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iPHIS User Guide: Adverse Events Following Immunization (AEFIs)

Manual

Outbreak Module, Version 4.0

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Public Health Ontario

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Introduction

This user guide outlines the standardized data entry procedures and requirements for adverse events following immunization (AEFIs) into the Outbreak Management module of the integrated Public Health Information System (iPHIS). It highlights data fields in iPHIS that are required for provincial vaccine safety surveillance. This document is intended to help staff working in Ontario public health units (PHUs) with documenting AEFI investigations. A shorter version of this user guide also available as a companion guide to this user guide (Quick Reference Guide for Entering Adverse Events Following Immunization (AEFI) in iPHIS).

Online training available:
eLearning training, including demonstrations on entering AEFIs into iPHIS, is available on the Public Health Ontario (PHO) vaccine safety webpage.

PHO is here to help Public Health Units:
Contact the Immunization and Vaccine-Preventable Diseases (IVPD) team at ivpd@oahpp.ca if you have questions about AEFIs, iPHIS data entry or the AEFI eLearning module.

For technical issues in iPHIS, contact the Public Health Solutions Service Desk at 1-866-272-2794 or PublicHealthSolutions@Ontario.ca

What is an AEFI?

An AEFI is an unwanted or unexpected health effect that happens after someone receives a vaccine. An AEFI may or may not be caused by the vaccine.

An AEFI may be either an expected event (i.e., listed in product monograph) or an unexpected event. In either scenario, it is reportable to the provincial surveillance system if it meets the surveillance definitions outlined in AEFI Appendix 1, Infectious Diseases Protocol. All reported AEFIs must be assessed using these criteria. The Adverse Events of Special Interest (AESI) for COVID-19 Vaccine Surveillance technical brief outlines the criteria for AESIs associated with COVID-19 vaccines.

For provincial AEFI reporting, only complete an AEFI report when the adverse event(s) follows administration of one or more active immunizing agents (see Appendix 2 for a list). Do not complete an AEFI report if an adverse reaction follows the administration of a passive immunizing agent (e.g., immune globulin), a diagnostic agent (e.g., tuberculin skin test), or any other drug product, without administration of concurrent active immunizing agent(s). Instead, follow the established procedures for reporting adverse drug reactions via Health Canada using the Consumer Side Effect Reporting Form.

Ontario AEFI Reporting Form

Use of the AEFI Reporting Form is highly recommended for initial reporting of AEFI information – either by health professionals reporting AEFIs to their local PHU or by PHUs recording AEFI information reported to them.

The form is designed to capture the information needed for provincial vaccine safety surveillance and for complete and accurate iPHIS data entry. PHUs may use supplementary forms for their own AEFI case investigation and management procedures. Appendix 1 provides an annotated version of the Ontario AEFI Reporting Form and shows how data elements on the form correspond to data entry fields in iPHIS. PHUs do not need to send the completed AEFI reporting forms to PHO.

Timely Entry and Completion of AEFI Reports

In order to effectively monitor vaccine safety, it is important to complete AEFI reports in iPHIS in a timely manner. Users must enter new AEFI reports into iPHIS within **five business days** of receipt of an AEFI report by the PHU in accordance with iPHIS Bulletin #17 – Timely Entry of Cases and Outbreaks (revised October 2023). This should include the "minimum mandatory data elements" for the Client Demographics module and the Outbreak Management module as defined in Bulletin #17. Once follow-up is complete and no further investigation is required, PHUs have **30 days** to complete data entry and close the case in iPHIS. In cases where AEFI reports need to be transferred between PHUs, refer to iPHIS Bulletin #13 which provides guidance on a standardized process of transferring clients from one PHU to another within iPHIS.

If there is enough information available within five days of receipt of an AEFI report to indicate that the case clearly does not meet the provincial surveillance definition outlined in AEFI Appendix 1, Infectious Diseases Protocol, then entry of the case as 'Does not meet definition' into iPHIS is at the discretion of the PHU; there is no expectation for additional case details to be entered, including case notes. However, if it is unknown whether the AEFI report meets case definition within five business days of receiving the report and requires further investigation, then the report should be entered as a 'Person under investigation (PUI)' and the classification updated to 'Confirmed' or 'Does not meet definition' as soon as there is enough information available to support the classification.

Historical AEFIs (i.e., a newly reported adverse events associated with vaccine administration occurring in the past) may be reported if there is enough information available to determine if the adverse event(s) meets the confirmed case definition. Report should have enough data to complete all mandatory and required data fields in iPHIS.

iPHIS has certain data fields that are shown with a red diamond. These are system **mandatory (M)** data fields that must have data entry in order to save the record. There are also additional data fields that are **required (R)** for provincial AEFI surveillance. **Information from both mandatory and required data fields is necessary for vaccine safety surveillance in Ontario.** These fields are included in PHO's routine data quality checks and in annual provincial data cleaning. PHUs may enter information in other data fields for their own internal use; however, this information will **not** be extracted from iPHIS for provincial surveillance or sent to the Public Health Agency of Canada for inclusion in the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS), the national database containing AEFIs reported from all provinces and territories in Canada.

PHO continuously monitors AEFI information in iPHIS to ensure timely surveillance of vaccine safety in Ontario. Therefore, it is important to enter AEFI reports as soon as possible and to update information as it becomes available during the investigation.

Vaccine Safety Surveillance at PHO

The provincial vaccine safety surveillance system relies on passive reporting of AEFIs by healthcare providers, vaccine recipients, or their caregivers to their local PHU. Additionally, some AEFIs may be reported through active vaccine safety surveillance systems, such as the Canadian National Vaccine Safety Surveillance Network (CANVAS). More information about vaccine safety surveillance in Ontario can be found here.

The Immunization and Vaccine Preventable Diseases (IVPD) team at PHO is responsible for provincial vaccine safety surveillance. This includes monitoring of AEFIs reported in iPHIS to identify and investigate any vaccine safety issues and contribute to evaluation of immunizations programs. Provincial vaccine safety data are also submitted for inclusion in the CAEFISS.

The IVPD team is available to PHU staff for consultation on individual AEFI reports and can help with understanding AEFI reporting requirements, including case definitions. The team also developed AEFI resources for PHUs and health care providers, which are available on the PHO Vaccine Safety website.

Supporting Resources

- AEFI Appendix 1, Infectious Diseases Protocol
- Technical Brief: Adverse Events of Special Interest (AESIs) for COVID-19 Surveillance
- Ontario AEFI Reporting Form
- PHO's iPHIS resources
- iPHIS and Cognos Document Repository (only available to public health unit Problem Resolution Coordinators (PRCs) and Designated Trainers (DTs))

PHO is here to help public health units

Contact the IVPD team at PHO (ivpd@oahpp.ca) if you have any questions about a specific AEFI report, the reporting process including this User Guide, the AEFI reporting form, guidance in AEFI Appendix 1, Infectious Diseases Protocol or data entry in iPHIS.

For technical issues in iPHIS, contact the Public Health Solutions Service Desk at 1-866-272-2794 or PublicHealthSolutions@Ontario.ca

1.0 Case Details

> Follow these instructions to create a case. Occasionally you may receive multiple AEFI reports on the same day for the same client following vaccines administered on different dates. There are some technical limitations in iPHIS that make these difficult to enter. Refer to Appendix 4 for detailed instructions on how to enter these cases.
>
> You can always contact the IVPD team at PHO (ivpd@oahpp.ca) if you are uncertain about how to proceed with data entry or need support with anything AEFI-related.

Creating a Case

Steps:

1. Create the client or update an existing client as per the Client Demographics user guide.
2. Then, from the left navigation menu, select **Outbreak > Management**. The **Outbreak Search** screen displays (see Appendix 10, Outbreak Search Screen).
3. Enter **0000-2005-001** in the **Outbreak Number** field.
4. Select **Search**.
5. The 'Sporadic Adverse Vaccine Event Cases' outbreak will appear. Select the **Details** button to the far right (see Appendix 10, Sporadic AEFI Outbreak Results).
6. Enter relevant search criteria (e.g., client ID or first and last name) to check if the case has previously been created. The **Health Unit Responsible** field defaults to your PHU. Set this to the blank line at the top of the dropdown to widen your search.
7. Select **Search.** If the case is found, select the **Details** button to access the **Case Details** screen for that case. The case **Status** must be set to 'Open' for a case to be updated.
8. If the case has not yet been created, select the **New Case** button (see Appendix 10, Case Results).
9. Complete a Client sub-search using the Client ID generated in Step 1 (see Appendix 10, Client Sub-Search Screen).
10. Click on the **Select** button for the client.

Entering Case Details

> Enter the case details of the AEFI report on this screen. Key information necessary for AEFI surveillance includes **Case Classification**. The **Case Classification** is used for surveillance purposes only (i.e., detecting potential vaccine safety signals, monitoring trends over time). It is not a medical diagnosis and it does not mean that the vaccine caused the adverse event. Pending Medical Officer of Health (MOH) recommendations does not preclude classifying an AEFI according to surveillance definitions. Please see Case Details Quick List Table 1a below for further instructions.

Steps:

1. Enter the information from Case Details Quick List on the **Case Details** screen. Refer to Table 1a for more detailed information.
2. Select **Save**.

Case Details Quick List– Mandatory (M) and Required (R) Data Fields

All data fields below are necessary for provincial AEFI surveillance.

M - Reported Date
M - Health Unit Responsible
M - Branch Office
M - Diagnosing HU
M - Disease
M - Aetiologic Agent
M - Classification
M - Outbreak Case Classification
M - Disposition
M - Status
M - Priority
M - Classification Date
M - Outbreak Classification Date
M - Disposition Date
M - Status Date
R - Client Address at Time of Case
R - Reporting source
R - Other reporting source type
R - Other reporting source name
M - Investigator

Table 1a: Case Details Detailed Guide - Mandatory and Required Data Fields

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
Case ID	The Case ID auto-populates with a unique system-generated identifier for each case.	None; auto-populated.
Reported Date (M)	Enter the date the AEFI was reported to the PHU (i.e., through a health care provider, vaccine recipient, or caregiver). If a client is transferred to another PHU, the Reported Date should **not** change and should remain as the date when the initial PHU became aware of the case.	None; manual entry.
Assigned Date	This field auto-populates to the date of entry and may need to be changed.	None; auto-populated.
Health Unit Responsible (M)	Enter the PHU responsible for completing the case investigation. **Note:** Bulletin #13 – Transferring client responsibility (revised March 2020) provides guidance on how to assign Health Unit Responsible and Diagnosing HU (health unit) in special circumstances (e.g., client's address is uncertain, client moves, etc.).	**All PHUs in Ontario** **MOHLTC - PHD** – when the case moves out of Ontario during case investigation.
Branch Office (M)	PHU-specific. Select as appropriate.	PHU-specific drop-down values.
Diagnosing HU (M)	Enter the PHU where the client was living when the AEFI was reported to public health (e.g., address on the Ontario AEFI Reporting Form). Do not change this if the client moves during the episode. Non-residents of Ontario who were vaccinated in Ontario should have 'MOHLTC – PHD' selected. Refer to Appendix 6 for more information on out-of-province AEFI reports.	**All PHUs in Ontario** **MOHLTC - PHD** – for non-residents of Ontario.
Disease (M)	Auto-populates.	None; auto-populated.
Aetiologic Agent (M)	Auto-populates.	None; auto-populated.

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
Classification (M)	Use the AEFI case classification definitions and criteria outlined in AEFI Appendix 1, Infectious Diseases Protocol or AESIs for COVID-19 Vaccines technical brief. Classify the case as 'Confirmed' or 'Does not meet definition' as soon as there is enough information to support the classification. Details that support the 'Confirmed' classification should be entered in iPHIS promptly. This is to ensure that timely and complete information is available for provincial vaccine safety surveillance. Use 'Person under investigation (PUI)' only when an AEFI is under investigation and there is not enough information to classify as 'Confirmed' or 'Does not meet definition'. **Case must be closed as either 'Confirmed' or 'Does not meet'. A case cannot be closed as 'Person under investigation (PUI)'.** **Note:** Case classification is for surveillance purposes only (i.e., detecting potential vaccine safety signals). It is not a medical diagnosis and it does not mean that the vaccine caused the adverse event.	**Confirmed** An event meeting the case definition in a vaccine recipient that follows immunization that cannot be clearly attributed to other causes. **Does not meet definition** An event in a vaccine recipient that follows immunization that has been clearly attributed to other causes. Also use when the Disposition is 'Entered in Error' or 'Closed duplicate'. **Person under investigation (PUI)** Only use when an AEFI is under investigation and there is not enough information to classify as 'Confirmed' or 'Does not meet definition'.
Classification Date (M)	The date the case was classified. When the Classification field is updated, enter the date the decision was made. This may not necessarily be the same day the field is updated in iPHIS.	None; manual entry.
Outbreak Case Classification (M)	Enter the same value selected for the Classification field.	See Classification above.

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
Outbreak Classification Date (M)	Enter the same value as the Classification Date field.	None; manual entry.
Disposition (M)	Value pre-populates to 'Pending'. Select the value reflecting the current state of the investigation. Determining the requirements for assessing whether case investigation/management is complete is at the discretion of the PHU. The case classification and disposition are different fields and are slightly independent of each other. If there is enough information to classify a case, this should be done regardless of the disposition. **Note:** Cases with a disposition of 'Lost to follow-up' or 'Untraceable' can be classified as 'Confirmed' if there is enough information from the initial report/investigation to support this classification. If there is not enough information to meet a 'Confirmed' classification, the investigation should be closed as 'Does not meet definition'.	**Pending** Select if the investigation is ongoing and the Status is 'Open'. Update this when the Status is changed to 'Closed'. **Does not meet definition** Do not use. Use the Classification field to indicate that a case does not meet definition. **Complete** Select if case investigation/ management is complete. **Entered in error** Select if the case has been created in error. Also select 'Does not meet definition' as the Classification. **Closed – duplicate – do not use** Select if the case is a duplicate case and should **not** be counted. Also select 'Does not meet definition' as the Classification. **Referred to FNIHB** Select if the case is a federal client, defined as an individual who primarily resides and receives health care in Ontario on federally designated lands or in federally administered institutions, and the case is being managed by a federal agency or institution (i.e., First Nations and Inuit Health Branch) or an independent First Nations-led health authority/centre.

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
		Lost to follow-up* Select if the investigation was started but was not completed due to problems contacting the case. **Untraceable*** Select if there is information on the case and the adverse event but the PHU was unable to contact the case and could not begin the investigation.
Disposition Date (M)	The date the disposition was determined or date that the decision was made to update the disposition. This may not necessarily be the same day this field is updated in iPHIS.	None; manual entry.
Status (M)	Indicates whether the case is open or closed. Value pre-populates to 'Open'. Once follow-up is completed and no further investigation is required, PHUs have 30 calendar days to complete data entry and close cases in iPHIS.	**Open** Select when the investigation is ongoing. **Closed** Select when the investigation and all necessary data fields have been completed in iPHIS. Ensure the Disposition is not 'Pending' if the Status is 'Closed'.
Status Date (M)	The date the status was determined or the date that the decision was made to update the status. This may not necessarily be the same day this field is updated in iPHIS.	None; manual entry.
Priority (M)	Enter according to the procedure of each individual PHU. **Note:** This field is **not** used for provincial reporting purposes.	• High • Medium • Low
Client Address at Time of Case (R)	Select the address where the client was living at the time of the adverse event.	Populated by the address entered in the Client Demographics module.

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
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. 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.)
Other Reporting Source Type (R)	Use this data 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, select 'Self (Client)'. If the reporting source is a family member (e.g., parent) select '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 • Detention centre • Family member • Friend • Insurance • Healthcare professional • Group home • Shelter • Other (Specify) • Self (Client) • SPRINT-KIDS-AEFI ONLY • Workplace • Other agency • CIC (Citizenship and Immigration Canada)

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
Other Reporting Source Name (R)	Use this field 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 'SELF' or the relationship (e.g., 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 enter actual names**.
Investigator (M)	Select the name of the investigator currently responsible for the case investigation. Update if the investigator changes.	The list of names auto-populates based on the Responsible Health Unit.
Assignment Date/Time	Auto-populates the date and time each time the investigator is saved.	None; manual entry.

2.0 Risks

Enter information related to required medical risk factors, as indicated below in Table 2a, of the client at the time of vaccine administration. Answer each of the risk factors with either 'Yes', 'No' or 'Unknown'. If the question was not asked, select 'Unknown'. Do not use 'Not Asked'.

Medical risk factors not outlined in Table 2a can be completed at the discretion of the PHU. Behavioural risk factors are not required for provincial vaccine safety surveillance; completion is at the discretion of the PHU.

Steps:

1. Navigate to Cases > Case > Risks.
2. Only enter information on the risk factors listed in Risks Quick List. Refer to Table 2a and Appendix 10, Risk Factor Entry for AEFI Screen for more detailed information.
3. Select the appropriate value from the dropdown beside each listed risk factor.
4. Select Save.
5. If you select 'Yes' to IMMUNIZATION PROGRAM ERROR, select the type of error from the drop down menu located next to the Save button. If you select 'Yes' to one of the other required risk factors, enter brief details in the free text field beside the relevant risk factor. If needed, more information can be added in the case notes (Cases>Case>Notes).

Risks Quick List–Mandatory (M) and Required Data Fields

All data fields in this table are necessary for provincial AEFI surveillance.

R – Chronic illness/underlying medical condition (specify)
R – History of AEFI
R – History of allergy
R – Immunocompromised (specify)
R – Pregnant
R – Immunization program error (specify)

Table 2a: Risks Detailed Guide - Mandatory and Required Data Fields

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
Chronic illness/ underlying medical condition (specify) (R)	Use if case had a chronic illness or underlying medical condition at the time of vaccine administration. If 'Yes' is selected, enter brief details in the free text box directly beside the risk factor. If needed, more information can be added in case notes (Cases>Case>Notes).	• Yes • No • Unknown Do **not** use 'Not Asked'. Use 'Unknown' instead.
History of AEFI (R)	Use to indicate if the case had any previous adverse events following immunization associated with any vaccine (both self-reports or reports that have already been reported in iPHIS or CCM). If 'Yes' is selected, enter the Case ID of previous AEFI report (if in iPHIS) in the free text box directly beside the risk factor. Enter the vaccine, date of AEFI and adverse events that occurred (if available) in case notes (Cases>Case>Notes). If during the current investigation the client reports a historical AEFI (i.e., a newly reported adverse event associated with vaccine administered in the past), determine if the AEFI is reportable and then enter as a separate AEFI case provided all the necessary information is available to complete the record.	• Yes • No • Unknown Do **not** use 'Not Asked'. Use 'Unknown' instead.
History of allergy (R)	Use to indicate if case had any known allergy to vaccine(s), drug(s), food(s), or other allergen(s) at the time of vaccine administration. If 'Yes' is selected, enter brief details in the free text box directly beside the risk factor. If needed, more information can be added in case notes (Cases>Case>Notes).	• Yes • No • Unknown Do **not** use 'Not Asked'. Use 'Unknown' instead.

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
Immuno-compromised (specify) (R)	Use if the case was immunocompromised at the time of vaccine administration. If 'Yes' is selected, enter brief details in the free text box directly beside the risk factor. If needed, more information can be added in case notes (Cases>Case>Notes).	• Yes • No • Unknown Do **not** use 'Not Asked'. Use 'Unknown' instead.
History of allergy (R)	Use to indicate if case had any known allergy to vaccine(s), drug(s), food(s), or other allergen(s) at the time of vaccine administration. If 'Yes' is selected, enter brief details in the free text box directly beside the risk factor. If needed, more information can be added in case notes (Cases>Case>Notes).	• Yes • No • Unknown Do **not** use 'Not Asked'. Use 'Unknown' instead.
Pregnant (R)	Use to indicate if case was known to be pregnant at the time of immunization. If 'Yes' is selected, enter the gestation (in weeks) at time of immunization in the free text box directly beside the risk factor.	• Yes • No • Unknown Do **not** use 'Not Asked'. Use 'Unknown' instead.
Immunization program error (specify) (R)	Use to indicate if the adverse event followed an immunization program error (e.g., incorrect site, incorrect dose, vaccine not indicated/contraindicated, etc.) Only immunization errors that are associated with an adverse event should be reported here. If 'Yes' is selected, use the dropdown field next to the Save button to specify the error type. If needed, additional details can be added in case notes (Cases>Case>Notes).	• Yes • No • Unknown Do **not** use 'Not Asked'. Use 'Unknown' instead.

3.0 Immunizations

Enter immunization information on this screen.

Before entering data on the Adverse Event Details page under the client record, the immunization(s) associated with the adverse event **must** first be created in the **Cases > Case > Intervent/Treatments > Immunizations/Chemoprophylaxis** section. This allows immunization information to be cross-referenced with the data in the Adverse Event Details page. It is essential that the immunizations entered in this section be marked as editable. If an agent appears here but does not have a check mark (✓) under the editable column, you will need to re-enter the agent in this section so it can be linked to the adverse event. See Appendix 10, Example of a Completed Expanded Immunization/Chemoprophylaxis Section for an example of an agent marked as editable.

iPHIS uses the immunizations entered in **Cases > Case > Intervent/Treatments > Immunizations/Chemoprophylaxis** section to populate the list of available agents on the **Cases > Client > Adverse > Agent** screen.

Steps:

1. Navigate to Cases > Case > Intervent/Treatments.
2. Scroll down the page and click on the (+) symbol beside Immunizations/Chemoprophylaxis (see Appendix 10, Immunization/Chemoprophylaxis Section of the Intervention Screen).
3. Select New Immunization (see Appendix 10, Expanded Immunization/Chemoprophylaxis Section).
4. Enter the information from the Immunization Quick List. Refer to Table 3a and Appendix 10, Immunization Details Screen and Example of a Completed Expanded Immunization/Chemoprophylaxis Section for more detailed information.
5. Select Save.
6. Repeat steps 3-5 for each immunization associated with the AEFI case.

Immunization Quick List–Mandatory (M) and Required (R) Data Fields

All data fields in this table are necessary for provincial AEFI surveillance.

M - Administration Date/Time
R - Accurate
M - HU
M - Branch
M - Provider/Personnel filters
R - Provider/Personnel
R - Where administered
M - Agent
M - Lot Number (Expiry Date)
M - Site
R - Route
R - Dosage
R - Dosage units
R - Dose #
M - Informed Consent
R - Comments

Table 3a: Immunization Detailed Guide– Mandatory and Required Data Fields

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
Administration Date/Time (M)	Auto-populates with the Reported Date. Update to the date of vaccine administration. If administered date is unknown, enter "1900-01-01". Enter "YYYY-MM-01" if the year and month of administered date are known, but not the day. Enter "YYYY-01-01" if the year of administration is known, but not the month and day. Enter in the Comments field that this administration date is an approximation. The time stamp is not required for provincial surveillance.	None; manual entry.
Accurate (R)	Check the **Accurate** box to indicate that the exact administration date is known.	None.
HU (M)	Defaults to the user's PHU. If different, select the PHU where the immunization was received. If unknown or if the immunization was received outside of Ontario, select 'MOHLTC – PHD'. Also enter this in the Comments section below.	**All PHUs in Ontario** **MOHLTC - PHD** – for immunizations received outside of Ontario.
Branch (M)	PHU-specific. Select as appropriate.	PHU-specific drop-down values.
Provider/ Personnel Filters (M)	If a physician/nurse practitioner administered the immunization, select search terms from the following four filters: Professional Status; Source Name; HU; and City. Then click Filter to search for the provider. Search may be broadened by leaving the HU and City blank as some providers may be registered in more than one location. **Note:** A maximum of 200 results are presented in the dropdown. Narrow your search by entering as much information as possible.	None; this is a search field.

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
	If the immunization was **not** administered by a physician/nurse practitioner or the provider was not found through the search, select 'External, other' by entering 'ext%' in the Source Name field (leave everything else blank). Click Filter. If the administrator is unknown. Enter 'unk%' as the Source Name and click Filter. Select 'UNKNOWN'.	
Provider/ Personnel (R)	If the immunization was administered by a physician/nurse practitioner, select the provider's name from the dropdown list generated from the Provider/Personnel Filter search. If the immunization was **not** administered by a physician/nurse practitioner or the provider's name was not returned through the search or the name of the provider was unknown, follow the procedure outlined above to select 'External, Other'.	Custom dropdown values are generated by the Provider/Personnel Filters.
Where Administered (R)	Select the facility/location where the vaccine was administered. For individuals who have received the vaccine at their 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
Agent (M)	Select an active immunizing agent(s) temporally associated with the adverse event(s) (i.e., event happened after receipt of vaccine). See Appendix 2 for a complete list of agent values in iPHIS and corresponding product (trade) names.	See Appendix 2.

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
	Do **not** use an inactivated agent marked with an (I) unless the AEFI is a historical event for a discontinued vaccine. Only include active immunizing agents in the AEFI record. Passive agents (e.g., rabies immunoglobulin), diagnostic tests (e.g., tuberculin skin tests) or drugs should not be included in an AEFI report. **Note:** For AEFI reports that **only** involve an injection site reaction, only include the agent(s) administered at the affected injection site.	
Lot Number (Expiry Date) (M**)**	Select the appropriate lot number. Lot numbers are an essential component of vaccine safety surveillance. Please ensure these are collected during the AEFI investigation. **If lot number is unavailable in iPHIS**: If you know the lot number and expiry date but this is not available in iPHIS, ask your PHU's PRC to submit a ticket to the **Public Health Solutions Service Desk** (PublicHealthSolutions@Ontario.ca or 1-866-272-2794) to request adding the lot number in iPHIS. This is generally a quick process. In the meantime, use the default code 'DC (2099-01-01)' to save the immunization record. Enter 'Lot number pending' in the Comments field if waiting for the lot number to be added by Public Health Solutions Service Desk. **Be sure to return to update the lot number when it is added and remove the related information in the Comments field.** **If expiry date is unknown:** If you have the lot number but not the expiry date, you can look it up in the National Vaccine Catalogue: Vaccine lot.	The system populates this dropdown list based on the agent selected above.

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
	If the lot number is truly unknown: Select the default code 'DC (2099-01-01)' and indicate 'Unknown lot number' in the Comments field.	
Site (M)	Enter the body site of vaccine administration. LA – Left arm LL – Left leg RA – Right arm RL – Right leg ?? – Unknown site ?A – Arm (side unknown) ?L – Leg (side unknown) ?B – Buttock (side unknown) BB – Both buttocks LB – Left buttock MOUTH NOSE RB – Right buttock	• LA • LL • RA • RL • ?? • ?A • ?L • ?B • BB • LB • RB • Mouth • Nose
Route (R)	Select the route of vaccine administration. If the route is unknown, select 'Unknown'.	• Intradermal • Intramuscular • Intranasal • Intravenous • Oral • Subcutaneous • Topical • Unknown
Dosage (R)	Enter the numeric value of the dosage administered.	N/A
Dosage unit (R)	Enter the units of the dosage (e.g., cc, ml).	• cc • grams • international units • mg • ml • mu • vials

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
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.	None; manual entry.
Informed consent (M)	This field is mandatory but not relevant for entering an immunization record that has already occurred. It is acceptable to leave 'Unknown' as the default value.	• Yes • No • Unknown
Comments (R)	Only use this field to note information about: • Provider/personnel who gave the immunization including location • Unknown/pending lot number • If administration date is an approximation **Note:** Do not enter any other notes in this field. All notes describing the AEFI should be entered under Cases > Case > Notes.	N/A

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.** All other outcome information should be entered in 6.1 Adverse Event Details. If there was not a fatal outcome, skip to 6.0 Adverse Event(s) List.
>
> 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.
2. Complete the Outcome, Outcome Date, and Accurate (checkbox) data fields. Refer to Table 4a and Appendix 10, Case Outcome Screen for more detailed information.
3. Click Save.
4. When 'Fatal' is selected as the Outcome, the screen refreshes and a series of new fields display (see Appendix 10, Fatal Outcome Options Screen).
5. Enter the additional information from Outcome Quick List. Refer to Table 4a and Appendix 10, Case Outcome Screen for more detailed information.
6. Select Add (see Appendix 10, Fatal Outcome Options Screen).
7. If there is more than one cause of death identified, repeat steps 4 and 5 to enter multiple values as needed.

Outcome Quick List–Mandatory (M) and Required (R) Data Fields

If a death occurred after a person received a vaccine, all data fields listed below are necessary for provincial AEFI surveillance.

M - Outcome (fatal)
R - Outcome Date
R - Accurate

M - Cause of Death
M - Type of Death
R - Source

Table 4a: Outcome Detailed Guide – Mandatory and Required Data Fields

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
Outcome (M)	**This area is for recording a fatal outcome only. Do not record any other outcome information here**. Select **'**Fatal**'** to report a death that is temporally associated with receipt of a vaccine. PHUs should request a Medical Certificate of Death for an AEFI involving a fatal outcome. Detailed notes describing the fatal outcome can be captured in Cases > Case > Notes. Refer to Appendix 7 for further guidance on how to report AEFIs involving fatal outcome. For all other AEFI reports enter outcome information in Cases > Client > Adverse > Details.	**Fatal**
Outcome Date (R)	Enter the date of death for the fatal outcome.	None; manual entry.
Accurate (R)	Select if the exact date of death/outcome date was entered.	None.
Cause of Death (M)	If a Medical Certificate of Death is received, Part I and/or Part II of Section 11 of the Cause of Death section of this document should be transcribed in the Cause of Death field. In the absence of a Medical Certificate of Death, other available information indicating the cause of death (e.g., clinical records, hospital reports) may be entered. If the PHU is unable to determine the cause of death, enter 'Unknown' in this field.	None; manual entry.
Type of Death (M)	Select 'Unknown' unless there is clear information obtained from the relevant clinical documentation 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
Source (R)	Enter the source of cause of death information (e.g., autopsy).	None; manual entry.

5.0 Case Notes

Each AEFI report requires a case note to describe how it meets the case definition and criteria outlined in AEFI Appendix 1 or the AESIs for COVID-19 Vaccines technical brief. Record a detailed description of the event including the chronology of signs and symptoms, investigation, therapy, findings of medical consultation (including specialist), relevant medical history, allergies, medications and any prior adverse events. Include enough detail 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 (PHI) is not transmitted to external stakeholders as part of national vaccine safety surveillance.

Although PHO provides the Ontario AEFI reporting form on the PHO Vaccine Safety website as a tool for reporting AEFIs, PHO does not receive or have access to the completed forms that are submitted to/used by PHUs. Therefore, it is important that all relevant information on these forms is entered into iPHIS so that it can be accessed and used for provincial vaccine safety surveillance.

See Appendix 1 for a copy of the form and a table of corresponding data fields in iPHIS. Use the **Cases > Case > Notes** to add any additional, relevant information that does not have a corresponding data field in iPHIS.

Steps:

1. Navigate to Cases > Case > Notes.
2. Select Create New Note (see Appendix 10, Adding Case Notes).
3. Complete the information in Case Notes Quick List. Refer to Table 5a and Appendix 10, Example of Case Notes Entry for more detailed information.
4. Select Save.
5. Repeat steps 2-4 to create additional notes.

Case Notes Quick List–Mandatory (M) and Required (R) Data Fields

All data fields in this table are necessary for provincial AEFI surveillance.

M - Note date and time
M - Provider
M - Note

Table 5a: Case Notes Detailed Guide– Mandatory and Required Data Fields

Field Name (M=mandatory) or (R=required)	**Data entry information**
Note Type	Auto-populates.
Note Date and Time (M)	Auto-populates.
Note (M)	Record a detailed description of the event including, but not limited to: • chronology of signs and symptoms • investigation • therapy • findings of medical consultation (including specialist) • relevant medical history • allergies • medications • any prior adverse events. Include enough detail to support the selected adverse event(s). **Do not include any identifying information in the case notes.**
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.
Created By	Auto-populates.
Created Date	Auto-populates.

6.0 Adverse Event(s) List

You must create or select an adverse event on this page before you can access the Details, Reactions, Agents and Recommendations sections (described in Sections 6.1- 6.4).

If you receive a report involving two or more agents administered on different dates and you are unsure if they should be part of one case or separate cases, contact the IVPD team at PHO to determine how to proceed with data entry (ivpd@oahpp.ca).

See Appendix 5 for instructions on how to modify or delete previously saved information in the adverse events section.

Steps:

1. Navigate to **Cases > Client > Adverse > List** (see Appendix 10, Navigation Path to Access Adverse Events Details).
2. If the adverse event exists, select the **Details** button to view or edit the event record.
3. If the adverse event does not exist, select **New Adverse Event** (see Appendix 10, Adverse Event Options Screen).

6.1 Adverse Event Details

Enter the basic details related to the adverse event on this screen.

Use the criteria outlined in AEFI Appendix 1, Infectious Diseases Protocol and/or the Adverse Events of Special Interest (AESI) for COVID-19 Vaccine Surveillance technical brief to determine if the case and adverse event classification criteria are met. All AEFIs reported in iPHIS must be assessed using these criteria. Adverse events that are specific to COVID-19 vaccines (AESI) can be selected if the AEFI is associated with a COVID-19 vaccine.

If unsure of how to classify and enter AEFI cases, contact the IVPD team (ivpd@oahpp.ca) as the correct details are very important to provincial vaccine safety surveillance.

See Appendix 5 for instructions on how to modify or delete previously saved information in the adverse events section.

Steps:

1. After navigating to **Cases > Client > Adverse > List** and selecting **New Adverse Event,** or if the event already exists, selecting **Details** to update any information as needed.
2. Enter the information from Adverse Event Details Quick List. Refer to Table 6a and Appendix 10, Adverse Event Details Screen for more detailed information.
3. Select **Save**.

Adverse Event Details Quick List–Mandatory (M) and Required (R) Data Fields

All data fields in this table are necessary for provincial AEFI surveillance.

M - Branch
M - Reported Date
M - FOI discussed
M - Administration Date/Time
R - Accurate
R - Physician filter
R - Physician Name
M - Medical consultation sought
R - Consultation date
R - Seen in ER
R - Date seen in ER
M - Hospitalized
R - Hospital filter
R - Hospital name
R - Admit date
R - Discharge date
M - Outcome code

Table 6a: Adverse Event Details Detailed Guide - Mandatory and Required Data Fields

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
Health Unit	Auto-populates.	None; auto populates.
Branch (M)	PHU-specific. Select as appropriate.	PHU-specific drop-down values.
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 (Table 1a). Do not change this date if a client is transferred from another PHU.	None; manual entry.
FOI Discussed (M)	Freedom of Information (FOI). Select 'Unknown' unless the PHU has spoken with the client.	• Yes • No • Unknown
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.	None; manual entry.
Accurate (Administration Date/Time) (R)	Check the **Accurate** box to indicate that the exact administration date is known.	None.

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
Physician Filter (R)	If known, enter the physician or nurse practitioner who provided medical care. Select search terms from the following four filters: Professional Status; Source Name; HU; and City. Then select Filter to search for the provider. Search may be broadened by leaving the HU and City blank as some providers may be registered in more than one location. A maximum of 200 results are presented in the dropdown. Narrow your search by entering as much information as possible.	
Physician Name (R)	Select the physician or nurse practitioner from the dropdown list generated from the search. If the provider's name was not found through the search or the provider name was unknown, select UNKNOWN by entering 'unk%' as the Source Name and clicking Filter in the Physician Filter.	Generated by the Provider/ Personnel Filters.
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. If the case had more than one medical consultation, these may be described in Cases > Case > Notes.	• Yes • No • Unknown
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.	None; manual entry.
Seen in ER (R)	Select 'Yes' if the case was assessed in an emergency department for the adverse event. If the case had more than one ER visit, these may be described in Cases > Case > Notes.	• Yes • No • Unknown

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
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.	None; manual entry.
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. This field should not be used to capture non-urgent, outpatient medical consultation. If 'Yes' is selected, enter the admission and discharge dates. If the case had more than one hospitalization, these may be described in Cases > Case > Notes.	• Yes • No • Unknown
Hospital Filter (R)	Enter the hospital name if the case had in-patient hospitalization (if known). Type the hospital name in the Source Name field and/or select the city where the hospital is located. Click Filter to search for the hospital where the case was hospitalized.	None; this is a search field.
Hospital Name (R)	Select the hospital from the dropdown list generated from the hospital filter search. A maximum of 200 results are presented in the dropdown. Narrow your search by entering as much information as possible. A combination of partial data and the wildcard character (%) in the Source Name field can help narrow the search.	Generated by the hospital filter search.
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. This field is used to calculate the length of hospitalization.	None; manual entry.

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
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. This is used to calculate the length of hospitalization.	None; manual entry.
Outcome Code (M)	Select the value that best reflects outcome of the case at the time of iPHIS entry. Update if it is known that 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 (see Section 4.0 for data entry guidelines).	**Fatal** Select if death is temporally associated with receipt of a vaccine. **Not yet recovered** Select if an event has not yet resolved when the investigation has been completed but the case is expected to recover (e.g., rash). **Recovered** Select if the case recovered from the event based on the PHU's assessment. **Residual effects** Select if the case has any residual effects, defined as any persistent or significant disability/incapacity related to the adverse event (e.g., neuropathic pain following GBS). **Unknown**
Comments	**Do not use.** Enter all notes describing the case in Cases > Case > Notes	None; manual entry.

6.2 Adverse Event Reactions

Enter the adverse event reaction(s) on this screen. An AEFI investigation can have more than one adverse event (i.e., multiple adverse events associated with the same dose of vaccine or doses of more than one co-administered vaccine). Each event should be entered separately. Do not create separate AEFI investigations for adverse events attributed to the same dose of vaccine.

If you are unsure about which adverse events described in AEFI Appendix 1 apply to the case, contact the IVPD team at PHO (ivpd@oahpp.ca).

There are a number of adverse events that are specific to COVID-19 vaccines (i.e., adverse events of special interest). Only select these if the AEFI is also associated with a COVID-19 vaccine, as described in the Adverse Events of Special Interest (AESI) for COVID-19 Vaccine Surveillance technical brief.

For 'Event managed as anaphylaxis', complete the dynamic questionnaire that can be accessed via Cases > Case > Questionnaire to report supplemental information relating to the event managed as anaphylaxis.

See Appendix 5 for instructions on how to modify or delete previously saved information in the adverse events section.

Steps:

1. Navigate to **Cases > Client > Adverse > Reaction**. Ensure that you have previously entered the adverse event (i.e., by first opening the applicable **Adverse Event Details** screen, see section 6.1) before navigating to the Reactions screen.
2. Enter the information specified in Adverse Event Reactions Quick List. Refer to Table 6b and Appendix 10, Adding an Entry for an Adverse Event(s) Reaction for more detailed information.
3. Click Add.
4. Repeat steps 2-3 to add additional adverse event reactions (as illustrated in the screen shot in Appendix 10, Adding an Entry for an Adverse Event(s) Reaction), which will populate in a list below the data entry fields.

Adverse Event Reactions Quick List–Mandatory (M) and Required (R) Data Fields

All data fields in this table are necessary for provincial AEFI surveillance.

M - Adverse Event(s) Reactions
R - Interval to onset – Days
R - Interval to onset – Minutes
R - Treatment type
R - Duration – Hours
R - Onset Date/Time
R - Interval to onset - Hours
R - Treatment received
R - Duration - Days
R - Duration - Minutes

Table 6b: Adverse Event Reactions Detailed Guide– Mandatory and Required Data Fields

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
Adverse Event(s) Reactions (M)	A case can have more than one adverse event. Create a new adverse event reaction for each event. Select the value(s) that describes the event(s). See Appendix 3 for a list of available values and complete definitions in AEFI Appendix 1. Adverse events of special interest (AESIs) for COVID-19 vaccines should only be selected when the AEFI is associated with a COVID-19 vaccine. All adverse event reactions must be described in detail in the case notes (Cases > Case > Notes) and how they meet the case definition and criteria outlined in the AEFI Appendix 1, Infectious Diseases Protocol or the AESIs for COVID-19 Vaccines Surveillance technical brief.	See Appendix 3.
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 following vaccine administration. If the event involves multiple episodes with different onset date/time, enter the earliest date and time of the onset following vaccine administration	None; manual entry.
Interval to onset (R)	Enter the interval from immunization to the first symptom/sign onset.	None; manual entry.
Days	Use if the interval is greater than one day.	None; manual entry.
Hours	Use if the interval is less than or equal to 24 hours.	None; manual entry.
Minutes	Use if the interval is less than one hour.	None; manual entry.
Treatment Received (R)	Select 'Yes' if treatment was received for the reported event (e.g., analgesic/antipyretic, adrenaline, antihistamine).	• Yes • No • Unknown
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

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
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). If AEFI has not yet resolved, also select the 'Not Yet Recovered' in the Outcome Code field on the Adverse Events Details screen.	None; manual entry.
Days	Use if the interval is greater than one day.	None; manual entry.
Hours	Use if the interval is less than or equal to 24 hours.	None; manual entry.
Minutes	Use if the interval is less than one hour.	None; manual entry.

6.2.1 Events managed as anaphylaxis

Users must enter details of events managed as anaphylaxis in the Questionnaire by navigating to **Cases > Case > Questionnaire**. Select an appropriate dropdown response for:

- Prior anaphylaxis (M)
- Prior allergic reaction(s) (M)
- Epinephrine Administered (M)

If 'Yes' is selected for Epinephrine Administered, enter the details about epinephrine administration in the subsequent fields (up to five doses). Refer to Appendix 11 for a glossary of signs and symptom terms related to event managed as anaphylaxis.

6.3 Adverse Event Agents

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.

See Appendix 5 for instructions on how to modify or delete previously saved information in the adverse events section.

Steps:

1. Navigate to **Cases > Client > Adverse > Agents.** Ensure that you had previously entered the applicable adverse event (i.e., by first opening the applicable **Adverse Event Details** screen, see section 6.1) before navigating to the **Agent** screen.
2. Select the immunization(s) from the Code/Description dropdown menu. The list is pre-populated with the agents entered for the case in Section 3.0 Immunizations.
3. Click Add.
4. Repeat steps 2-3 if there is more than one immunization involved with this AEFI**.** The immunizations will populate in the dropdown of Code/Description. Note: If there are immunizations administered on different dates, but all are temporally associated with the Adverse Event(s) Reactions selected, select the immunizations administered on the earliest date only. Do not enter a duplicate Adverse Event(s) Reactions to capture the vaccine(s) administered on a different date. Ensure all vaccines associated with the Adverse Event(s) Reactions are entered in the **Cases > Case > Intervent/Treatments > Immunizations/Chemoprophylaxis** section.

6.4 Adverse Event Recommendations

Enter the adverse event recommendation(s) on this screen. The purpose of this section is to document recommendations from the PHU's MOH, AMOH, or designate regarding subsequent immunization in someone who has experienced an AEFI. This section should be completed independent of the case classification (e.g., pending MOH recommendation(s) should not delay classification of the AEFI for surveillance purposes). Only include recommendations made by the Medical Officer of Health (MOH), Associate MOH (AMOH), or designate (e.g., RN). Recommendations from a specialist/medical provider who are not the MOH, AMOH or designate should be entered in the Case Notes.

See Appendix 5 for instructions on how to modify or delete previously saved information in the adverse events section.

Steps:

1. Navigate to **Cases > Client > Adverse > Recomm.** Ensure that you had previously entered the applicable adverse event (i.e., by first opening the applicable **Adverse Event Details** screen, see section 6.1) before navigating to the **Recommendations** screen.

2. Complete the information in Adverse Event Recommendations Quick List. Refer to Table 6c and Appendix 10, Adverse Event(s) Recommendations Screen for more detailed information.

3. Click Add.

4. Repeat steps 1-3 if more than one recommendation was made**.** All of the recommendations entered will be displayed below the data entry fields.

Adverse Event Recommendations Quick List–Mandatory (M) and Required Data Fields

All data fields in this table are necessary for provincial AEFI surveillance.

M - Recommendations
M - MOH/Physician Name
R - Comments

Table 6c: Adverse Event Recommendations Detailed Guide– Mandatory and Required Data Fields

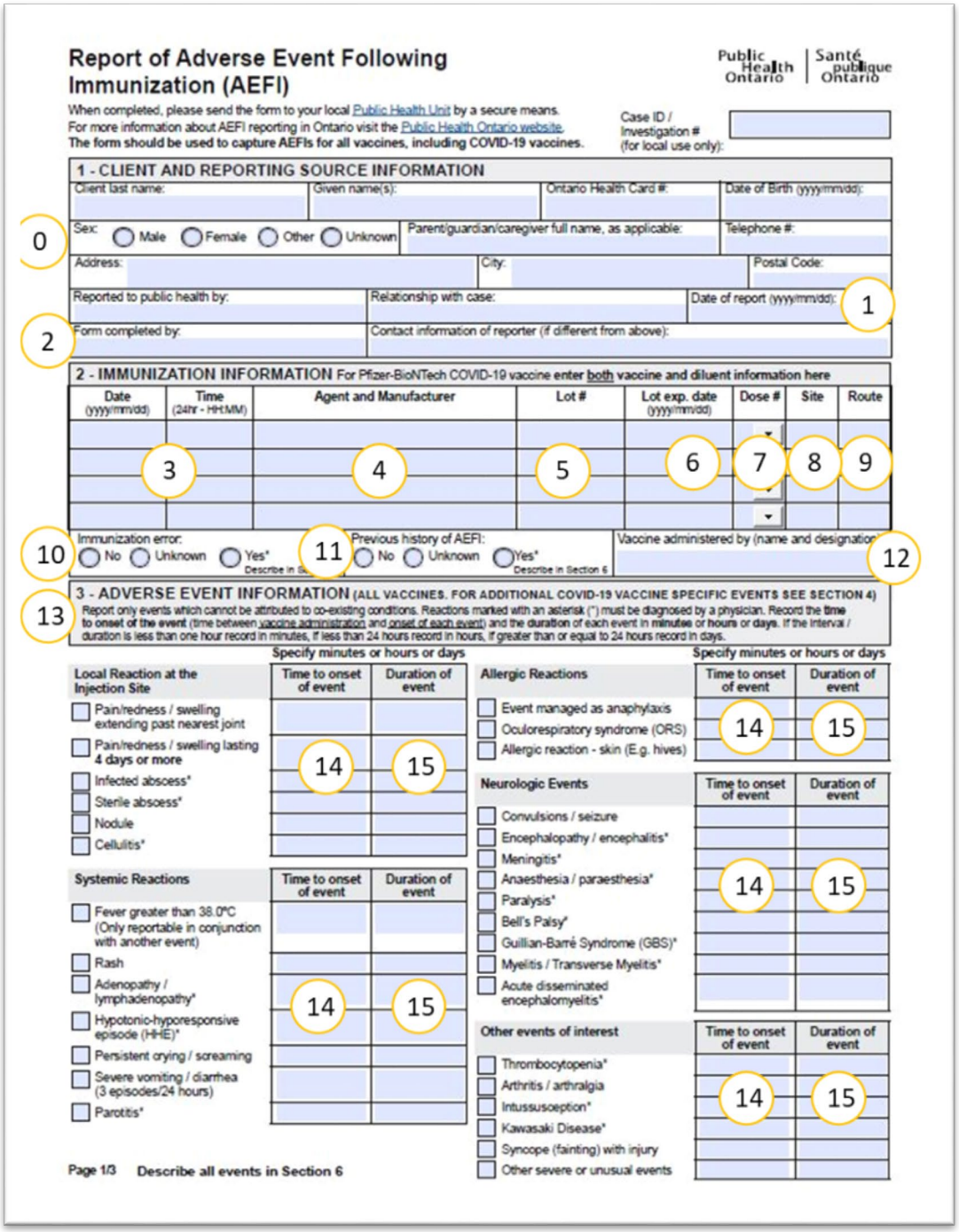
Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
Reported Date	Auto-populates.	None; auto-populates.
Recommendations (M)	Select the recommendation(s) made by the MOH or designate. Do not enter recommendations made by external healthcare providers (e.g., family physician or specialist). If no recommendations were made by the MOH or designate, select 'No recommendation'. If the value includes 'Specify', include additional detail in the comments field.	• 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)

Field Name (M=mandatory) or (R=required)	**Data entry information**	**Dropdown Values**
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 person is new to your PHU and is not yet included in this list, select '0CDOMINTAKE' and enter the name in the Comments section below**.** Contact both the person in question and your PHU's Local Resource Coordinator (LRC) either to have this person registered as an iPHIS user or to have their name added to your PHU's dropdown list as an iPHIS non-user.	PHU-specific drop down list.
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.	None; manual entry.

Appendices

Appendix 1– AEFI reporting form cross-referenced with mandatory and required iPHIS data fields

Note: there may be a more current version of this form available online



Report of Adverse Event Following Immunization (AEFI)

Public Health Ontario | Santé publique Ontario

When completed, please send the form to your local Public Health Unit by a secure means.
For more information about AEFI reporting in Ontario visit the Public Health Ontario website.
The form should be used to capture AEFIs for all vaccines, including COVID-19 vaccines.

Case ID / Investigation # (for local use only):

1 - CLIENT AND REPORTING SOURCE INFORMATION

Client last name: | Given name(s): | Ontario Health Card #: | Date of Birth (yyyy/mm/dd):

0 Sex: Male Female Other Unknown | Parent/guardian/caregiver full name, as applicable: | Telephone #:

Address: | City: | Postal Code:

Reported to public health by: | Relationship with case: | Date of report (yyyy/mm/dd): 1

2 Form completed by: | Contact information of reporter (if different from above):

2 - IMMUNIZATION INFORMATION For Pfizer-BioNTech COVID-19 vaccine enter **both** vaccine and diluent information here

Date (yyyy/mm/dd)	Time (24hr - HH:MM)	Agent and Manufacturer	Lot #	Lot exp. date (yyyy/mm/dd)	Dose #	Site	Route
	3	4	5	6	7	8	9

10 Immunization error: No Unknown Yes* Describe in Section 6 | 11 Previous history of AEFI: No Unknown Yes* Describe in Section 6 | Vaccine administered by (name and designation) 12

13 **3 - ADVERSE EVENT INFORMATION** (ALL VACCINES. FOR ADDITIONAL COVID-19 VACCINE SPECIFIC EVENTS SEE SECTION 4)

Report only events which cannot be attributed to co-existing conditions. Reactions marked with an asterisk (*) must be diagnosed by a physician. Record the **time to onset of the event** (time between vaccine administration and onset of each event) and the **duration** of each event in **minutes** or **hours** or **days**. If the interval / duration is less than one hour record in minutes, if less than 24 hours record in hours, if greater than or equal to 24 hours record in days.

Specify minutes or hours or days

Local Reaction at the Injection Site	Time to onset of event	Duration of event
☐ Pain/redness / swelling extending past nearest joint		
☐ Pain/redness / swelling lasting 4 days or more	14	15
☐ Infected abscess*		
☐ Sterile abscess*		
☐ Nodule		
☐ Cellulitis*		

Systemic Reactions	Time to onset of event	Duration of event
☐ Fever greater than 38.0°C (Only reportable in conjunction with another event)		
☐ Rash		
☐ Adenopathy / lymphadenopathy*	14	15
☐ Hypotonic-hyporesponsive episode (HHE)*		
☐ Persistent crying / screaming		
☐ Severe vomiting / diarrhea (3 episodes/24 hours)		
☐ Parotitis*		

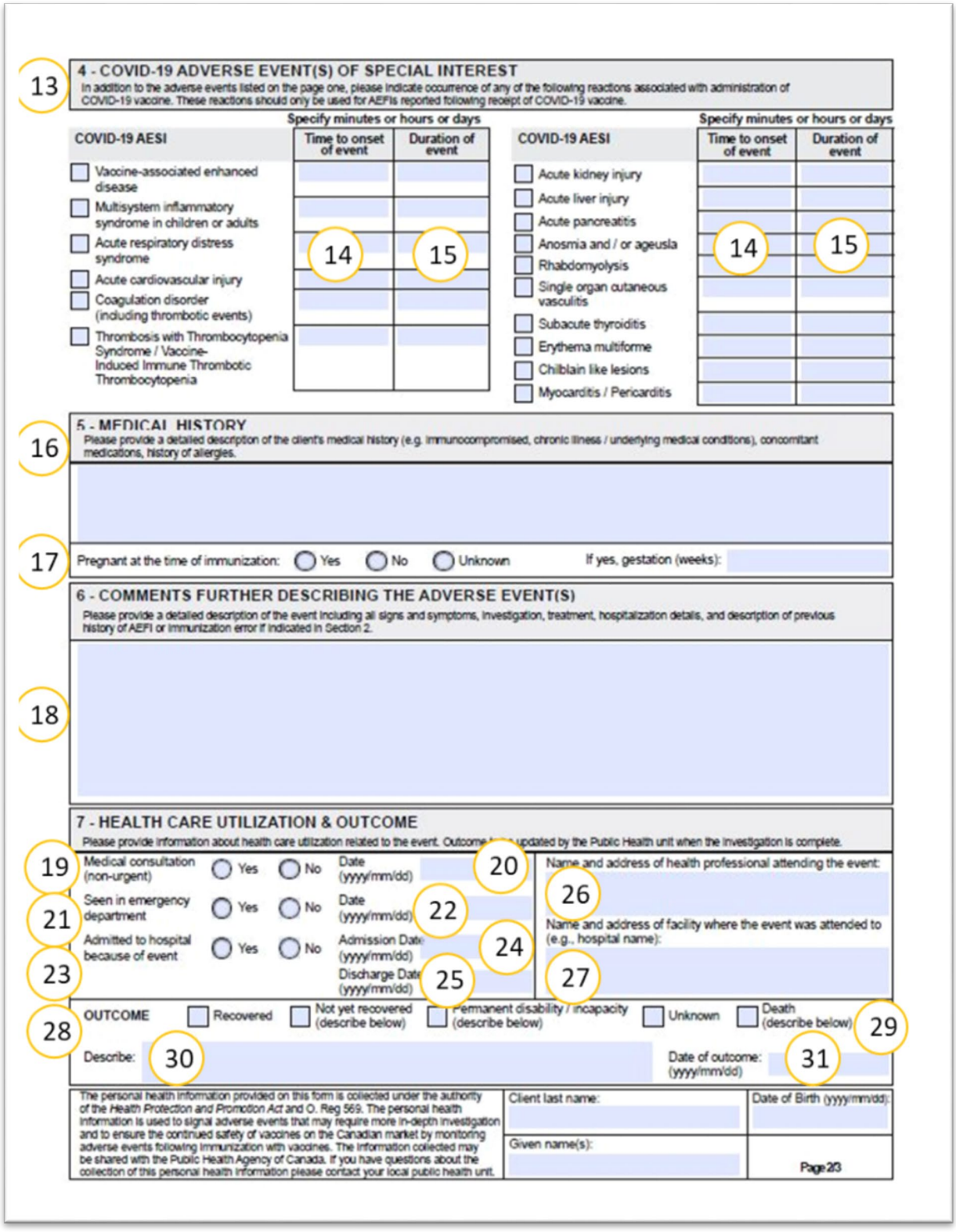
Specify minutes or hours or days

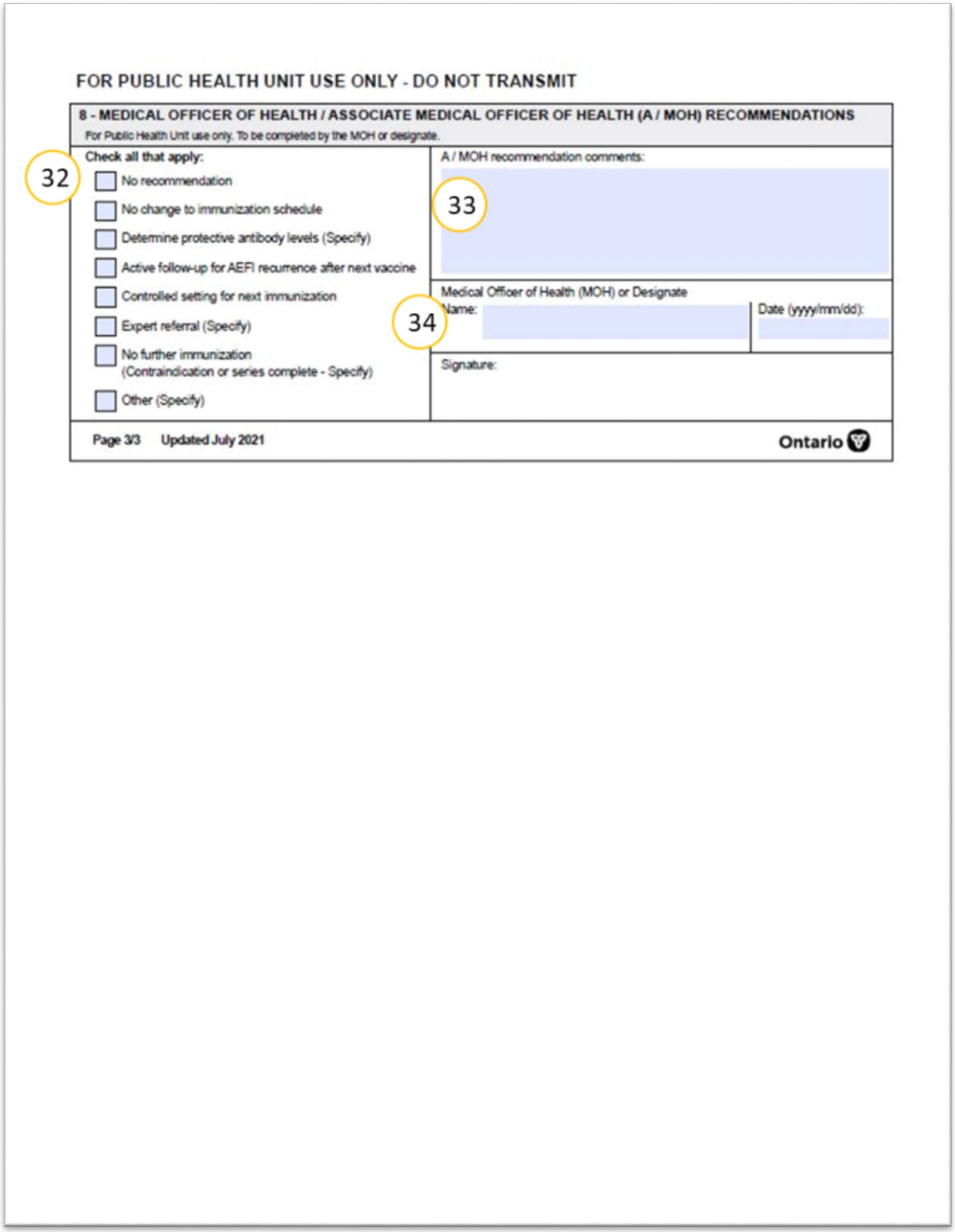
Allergic Reactions	Time to onset of event	Duration of event
☐ Event managed as anaphylaxis		
☐ Oculorespiratory syndrome (ORS)	14	15
☐ Allergic reaction - skin (E.g. hives)		

Neurologic Events	Time to onset of event	Duration of event
☐ Convulsions / seizure		
☐ Encephalopathy / encephalitis*		
☐ Meningitis*		
☐ Anaesthesia / paraesthesia*	14	15
☐ Paralysis*		
☐ Bell's Palsy*		
☐ Guillian-Barré Syndrome (GBS)*		
☐ Myelitis / Transverse Myelitis*		
☐ Acute disseminated encephalomyelitis*		

Other events of interest	Time to onset of event	Duration of event
☐ Thrombocytopenia*		
☐ Arthritis / arthralgia	14	15
☐ Intussusception*		
☐ Kawasaki Disease*		
☐ Syncope (fainting) with injury		
☐ Other severe or unusual events		

Page 1/3 **Describe all events in Section 6**


13
4 - COVID-19 ADVERSE EVENT(S) OF SPECIAL INTEREST
In addition to the adverse events listed on the page one, please indicate occurrence of any of the following reactions associated with administration of COVID-19 vaccine. These reactions should only be used for AEFIs reported following receipt of COVID-19 vaccine.
Specify minutes or hours or days
COVID-19 AESI
Time to onset of event
Duration of event
Vaccine-associated enhanced disease
Multisystem inflammatory syndrome in children or adults
Acute respiratory distress syndrome
Acute cardiovascular injury
Coagulation disorder (including thrombotic events)
Thrombosis with Thrombocytopenia Syndrome / Vaccine-Induced Immune Thrombotic Thrombocytopenia
14
15
Specify minutes or hours or days
COVID-19 AESI
Time to onset of event
Duration of event
Acute kidney injury
Acute liver injury
Acute pancreatitis
Anosmia and / or ageusia
Rhabdomyolysis
Single organ cutaneous vasculitis
Subacute thyroiditis
Erythema multiforme
Chilblain like lesions
Myocarditis / Pericarditis
14
15
16
5 - MEDICAL HISTORY
Please provide a detailed description of the client's medical history (e.g. immunocompromised, chronic illness / underlying medical conditions), concomitant medications, history of allergies.
17
Pregnant at the time of immunization: Yes No Unknown
If yes, gestation (weeks):
6 - COMMENTS FURTHER DESCRIBING THE ADVERSE EVENT(S)
Please provide a detailed description of the event including all signs and symptoms, investigation, treatment, hospitalization details, and description of previous history of AEFI or immunization error if indicated in Section 2.
18
7 - HEALTH CARE UTILIZATION & OUTCOME
Please provide information about health care utilization related to the event. Outcome to be updated by the Public Health unit when the investigation is complete.
19
Medical consultation (non-urgent)
Yes
No
Date (yyyy/mm/dd)
20
Name and address of health professional attending the event:
26
21
Seen in emergency department
Yes
No
Date (yyyy/mm/dd)
22
Name and address of facility where the event was attended to (e.g., hospital name):
23
Admitted to hospital because of event
Yes
No
Admission Date (yyyy/mm/dd)
24
Discharge Date (yyyy/mm/dd)
25
27
28
OUTCOME
Recovered
Not yet recovered (describe below)
Permanent disability / incapacity (describe below)
Unknown
Death (describe below)
29
Describe:
30
Date of outcome: (yyyy/mm/dd)
31
The personal health information provided on this form is collected under the authority of the Health Protection and Promotion Act and O. Reg 569. The personal health information is used to signal adverse events that may require more in-depth investigation and to ensure the continued safety of vaccines on the Canadian market by monitoring adverse events following immunization with vaccines. The information collected may be shared with the Public Health Agency of Canada. If you have questions about the collection of this personal health information please contact your local public health unit.
Client last name:
Date of Birth (yyyy/mm/dd):
Given name(s):
Page 2/3



FOR PUBLIC HEALTH UNIT USE ONLY - DO NOT TRANSMIT

8 - MEDICAL OFFICER OF HEALTH / ASSOCIATE MEDICAL OFFICER OF HEALTH (A / MOH) RECOMMENDATIONS

For Public Health Unit use only. To be completed by the MOH or designate.

32

Check all that apply:

- ☐ No recommendation
- ☐ No change to immunization schedule
- ☐ Determine protective antibody levels (Specify)
- ☐ Active follow-up for AEFI recurrence after next vaccine
- ☐ Controlled setting for next immunization
- ☐ Expert referral (Specify)
- ☐ No further immunization (Contraindication or series complete - Specify)
- ☐ Other (Specify)

33

A / MOH recommendation comments:

34

Medical Officer of Health (MOH) or Designate

Name:

Date (yyyy/mm/dd):

Signature:

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Ontario

Table 8a: AEFI Reporting Form Cross-Referenced with Mandatory and Required iPHIS Data Entry Fields

iPHIS data entry fields needed for provincial vaccine safety surveillance	Corresponding AEFI reporting form reference number
M - Client demographics module	0

1.1 Case Details

iPHIS data entry fields needed for provincial vaccine safety surveillance	Corresponding AEFI reporting form reference number
M - Reported date	1
M - Health unit responsible	Not collected on form
M - Branch office	Not collected on form
M - Diagnosing HU	Not collected on form
M - Disease	Not collected on form
M - Aetiologic agent	Not collected on form
M - Classification	Not collected on form
M - Classification date	Not collected on form
M - Outbreak case classification	Not collected on form
M - Outbreak classification date	Not collected on form
M - Disposition	Not collected on form
M - Disposition date	Not collected on form
M - Status	Not collected on form
M - Status date	Not collected on form
M - Priority	Not collected on form
R - Address at time of case	0
R - Reporting source (physician filter)	2
R - Other reporting source type	2
R - Other reporting source name	2
M - Investigator	Not collected on form

2.0 Risks

iPHIS data entry fields needed for provincial vaccine safety surveillance	Corresponding AEFI reporting form reference number
R - Immunization program error	10, 18
R - Immunization program error (notes)	18
R - Chronic illness/underlying medical condition	16, 17
R - Chronic illness/underlying medical condition (notes)	16
R - Immunocompromised	16
R - Immunocompromised (notes)	16
R - History of allergy	16
R - History of allergy (notes)	16
R - History of AEFI	11
R - History of AEFI (notes)	11, 16
R - Pregnant	17

3.0 Immunizations

iPHIS data entry fields needed for provincial vaccine safety surveillance	Corresponding AEFI reporting form reference number
M - Administration date/time	3
M - HU	Not collected on form
M - Branch	Not collected on form
R - Provider/personnel	12
R - Where administered	Not collected on form
M - Agent	4
M - Lot number & expiry date	5, 6
Site	8
R - Route	9
R - Dose #	7
M - Informed consent	Not collected on form
R - Comments (for missing lot# only)	Not collected on form

4.0 Outcome (fatal cases only)

iPHIS data entry fields needed for provincial vaccine safety surveillance	Corresponding AEFI reporting form reference number
M - Outcome (fatal)	28, 30
R - Outcome date	31
R - Accurate	Not collected on form
M - Cause of death	18, 30
M - Type of death	18, 30
Source	18, 30

5.0 Case Notes

iPHIS data entry fields needed for provincial vaccine safety surveillance	Corresponding AEFI reporting form reference number
M - Note date and time	Not collected on form
M - Note	18, 30, 33
M - Provider	Not collected on form

6.1 Adverse Event Details

iPHIS data entry fields needed for provincial vaccine safety surveillance	Corresponding AEFI reporting form reference number
R - Health Unit	Not collected on form
M - Branch	Not collected on form
M - Reported date	1
M - FOI discussed	Not collected on form
M - Administration date/time	3
R - Physician Name	26
M - Medical consultation sought	19
R - Consultation date	20
R - Seen in ER	21
R - Date seen in ER	22
M - Hospitalized	23
R - Hospital name	27
R - Admit date	24
R - Discharge date	25

iPHIS data entry fields needed for provincial vaccine safety surveillance	Corresponding AEFI reporting form reference number
M - Outcome code	28

6.2 Adverse Event Reactions

iPHIS data entry fields needed for provincial vaccine safety surveillance	Corresponding AEFI reporting form reference number
M - Adverse event(s) reaction	13
R - Onset date/time	14
R - Interval to onset - Days	14
R - Interval to onset - Hours	14
R - Interval to onset - Minutes	14
R - Treatment received	18
R - Treatment type	18
R - Duration - Days	15
R - Duration - Hours	15
R - Duration - Minutes	15

6.3 Adverse Event Agents

iPHIS data entry fields needed for provincial vaccine safety surveillance	Corresponding AEFI reporting form reference number
R - Code/description	4

6.4 Adverse Event Recommendations

iPHIS data entry fields needed for provincial vaccine safety surveillance	Corresponding AEFI reporting form reference number
M - Recommendations	32
M - MOH/Physician name	34
R - Comments	33

Appendix 2 - List of "agent" values in iPHIS and corresponding vaccine products

Table 9a: List of Agent Values in iPHIS and Corresponding Vaccine Products (active immunizing agents only)

Vaccine abbreviations	Agent values in iPHIS (as of August 2024)	Product/trade name authorized in Canada
BCG	BCG - Bacillus Calmette Guerin	BCG vaccine
Chol-Ecol-O	Chol-Ecol-O - Cholera - E.coli (Oral)	Dukoral®
Chol-O	Chol-O – Cholera Oral	Vaxchora®
Chol-I	Chol-I – Cholera Injectable	No product currently marketed in Canada
COVID-19	COVID-19 – COMIRNATY – PFIZER-BIONTECH, COVID-19 – COVIFENZ – MEDICAGO, COVID-19 – COVISHIELD – VERITY, COVID-19 – JOHNSON & JOHNSON – JANSSEN, COVID-19 – NUVAXOVID – NOVAVAX, COVID-19 – SPIKEVAX – MODERNA, COVID-19 – VAXZEVRIA - ASTRAZENECA	Comirnaty® Omicron XBB.1.5, Comirnaty® Original and Omicron BA.4/BA.5, Comirnaty® Original/Omicron BA.1, Spikevax® XBB.1.5, Spikevax® Bivalent (Original/Omicron BA.1), Spikevax® Bivalent (Original/Omicron BA.4/BA.5), Nuvaxovid™, Novavax Nuvaxovid XBB.1.5
DTaP-IPV	DTap-IPV - Diphtheria, Tetanus, acellular Pertussis, Polio	Quadracel®, Infanrix-IPV®, Kinrix®, Tetravac-Acellulaire®
DTaP-IPV-Hib	DTap-IPV-Hib - Diphtheria, Tetanus, acellular Pertussis, Inactivated Poliomyelitis, Haemophilus b (Pediatric)	Pediacel®, Infanrix®- IPV/Hib, Pentacel®
HA	HA – Hepatitis A, HA - Hepatitis A (Adult), HA - Hepatitis A (Pediatric)	Avaxim®, Avaxim® - Pediatric, Havrix 1440®, Havrix® 720 Junior, Vaqta®, Vaqta pediatric®
HAHB	HAHB - Hepatitis A and B	Twinrix®, Twinrix® Junior
HA-Typh-I	HA-Typh-I - Hepatitis A and Typhoid (Injection)	ViVaxim®
HB	HB - Hepatitis B, HB – Hepatitis B (Pediatric)	Engerix®-B, Engerix®-B (Pediatric), Recombivax HB®, Recombivax HB® (Dialysis), Recombivax HB pediatric®
Hib	Hib - Haemophilus influenza type b	Act-HIB®, Hiberix®
HPV2	HPV2 - Human Papilloma Virus	Cervarix®
HPV4	HPV4 - Human Papilloma Virus	Gardasil®

Vaccine abbreviations	Agent values in iPHIS (as of August 2024)	Product/trade name authorized in Canada
HPV9	HPV9 - Human Papilloma Virus	Gardasil®9
Inf	Inf Influenza *this table may not include all authorized products	Agriflu®, Afluria® Tetra, Influvac® Tetra, Flumist®, Flumist® Quadrivalent, Fluad®, Fluad®Pediatric, Flulaval™ Tetra, Fluviral®, Fluzone®, Fluzone® HD, Fluzone® Quadrivalent, Fluzone® HD Quadrivalent, Vaxigrip® , Flucelvax® Quad, Supemtek™
Inf	Inf – Adjuvanted pandemic influenza A (H1N1) 2009 Inf – Unadjuvanted pandemic influenza A (H1N1) 2009	-
IPV	IPV - Inactivated Poliomyelitis (Vero Cell)	Imovax® Polio
JE	JE - Japanese Encephalitis	Ixiaro®
Men-B	Men-B – Meningococcal - B	Bexsero®, Trumenba®
Men-C-ACWY	Men-C-ACWY - Meningococcal - Conjugate ACWY	Menactra®, Menveo™, Nimenrix®, MenQuadfi™
Men-C-C	Men-C-C - Meningococcal - Conjugate C	NeisVac-C®, Menjugate®
Men-P-ACWY	Men-P-ACWY – Meningococcal – Polysaccharide - ACWY	MENOMUNE-A/C/Y/W-135
MMR	MMR - Measles, Mumps, Rubella	M-M-R®II, Priorix®
MMRV	MMRV - Measles, Mumps, Rubella, Varicella	Priorix-Tetra®, ProQuad™
Pneu-C-7	Pneu-C-7 - Pneumococcal Conjugate 7 Valent	Prevnar® 7
Pneu-C-10	Pneu-C-10 - Pneumococcal Conjugate 10 Valent	Synflorix®
Pneu-C-13	Pneu-C-13 - Pneumococcal Conjugate 13 Valent	Prevnar® 13
Pneu-C-15	Pneu-C-15 - Pneumococcal Conjugate 15 Valent	Vaxneuvance®
Pneu-C-20	Pneu-C-20 - Pneumococcal Conjugate 20 Valent	Prevnar™ 20
Pneu-P-23	Pneu-P - Pneumococcal - Polysaccharide 23 Valent	Pneumovax® 23
Rab	Rab - Rabies (Purified Chick Embryo Cell) Rab - Rabies Vaccine Inactivated (Diploid Cell)	RabAvert®, Imovax® Rabies

Vaccine abbreviations	Agent values in iPHIS (as of August 2024)	Product/trade name authorized in Canada
Rot-1	Rot-1 - Rotavirus	Rotarix®
Rot-5	Rot-5 - Rotavirus	Rota Teq®
RSV	RSV - Respiratory Syncytial Virus	Abrysvo™, Arexvy
Sma	Sma - Smallpox	ACAM2000®
SMV	SMV – Smallpox and monkeypox, modified non-replicating	Imvamune®
Td	Td - Diphtheria, Tetanus - Adult	Td Adsorbed
Tdap	Tdap - Tetanus, Diphtheria, acelluar Pertussis	Adacel®, Boostrix®
Tdap-IPV	Tdap-IPV - Tetanus, Diphtheria, acelluar Pertussis, Inactivated Poliomyelitis	Adacel®-Polio, Boostrix®-Polio
Td-IPV	Td-IPV - Tetanus, Diphtheria, Inactivated Poliomyelitis (Adult)	Td Polio Adsorbed
Typh-I	Typh-I - Typhoid (Injection)	Typherix®, Typhim Vi®
Typh-O	Typh-O - Typhoid Oral	Vivotif®
Var	Var - Varicella	Varilrix®, Varivax® III
YF	YF - Yellow Fever	YF-VAX®
Zos	Zos (LZV) – live virus zoster vaccine	Zostavax® II
Zos	Zos (RZV) – recombinant zoster vaccine	Shingrix

*Refer to the National Vaccine Catalogue for current information on all vaccine authorized for use in Canada.

Table 9b: List of Inactivated agents

The following agents are no longer used in Ontario. Check carefully to make sure the agent associated with the adverse event is not in the above list. Only use an inactivated (I) agent if it truly was the immunizing agent that was used (e.g., historical adverse event).

Vaccine abbreviations	Agent values in iPHIS (as of August 2024)
N/A	(I) Diphtheria, Pertussis, Tetanus, Polio
(I) aP	(I) ap – Acellular Pertussis
(I) DaPTP	(I) DaPTP – Diphtheria, acellular Pertussis, Tetanus, Polio
(I) DPTPH	(I) DPTPH – Diphtheria, Pertussis, Tetanus, Polio, HIB
(I) DT	(I) DT – Diphtheria, Tetanus – Pediatric
(I) dTap	(I) dTap – Diphtheria, Tetanus, acellular Pertussis – Adolescent/adult
(I) DT-IPV	(I) DT-IPV – Diphtheria, Tetanus, inactivated Poliomyelitis – Pediatric
(I) DTP	(I) DTP – Diphtheria, Tetanus, Polio – Paed
(I) IPV	(I) IPV – Inactivated Poliomyelitis (diploid cell)
(I) Lym	(I) Lym – Lyme
(I) M	(I) M – Measles
(I) MR	(I) MR – Measles, Rubella
(I) Men	(I) Men – Meningococcal
(I) Men-P-AC	(I) Men-P-AC – Meningococcal – Polysaccharide AC
(I) Mu	(I) Mu – Mumps
(I) OPV	(I) OPV – Polio –oral
(I) Pneu	(I) Pneu – Pneumococcal
(I) R	(I) R – Rubella
(I) Rabo	(I) Rabies vaccine (other specify)
(I) Rabo	(I) Rabies vaccine (type unknown)
(I) Rot	(I) ROT – Rotavirus
(I) T	(I) T – Tetanus
(I) TdP	(I) TdP – Diphtheria, Tetanus, Polio – Adults
N/A	(I) COVID-19 – mRNA VACCINE – Pfizer / BioNTech (inactivated as of 2021-10-08)
N/A	(I) COVID-19 – DILUENT – Pfizer / BioNTech (inactivated as of 2021-10-08)
N/A	(I) COVID-19 – mRNA VACCINE – MODERNA (inactivated as of 2021-10-08)
N/A	(I) COVID-19 – DILUENT – MODERNA (inactivated as of 2021-10-08)

Appendix 3 – List of current adverse event reaction(s) values in iPHIS

Table 10a: List of current adverse event reaction(s) values in iPHIS

Adverse event category for analysis	Adverse event reaction(s) values in iPHIS (as of August 2024)
Allergic events	Allergic reaction – skin
Allergic events	Event managed as anaphylaxis – complete reporting at cases>case>questionnaire
Allergic events	Oculorespiratory syndrome (ORS)
Injection site reactions	Abscess at the injection site (infected)
Injection site reactions	Abscess at the injection site (sterile)
Injection site reactions	Cellulitis
Injection site reactions	Nodule
Injection site reactions	Pain/redness/swelling extending beyond nearest joint
Injection site reactions	Pain/redness/swelling lasting 4-10 days
Injection site reactions	Pain/redness/swelling lasting greater than 10 days
Neurologic events	Acute disseminated encephalomyelitis (ADEM)
Neurologic events	Anaesthesia/paraesthesia
Neurologic events	Bell's palsy
Neurologic events	Convulsions/seizure
Neurologic events	Encephalopathy/ encephalitis
Neurologic events	Guillain-Barré syndrome (GBS)
Neurologic events	Meningitis
Neurologic events	Myelitis / Transverse Myelitis
Neurologic events	Paralysis
Other severe/unusual events	Other severe or unusual events
Systemic events	Adenopathy/lymphadenopathy
Systemic events	Arthritis/arthralgia
Systemic events	Fever in conjunction with another reportable event
Systemic events	Hypotonic-hyporesponsive episode (HHE)
Systemic events	Intussusception
Systemic events	Kawasaki disease
Systemic events	Parotitis
Systemic events	Persistent crying/screaming
Systemic events	Rash

Adverse event category for analysis	Adverse event reaction(s) values in iPHIS (as of August 2024)
Systemic events	Severe vomiting/diarrhea
Systemic events	Syncope (fainting) with injury
Systemic events	Thrombocytopenia
COVID-19 AESI	COVID-19 AESI - Acute cardiovascular injury
COVID-19 AESI	COVID-19 AESI - Acute kidney injury
COVID-19 AESI	COVID-19 AESI - Acute liver injury
COVID-19 AESI	COVID-19 AESI - Acute pancreatitis
COVID-19 AESI	COVID-19 AESI - Acute respiratory distress syndrome
COVID-19 AESI	COVID-19 AESI - Anosmia, ageusia
COVID-19 AESI	COVID-19 AESI - Chilblain like lesions
COVID-19 AESI	COVID-19 AESI - Coagulation disorder (including thrombotic events)
COVID-19 AESI	COVID-19 AESI - Erythema multiforme
COVID-19 AESI	COVID-19 AESI - Multisystem inflammatory syndrome in children/adults
COVID-19 AESI	COVID-19 AESI - Myocarditis/pericarditis
COVID-19 AESI	COVID-19 AESI – Rhabdomyolysis
COVID-19 AESI	COVID-19 AESI - Single organ cutaneous vasculitis
COVID-19 AESI	COVID-19 AESI - Subactute thyroiditis
COVID-19 AESI	COVID-19 AESI - Vaccine-associated enhanced disease
COVID-19 AESI	COVID-19 AESI - Thrombosis with Thrombocytopenia Syndrome/Vaccine-Induced Immune Thrombotic Thrombocytopenia

Appendix 4 – How to record two or more AEFIs reported on the same day

Occasionally, you may receive two or more separate AEFI reports for the same client reported on the same day, following vaccines administered on different days. These are considered separate AEFI reports and need to be entered into iPHIS as separate cases. However, there are some technical challenges in iPHIS to be aware of:

- iPHIS does **not** allow more than one AEFI case to be open for the same client.
- iPHIS does **not** allow a client to have two (or more) AEFI cases with the same reported date.

Follow the steps below to enter two (or more) AEFI cases reported on the same day for the same client.

Steps:

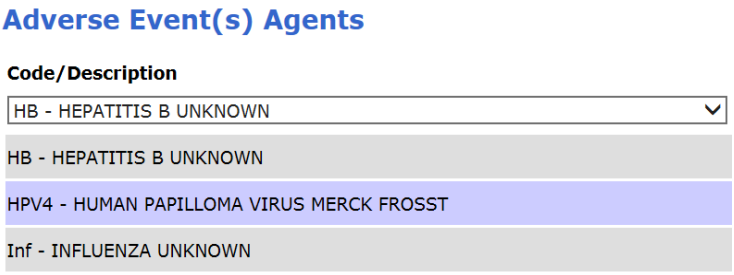
1. Investigate and document **all** AEFI cases reported on the same date for this client.
2. Open a new AEFI case in iPHIS for the client. Enter the AEFI that occurred most recently.
3. Use the date the AEFI was reported to the PHU as the **Reported Date**. For example, if the AEFI was reported on 1 May 2024, use this date.
4. Complete data entry for the first AEFI case (according to this guide).
5. Close the case.
6. Open a second AEFI case for the client. For the **Reported Date,** enter the date **after** the AEFI was reported to the PHU. For example, if the AEFI was reported on 1 May 2024, use 2 May 2024.
7. Complete data entry for the second AEFI case (according to this guide).
8. Close the case.
9. Repeat steps 6-8 for each additional AEFI case reported on the same date.

Appendix 5 – How to make changes to adverse event details

> Occasionally, you may need to modify or delete previously saved information entered in the adverse event section of iPHIS. In order to do this, you will need permission to make deletions within the Outbreak Management module of iPHIS. If you do not have this (i.e., you get an "Access denied" message), contact your PHU's Problem Resolution Coordinator (PRC) and request to have your permissions amended. The PRC at your PHU is responsible for registering and maintaining iPHIS users and for requesting permission changes within iPHIS.
>
> You must first unlink the agent(s) linked to the adverse event before you can make any changes within the adverse event section of iPHIS. After the changes are made and saved, relink the agent(s) to the adverse event.

Steps:

1. Navigate to **Cases > Client > Adverse > List**
2. Select Details next to the event that needs to be updated.
3. Navigate to **Cases > Client > Adverse > Agents**



Tip: Taking a screenshot of the agents screen (before unlinking in the next step) will help to relink at Step 8 (sample image above).

4. Delete all agents linked to the adverse event.
5. Navigate to **Cases > Client > Adverse > Details**
6. Update the required information on the **Adverse Event(s) Details** screen (e.g., enter the "Date seen In ER"). Select **Save.**
7. Navigate to **Cases > Client > Adverse > Agents** to relink the agents.
8. Select the agent(s) from the Code/Description dropdown list.

a. Do not use the Immunization Quick Entry menu. This is not linked to the client's information and cannot be used for provincial vaccine safety surveillance.

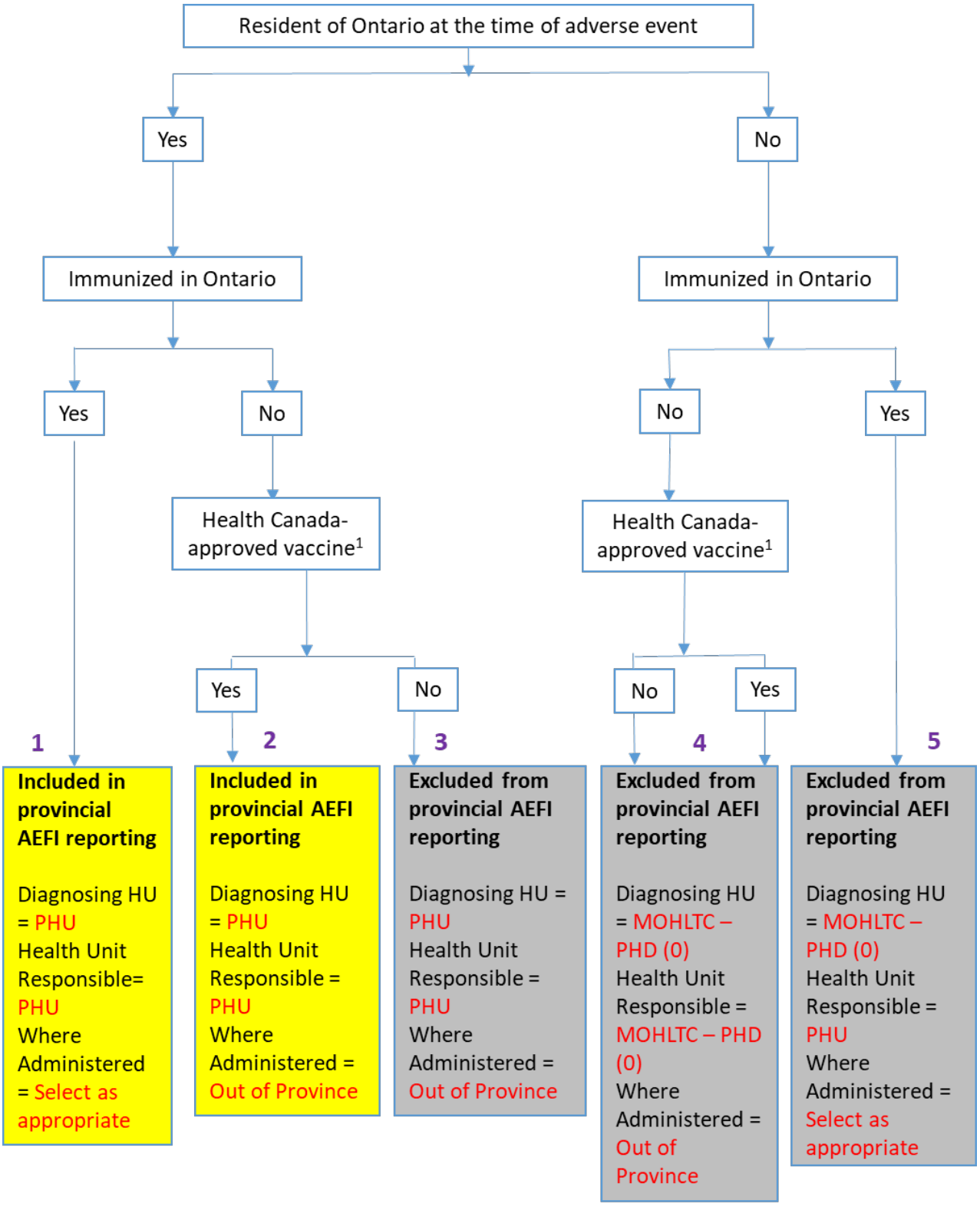
9. Select **Add** to relink the agent.

Appendix 6 – How to report AEFIs in non-residents of Ontario and/or AEFIs following vaccine(s) administered out-of-province

In general, all AEFIs for residents of Ontario should be reported in iPHIS, regardless of the location where the vaccine was administered (Boxes 1 and 2 in flowchart below, highlighted in yellow). All AEFIs reported in individuals who were residents of Ontario at the time of the adverse event following Health Canada-approved vaccines are included as part of provincial AEFI reporting. This is consistent with the process for other diseases of public health significance. However, if a resident of Ontario was vaccinated out-of-province with a vaccine that is not authorized for use in Canada, this AEFI can still be reported in iPHIS at the discretion of the PHU but will be excluded from provincial AEFI reporting (Box 3 in flowchart below).

AEFIs reported in non-residents of Ontario but who were vaccinated in Ontario will be excluded from provincial AEFI reporting (Boxes 4 and 5 in flowchart below). Non-residents of Ontario must have the Diagnosing HU selected as 'MOHLTC – PHD' to ensure these reports are excluded from provincial reporting. These reports can be sent to the jurisdiction of the client's residence via an interjurisdictional notification.

Figure 1. Flowchart for determining how to report AEFIs in non-residents of Ontario and/or AEFIs following vaccine(s) administered out-of-province



Appendix 7 – How to report a death/fatal outcome

The monitoring of adverse events following immunization (AEFIs) including deaths is an important part of vaccine safety surveillance in Ontario. For any death temporally associated with receipt of a vaccine, PHUs should immediately contact the IVPD team at ivpd@oahpp.ca. PHUs should also request a Medical Certificate of Death for an AEFI involving a death or fatal outcome. Information contained in this document is important for completion of the Type of Death and Cause of Death fields.

Reporting of deaths in the context of AEFI surveillance in Ontario

As outlined in the Ministry of Health Infectious Diseases Protocol AEFI Appendix 1, confirmed AEFIs are defined as any untoward medical occurrence in a vaccine recipient that follows immunization that cannot be clearly attributed to other causes. A causal relationship with the administration of the vaccine does not need to be established in order to be reported as a confirmed AEFI.

In the context of provincial AEFI surveillance, death can be both the adverse event itself and/or the outcome. This includes for example a fatal outcome in a vaccine recipient **following the occurrence of an adverse event** OR a report of death **as the adverse event** in a vaccine recipient with no other reportable event. All AEFI reports involving death/fatal outcome of the vaccine recipient should be reported in iPHIS as described below.

Data entry for AEFIs involving a death/fatal outcome (Outcome section in iPHIS)

- **Outcome** should be selected as 'FATAL'
- **Date of Death** should be entered
- **Type of Death** should be selected as 'UNKNOWN' unless there is sufficient information that clearly attributes the cause of death to the receipt of vaccine (i.e., based on autopsy/coroner's report findings)
- **Cause of Death** should contain Part I and/or Part II of Section 11 of the Cause of Death section of the Medical Certificate of Death, if available. In the absence of a Medical Certificate of Death other available information indicating the cause of death (e.g., clinical records, hospital reports) may be entered. If the PHU is unable to determine the cause of death, enter 'Unknown' in this field.

The **Type of Death** field is meant to capture any association that may exist between the receipt of the vaccine and the cause of death. Given that there is currently no formal causality assessment process as part of provincial AEFI surveillance and no expectation for PHUs to conduct a causality assessment of deaths beyond applying definitions outlined in AEFI Appendix 1 or the AESI Technical brief, PHO is advising PHUs to select 'UNKNOWN' for the **Type of Death** field unless there is sufficient information that clearly attributes the cause of death to the receipt of the vaccine (i.e., PHU would then select either 'Reportable disease was underlying cause of death' or 'Reportable disease contributed to but was not underlying cause of death' depending on findings from an autopsy or coroner's report). Of note, all reported AEFIs involving death/fatal outcome undergo a case review at PHO and all those classified as 'Confirmed' in iPHIS are further reviewed at the federal level by the Public Health Agency of Canada (PHAC), using the WHO-UMC causality assessment categories.

For reports of death/fatal outcome where the PHU has determined that the case 'Does not meet definition', there is no expectation for entering complete details including **Adverse Event Reactions** or notes into iPHIS; however, any information on the cause of death, should be entered in the **Outcome** section before closing the case, as all reports of death, of any case classification are reviewed carefully by PHO. Note: DNM cases are not included in case counts and not transmitted to PHAC for further assessment.

In terms of data entry for the **Adverse Events,** PHUs are reminded to enter the applicable adverse event(s) preceding the death according to the specific event-type criteria outlined in AEFI Appendix 1 (Types of Adverse Events) or the AESI technical brief. Where the death itself is the adverse event (e.g., no preceding event, criteria not met for other events listed in AEFI Appendix 1/AESI technical brief), then **E.6 Other Severe OR Unusual Events** may be selected according to the criteria outlined in AEFI Appendix 1: any death of a vaccine recipient temporally linked (within one month) to immunization, where no other clear cause of death can be established.

PHUs are reminded to include a note in **Cases>Case>Notes** describing the following details regarding the death/fatal outcome should be entered, if available:

- Detailed information related to the cause of death (e.g., from a death certificate, coroner's autopsy report, etc.)
- Information related to the event and a timeline of events leading up to the death
- Any relevant medical history

If PHUs are uncertain about the **Type of Death** or **Cause of Death** fields, please contact the IVPD team at ivpd@oahpp.ca.

Appendix 8 – Receiving AEFIs discovered through CANVAS or SPRINT-KIDS

The Canadian National Vaccine Safety (CANVAS) network is a national active surveillance platform that monitors vaccine safety for seasonal influenza vaccines and other newly approved vaccines (e.g., COVID-19 vaccine and Imvamune). In Ontario, vaccine recipients may be invited to participate in a study if they provide consent to use their e-mail address collected at the time of immunization. Participation in the study is voluntary. Information is collected by an electronic survey sent to the participants to collect information on potential AEFIs, and telephone follow-up if required.

SPRINT-KIDS is a national pediatric active surveillance system that replaced IMPACT in 2024. The system consists of a network of 15 pediatric emergency departments across Canada to conduct active surveillance for select adverse events. There are five participating centres in Ontario: The Hospital for Sick Children (Toronto), CHEO (Ottawa), London Health Sciences Centre (London), McMaster Children's Hospital (Hamilton) and Kingston Health Sciences Centre (Kingston).

Any reportable AEFIs that are discovered through the SPRINT-KIDS or the CANVAS network are sent to PHO for provincial reporting. If the client and AEFI case do not yet exist in iPHIS, PHO will create both the client and AEFI investigation in iPHIS. PHO will do a thorough search in iPHIS to ensure that duplicate clients/investigations are not created. PHO will transfer the investigation to the relevant PHU by sending an iPHIS referral to the PHU of client's residence for further investigation and subsequent data entry by the PHUs. PHO will attach the completed AEFI form and any supplemental information to the iPHIS referral. If the AEFI reported through the CANVAS network or SPRINT-KIDS already exists in iPHIS, PHO will notify the PHU. Please contact ivpd@oahpp.ca for any questions on this process.

Appendix 9 – How to determine which vaccine(s) should be included in the AEFI investigation if a client received more than one vaccine close in time but on different days

In general, co-administration refers to vaccines administered on the same day. However, there are other scenarios where two (or more) vaccines may also be reported as 'co-administered', such as if both vaccines are administered close together in time but on different days (e.g., a few days apart) where both could be temporally associated with the same adverse event.

To determine if vaccines administered on the same day or close in time should be reported as part of a single AEFI investigation, the PHU should review the temporal criteria for the event(s) being reported, as outlined in AEFI Appendix 1, Infectious Diseases Protocol. If vaccine administration dates for all vaccines fit within the temporal time frame (e.g., event onset from 0-42 days following immunization) for the reported event, they may be reported as part of a single AEFI investigation. One exception may be when a local reaction at the injection site is clearly linked to one of the vaccines being administered; in this case, the second vaccine administered in a different anatomical site need not be reported unless there are other events that meet reporting criteria.

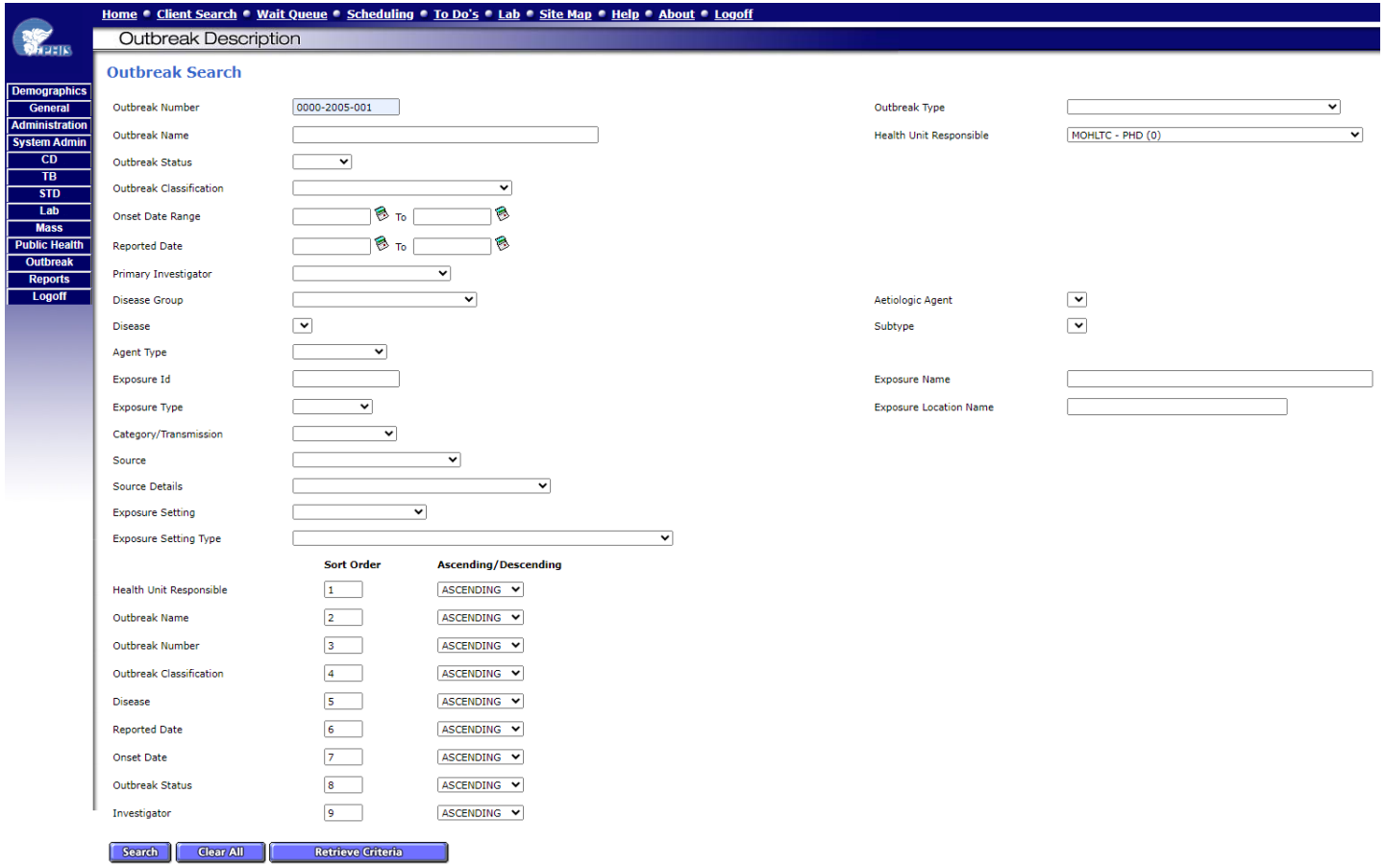
PHUs with questions regarding AEFI reports following co-administered vaccines can contact the IVPD team at ivpd@oahpp.ca.

Appendix 10 – iPHIS Application Screen Shots

1.0 Creating a Case

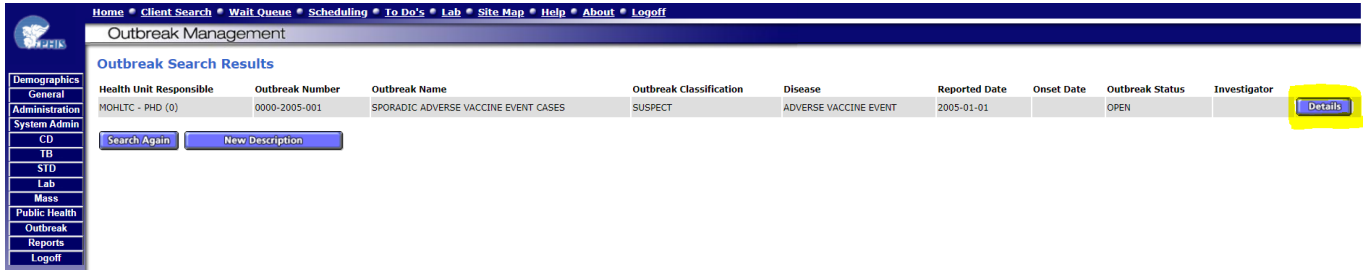
Outbreak Search Screen

[Return to Section 1.0 Case Details]

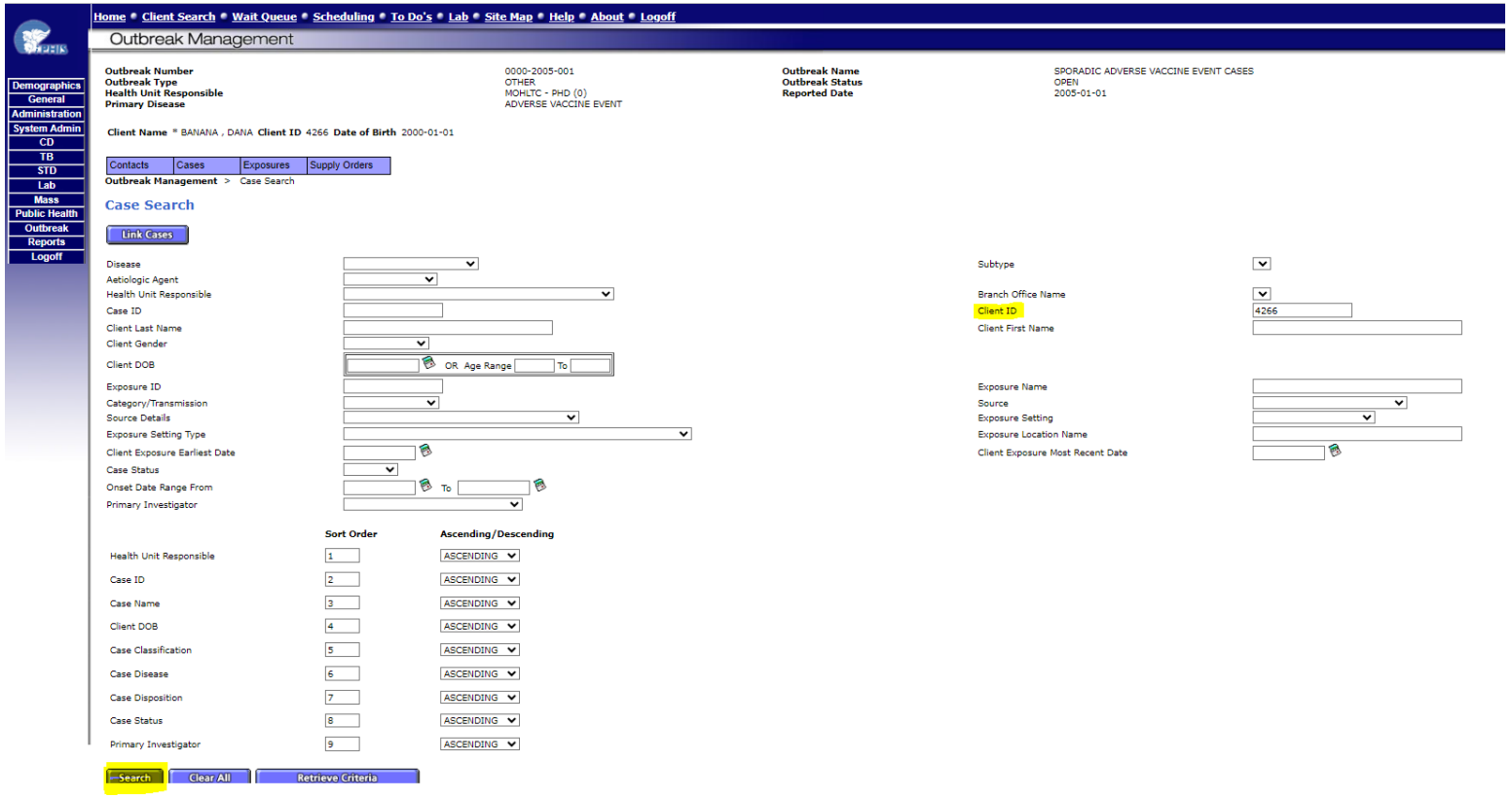


Sporadic AEFI Outbreak Results

[Return to Section 1.0 Creating a Case]

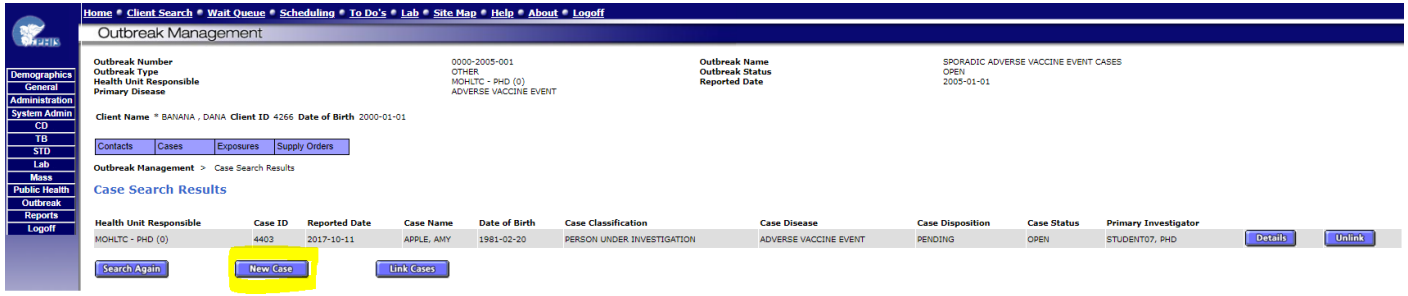


Case Search



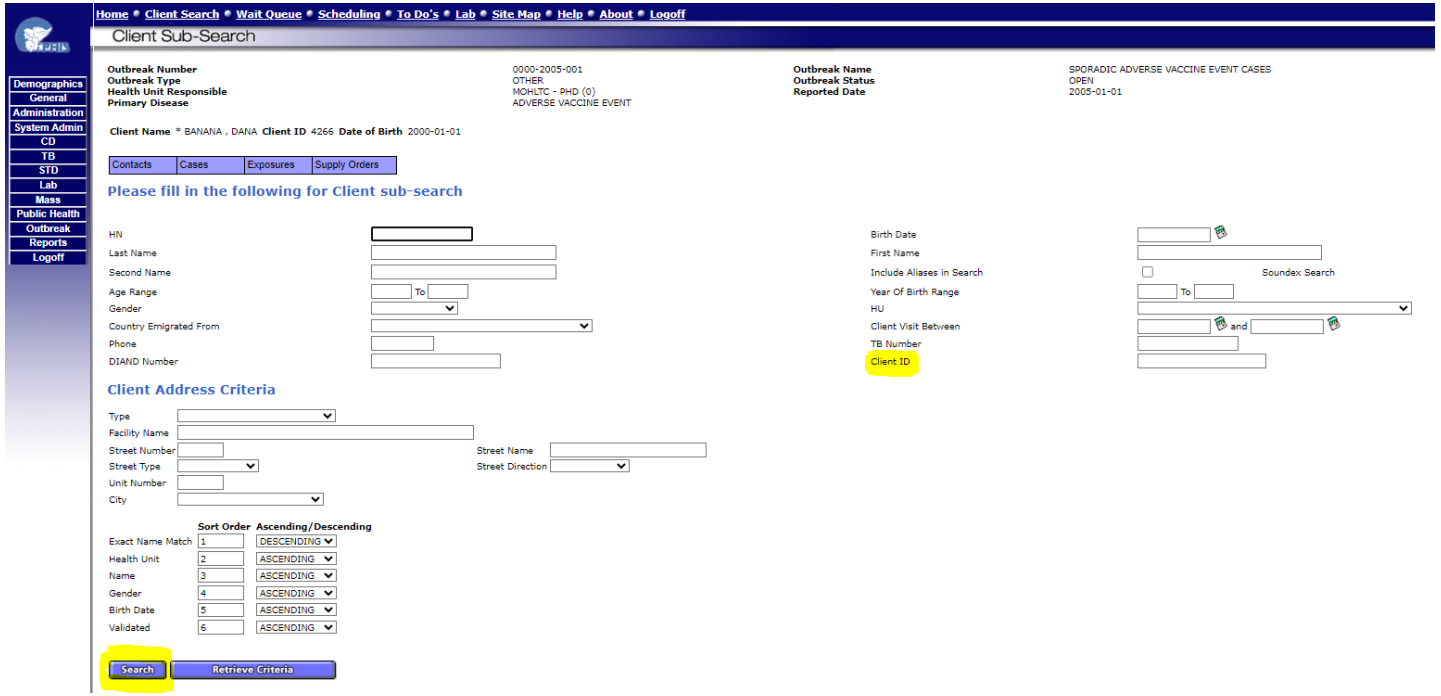
Case Results

Return to Section 1.0 Creating a Case



Client Sub-Search Screen

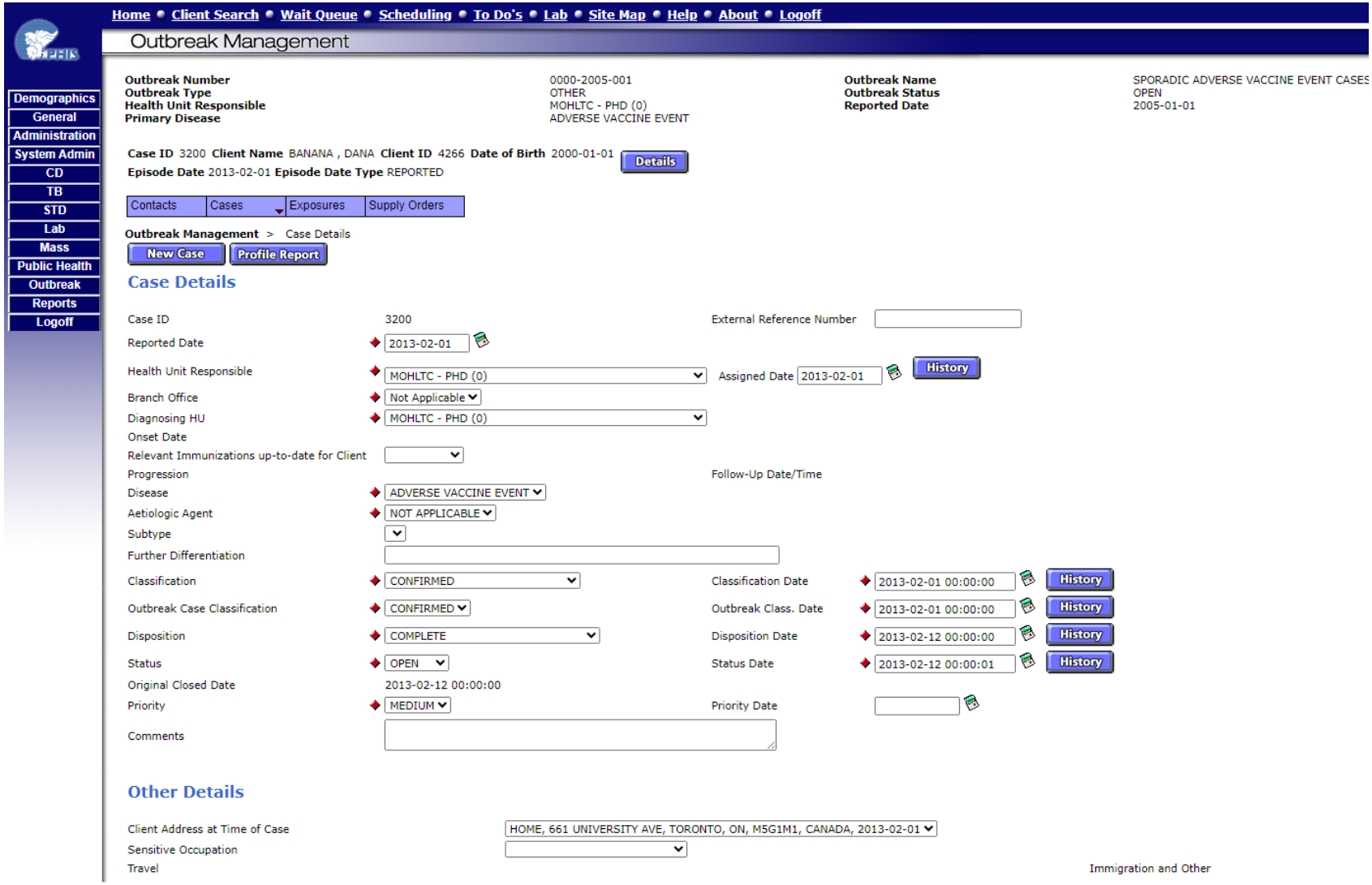
Return to Section 1.0 Creating a Case



1.1 Case Details

Case Details Screen

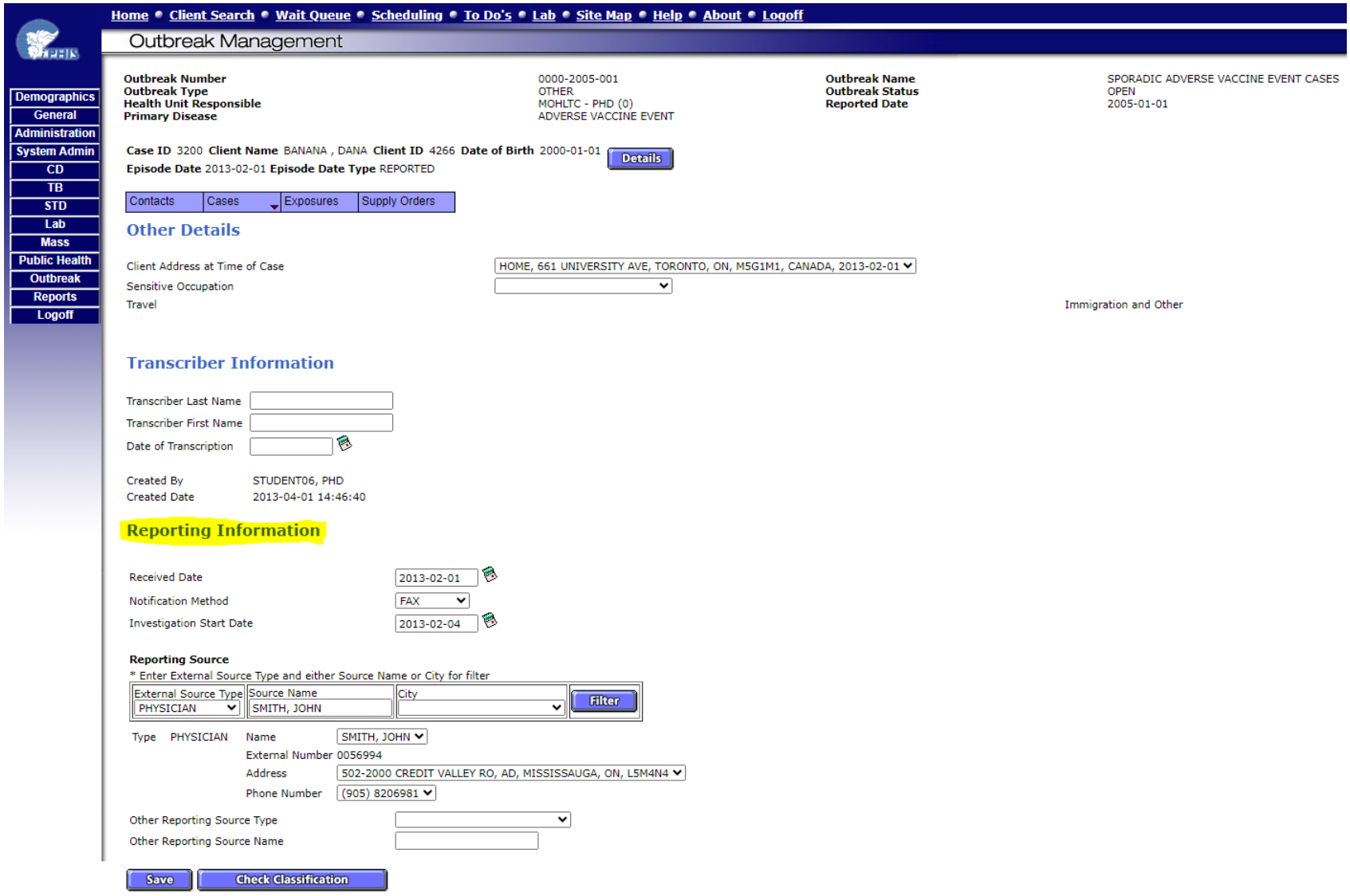
Return to Section 1.1 Case Details



1.2 Reporting information

Reporting Information Section

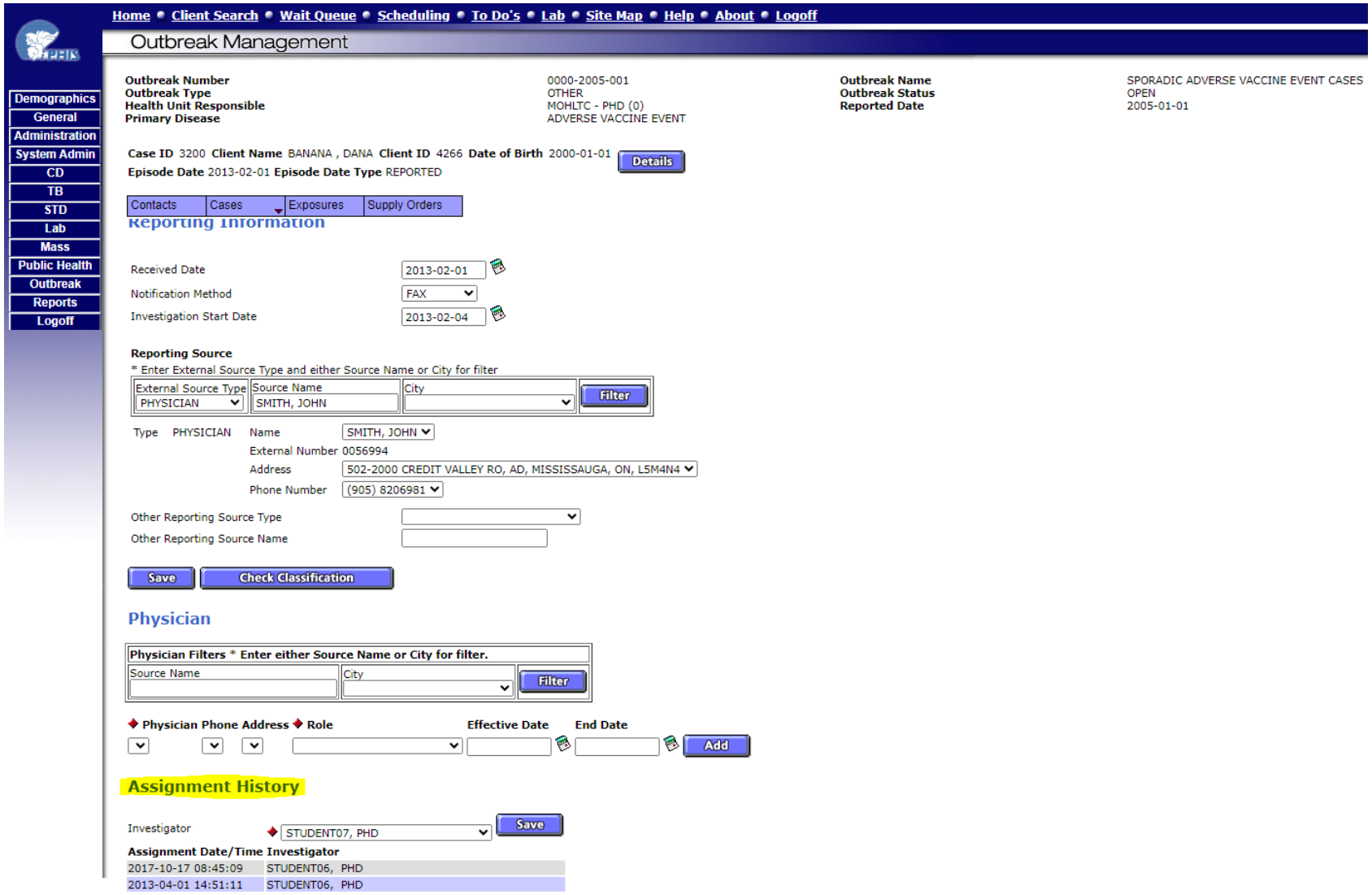
[Return to Section 1.1 Case Details]



1.3 Assignment history

Assignment History Section

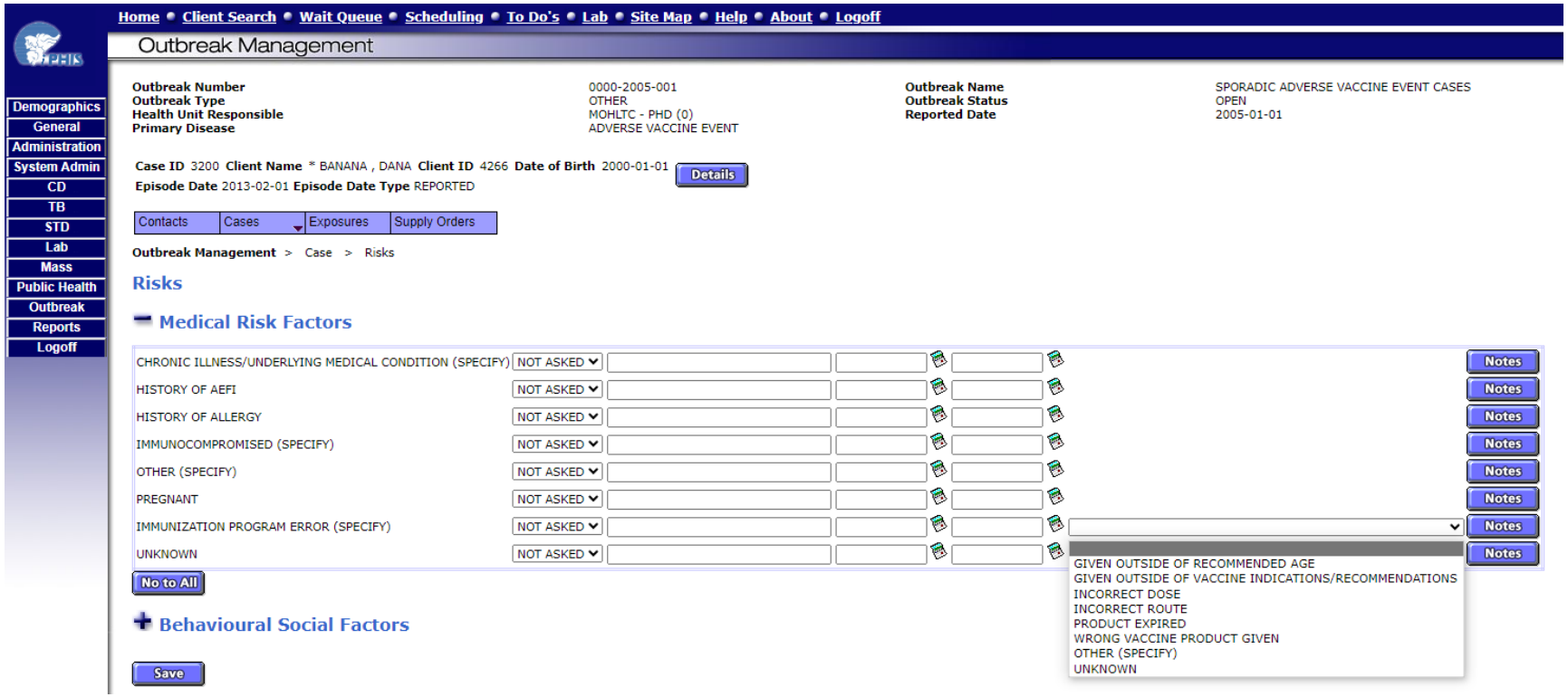
[Return to Section 1.1 Case Details]



2.0 Risks

Risk Factor Entry for AEFI Screen

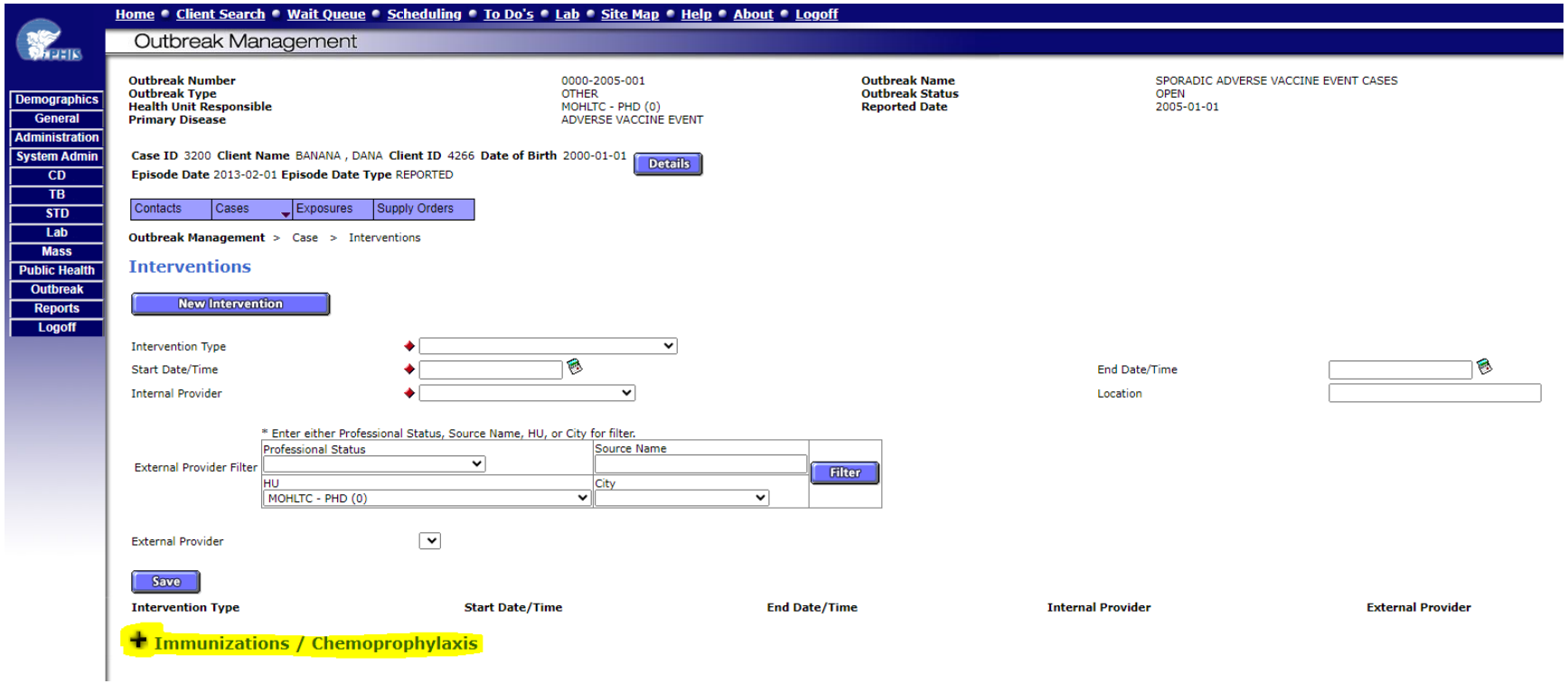
Return to Section 2.0 Risks



3.0 Immunizations

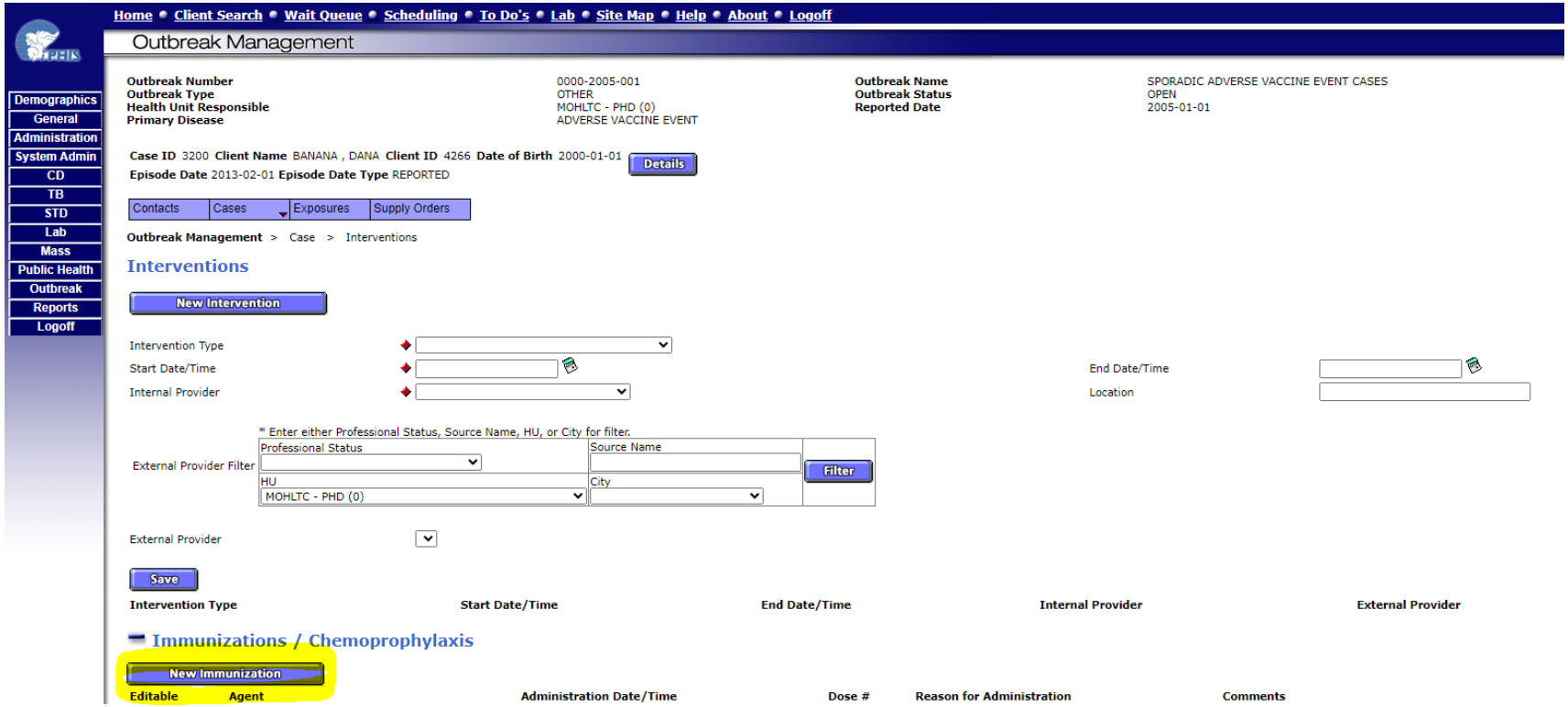
Immunization/Chemoprophylaxis section of the Intervention screen

Return to Section 3.0 Immunizations



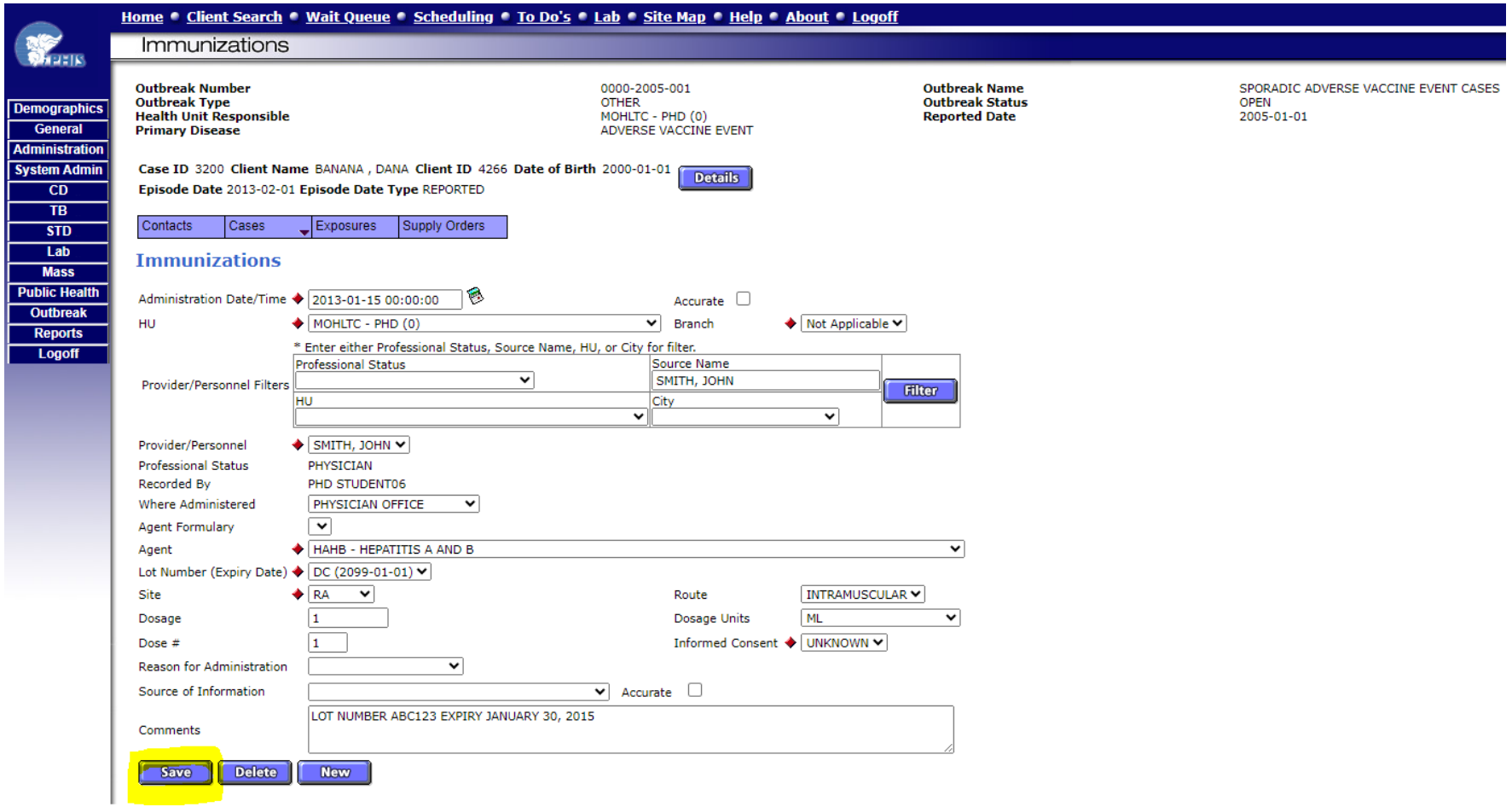
Screen shot 3.0b Expanded Immunization/Chemoprophylaxis Section

Return to Section 3.0 Immunizations



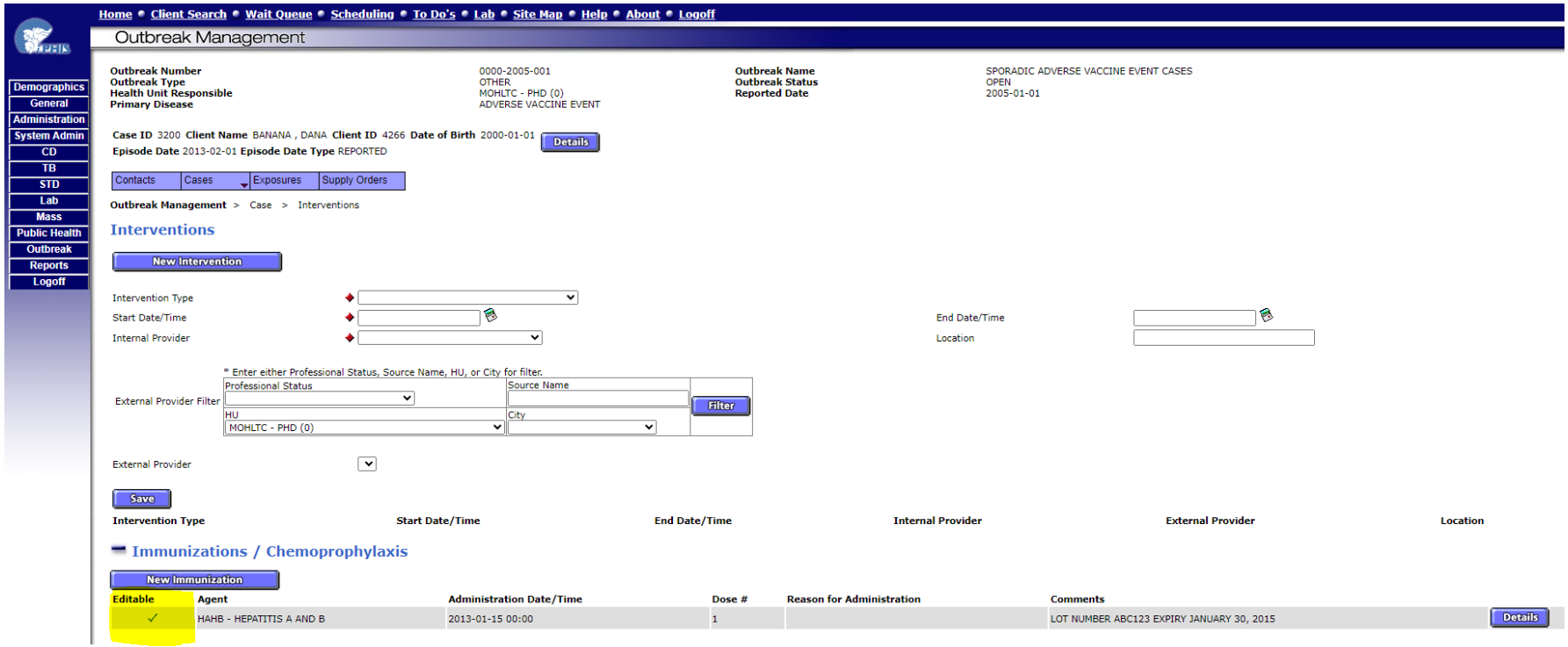
Immunization Details Screen

Return to Section 3.0 Immunizations



Example of a Completed Expanded Immunization/Chemoprophylaxis Section

Return to Section 3.0 Immunizations



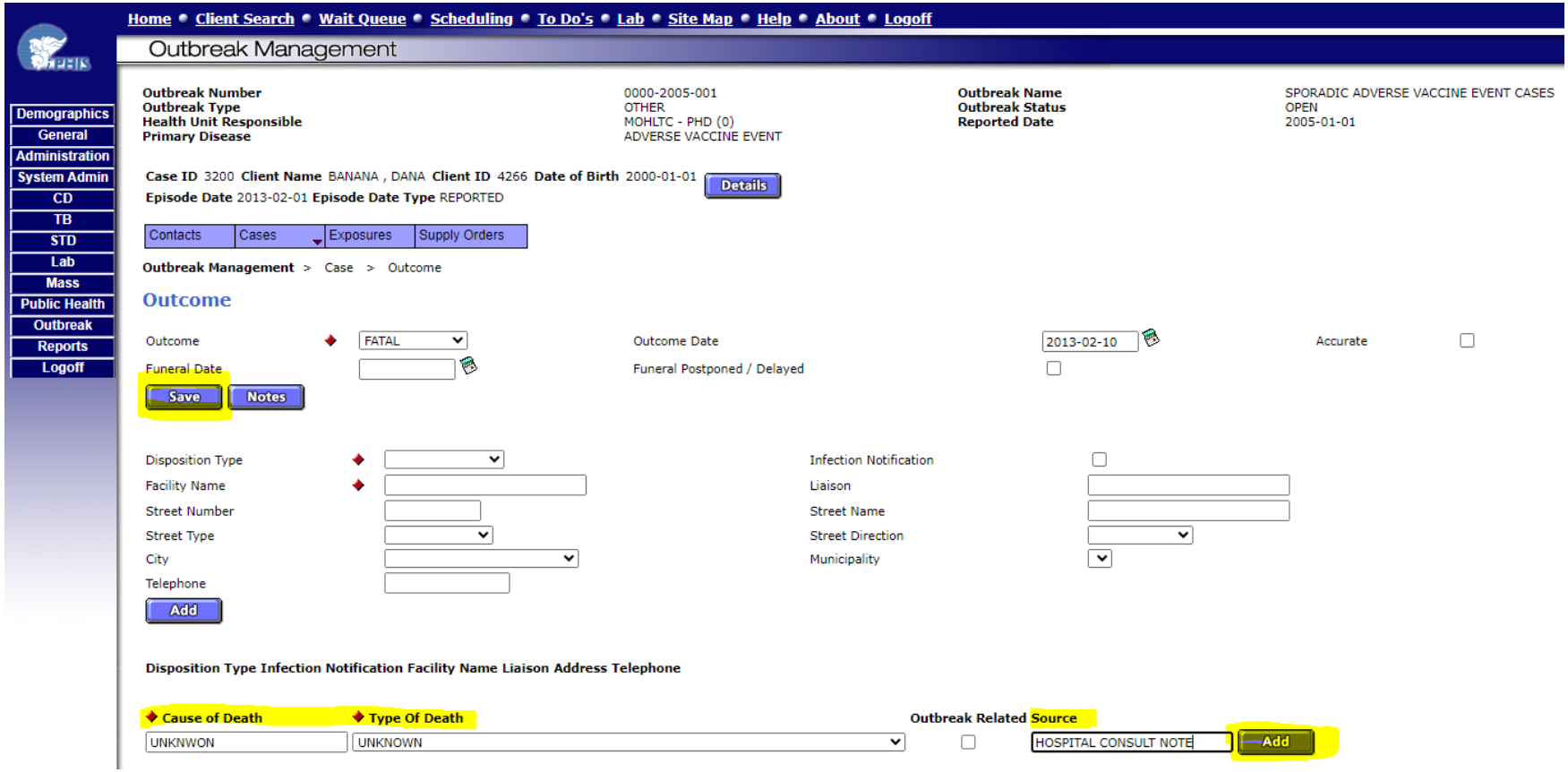
4.0 Outcome (Fatal Outcomes Only)

Case Outcome Screen

Return to Section 4.0 Outcome (Fatal outcomes only)

Fatal Outcome Options Screen

Return to Section 4.0 Outcome (Fatal Outcomes Only)



5.0 Case Notes

Adding Case Notes

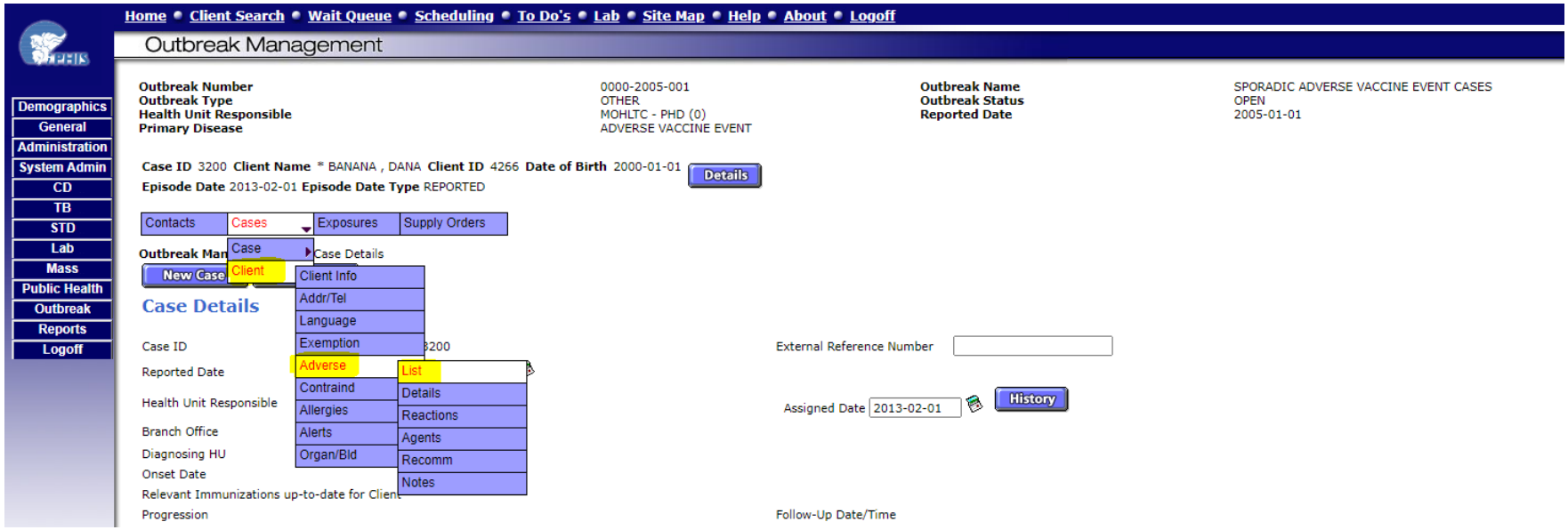
[Return to Section 5.0 Case Notes]

Example of Case Notes Entry

6.0 Adverse Event List

Navigation Path to Access Adverse Event Details

[Return to Section 6.0 Adverse Event List]



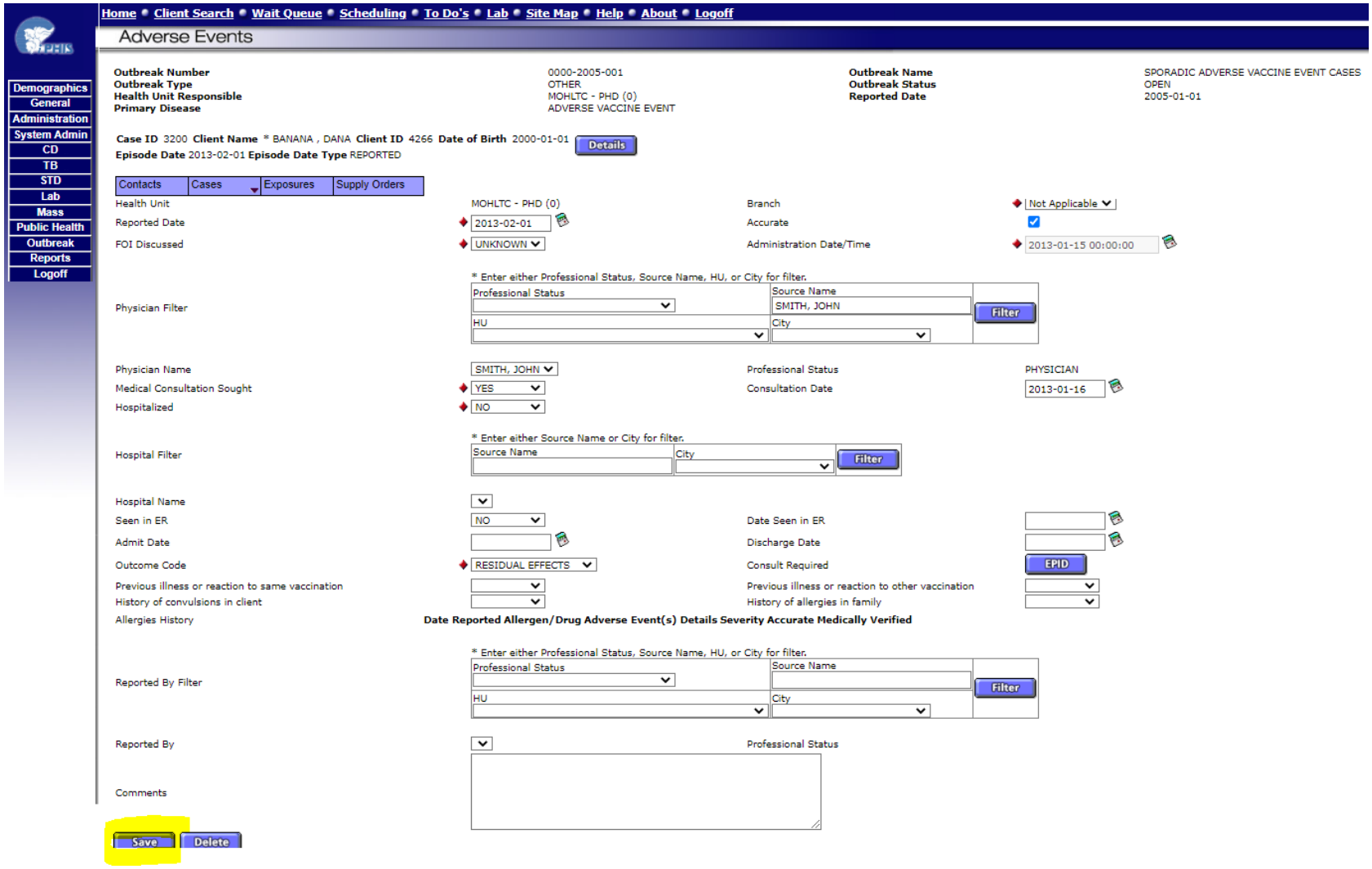
Adverse Event Options Screen

Return to Section 6.0 Adverse Event List

6.1 Adverse Event Details

Adverse Event Details Screen

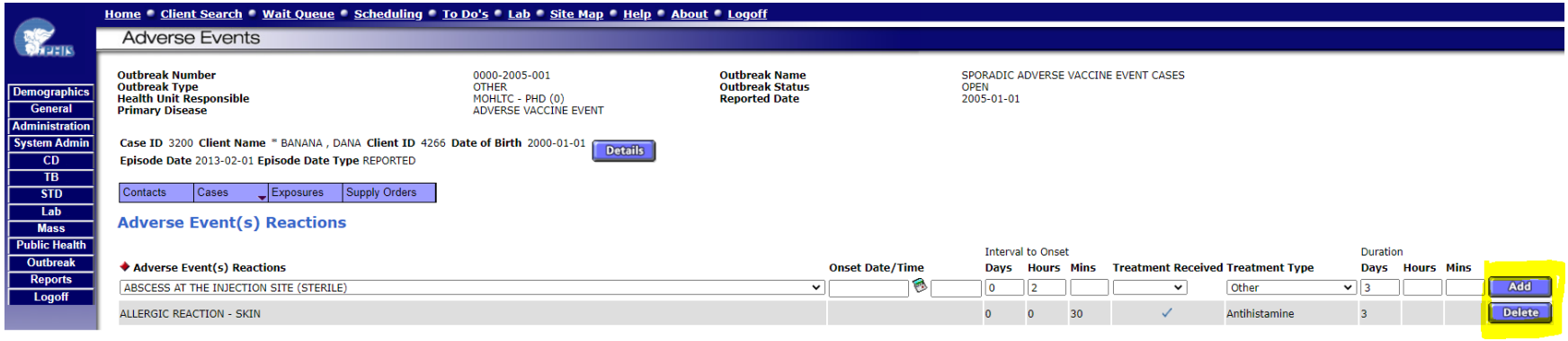
[Return to Section 6.1 Adverse Event Details]



6.2 Adverse Event Reactions

Adding an Entry for an Adverse Event(s) Reaction

[Return to Section 6.2 Adverse Event Reactions]



6.3 Adverse Event Agents

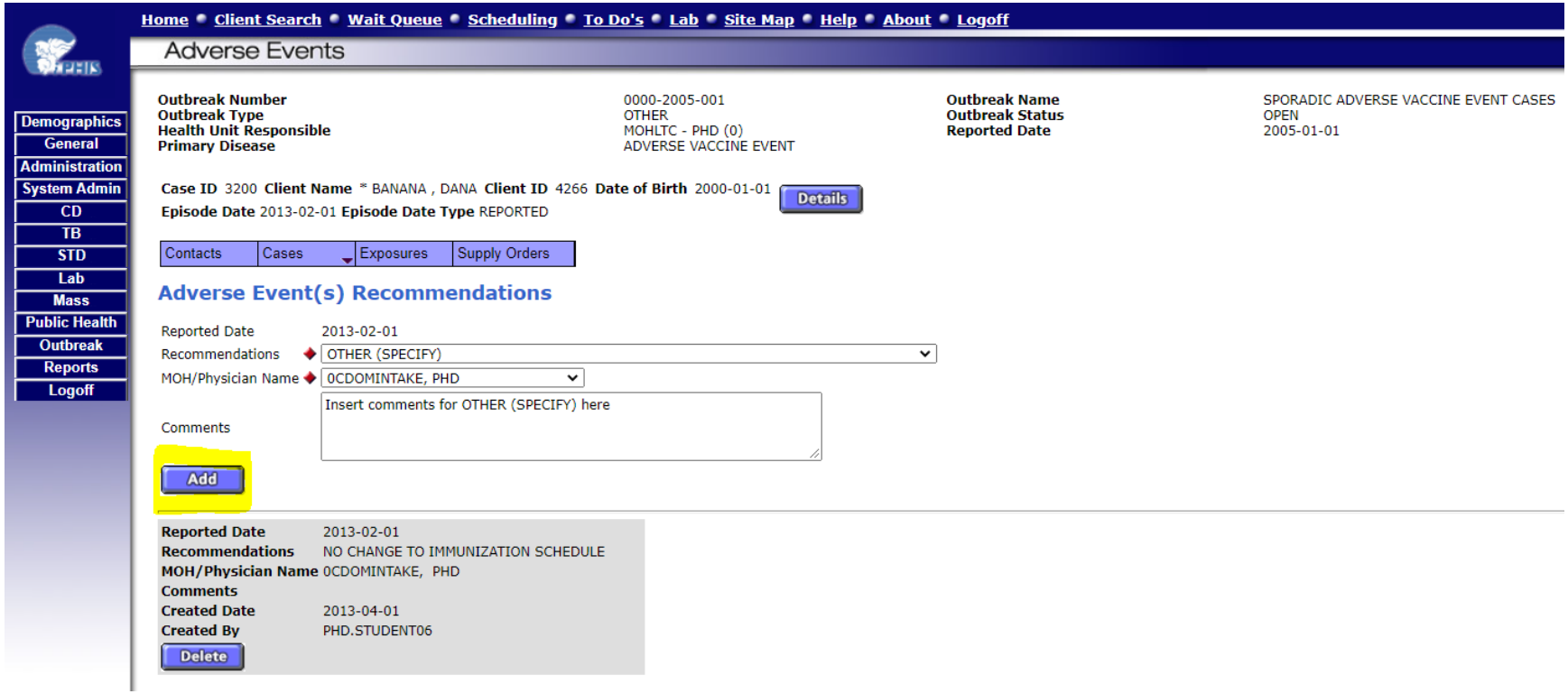
Screen shot 6.3a Adverse Event(s) Agents Quick Entry Section

[Return to Section 6.3 Adverse Event Agents]

6.4 Adverse Event Recommendations

Adverse Event(s) Recommendations Screen

[Return to Section 6.4 Adverse Event Recommendations]



Appendix 11 – Event managed as anaphylaxis signs and symptoms

Table 11. Glossary of anaphylaxis signs and symptoms terms by body system adapted from the AESI Case Definition Companion Guide: Anaphylaxis Version 2.

GLOSSARY OF TERMS BY BODY SYSTEM	
Rapid progression of symptoms and signs	From the start of symptoms or signs of possible anaphylaxis, there were multiple body systems involved (≥2 of skin, respiratory, cardiovascular or gastrointestinal) ***OR*** What started out involving 1 system spread to involve at least 1 other system within 1 hour of onset.
SKIN OR MUCOSAL	
Angioedema	Areas of deeper swelling of the skin or mucosal tissues which may not be well circumscribed and usually not itchy. NOTE: hereditary angioedema, usually with a history of recurrent episodes of swelling, should be excluded (affects 1 in 50,000)
Erythema	Abnormal redness of the skin without any raised skin lesions
Generalized	Involving >1 body site – that is each limb is counted separately as is the abdomen, back, head and neck. Synonym = widespread
Pruritus	Itchiness
Red and itchy eyes	Redness of the whites of the eyes (sclera) with sensation that provokes the desire to rub and/or scratch to obtain relief.
Urticaria (hives)	Localized redness of superficial layers of skin that is itchy, raised, sharply demarcated and transient (usually lasts <12 hours)
RESPIRATORY	
Accessory muscles	Muscles, primarily in the neck (sternocleidomastoid which elevates sternum; scalene group which elevates upper ribs) which assist but don't play a primary role in breathing. When used at rest they indicate a level of respiratory distress or increased work of breathing.
Cyanosis	A dark bluish or purplish discolouration of the skin and/or mucous membranes due to lack of oxygen in the blood
Grunting	A sudden and short noise with each breath when breathing out

GLOSSARY OF TERMS BY BODY SYSTEM	
In-drawing or retractions	Inward movement of the muscles between the ribs (inter-costal), in the lower part of the neck (supra- clavicular or tracheal tug) or below the chest (sub-costal).
Retractions	Indrawing of skin while breathing in (implies an obstruction to breathing); may be supraclavicular (above the collarbone), suprasternal (above the sternum), intercostal (between the ribs), substernal (below the sternum) or subcostal (abdomen just below the rib cage)
Runny nose	Rhinorrhea; discharge of thin nasal mucus from the nose
Sneezing	An involuntary (reflex), sudden, violent, and audible expulsion of air through the mouth and nose.
Stridor	A harsh and continuous sound made on inspiration (breathing in)
Tachypnoea	Faster than normal respiratory rate. Age (in years) specific upper normal limits for breaths/min: <1 year = 60; 1-<2 years = 40; 2-<5 years = 35; 5-<12 years = 30; >12 years = 16
Wheezing	A whistling, squeaking, musical or puffing sound made on expiration (breathing out)
CARDIAC	
Hypotension	An abnormally low blood pressure (BP) documented by appropriate measurement. Age dependent as follows: • <11 years: Systolic < the sum of: 70mm Hg + 2 times age in years ≥11 years: Systolic <90 mm Hg OR Diastolic <60 mm Hg OR > 30% decrease from the person's baseline systolic BP
Loss of consciousness	Total suspension of conscious relationship with the outside world as demonstrated by an inability to perceive and respond to verbal, visual or painful stimulus
GASTROINTESTINAL	
Diarrhea	Loose or watery stool. If aged <12 months must have ≥2 episodes
Vomiting	The reflex act of ejecting the contents of the stomach through the mouth (NOTE: does not apply if only oral vaccine(s) given). If aged <12 months must have ≥2 episodes
LABORATORY	
Mast cell tryptase	Inflammatory mediator released by mast cells during acute anaphylaxis. Typically, levels peak between 15 and 120 minutes after onset; samples for measurement should be taken within 6 hours of onset of signs/symptoms.

Appendix 12 – Frequently asked questions on AEFI reporting

Q1. What is the process of referring AEFIs to other PHUs?

A: The process is the same as other disease of public health significance (DoPHS) using iPHIS referrals. The process for referring to FNIHB/ISC is also the same as for other DoPHS.

Q2: For any reports of intussusception, will the supplemental form be required or will there be a new dynamic questionnaire like for events managed as anaphylaxis?

A: The intussusception form is no longer in use. No additional forms/information are required - enter all clinical details to support the event selection in the available fields and under Cases > Case > Notes.

Q3: Do we have the ability to upload documents into iPHIS?

A: iPHIS does not have the functionality for file uploads. All details of the AEFI investigation should be captured in the available fields, and any additional details documented in under Cases > Case > Notes.

Q4: If hospitalized is entered in the Adverse Event Details screen, does it also need to be entered under Interventions?

A: No. For AEFIs, hospitalization details only need to be captured in the Adverse Event Details screen. If the case was hospitalized on more than one occasion, enter the details of the earliest hospitalization in the Adverse Event Details screen and any additional hospitalization details under Cases > Case > Notes.

Q5: Who do we contact if the lot number isn't in iPHIS and need it added for the case?

A: If lot number is unavailable in iPHIS and you know the lot number and expiry date, contact the Public Health Solutions Service Desk (PublicHealthSolutions@Ontario.ca or 1-866-272-2794) to have it added. All tickets should be submitted by the PHU's PRC. This is generally a quick process. In the meantime, use the default code 'DC (2099-01-01)' to save the immunization record. Enter 'Lot number pending' in the Comments field while waiting for the lot number to be added by Public Health Solutions Service Desk. Be sure to return and update the lot number when it is added and remove the related information in the Comments field.

Q6: How do we enter vaccines where the lot number is known but the expiry date is unknown?

A: As long as you know the lot number you can enter this into iPHIS. In the lot number dropdown, iPHIS displays the lot number along with its corresponding expiry date.

If the lot number isn't in iPHIS and you are submitting it to PHS: you can find the lot number expiry date by using the National Vaccine Catalogue: Vaccine lot to look it up.

Q7: Can multiple notes be entered in an investigation?

A: Yes. Multiple narrative notes at different times can be entered under Cases > Case > Notes.

Q8: For immunizations that were not administered by a physician or nurse practitioner (NP), does entering EXT% still work in the Provider/Personnel Filters field?

A: Yes. Please enter 'External, other' by writing 'ext%' in the Source Name field, leave everything else blank, and click Filter to enter immunization providers other than physicians or NPs.

Q9: Are pharmacists included as reporting sources in iPHIS?

A: For pharmacists, you can choose 'Healthcare Professional' as the Other Reporting Source Type and specify the professional designation (e.g. pharmacist) in the Other Reporting Source Name field.

Q10: If we receive additional information after June 28, 2024 that may amend the classification, event selection, MOH recommendations, etc. of an AEFI investigation that was already closed in CCM, do we need to re-create the case in iPHIS to document the information?

A: If you receive new information that is important for the AEFI investigation, please re-create the case in IPHIS and note the CCM investigation number in the Comment field under Case Details: 'Duplicate entry of CCM investigation ##'.

Q11: Can users use the iPHIS referral functionality if they wanted to upload documents in addition to notes?

A: Users can use the referral functionality in iPHIS to upload documents based on their PHU's best practices in addition to entering case notes in iPHIS. Please note that uploading supporting documents does not replace entering case notes in iPHIS as PHO does not routinely review files that are attached to the investigations. It is important that users manually enter all notes into iPHIS so that this information can be extracted and used for provincial vaccine safety surveillance (as well as be submitted to CAEFISS).

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