

User Guide

IMMUNIZATION

Adverse Event Following Immunization

- Overview of the Adverse Event Record
- View Adverse Event
- Create Adverse Event
- Delete Adverse Event

Table of contents

A. Introduction.....	4
B. Overview of the Adverse Event Report.....	6
C. View Adverse Event	7
D. Create Adverse Event	9
1.0 Adverse Event Create	9
2.0 Adverse Event Review	23
3.0 Needs More Information / Consultation	26
E. Delete Adverse Event.....	28

NOTE: This user guide shows how to complete the AEFI Report in Panorama. It is important for all users to follow Saskatchewan policy and procedures when creating and reviewing an AEFI Report.

A. Introduction

The purpose of the Adverse Event functionality is to allow authorized Users to record/update Adverse Event Following Immunization (AEFI) information in the system and link it to specific Immunization Records when an AEFI has been reported to Public Health.

Regional Health Authority public health staff receive reports on AEFIs from clients, the parents or guardians of clients and from non-public health immunizers.

Within each RHA, the nurse creating the “draft” report will record the details and once all necessary information is recorded in the AEFI record in Panorama, selects “Submitted for Review” and the Workgroup for Review & Approve AEFI. This causes a system automated Task to be sent to the RHA Nursing Manager or Immunization Program Coordinator responsible requesting to approve the AEFI record meets expected quality/completeness of data and adherence to AEFI case definition criteria.

If approved, he/she selects “Submitted for Review” along with the Workgroup for “MHO AEFI Review” and a system automated Task will be sent to the regional MHO for his/her review, further testing or follow-up as required, and recording of the final recommendation as to how to proceed in the future with respect to the involved antigens.

Once the MHO has completed review and recommendations the record will be set to Completed, and a system-automated Task will be created for the AEFI submitter, in order to follow up with the Client or parents/guardian as well as to create any Special Consideration records required by the MHO’s recommendation.

High level steps are:

1. Draft AEFI (Submitter)
2. Submit for Review – AEFI Review & Approve WG notified
3. Reviewed & approved, Submit for Review to MHO – AEFI MHO Review & Recommend WG notified
4. Reviewed and recommendations recorded – Set to Complete – AEFI Submitter WG notified

Assumptions: The user has the appropriate security permissions to perform the assigned tasks. Only immunization events which meet one or more of the criteria below should be recorded as potential AEFIs:

- Of a serious nature
- Require urgent medical attention
- Unusual or unexpected
- Temporally associated with vaccination

Pre-requisites: To complete the steps within this user guide, the user must have the appropriate permissions and security access. User is in the Immunization module (tab), and has a client in context. The immunization related to the adverse event must be in the client's immunization record (within the Client Immunization Profile). Workgroups exist with the specific users required to submit, approve, review and recommend, complete and potentially report the AEFI to PHAC.

Related User Guides: Add Immunizations, Add Special Consideration.

B. Overview of the Adverse Event Report

The AEFI report is a multi-section electronic record. Each section can be expanded to view or update the corresponding information. The information within this report does not need to be completed in a specific order.

* Reporting Source	Show Reporting Source
* Immunization Data	Show Immunization Data
* Information at Time of Immunization and AEFI Onset	Show Information
* AEFI Details	Show AEFI Details
Impact of AEFI, Outcome and level of care	Show Impact
* Public Health Recommendations	Show Public Health Recommendations
Document Management	Show Document Management
Assigned To	Show Assigned To
AE History	Show AE History

TIP: The **Assigned To:** section requires the user to notify a Workgroup or user. This may be a group of individual users responsible for AEFI review and documentation. It is suggested that you notify (phone call / email) reviewers or other contributors that input is needed.

NOTE: Tasks are viewed and managed within the **Work Management** module.

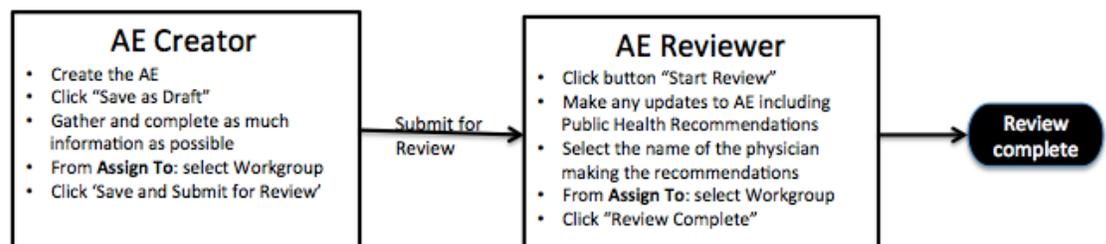
NOTE: Once the AEFI Report has been given the Status "Submitted for Review", multiple users may contribute to the AE Report. The username and the date of the contribution are recorded in the AE History.

The Adverse Event documentation may take some time to complete, and may involve contributions from multiple users. The system records the contributing user names and dates of those contributors within the **AE History**.

The **Assigned To** section allows the user to "pass" the document to another user by selecting Workgroup(s) for automated Task assignment. By assigning a Task to a Reviewer (this could be to a workgroup, or an individual within a workgroup), the **AE History** status changes. The status could be one of the following:

- Draft
- Submitted for Review
- Information Required
- Consultation Required
- Review Complete

Minimum Workflow



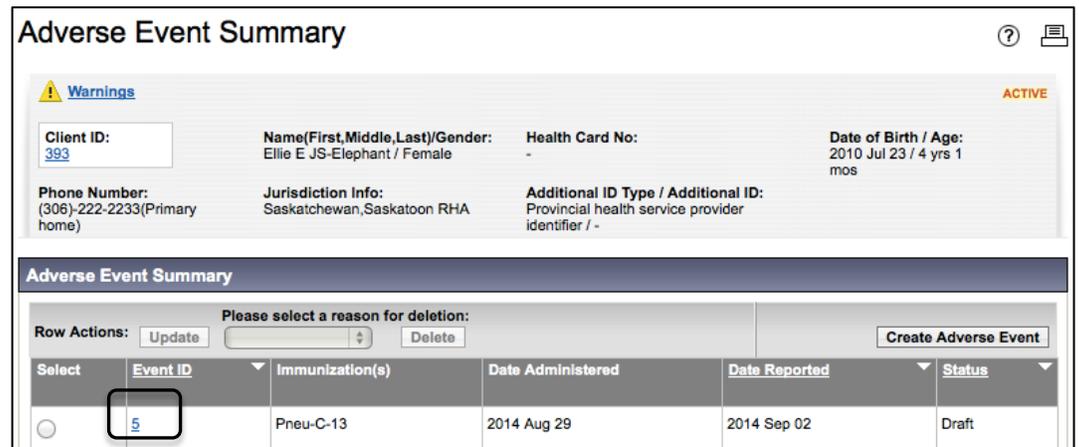
C. View Adverse Event

The **Adverse Event Summary** screen contains all of the AEFI records entered or deleted for the client.

Pre-requisites: The user has successfully logged into Panorama. User is in the Immunization module (tab). Client is in context.

Menu Access: **Select** Immunizations > Adverse Events (AEFI)

1. Click Immunizations > Adverse Events (AEFI) from the left navigation bar. The Adverse Event Summary screen displays.
2. To view an existing Adverse Event, click the **Event ID** hyperlink.



Adverse Event Summary ? [Print]

Warnings ACTIVE

Client ID: 393	Name(First,Middle,Last)/Gender: Ellie E JS-Elephant / Female	Health Card No: -	Date of Birth / Age: 2010 Jul 23 / 4 yrs 1 mos
Phone Number: (306)-222-2233(Primary home)	Jurisdiction Info: Saskatchewan, Saskatoon RHA	Additional ID Type / Additional ID: Provincial health service provider identifier / -	

Adverse Event Summary

Row Actions:

Please select a reason for deletion:

Select	Event ID	Immunization(s)	Date Administered	Date Reported	Status
<input type="radio"/>	5	Pneu-C-13	2014 Aug 29	2014 Sep 02	Draft

The **Adverse Event Details** screen displays.

3. View the AEFI details within each section.
4. To Print the AEFI Report, click on the Printer icon on the top right of the screen.
5. To exit this screen, click **Cancel**.

Adverse Event Details

P
Print

Warnings ACTIVE

Client ID: 393	Name(First,Middle,Last)/Gender: Ellie E JS-Elephant / Female	Health Card No.: -	Date of Birth / Age: 2010 Jul 23 / 4 yrs 1 mos
Phone Number: (306)-222-2233(Primary home)	Jurisdiction Info: Saskatchewan,Saskatoon RHA	Additional ID Type / Additional ID: Provincial health service provider identifier / -	

Cancel

Adverse Event ID: 5

Unique Episode #: **IMPACT Local Inventory Number (LIN):**

Health Region: Saskatoon RHA

Service Delivery Location: Saskatoon South East Public Health Office

Report events which have a temporal association with a vaccine and which cannot be clearly attributed to other causes. A causal relationship does not need to be proven, and submitting a report does not imply causality.

Of particular interest are those AEFIs which meet one or more of the following criteria:

- a. Is of a serious nature
- b. Requires urgent medical attention
- c. Is an unusual or unexpected event

*** Reporting Source**

*** Reporter**

Date Reported: 2014 Sep 02 **Setting:** Physician Office

Add a provider who is in the index: Dr Who

*** Source of Information**

Same as Reporter Client Other

D. Create Adverse Event

The AEFI report is a multi-section electronic record. Each section can be expanded to view / update the corresponding information. The information within this report does not need to be completed in a specific order.

Pre-requisites: The user has successfully logged into Panorama. User is in the **Immunization** module (tab). Client is in context. The immunization (that has caused the adverse event) is recorded for the client. All required AEFI Workgroups have been set up for the RHA of the user.

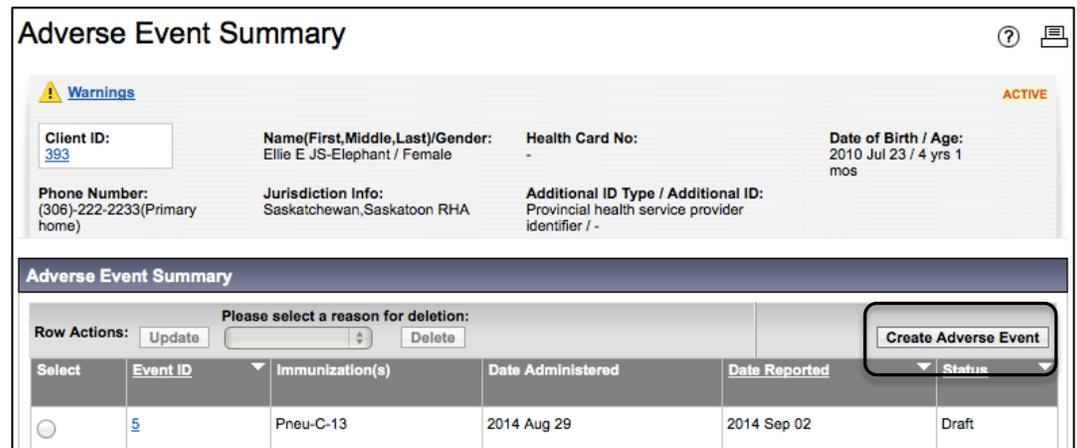
Menu Access: **Select** Immunizations > Adverse Events (AEFI)

1.0 Adverse Event Create

The Adverse Event Create process involves creating the AEFI Report in Panorama, and completing the form until all the information and mandatory fields are entered into the Report. The user will then click **Save and Submit** for review. Here are the steps:

1. Click Immunizations > Adverse Events (AEFI) from the left navigation bar.

The Adverse Event Summary screen displays.



Adverse Event Summary ? [Print]

Warnings ACTIVE

Client ID: 393	Name(First,Middle,Last)/Gender: Ellie E JS-Elephant / Female	Health Card No: -	Date of Birth / Age: 2010 Jul 23 / 4 yrs 1 mos
Phone Number: (306)-222-2233(Primary home)	Jurisdiction Info: Saskatchewan, Saskatoon RHA	Additional ID Type / Additional ID: Provincial health service provider identifier / -	

Adverse Event Summary

Row Actions: Update [Dropdown] Delete Create Adverse Event

Select	Event ID	Immunization(s)	Date Administered	Date Reported	Status
<input type="radio"/>	5	Pneu-C-13	2014 Aug 29	2014 Sep 02	Draft

2. Click **Create Adverse Event**.

The **Create Adverse Event** screen displays.

TIP: The user may save the AE Report at any time by clicking “Save as Draft” even if there are missing mandatory data. To do this, there are 2 required fields:

- Reporter - Who is reporting the AE
- Immunization that caused the AE.

Create Adverse Event ? 🖨

Warnings ACTIVE

Client ID: 393	Name(First,Middle,Last)/Gender: Ellie E JS-Elephant / Female	Health Card No: -	Date of Birth / Age: 2010 Jul 23 / 4 yrs 1 mos
Phone Number: (306)-222-2233(Primary home)	Jurisdiction Info: Saskatchewan,Saskatoon RHA	Additional ID Type / Additional ID: Provincial health service provider identifier / -	

Adverse Event ID:

Unique Episode #: **IMPACT Local Inventory Number (LIN):**

Health Region: Saskatoon RHA

To specify an Organization first click on the 'Find' button. Then search, or type the name of the Organization you wish to specify, select it and click on 'Select' button. Then click 'Close' to close.

Organization: Top Level > Level 2 (specific one) > Level 3 (specific one) > [Selected Level 4 Organization] Find 🔍

Service Delivery Location: Saskatoon South East Public Health Office **SDL ID :** 467

To specify a Service Delivery Location first click on the 'Find' button. Then search, or type the name of the Service Delivery Location you wish to specify, select it and click on 'Select' button. Then click 'Close' to close.

Service Delivery Location: Saskatchewan > Saskatoon RHA > [467 Saskatoon South East Public Health Office] Find 🔍

Report events which have a temporal association with a vaccine and which cannot be clearly attributed to other causes. A causal relationship does not need to be proven, and submitting a report does not imply causality.

Of particular interest are those AEFIs which meet one or more of the following criteria:

- a. Is of a serious nature
- b. Requires urgent medical attention
- c. Is an unusual or unexpected event

3. Add the **Unique Episode #** if this information is applicable / available. The recommended format is YYYY-##.
4. Add the **IMPACT Local Inventory Number (LIN)** if this information is applicable / available. Enter this number if the report was received from IMPACT; otherwise leave it blank. The number is used by the Public Health Agency of Canada to reconcile reports received both from the province and from IMPACT directly.
5. Update the **Health Region** if the default (user default) is not correct. To do this, click the **Find** button. Use the **Type** ahead or **Search** to locate the correct Health Region.
6. Update the **Service Delivery Location** if the default (user default) is not correct. To do this, click the **Find** button. Use the **Type** ahead or **Search** to locate the correct SDL.

TIP: The **Date Reported**, the **Reporting Source**, and the **Source of Information** are all required fields.

- Update the **Date Reported** as required. The default is set to current date.
- Select the AE **Setting** from the drop-list (e.g. Physician office, Public Health, etc.).

*** Reporting Source** ↑ Hide Reporting Source

*** Reporter**

Date Reported: Setting:

yyyy mm dd

Add a provider who is in the index: Dr Who ← Default Provider is based on the user's Immunization Defaults

Click Find to select a provider:

Provider:

Enter information for a non-indexed provider:

* Last Name: * First Name:

* Email Address:

or

Phone: () - ext.

Fax: () - ext.

* Address 1:

Address 2:

City: Province/Territory:

Postal Code:

Professional Status:

*** Source of Information**

Same as Reporter Client Other

- Select the **Provider** that is reporting the AE in Panorama. The default is the Provider set in the User's Immunization Defaults. To select a different Provider from the Index, click **Find**. Use the **Type** ahead or **Search** to locate the correct Provider. If the Provider is not in the Index, select the radio button **Enter information for a non-indexed provider**, and enter the provider information in the fields.
- Select the **Source of Information** radio button.

TIP: The **Immunizing Agent** related to the AEFI is a required field.

11. Select the **Existing Immunization(s)** applicable to the adverse event.
12. Click **Add** to move the immunizing agent to the right hand box – **Selected Immunizations**, (or **Create New** to record the immunization details from the

*** Immunization Data** ↑ Hide Immunization Data

Existing Immunizations View Details

2014 Aug 29 Pneu-C-13(Right lateral upper arm)
 2014 Aug 29 DTaP-IPV-Hib(Left lateral upper arm)
 2014 Aug 29 MMR-Var(Right arm)
 2014 Aug 29 HB(Left arm)
 2012 Mar 28 DTaP-IPV-Hib(NA)

Add>>

<<Remove

Selected Immunizations Create New

2014 Aug 29 Rota-unspecified(Mouth/Oral)

Hold Ctrl and then click to select multiple items.

Selected Immunization Details

Immunization Date	Immunization Agent	Trade Name	Manufacturer	Lot Number	Dose Number	Revised Dose Number	Dosage/Dosage Unit	Route	Site
2014 Aug 29	Rota-unspecified	ROTARIX	Hedy Canada	R0TA11 Exp. 2016/08/18	1		1.5 mL	Swallow, oral	Mouth/Oral

reporter).

The **Selected Immunization Details** Table automatically populates the specific details of the immunization.

TIP: The user must answer these two questions (required fields) before the report may be 'Submitted for Review':

- 1) Did an AEFI follow a previous dose of any of the above immunizing agents?
- 2) Did this AEFI follow an incorrect immunization?

13. Enter **Information at time of Immunization and AEFI Onset**.

*** Information at Time of Immunization and AEFI Onset** ↑ Hide Information

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

* No No Prior Dose Unknown Yes (provide details)

(4000 characters)
Add

Date	Prior Dose Details	Recorded By

Did this AEFI follow an incorrect immunization?

* No Unknown Yes (If Yes, choose all that apply and provide details)

Given outside the recommended age limits
 Dose # exceeded that recommended for age
 Incorrect route
 Wrong vaccine given
 Product expired
 Other, specify

(4000 characters)
Add

Date	Known Immunization Incident Details	Recorded By

Don't forget to click the Add button to save the comments to the Table.

14. Select the **Medical history up to the time of AEFI onset**. Add any comments, and click **Add** to save them to the Table.

Medical history (up to the time of AEFI onset):

(Check all that apply and provide details for each.)

Concomitant medication(s)

Known medical conditions/allergies

Acute illness/injury

(4000 characters) **Add**

Date	Medical History Details	Recorded By
------	-------------------------	-------------

15. Open up the AEFI Details section to add information related to the type of reaction.

*** AEFI Details** Hide AEFI Details

Adverse events following an immunization. Sections or items with an arrow (>) must be diagnosed by a physician. Open the reaction groups that apply. Specify the reaction details in the sections that will appear below.

Local reaction at or near injection site Show

Anaphylaxis or Other allergic events Show

Neurologic event Show

Other defined events of interest Show

Click on the hyperlink to expand the section

TIP: At least one of these sub-sections must be completed before the report can be 'Submitted for Review'.

16. Enter AEFI Details related to the **Local reaction at or near injection (vaccination) site**. Enter **Onset** time. Onset is mins/hrs/days from immunization to onset of first sign or symptom. If not yet resolved, select the Unresolved checkbox, and Duration will no longer be mandatory.

*** AEFI Details** Hide AEFI Details

Adverse events following an immunization. Sections or items with an arrow (>) must be diagnosed by a physician. Open the reaction groups that apply. Specify the reaction details in the sections that will appear below.

Local reaction at or near injection site Hide

*** Onset:**
mins hours days

*** Duration:**
mins hours days

Unresolved Onset is mins/hrs/days from immunization to onset of first symptom or sign. Duration is from onset of 1st symptom/sign to resolution of all symptoms/signs.

Infected abscess Sterile abscess Cellulitis Nodule Reaction crosses joint Lymphadenitis Other, specify

Don't forget to click the Add button to save the comments to the Table. (4000 characters) **Add**

Date	Comments	Recorded By
------	----------	-------------

TIP: If the AEFI is related to a 'Local reaction at or near injection site', required fields are: **Onset** and **Duration**.

17. Enter **Duration** time. Duration is from onset of first symptom/sign to resolution of all symptoms/signs.

18. Click the checkboxes for any local reactions that apply. If the reaction is not listed, click **Other, specify**; and enter details of the reaction in the comments box. Click **Add** to save the comments to the Table.
19. Add any additional information about the reaction near the injection site. Add any additional comments in the comments box, and click **Add** to save them to the Table.

TIP: At any time, click **Save as Draft** to ensure updates to the screen are saved to the AEFI report.

For any injection site reaction indicated above, check all that apply below and provide details in the comments area in this section:

<input type="checkbox"/> Swelling	<input type="checkbox"/> Pain	<input type="checkbox"/> Tenderness	<input type="checkbox"/> Erythema	<input type="checkbox"/> Warmth
<input type="checkbox"/> Induration	<input type="checkbox"/> Rash	<input type="checkbox"/> Largest diameter of injection site reaction (cm): <input type="text"/>	<input type="checkbox"/> Site(s) of reaction: <input type="text"/>	<input type="checkbox"/> Palpable fluctuance
<input type="checkbox"/> Fluid collection shown by imaging technique (e.g. MRI, CT, ultrasound)	<input type="checkbox"/> Spontaneous /surgical drainage	<input type="checkbox"/> Microbial results	<input type="checkbox"/> Lymphangitic streaking	<input type="checkbox"/> Regional lymphadenopathy

(4000 characters)

Date	Comments	Recorded By
------	----------	-------------

20. Enter AEFI Details related to **Anaphylaxis or Other allergic events**. Enter **Onset** time. Onset is mins/hrs/days from immunization to onset of first symptom or sign
21. Enter **Duration** time. Duration is from onset of first symptom/sign to resolution of all symptoms/signs.

TIP: If the AEFI is related to 'Anaphylaxis or Other allergic events', required fields are: **Onset** and **Duration**.

TIP: The **Clear** button will deselect both the radio buttons above it.

Anaphylaxis or Other allergic events [Hide](#)

Anaphylaxis
 Other allergic events

*** Onset:** *** Duration:**

<input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/> mins hours days	<input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/> mins hours days	<input type="checkbox"/> Unresolved
---	---	--

Onset is mins/hrs/days from immunization to onset of first symptom or sign. Duration is from onset of 1st symptom/sign to resolution of all symptoms/signs.

25. Click on any of the selections related to the Neurologic event. Once you click on a sub-section, the descriptive options are available for selection. Add comments as required, and click **Add** to save the to the Comments Table. Note: Use the Comment field of the Neurologic Event section to indicate: Absence, Myoclonic or

TIP: At any time, click **Save as Draft** to ensure updates to the screen are saved to the AEFI report.

Neurologic event Hide

*** Onset:** *** Duration:**

 Unresolved
 Onset is mins/hrs/days from immunization to onset of first symptom or sign.
 mins hours days mins hours days
 Duration is from onset of 1st symptom/sign to resolution of all symptoms/signs.

Seizure(s) (check all that apply)

Witnessed by healthcare professional Yes No Unknown
 Sudden loss of consciousness Yes No Unknown
 Focal Tonic Clonic Tonic-Clonic Atonic
 Generalized Tonic Clonic Tonic-Clonic Atonic
 Previous history of seizures Febrile Afebrile Unknown type

> Meningitis
 > Encephalopathy/Encephalitis
 > Guillain-Barré Syndrome (GBS)
 > Bell's Palsy
 > Other Paralysis
 > Other neurologic diagnosis , specify

For any neurologic event indicated above, check all that apply below and provide details in the comments area in this section:

Depressed/alterd level of consciousness, lethargy or personality change lasting >= 24hrs
 Focal or multifocal neurologic sign(s)
 Fever(>=38.0 C)
 CSF abnormality
 EEG abnormality
 EMG abnormality
 Neuroimaging abnormality
 Brain/spinal cord histopathologic abnormality

(4000 characters)

Date	Comments	Recorded By
------	----------	-------------

Partial seizure.

26. Enter AEFI Details related to **Other defined events of interest**. Enter **Onset** time. Onset is mins/hrs/days from immunization to onset of first symptom or sign.

Reminder: A fever needs to be greater than 38 degrees and present in conjunction with a reportable event.

TIP: If the AEFI is related to 'Other defined events of interest', required fields are: **Onset** and **Duration**.

1. Enter **Duration** time. Duration is from onset of first symptom/sign to resolution of all symptoms/signs.

Other defined events of interest [Hide](#)

*** Onset:** *** Duration:**

 Unresolved Onset is mins/hrs/days from immunization to onset of first symptom or sign.
 mins hours days mins hours days Duration is from onset of 1st symptom/sign to resolution of all symptoms/signs.

Click on any of the selections related to the “**Other defined events of interest**”. Once you click on a sub-section, the descriptive options are available for selection.

Note: The following “**Comments**” should be added to the “**Other defined events of interest**”, if applicable:

- Oculo Respiratory Syndrome (ORS) – record Unilateral Red Eyes in the Comment section.

Other defined events of interest [Hide](#)

*** Onset:** *** Duration:**

 Unresolved Onset is mins/hrs/days from immunization to onset of first symptom or sign.
 mins hours days mins hours days Duration is from onset of 1st symptom/sign to resolution of all symptoms/signs.

Hypotonic-Hyporesponsive Episode (age < 2 years)
 Limpness
 Pallor/cyanosis
 Reduced responsiveness/unresponsiveness

Persistent crying (crying which is continuous and unaltered for >= 3hrs)

Rash (for Rash at injection site or Rash in allergic reaction, use other section)
 Generalized Localized at non-injection site

> Intussusception

Arthritis (check all that apply)
 Joint redness
 Joint warm to touch
 Joint swelling
 Inflammatory changes in synovial fluid

Parotitis (parotid gland swelling with pain and/or tenderness)

> Thrombocytopenia **This must be diagnosed by a physician**
 Clinical evidence of bleeding
 Platelet count <150 x 10⁹/L

Oculo-Respiratory Syndrome (ORS) (Note: this is different from allergic/respiratory symptoms)
 Bilateral red eyes
 Cough
 Wheeze
 Sore throat
 Difficulty swallowing
 Difficulty breathing
 Chest tightness
 Hoarseness
 Facial swelling

Fever >= 38.0 C
 Other severe events not listed above

(4000 characters)

Date	Comments	Recorded By

- Thrombocytopenia – record Pettechial Rash in the Comment Section.
- Record Anaesthesia/Parathesia in the Comment Section.

2. Add comments as required, and click **Add** to save the to the Comments Table.

Open up the **Impact of AEFI, Outcome, and level of care** section.

3. Enter related information in the drop-lists. Add any comments, and click **Add** to save the to the Comments Table.

4. Click **Save as Draft** to save information to the AEFI record.

5. Open the **Document Management** section if there are documents to attach to the AEFI Record.



6. Click **Document Management** to attach documents.

The **Context Document** screen displays.

Context Documents

Warnings ACTIVE

Client ID: 393 **Name(First,Middle,Last)/Gender:** Ellie E JS-Elephant / Female **Health Card No:** - **Date of Birth / Age:** 2010 Jul 23 / 4 yrs 1 mos

Phone Number: (306)-222-2233(Primary home) **Jurisdiction Info:** Saskatchewan,Saskatoon RHA **Additional ID Type / Additional ID:** Provincial health service provider identifier / -

Search Document Folders - Basic Hide Search

Enter Keywords to search. Leave search box empty to view all documents. Search will be performed on selected folder and its subfolders if applicable. Search results will appear in 'Document List' below.

Search Documents by keyword:

Document List Hide Document List

Row Actions:

Document Title	Size[KB]	Type	Posted By	Posted On	Description	Status
Total: 0 Page 1 of 1 Jump to page: <input type="text"/>						

7. Click **Add New**.

The **Document Management** screen displays.

Document Management

Add New Document

* File name:

File uploaded:

Selected Document:

* Document Title:

* Effective Date: 2012 / 06 / 27 Expiration Date: / /

Status: * active

Enter Keyword: Selected Keywords:

Description:

Document Added by: ephs.TRAINERooT on: 2012 Jun 27

NOTE: The file must be of an acceptable type as per system configuration (e.g. .pdf)

TIP: If you decide to **cancel** the upload, just click Cancel until you return to the **AEFI** screen.

8. Click **Browse** and select the document to be attached from your system. Click **Upload** to upload the file.
9. Fill in required and mandatory fields.

Document Management

Add New Document

* File name: no file selected ← **Click Upload File and the File Uploaded: is displayed here.**

File uploaded: **AEFI document.pdf** ←

Selected Document:

* Document Title: ← **Don't forget to give the file a title. This is a required field.**

* Effective Date: / / Expiration Date: / /

Status: *

Use CTRL key for multiple selections.

Enter Keyword: Selected Keywords:

Description:

Document Added by: panorama, user1 on: 2014 Sep 09

10. Click **Submit**.

The **Context Documents** screen redisplay with the file within the Table.

NOTE: The file is not attached in the screenshot as this functionality was currently under configuration at time of user guide development.

Context Documents

Warnings ACTIVE

Client ID: 393	Name(First,Middle,Last)/Gender: Ellie E JS-Elephant / Female	Health Card No: -	Date of Birth / Age: 2010 Jul 23 / 4 yrs 1 mos
Phone Number: (306)-222-2233(Primary home)	Jurisdiction Info: Saskatchewan,Saskatoon RHA	Additional ID Type / Additional ID: Provincial health service provider identifier / -	

Search Document Folders - Basic

Enter Keywords to search. Leave search box empty to view all documents. Search will be performed on selected folder and its subfolders if applicable. Search results will appear in 'Document List' below.

Search Documents by keyword:

Document List

Row Actions:

Document Title	Size[KB]	Type	Posted By	Posted On	Description	Status
Document information should be within the Table.						

Total: 0 Page 1 of 1 Jump to page:

11. Click **Cancel** to return to the **Create Adverse Event** screen. Note that the file attached is now seen in the Document Management section of the AEFI Record.

NOTE: The Manager of the Workgroup (e.g. AEFI Review) will receive a Task in Work Management. Tasks are viewed and managed within the **Work Management** module. It is the jurisdiction's prerogative to utilize the **Work Management** module or solely rely on telephone / email communications to notify the reviewer and contributors of the AEFI Report.

12. Open up the **Assigned To** section of the AEFI Record.

* Assigned To

Select at least one assignee: a user (within a workgroup) or a workgroup.

Workgroup Organization: Saskatoon RHA

To specify an Organization first click on the 'Find' button. Then search, or type the name of the Organization you wish to specify, select it and click on 'Select' button. Then click 'Close' to close.

Organization: Saskatchewan > [Saskatoon RHA]

Workgroups: **User:**

13. Select a **Workgroup** from the drop-list. Select an individual **User** from the drop-list if appropriate. This field is mandatory before the user can 'Save and Submit' for review. By sending the notification to the Workgroup, this action changes the status of the AEFI Record to 'Under Review'.

The AE History does not show activity while the AEFI Record is still in 'Draft' mode.

TIP: There are a number of fields within the report that are required, but are not indicated by the *. Depending on the information recorded on the AEFI, certain fields then become mandatory.

TIP: Fix any error messages by updating the AEFI Report, then click 'Save as Draft'. The data must first be saved before it can be submitted.

14. When ready to add the recommendations (review process) to the Record, click **Save and Submit**. This is at the bottom and top of the AEFI Record.

Note: there may be some required fields that need to be completed before the Record is saved and submitted. Error messages are displayed on the Header, indicating to the user which fields must be completed. See examples below.

Warnings ACTIVE

Client ID: 393 Name(First,Middle,Last)/Gender: Ellie E JS-Elephant / Female Health Card No: - Date of Birth / Age: 2010 Jul 23 / 4 yrs 1 mos

Phone Number: (306)-222-2233(Primary home) Jurisdiction Info: Saskatchewan, Saskatoon RHA Additional ID Type / Additional ID: Provincial health service provider identifier / -

X At least one sub-level item is required if Rash is selected.
 X At least one sub-level item is required if Arthritis is selected.
 X At least one sub-level item is required if Thrombocytopenia is selected.
 X At least one sub-level item is required if Oculo-Respiratory Syndrome (ORS) is selected.

Save as Draft Save and Submit Print Cancel

15. Update the AEFI Record as indicated by the **X error messages**.

16. Click **Save as Draft**. [It is important to first save the information to the Record before it is submitted].

17. Click **Save and Submit**.

The **Adverse Event Summary** screen displays with a message in the Header stating that the Adverse even is submitted successfully.

The status of the AEFI shows “Submitted for Review”.

Adverse Event Summary

Warnings ACTIVE

Client ID: 393 Name(First,Middle,Last)/Gender: Ellie E JS-Elephant / Female Health Card No: - Date of Birth / Age: 2010 Jul 23 / 4 yrs 1 mos

Phone Number: (306)-222-2233(Primary home) Jurisdiction Info: Saskatchewan,Saskatoon RHA Additional ID Type / Additional ID: Provincial health service provider identifier / -

Adverse event is submitted successfully.

Adverse Event Summary					
Row Actions:	Please select a reason for deletion:			Create Adverse Event	
Select	Event ID	Immunization(s)	Date Administered	Date Reported	Status
<input type="radio"/>	5	Pneu-C-13	2014 Aug 29	2014 Sep 02	Review complete
<input type="radio"/>	6	MMR-Var	2014 Aug 29	2014 Sep 01	Submitted for review
<input type="radio"/>	11	Rota-unspecified	2014 Aug 29	2014 Sep 05	Submitted for review

2.0 Adverse Event Review

Once the AEFI Record is submitted for review, a new section is activated within the Record, called **Public Health Recommendations**. This section must be completed in its entirety before the user can complete the AEFI Record. Once the user “Starts Review”, the user may “need more information” or “need consultation”. See the following sub-section for details relating to this functionality.

These are steps to take the Record from “Submitted for Review” to “Review Complete”.

1. Click Immunizations > Adverse Events (AEFI) from the left navigation bar. The Adverse Event Summary screen displays.

Adverse Event Summary

Warnings ACTIVE

Client ID: 589 Name(First,Middle,Last)/Gender: Penelope JS-Platypus / Female Health Card No: - Date of Birth / Age: 2010 Feb 23 / 4 yrs 6 mos

Phone Number: (306)-333-4300(Primary home) Jurisdiction Info: Saskatchewan,Saskatoon RHA Additional ID Type / Additional ID: Provincial health service provider identifier / -

Adverse Event Summary					
Row Actions:	Please select a reason for deletion:			Create Adverse Event	
Select	Event ID	Immunization(s)	Date Administered	Date Reported	Status
<input type="radio"/>	12	DTaP-IPV-Hib	2014 Sep 04	2014 Sep 09	Submitted for review

Cancel

- Click the radio button beside the AEFI that is “Submitted for Review”, and click **Update**.

The **Create Adverse Event** screen displays. Notice that the screen opens up to the new section, **Public Health Recommendations**.

NOTE: The AEFI Report must be “reviewed” in Panorama before it can be complete. It is important for all users to follow Saskatchewan policy and procedure when creating and reviewing an AEFI Report.

* Public Health Recommendations
Hide Public Health Recommendations

AEFI Status: Submitted for review Last Review Date: Eligible for reporting to PHAC:

Reviewer

On behalf of Health Service Provider
Click Find to select a provider:

Provider: Find

Public Health Recommendations

Public Health Recommendations:

<input type="checkbox"/> No change to immunization schedule	<input type="checkbox"/> Expert referral, specify
<input type="checkbox"/> Determine protective antibody level	<input type="checkbox"/> Controlled setting for next immunization
<input type="checkbox"/> No further immunizations, specify	<input type="checkbox"/> Active follow-up for AEFI recurrence after next vaccine.
<input type="checkbox"/> Other, specify	<input type="checkbox"/> No recommendations

Recommendation Comments:

(4000 characters)

Add Recommendations

Date	Public Health Recommendations	Recommendation Comments	Recorded By
------	-------------------------------	-------------------------	-------------

Document Management
Show Document Management

0 attached documents Click on Document Title to open or save attachment.

Document Title	Size (KB)	Type	Posted By	Posted On
----------------	-----------	------	-----------	-----------

Assigned To
Show Assigned To

AE History
Show AE History

Save
Save and Resubmit
Start Review
Print
Cancel

Enter the Public Health Recommendations as required.

- Click the checkbox if the AEFI is **Eligible for Reporting to PHAC**.
- In the Reviewer section, click **Find** to locate the Provider in the Index.
- Click the checkbox **On behalf Of Health Service Provider**, if the Panorama user is not the Provider.
- Select the **Public Health Recommendations** applicable to the AEFI.
- Enter comments in the Recommendations Comments section. Click **Add Recommendations** to add the recommendations to the Table.
- Add any other information to the AEFI Record as required (see ‘Adverse Event Create’ section for more details).

TIP: To Print the AEFI Report, go to the “Adverse Event Details” screen, and click the Printer icon at the top of the page. For more information, go to the ‘View Adverse Event’ section of this user guide.

9. Depending on the policy and procedure, the user may choose to **Save**, **Save and Resubmit**, or **Start Review**.

The screenshot shows the 'AE History' table with the following data:

Date	Comments	Recorded By	User Role	Status
2014 Sep 09	here are some comments - save and resubmit was clicked	user1, panorama	superservice	Submitted for review
2014 Sep 09	here is some info	user1, panorama	superservice	Submitted for review
2014 Sep 09		user1, panorama	superservice	Submitted for review

Below the table are buttons: **Save**, **Save and Resubmit**, **Start Review**, **Print**, and **Cancel**.

Callout 1 (pointing to the 'Save' button): If you click **Save**, you are prompted to enter comments. These are stored in the AE History in the Comments column.

Callout 2 (pointing to the 'Save and Resubmit' button): If you click **Save and Resubmit**, you are prompted to enter comments. These are stored in the AE History in the Comments column. You must select a Workgroup in the **Assign To** section.

If the user clicks the **Start Review** button, the user is prompted to add comments. The screen is updated, within the AE History section, the status of the AEFI Record changes to “Review in progress”, and new buttons are activated.

The screenshot shows the 'AE History' table with the following data:

Date	Comments	Recorded By	User Role	Status
2014 Sep 09	I clicked the "Start Review" button	user1, panorama	superservice	Review in progress
2014 Sep 09	here are some comments - save and resubmit was clicked	user1, panorama	superservice	Submitted for review
2014 Sep 09	here is some info	user1, panorama	superservice	Submitted for review
2014 Sep 09		user1, panorama	superservice	Submitted for review

Below the table are buttons: **Save**, **Save and Resubmit**, **Need More Information**, **Need Consultation**, **Review Complete**, **Print**, and **Cancel**.

Depending on completion of the AEFI Record, the user may choose to complete the Record or indicate that more information or consultation is required.

10. If the documentation is complete, select a Workgroup from the **Assign To** section, and click **Review Complete**. The user is required to enter comments in the text box.

The user is taken to the **Adverse Event Summary** screen, and a message indicates that the Adverse Event was saved successfully.

TIP: If the users are not actively using the Work Management Module (Tasks), then this functionality may still be used in the AEFI report. Notification just needs to be done through email / telephone.

NOTE: Every time the AEFI Report is updated a comment is required. This is meant to track the changes made by the different contributors as audit information if required. It is not displayed from the record.

3.0 Needs More Information / Consultation

The **Need More Information** and **Needs Consultation** functionality may be useful if the people that provide the information or consultation are Panorama users. When these buttons are selected, the user must select that individual or Workgroup in the **Assign To** section. The user(s) are notified through the **Work Management** Module with a Task. This task includes the comments and a hyperlink to the AEFI, so that the user may click directly to the Adverse Event. Once the user accesses the AEFI Record, updates and contributions are made, and then it is re-submitted.

This is the equivalent of passing the AEFI Record to another user to make contributions. Follow these steps for “Need More Information”. The “Need Consultation” is the same and therefore not documented in this user guide.

1. While the AEFI Record is in status ‘Review in Progress’, select a Workgroup / user in the **Assign To** section. Click the **Needs More Information** button. The user is prompted to add comments.

The user is taken to the **Adverse Event Summary** screen, and a message on the Header indicates that the Adverse Event has been updated.

2. The Workgroup /user is notified to make a contribution to the AEFI Record.
3. The user will navigate to the **Adverse Event Summary** screen and click on the radio button beside the adverse event and click **Update**.

The **Create Adverse Event** screen is displayed. At the bottom of the screen, open up and view the **AE History**. The comments and status, etc. are shown.

AE History ↑ Hide AE History				
Date	Comments	Recorded By	User Role	Status
2014 Sep 09	Need more Information was clicked	user1, panorama	superservice	Information required
2014 Sep 09	I clicked the "Start Review" button	user1, panorama	superservice	Review in progress
2014 Sep 09	here are some comments - save and resubmit was clicked	user1, panorama	superservice	Submitted for review
2014 Sep 09	here is some info	user1, panorama	superservice	Submitted for review
2014 Sep 09		user1, panorama	superservice	Submitted for review

4. The user makes necessary contributions to the AEFI Record, click **Save**.

- Once the user is finished adding the information in the Record, and is ready to submit, navigate to the **Assign To** section and select a Workgroup / user. Click **Save and Resubmit**. The user must add comments in the text field.

The **Adverse Event Summary** is displayed, with a message indicating that the Adverse Event was resubmitted successfully.

The user to whom it is assigned will receive notification to contribute or finish the review of the AEFI Record.

- This user must once again update the Adverse Event. To do this, navigate to the **Adverse Event Summary** screen and click on the radio button beside the Adverse Event and click **Update**.

The **Create Adverse Event** screen is displayed. At the bottom of the screen, open up and view the **AE History**. The comments and status, etc. are shown.

AE History ↑ Hide AE History				
Date	Comments	Recorded By	User Role	Status
2014 Sep 09	Added information and now save and Resubmit	user1, panorama	superservice	Submitted for review
2014 Sep 09	Need more Information was clicked	user1, panorama	superservice	Information required
2014 Sep 09	I clicked the "Start Review" button	user1, panorama	superservice	Review in progress
2014 Sep 09	here are some comments - save and resubmit was clicked	user1, panorama	superservice	Submitted for review
2014 Sep 09	here is some info	user1, panorama	superservice	Submitted for review

- The user may choose to **Start Review**. Comments must be added to the text box.

A message is displayed at the top of the screen indicating that the Adverse Event is under review.

- Make any changes necessary, then, once complete, select the Workgroup / user in the **Assign To** section, and click **Review Complete**.

E. Delete Adverse Event

An Adverse Event may be deleted if entered in error, a decision was altered, or for another reason. Please be sure to follow Saskatchewan policy and procedures before deleting clinical records.

The **Adverse Event Summary** screen contains all of the AEFI Records entered or deleted for the client.

Pre-requisites: The user has successfully logged into Panorama. User is in the Immunization module (tab). Client is in context. An AEFI Record currently exists.

Menu Access: **Select** Immunizations > Adverse Events (AEFI)

1. Click Immunizations > Adverse Events (AEFI) from the left navigation bar. The Adverse Event Summary screen displays.
2. To select an existing Adverse Event, click the radio button beside the adverse event to be deleted.

Adverse Event Summary ? [Print]

Warnings ACTIVE

Client ID: 589	Name(First,Middle,Last)/Gender: Penelope JS-Platypus / Female	Health Card No: -	Date of Birth / Age: 2010 Feb 23 / 4 yrs 6 mos
Phone Number: (306)-333-4300(Primary home)	Jurisdiction Info: Saskatchewan,Saskatoon RHA	Additional ID Type / Additional ID: Provincial health service provider identifier / -	

Adverse Event Summary

Row Actions:

Please select a reason for deletion:

Select	Event ID	Altered decision Entered in error Other	Date Administered	Date Reported	Status
<input checked="" type="radio"/>	12	DTap-IPV-Hib	2014 Sep 04	2014 Sep 09	Review in progress
<input type="radio"/>	13	MMR-Var	2011 Nov 23	2014 Sep 02	Review complete
<input type="radio"/>	14	Pneu-C-13	2010 Jun 28	2014 Aug 31	Information required

3. Select a reason for deletion. If Reason is **Other**, then add details in the text box that becomes activated.

The message displays that the Adverse Event was deleted successfully.

The Adverse Event Summary screen shows the AEFI Record is now deleted, and can no longer be updated (the radio button beside it is removed).

Adverse Event Summary

Warnings ACTIVE

Client ID: [589](#) **Name(First,Middle,Last)/Gender:** Penelope JS-Platypus / Female **Health Card No:** - **Date of Birth / Age:** 2010 Feb 23 / 4 yrs 6 mos

Phone Number: (306)-333-4300(Primary home) **Jurisdiction Info:** Saskatchewan,Saskatoon RHA **Additional ID Type / Additional ID:** Provincial health service provider identifier / -

Adverse Event Summary

Please select a reason for deletion:

Row Actions:

Select	Event ID	Immunization(s)	Date Administered	Date Reported	Status
<input type="radio"/>	12	DTaP-IPV-Hib	2014 Sep 04	2014 Sep 09	Deleted
<input type="radio"/>	13	MMR-Var	2011 Nov 23	2014 Sep 02	Review complete
<input type="radio"/>	14	Pneu-C-13	2010 Jun 28	2014 Aug 31	Information required

4. To view the Adverse Event, click on the hyperlink.

The **AE History** at the bottom of the Record indicates the reason for deletion.

AE History

Date	Comments	Requested by	User Role	Status
2014 Sep 09	Altered decision	user1, panorama	superservice	Deleted
2014 Sep 09		user1, panorama	superservice	Review in progress
2014 Sep 09	here is some info saved	user1, panorama	superservice	Submitted for review
2014 Sep 09	saved info	user1, panorama	superservice	Submitted for review
2014 Sep 09		user1, panorama	superservice	Submitted for review

5. Click **Cancel** to return to the **Adverse Event Summary** screen.