special Considerations** as precaution
- **‘Active follow-up for AEFI recurrence after next vaccine’**

- ‘**Other**’ – Need to specify in corresponding comment box, including enter information under **Special Considerations** as contraindication, exemption or precaution
- ‘**No recommendations**’

Must select at least one recommendation and click ‘Add Recommendations’. If that selection includes ‘specify’, then you must provide a comment or you will be prompted to do so before going to the next step.

**Recommendation Comments:** Provide any additional pertinent details in the corresponding comment box. *Remember that in Panorama, once comment is added, it cannot be modified or deleted without having to delete the entire record.*



## **Document Management**



*Not currently in use.*



## **Assigned To**

**Workgroups:** Select the workgroup that reporter/reviewer wishes to assign the AEFI report to. **Users must select a Workgroup in order to submit the form.** The AEFI workgroup will be defaulted to the region under which you are logged in as, so choose the AEFI workgroup associated with your login even if it is not the same as the one the AEFI is associated to. The workgroup does not change the region the AEFI was assigned to when it was created.

**User:** Not currently in use.



## **Follow-up Information for a Subsequent Dose of Same Vaccine(s)**

If ‘Active follow-up for AEFI recurrence after next vaccine’ is checked as a public health recommendation, this section will appear after the recommendation is saved and review is completed. Complete this section when an individual who has previously experienced an AEFI following administration of a vaccine receives a subsequent dose of the same vaccine.

Select one of the responses as described below to describe the outcome following the administration of the subsequent dose of vaccine and provide all pertinent details in the corresponding comments box:

‘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. Need to complete a new report for the subsequent AEFI.

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

*'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. Need to complete a new report for the subsequent AEFI.*

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



## **Reviewing/Completing an AEFI Report in Panorama**

*'Start Review': When the AEFI is submitted, the MOH can begin their review. "Start Review" can be selected. A message will pop up prompting the user to enter comments. The user should enter in the space provided who is reviewing and what phase of review.*

*'Need More Information': If more information is required from the reporter, 'Need More Information' can be selected. A message will pop up prompting the user to enter comments. The user should enter in the space provided what information is needed and from who.*

*'Need Consultation': If consultation with a central provincial MOH or other specialist is required before recommendations can be made, 'Need Consultation' can be selected. A message will pop up prompting the user to enter comments. The user should enter in the space provided who needs to be consulted and for what issue.*

*'Review Complete': If the MOH has completed their review and finished public health recommendations, select "Review Complete". This indicates that the AEFI has been completed and can be reviewed centrally for submission to PHAC.*



## **AE History**

*The chronological progress of the AEFI report from beginning to most recent status is outlined here.*