iPHIS User Guide: Entering Adverse Events Following Immunization (AEFIs) in iPHIS

Updated: September 2024

Introduction

This quick reference guide will help public health unit (PHU) investigators enter Adverse Events Following Immunization (AEFI) investigation details in iPHIS. This is a companion guide to the iPHIS User Guide: Adverse Events Following Immunization; it is a condensed version of the full user guide that focuses on the required data fields that are essential for AEFI case entry. Refer to the iPHIS User Guide: Adverse Events Following Immunization for more detailed information and guidance.

How will this help you?

- This easy to follow guide will make your work quicker and easier.

- Correct data entry means no future data cleaning required.

- High quality data to benefit your PHU programs.

- Better data to answer your questions.

How iPHIS AEFI data are used to:

- Identify and investigate serious or unexpected occurrences of AEFI, particularly for new vaccines.

- Detect and investigate safety signals (e.g. lot specific problems).

- Estimate provincial rates of reported AEFI by vaccine.

- Shared with the Public Health Agency of Canada (PHAC) for national AEFI surveillance.

- Report to stakeholders on the safety of publicly funded vaccines in Ontario.

- Maintain public confidence in vaccine programs.

Note:

- (M) means that the field is system mandatory. These fields are marked with a red diamond (♦) in iPHIS. Users cannot save the record without appropriate data entry.

- (R) means that the field is required for provincial surveillance. These fields are included in PHO's routine data quality checks and in annual provincial data cleaning.

1.0 Case Details Screen

Follow these steps to create an AEFI case. When the investigation is complete, close the case as either 'Confirmed' or 'Does not meet definition'.

Steps:

Navigate to **Cases > Case > Case Details** and complete according to the instructions below.

Table 1. Case Details Data Fields Guide

Field Name	Data Entry Information	Dropdown Values	Page # in iPHIS Guide
Reported Date (M)	Enter date reported to PHU.	None; manual entry	10
Health Unit Responsible (M)	PHU completing investigation.	• All PHUs in Ontario • MOHLTC - PHD	10
Branch Office (M)	Select as appropriate.	PHU-specific values	10
Diagnosing HU (M)	PHU where client was living when case reported to public health.	• All PHUs in Ontario • MOHLTC - PHD	10
Classification (M)	Select the value that aligns with the status of the investigation and the case classification definitions outlined in the AEFI-specific Appendix 1, Infectious Disease Protocol and Adverse Events of Special Interest (AESIs) for COVID-19 Vaccines Surveillance. Update as necessary.	• Person Under Investigation (only use during the investigation and there is not enough information to classify as 'Confirmed' or 'Does not meet definition') • Confirmed • Does Not Meet Definition	11
Classification Date (M)	Date the **Classification** was determined or changed.	Manual entry.	12
Outbreak Case Classification	Choose same value as Classification.	See **Classification** above	12
Outbreak Class. Date (M)	Same value as the Classification Date.	Manual entry.	12

Field Name	Data Entry Information	Dropdown Values	Page # in iPHIS Guide
Disposition (M)	Current state of the investigation. Update as necessary. ***Cases with a Disposition of 'LOST TO FOLLOW UP' or 'UNTRACEABLE' can still be classified as a 'CONFIRMED' case as long as there is enough information to support meeting the surveillance case definition.	Only use these: • Pending • Complete • Closed-duplicate-do not use • Entered in error • Lost to follow up* • Referred to FNIHB • Untraceable*	12
Disposition Date (M)	Date **Disposition** was determined or changed.	Manual entry.	14
Status (M)	Current state of the investigation. Update as necessary.	• Open • Closed	14
Status Date (M)	Date case was opened or closed.	Manual entry.	14
Priority (M)	This is PHU-specific. Enter the priority level determined by your PHU.	• High • Medium • Low	14
Client Address at Time of Case (R)	Select address of client at time of AEFI report.	Populated from address in the Client Demographics module.	15
Reporting Source (R)	Only use this data field when the AEFI was reported by a physician or nurse practitioner (RN-EC). Enter External Source Type and either Source Name or City to filter and select the reporting source from the Name dropdown list. For all other reports (i.e., RN, RPN, pharmacist, family member), enter the reporting source under Other Reporting Source Type.	Physician (includes nurse practitioners) ***Do not use any other value** (e.g., Hospital, Agency, Branch Office, Health Area, Lab, etc.)	15

Field Name	Data Entry Information	Dropdown Values	Page # in iPHIS Guide
Other Reporting Source Type (R)	Use this field when the AEFI was reported by someone other than a physician or nurse practitioner. Select the value that best reflects the source of the initial report. If the initial report was from the client or a family member, select 'Self (Client)' or 'Family Member'. For reports received from an active vaccine surveillance program (i.e., CANVAS, SPRINT-KIDS), select either 'CANVAS –AEFI ONLY' or 'SPRINT-KIDS - AEFI ONLY' and not the healthcare professional associated with the initial AEFI report. If the reporting source is a pharmacist, RN, RPN, or another healthcare provider other than a physician or nurse practitioner, select 'Healthcare professional'.	• Canadian Blood Services • CANVAS –AEFI ONLY • SPRINT-KIDS - AEFI ONLY • Detention centre • Family member • Friend • Insurance • Healthcare professional • Group home • Shelter • Other (Specify) • Self (Client) • Workplace • Other agency • CIC (Citizenship and Immigration Canada)	15
Other Reporting Source Name (R)	Use to specify the reporting source when Other Reporting Source Type is completed. If 'Healthcare Professional' is selected for Other Reporting Source Type, record the name and professional designation (e.g., June Juniper, pharmacist). If 'Self (Client)' or 'Family member' is selected for Other Reporting Source Type, specify the relationship (e.g., self, mother) but **DO NOT record the name of the family member or client in this field**. This field is shared with PHAC and should not contain this personal health identifier (PHI).	Add the name of the healthcare reporter and professional designation. If reported by self or a family member, type in 'SELF' or 'MOM', 'DAD', etc., as appropriate. DO NOT TYPE ACTUAL NAMES.	16
Investigator (M)	Auto-populates to iPHIS user entering the data. Change as needed.	Values specific to Responsible Health Unit.	16

2.0 Risk Factors

Important Notes:

- Select a response of 'yes', 'no', or 'unknown' for each medical risk factor listed in the table below. Do not leave as 'not asked'. Other medical risk factors not outlined in the table below can be completed at the discretion of the PHU.

- If 'yes' is selected for the risk factor 'Immunization Program Error', select the appropriate immunization error from the dropdown menu located beside the risk factor.

- If 'yes' is selected for any other risk factor, enter a brief description in the Notes section of the relevant risk factor.

Steps:

1. Navigate to Cases > Case > Risks and click the (+) beside Medical Risk Factors
2. Select the appropriate response for **each** risk factor

Table 2. Risk Factors Data Fields Guide

Field Name	Data Entry Information	Dropdown Values	Page # in iPHIS Guide
Medical Risk Factors (R)	Select 'yes', 'no' or 'unknown' for each risk factor: • Chronic illness/underlying medical condition (specify) • History of AEFI • History of allergy • Pregnant (if yes, include the gestational weeks in Notes) • Immunocompromised (specify) • Immunization program error If 'Yes' is selected for Immunization program error, select the appropriate immunization error type from the dropdown menu beside the risk factor.	• Yes* • No • Unknown *If 'yes', enter brief details in the free text box directly beside the risk factor. If needed, more information can be added in Case Notes.	18-20

3.0 Immunizations

Important notes:

- **Only enter the immunization(s) associated with the AEFI case under investigation**. If the case reports multiple adverse events from different immunization dates, you will need to create separate AEFI investigation(s); see Appendix 4 for instructions on entering two or more AEFIs reported on the same day.

- All entries for the case must have a check mark (✓) under the editable column. If you do not see this checkmark, you will need to re-enter the agent in this section so it will be associated with the adverse event.

- If the exact administration date(s) is unknown, enter the best approximation of the date.

Steps:

1. Navigate to Cases > Case > Intervent/Treatments and click the (+) beside Immunizations/Chemoprophylaxis

2. Click **New Immunization** and enter all relevant details per the instructions below.

Table 3. Immunizations Data Fields Guide

Field Name	Data Entry Information	Dropdown Values	Page # in iPHIS Guide
Administration Date/ Time (M)	Auto-populates with the Reported Date. Update with immunization administration date. Check the Accurate box to indicate that the exact administration date is known. If the exact date is unknown, enter as much of the date as possible (e.g., '2021-06-01' for an immunization given sometime in June 2021). If no date information is known, enter as '1900-01-01'. Make a note that this is an approximation in the Comments field.	Manual entry.	22
HU (M)	Auto-populates with the user's PHU. If needed, change to the PHU where client received vaccine.	All PHUs in Ontario **MOHLTC – PHD:** select for immunizations received outside of Ontario.	22
Branch (M)	Select as appropriate.	Values are PHU-specific.	22

Field Name	Data Entry Information	Dropdown Values	Page # in iPHIS Guide
Provider/ Personnel (R)	If administered by a physician/nurse practitioner: Enter surname and filter by 'PHYSICIAN' as Professional Status. Select correct name from dropdown list. If not administered by physician/nurse practitioner or the provider was not found through the search: Enter 'Ext%' as Source Name and click Filter. Select 'External, Other' and enter provider's name and professional designation (if applicable) in the Comments field below. If administrator is unknown, enter 'unk%' as the Source Name and click Filter. Select 'UNKNOWN'.	Generated by the Provider/Personnel Filters. Narrow your search by entering as much information as possible.	22-23
Where Administered (R)	Select the facility/location where the vaccine was administered. If received at a workplace that is also a health care setting (e.g., hospital), select the actual physical location (e.g., 'Hospital') and not 'Workplace'. If the vaccine was administered outside of Ontario, select 'Out of province'. If 'Other (Specify)' is selected, record the location in the Comments section below. Note: All other narrative notes should be entered under Cases > Case > Notes.	• Correctional Facility • Health Unit • Hospital • Other (Specify) • Out of province • Physician Office • School • Shelter • Workplace • Unknown	23
Agent (M)	Select the vaccine received. Do not use an inactivated agent marked with an (I) unless the AEFI is a historical event for a discontinued vaccine.	Select appropriate agent from dropdown list.	23-24
Lot Number (Expiry Date) (M)	Select the lot number of the vaccine received. If unknown, select 'DC (2099-01-01)' and enter 'Unknown lot number' in the Comments field below. If lot number is known but is unavailable in iPHIS, select 'DC (2099-01-01)' for the time being and ask your PHU's PRC to contact the Service Desk (PublicHealthSolutions@Ontario.ca), to have it added. Return and update the lot number when it has been added to iPHIS.	Values are specific to each Agent. DC (2099-01-01) is used for unknown lot numbers.	24-25

Field Name	Data Entry Information	Dropdown Values	Page # in iPHIS Guide
Site (M)	Select the site of vaccine administration from the dropdown list. If unknown, choose '?? – Unknown site'	Select appropriate site from dropdown list	25
Route (R)	Select the route of vaccine administration. If the route is unknown, select 'Unknown'.	• Intradermal • Intramuscular • Intranasal • Intravenous • Oral • Subcutaneous • Topical • Unknown	25
Dosage (R)	Enter the numeric value of the dosage administered.	Manual entry	25
Dosage unit (R)	Enter the units of the dosage (e.g., cc, ml).	• cc • grams • international units • mg • ml • mu • vials	25-26
Dose # (R)	Enter the dose number of the received vaccine if it is a part of a multi-dose series. Indicate in Cases>Case>Notes if the case has a prior history of receiving the vaccine. Enter '1' for a single-dose vaccine series (e.g., Pneu-P-23). If the dose number is unknown, leave the field blank.	Manual entry	26
Informed Consent (M)	Mandatory field, but not needed for provincial AEFI surveillance. If unknown, leave as 'Unknown'.	• Yes • No • Unknown	26
Comments	Only use to enter any of the following: If Administration Date/Time is partially known, enter any known parts of the date (e.g., year and month). Provider/Personnel is 'External, Other' or 'Internal, Other', enter provider name & professional designation If the Lot Number (Expiry Date) is entered as 'DC (2099-01-01)' enter 'Unknown/pending lot number'.	Manual entry	26

4.0 Outcome (fatal cases only)

Only enter outcome information on this screen when reporting a death that is temporally associated with receiving a vaccine. For any death temporally associated with receipt of a vaccine, immediately contact the IVPD team at PHO at ivpd@oahpp.ca.

Steps:

1. Navigate to **Cases > Case > Outcome** and complete data entry according to the instructions below.

Table 4. Outcome (fatal cases only) Data Fields Guide

Field Name	Data Entry Information	Dropdown Values	Page # in iPHIS Guide
Outcome (M)	Select 'FATAL' if case died. **Do not record any other outcome.**	Fatal	28
Outcome Date (R)	Enter date of death.	Manual entry	28
Accurate (R)	Select if the exact date of death was entered.	None	28
Cause of Death (M)	Enter cause of death as per Part I and/or Part II of Section 11 of the Cause of Death section of the Medical Certificate of Death, if available. If unknown, type 'Unknown'.	Select 'UNKNOWN' unless there is clear information obtained from the relevant clinical documentation to support the selection of an alternate value.	28
Type of Death (M)	Select 'Unknown' unless there is sufficient information obtained from relevant clinical documentation (i.e., based on autopsy/coroner's report findings) to support the selection of an alternate value.	Reportable disease contributed to but was not underlying cause of death Reportable disease was underlying cause of death Reportable disease was unrelated to cause of death Unknown	28
Source (R)	Enter the source of cause of death information (e.g., autopsy).	Manual entry	29

5.0 Case Notes

Important notes:

- Enter detailed case notes on this screen. Each AEFI report requires a case note to describe how it meets the case definition and adverse event criteria outlined in AEFI Appendix 1 or the AESIs for COVID-19 Vaccines Surveillance technical brief. Record a detailed description of the event to support the selected adverse event.

- Do not include any identifying information in the case notes. This includes, but is not limited to, the name, date of birth or address of the client, attending health care worker(s), or the AEFI reporter. The purpose of this is to help ensure personal health information is not transmitted to external stakeholders as part of national vaccine safety surveillance.

Steps:

1. Navigate to **Cases > Case > Notes.**

2. Select **Create New Note**

3. Complete the information and select **Save.**

Table 5. Case Notes Data Fields Guide

Field Name	Data Entry Information	Page # in iPHIS Guide
Note (M)	Record a detailed description of the event including: • Chronology of signs and symptoms • Investigation • Therapy • Findings of medical consultation (including specialist) • Relevant medical history • Allergies • Medications • Prior adverse events Include enough detail to support the selected adverse event. **Do not include any identifying information in the case notes.**	31
Provider (M)	Auto-populates with the name of the iPHIS user entering the note. Select a different name if entering the note on behalf of another iPHIS user.	31

6.0 Adverse Events

Important notes:

- Before you can interact with the Adverse Event sections, you must navigate to Cases > Client > Adverse > List

- If you need to make a change after saving, see Appendix 5 of the iPHIS User Guide for AEFIs for instructions on modifying or deleting previously saved information in the adverse events section.

6.1 Adverse Event Details

Steps:

1. Navigate to **Cases > Client > Adverse > List**

2. If the adverse event does not exist, select **New Adverse Event**. If the adverse event exists, select the **Details** button to view or edit the event record.

3. Enter all relevant information and Select **Save**.

Table 6a. Adverse Events Data Fields Guide

Field Name	Data Entry Information	Dropdown Values	Page # in iPHIS Guide
Health Unit	Auto-populates.	Auto populates	34
Branch (M)	PHU-specific. Select as appropriate.	PHU-specific values.	34
Reported Date (M)	Enter the date the adverse event was first reported to the PHU. This should be the same date entered in the Case Details screen. Do not change this date if a client is transferred from another PHU.	Manual entry.	34
FOI Discussed (M)	Freedom of Information (FOI). Select 'Unknown' unless the PHU has spoken with the client.	• Yes • No • Unknown	34
Administration Date / Time (M)	Select the date/time of vaccine administration. iPHIS populates this field using the immunization date entered in Cases > Case > Intervent/Treatments. Note: If more than one agent is temporally associated with the event, select the earliest administration date.	Manual entry.	34
Accurate (Administration Date/Time)	Check the Accurate box if the exact administration date known.	None.	34

Field Name	Data Entry Information	Dropdown Values	Page # in iPHIS Guide
Physician Filter (R)	If known, enter the physician or nurse practitioner who provided medical care by entering search terms in the filter.	None.	34-35
Physician Name (R)	Select the physician or nurse practitioner from the dropdown list generated from the search.	Custom values generated by Provider/ Personnel Filters	35
Medical Consultation Sought (M)	Select 'Yes' if the case had a non-urgent, outpatient consultation (including telephone consultation) by a healthcare provider for the adverse event.	• Yes • No • Unknown	35
Consultation Date (R)	If 'Yes' is selected above, enter the date of medical consultation. If the case had more than one medical consultation, enter the date of the earliest consultation.		35
Seen in ER (R)	Select 'Yes' if the case was assessed in an emergency department for the adverse event.	• Yes • No • Unknown	35
Date Seen in ER (R)	If 'Yes' is selected above, enter the emergency department assessment date. If the case had more than one emergency department visit, enter the date of the earliest visit.		35
Hospitalized (M)	Select 'Yes' if the case was admitted to hospital as an in-patient for the current adverse event or if an existing hospitalization was prolonged because of the adverse event. Note: If 'Yes' is selected, enter the admission and discharge dates.	• Yes • No • Unknown	35-36
Hospital Filter (R)	Enter the hospital name if the case had in-patient hospitalization (if known). Type in the information and select Filter to search for the hospital.	None.	36
Hospital Name (R)	Select the hospital from the dropdown list generated from the hospital filter search.	Values generated by the hospital search filter.	36
Admit Date (R)	If the case had an in-patient hospitalization, enter the admission date. If the case had multiple hospitalizations, enter the admission date of the first hospitalization.	Manual entry.	36

Field Name	Data Entry Information	Dropdown Values	Page # in iPHIS Guide
Discharge Date (R)	If the case had an in-patient hospitalization, enter the date of discharge (or date of death, if the case died while in hospital). If the case had multiple hospitalizations, enter the discharge date of the first hospitalization.	Manual entry.	36
Outcome Code (M)	Select the value that best reflects outcome of the case at the time of iPHIS entry. Update if the outcome has changed when closing the case. If the outcome is 'Fatal' (i.e., death has been temporally associated with receipt of vaccines), it is mandatory to also enter this under Cases > Case > Outcome	• Fatal • Not yet recovered • Recovered • Residual effects • Unknown	37

6.2 Adverse Event Reactions

Steps:

1. Navigate to **Cases > Client > Adverse > Reaction**.

2. Enter all the information specified in the table below and select **Add**.

3. Repeat the steps to add additional adverse event reactions.

Table 6b. Adverse Events Reactions Data Fields Guide

Field Name	Data Entry Information	Dropdown Values	Page # in iPHIS Guide
Adverse Event(s) Reactions (M)	A case can have more than one adverse event. Create a new adverse event reaction for each event. All adverse event reactions must be described in detail in the case notes (Cases > Case > Notes).	Appendix 3 of the iPHIS AEFI user guide lists all available reactions.	39
Onset Date/Time (R)	Enter the date/time of event onset. If the event involves multiple signs and symptoms, enter the date/time of the earliest sign/symptom onset.	Manual entry.	39
Interval to onset (R)	Enter the interval from immunization to the first symptom/sign onset.	Manual entry.	39
Days	Use if the interval is greater than one day.	Manual entry.	39

Field Name	Data Entry Information	Dropdown Values	Page # in iPHIS Guide
Hours	Use if the interval is less than or equal to 24 hours.	Manual entry.	39
Minutes	Use if the interval is less than one hour.	Manual entry.	40
Treatment Received (R)	Select 'Yes' if treatment was received for the reported event (e.g., analgesic/antipyretic, adrenaline, antihistamine).	• Yes • No • Unknown	40
Treatment Type (R)	Complete if 'Yes' is selected under 'Treatment Received'. Describe treatment details in case notes (Cases > Case > Notes).	• Analgesic/Anti-pyretic • Adrenaline • Antihistamine • Other	40
Duration (R)	Enter the duration of the event (from time of earliest sign/symptom onset to resolution or if not resolved, to the time of closing the case).	Manual entry.	40
Days	Use if the interval is greater than one day.	Manual entry.	40
Hours	Use if the interval is less than or equal to 24 hours.	Manual entry.	40
Minutes	Use if the interval is less than one hour.	Manual entry.	40

6.2.1 Special instruction: Events managed as anaphylaxis

Follow these steps if the AEFI case includes the reaction 'event managed as anaphylaxis'.

Steps:

1. Navigate to **Cases > Case > Questionnaire.** iPHIS will display the Event Managed as Anaphylaxis questionnaire form.

2. Select an appropriate response for:
   - Prior anaphylaxis (M)
   - Prior allergic reaction(s) (M)
   - Epinephrine Administered. (M)

3. If 'Yes' is selected, enter details about epinephrine administered (up to five doses). Refer to Appendix 11 of the iPHIS AEFI User Guide and complete the known fields.

4. Complete data entry for the other fields within the questionnaire.

5. Select **Save**.

6.3 Adverse Event Agents

Important notes:

- Enter the adverse event agent(s) on this screen. The agent dropdown list includes all immunizations that were entered in Cases > Case > Intervent/treatments with an administration date on or before the adverse event reported date.

Steps:

1. Navigate to **Cases > Client > Adverse > Agents**.

2. Select the immunization(s) from the Code/Description dropdown menu and select Add.

3. Repeat these steps if there is more than one immunization involved with this AEFI.

6.4 Adverse Event Recommendations

Important notes:

- Enter the adverse event recommendation(s) on this screen. This section should be completed independent of the case classification (e.g., pending MOH recommendation(s) does not prevent classification of the event for surveillance purposes). Only include recommendations made by the Medical Officer of Health (MOH), Associate MOH (AMOH) or designate (e.g., RN).

Steps:

1. Navigate to **Cases > Client > Adverse > Recomm**.

2. Complete the information in the table below and select **Add**.

3. Repeat these steps if more than one recommendation was made.

Table 6c. Adverse Events Recommendations Data Fields Guide

Field Name	Data Entry Information	Dropdown Values	Page # in iPHIS Guide
Reported Date	Auto-populates.	Auto populates.	43
Recommendations (M)	Only select the recommendation(s) made by the MOH or designate. Select 'No recommendation' if no recommendation was made by the MOH or designate.	- No recommendation - No change to immunization schedule - Determine protective antibody levels (specify) - Follow-up for AEFI after next vaccine - Controlled setting for next immunization - Expert referral (specify) - No further immunization – contraindication (specify vaccine) - No further immunization - series complete (specify vaccine) - Other (specify)	43

Field Name	Data Entry Information	Dropdown Values	Page # in iPHIS Guide
MOH/ Physician Name (M)	Select the name of the MOH/AMOH/public health physician who made the recommendation. If applicable, enter a designate's name instead (e.g., RN as designate). If the name is not listed select '0CDOMINTAKE' and enter the name in the 'Comments' section below.	Manual entry.	43-44
Comments (R)	Use this field to: - Document additional details here if the selected 'Recommendations' value includes 'Specify'. - Specify which vaccine(s) the recommendations are for. - Include the name of the MOH or designate who made the recommendation if it was not in the 'MOH/Physician Name' dropdown list. Enter all other narrative notes about the case in Cases > Case > Notes.	Manual entry.	44

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