Do you have a bleeding disorder or are you taking any medications that could affect blood clotting? • If unsure, ask the health care provider about your medical conditions. • If yes, provide details, **DEFER VACCINATION** until consultation with HCP.	☐ Yes ☐ No

I have read (or it has been read to me) and I understand the *Janssen COVID-19 Vaccine* information sheet and after care sheet. I have had the opportunity to ask questions and to have them answered to my satisfaction. I consent to the receiving the Janssen vaccine.

☐ I do consent ☐ I do not consent

_____	_____	_____
Signature	Print name	Date of signature

If signing for someone other than yourself, indicate your relationship to that other person:

_____

☐ I confirm that I am the parent / legal guardian or substitute decision maker.

Comments:

Information contained in this form is collected, used and disclosed in accordance with Yukon's *Health Information Privacy and Management Act* and other applicable laws. A written statement of Health and Social Services information practices can viewed at yukon.ca/healthprivacy or by contacting the department's Privacy Officer at healthprivacy@yukon.ca.

JANSSEN COVID-19 Vaccine Information

Please read this information sheet carefully and ensure all your questions have been answered by a health care provider before receiving the vaccine.

How does the vaccine work?

The Janssen (Johnson & Johnson) vaccine introduces instructions from the virus that causes COVID-19 using a non-COVID-19 virus that has been modified so as to be inactive and harmless. This is known as a vector.

The vector only carries the instructions to make a specific protein from the COVID-19 virus. Similar to the mRNA virus, once the body creates that protein, it produces an immune response that will recognize and fight future infections.

Who is the vaccine approved for?

Approved for use in people aged **18 and older**.

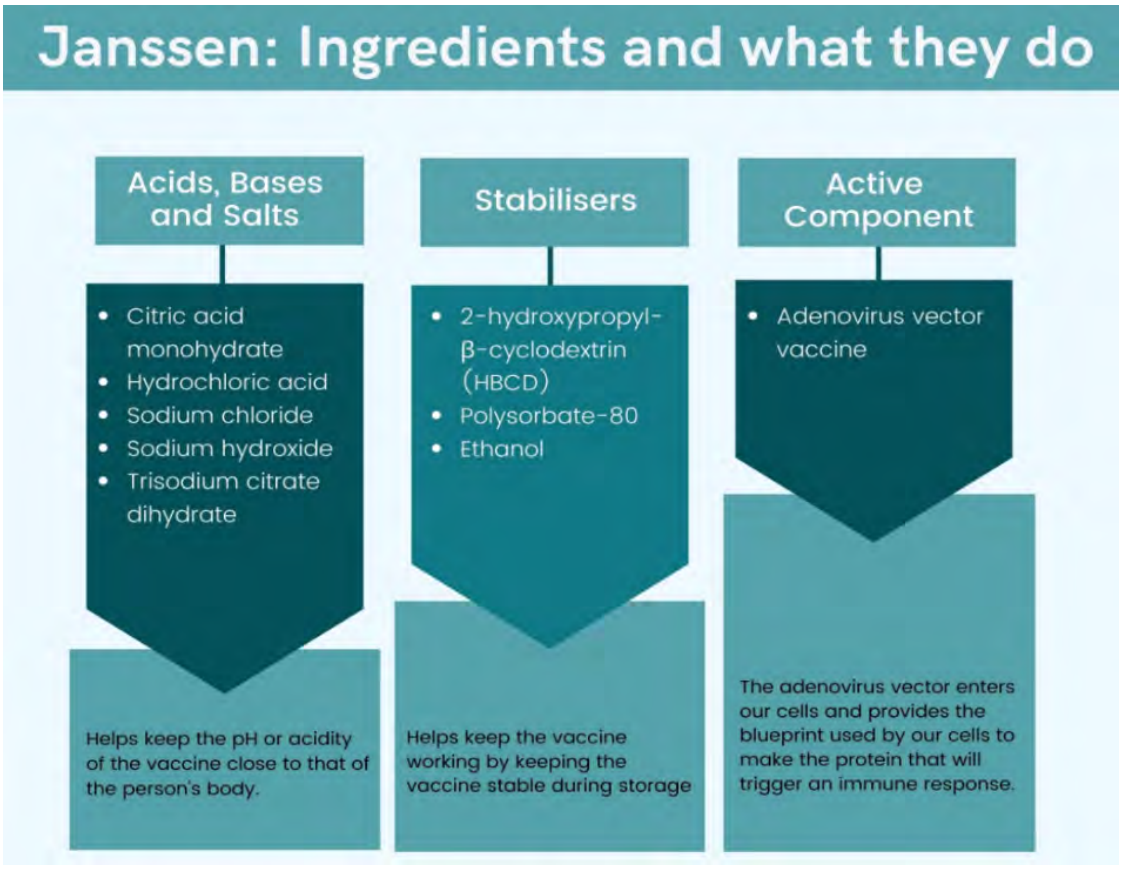
Dosage

A one time dose is injected into the upper arm muscle.

Effectiveness

Clinical trials showed that beginning 2 weeks after the single dose, the Janssen COVID-19 vaccine lowered the chance of getting sick from COVID-19 by **67%** and of getting seriously ill by 77%.

Vaccine Components



Expected Vaccine Side Effects

You may experience the following side effects a few days after getting the vaccine:

- Pain, swelling or redness at injection site
- Other symptoms may include tiredness, headache, muscle pain, joint pain, chills, and fever.

Symptoms to Look Out for

These rare events below have been reported after getting the Janssen vaccine.
Seek immediate medical care if you develop any of the symptoms below.

- **Blood clots with low platelets**
  - This condition causes blood clots, which prevent blood from flowing normally, and low count of platelets (blood cells which help blood clot).

- **Guillain-Barré syndrome (GBS)**
  - GBS is a rare neurological disorder where a person's immune system damages their nerves. Most people fully recover from this disorder.

- **Capillary leak syndrome (CLS)**
  - CLS is rare but serious condition that causes fluid to leak from small blood vessels (capillaries).
  - Those who have previously had capillary leak syndrome are at increased risk following a viral vector vaccination and should not receive this vaccine.

Who should NOT get the vaccine?

- People under 18 years of age.
- Anyone with a known allergy to any ingredient in the Janssen COVID-19 vaccine (such as polysorbate 80).
- History of thrombosis with thrombocytopenia following a previous dose of an adenovirus vector COVID-19 vaccine. These individuals should be offered an mRNA vaccine.
- History of capillary leak syndrome.
- Anyone with symptoms that could be due to COVID-19 should wait to be vaccinated so that they do not spread infection to others at the vaccine clinic.

Yukon

Yukon Immunization Program Manual

User Guide for Completion and Submission of Adverse Events Following Immunization (AEFI) Reports

User Guide for Completion and Submission of Adverse Events Following Immunization (AEFI) Reports

Table of Contents

1.0 PURPOSE

This user guide is intended to be used as a reference by community vaccine providers and public health providers who report an Adverse Event Following Immunization (AEFI) in Yukon using the AEFI Case Report Form or the online Panorama AEFI form. This guide complements the Panorama Reference Guides on AEFI reporting.

In this guide, Panorama specific guidance is provided in *italics* or explicitly stated.

For additional information on reporting criteria, clinical management and interpretation of AEFIs, and implications for subsequent immunization, refer to Section 13 – Adverse Events Following Immunization

2.0 DO YOUR PART IN REPORTING ADVERSE EVENTS

Questions & Answers

? What is an AEFI?

An adverse event following immunization (AEFI) is any untoward medical occurrence following administration of a vaccine which may or may not be caused by the vaccine.

? What type of AEFIs should be reported?

Any event which may be related to receipt of a vaccine, as outlined in Section 13 – AEFI of the Yukon Immunization Manual, must be reported even if you are unsure the vaccine caused the event.

? What types of AEFIs do not need to be reported?

Local injection site reaction and non-specific systemic reactions (e.g., headache, myalgia) should not be reported unless these are more frequent or severe than expected. Also events that are clearly attributed to other causes should not be reported.

? Why is it important to report AEFIs?

AEFI reporting provides vital information needed to monitor vaccine safety. This type of surveillance can detect rare side effects and identify safety signals not detectable through clinical trials.

? What happens after AEFIs are reported?

The Yukon Immunization Program reviews the AEFI and will forward it on to the Chief Medical Officer of Health, who will investigate and provide a recommendation as to whether your client can proceed with future immunizations. AEFI reports are sent to the Public Health Agency of Canada Adverse Events Following Immunization Surveillance System (CAEFISS). Canada also participates in vaccine safety monitoring at the World Health Organization. Vaccine safety matters on a territorial, national and international level!

? Who should report AEFIs?

Health professionals who are aware of an AEFI must report the event to the Yukon Immunization Program using the Panorama immunization registry.

? What do I tell my clients about AEFIs?

Clients should be made aware of potential vaccine side effects and how to manage common reactions. This information is outlined in vaccine information sheets found on the www.yukonimmunization.ca website. If reported events do not meet the reporting criteria, they may still be a cause for concern for your client and may impede their confidence in receiving future immunizations. Address these concerns and ensure your patients have received a recommendation on whether and how to proceed with future immunizations. Contraindications to future vaccine receipt are rarely required but should be clearly stated and documented on their record.

3.0 REPORTING ADVERSE EVENTS

A health professional who is aware of an adverse event following immunization must report the event to the Yukon Immunization Program. The Yukon Immunization Program reviews all AEFIs and submits these to the Chief Medical Officer of Health (CMOH)/ Medical Officer of Health (MOH) for review and recommendation(s).

3.1 When to report

An AEFI must be reported to the Yukon Immunization Program **within 3 days** of determining or being informed that a client has experience an adverse event following immunization.

3.2 What to report

Events that **must be reported** are outlined in Section 13 – Adverse Events Following Immunization. AEFI's must meet the general criteria:

a) follows immunization
b) cannot be attributed to a pre-existing condition, and
c) meets one or more of the following criteria:
    - the health occurrence is life threatening, could result in permanent disability, requires hospitalization or urgent medical attention, or for any other reason is considered to be of a serious nature;
    - the health occurrence is unusual or unexpected, including, without limitation, an occurrence that
        - has not previously been identified (i.e., Oculo-Respiratory Syndrome was first identified during the 2000/2001 influenza season), or
        - has previously been identified but is being reported at increased frequency (i.e., extensive local reactions);
    - the health occurrence cannot be explained by anything in the patient's medical history, including, without limitation, a recent disease or illness, or consumption of medication.
    - Clusters of events: known or new events that occur in a geographic or temporal cluster (i.e., 6 in a week, or 6 in a Health Service Delivery Area) that require further assessment, even if the total number of AEFIs may not be higher than expected.

4.0 GENERAL FIELDS SECTION

Field	Description
Adverse Event ID Panorama only	*A unique episode number is assigned to each AEFI report in Panorama. AEFI reports entered in Panorama automatically receive a system generated identifier labelled the "Adverse Event ID".*
Unique Episode Number Panorama only	*Do not use. The unique episode number should be left blank, entered by Immunization Program Nurse.*
IMPACT Local Inventory Number (LIN)	Do not use
Client address	Enter the client address of residence. The AEFI health region should usually correspond to where the client resides. Address of residence is used to help with follow-up, and reporting of the AEFI. *In Panorama: The value in this field is the branch office corresponding to that of the logged-in Panorama user by default. The branch office should be changed from the default selection if the branch office of the logged in user differs from the branch office responsible for the management/ follow up and reporting of the adverse event.*
Service Delivery Location Panorama only	*The SDL should reflect the health centre or clinic responsible for the management/ follow up and reporting of the adverse event.* *By default, the value in this field is the SDL corresponding to that of the logged-in Panorama user.*
AEFI Report Status Panorama only	*Indicates the status of the AEFI report.* *Select the option from the following list that best describes the AEFI report status:* **'Draft':** *Saved as draft, not submitted.* **'Submitted for review':** *Submitted, but review not yet started. Immunizers must select this option when submitting to YIP for review* **'Review in progress':** *Started review, but review is not yet complete.* **'Information required':** *Review begun and more information has been requested.* **'Consultation requested':** *Reviewed and requested further consultation.* **'Review complete':** *Report reviewed, recommendation provided and AEFI report complete.* **'Disregard-Entered in Error':** *AEFI report incorrectly created, e.g., wrong client selected.* **'Does not meet reporting criteria':** *Any reported event in a vaccine recipient which followsimmunization that has been clearly attributed to other causes, OR does not meet reporting criteria (e.g., mild vomiting).*

5.0 AEFI REPORTED BY SECTION

Reporter refers to the health care provider who received and reported the AEFI information to the Immunization Program. This may or may not be the same person as the user who administered the immunization.

Field	Description
Date Reported	Date on which the adverse event was reported to the Yukon Immunization Program. If the AEFI information has been reported before the current date, then record the earlier date. *In Panorama: Date Reported defaults to the date when report is created. If this date is before immunization date, a logic error will appear and it cannot be entered.*
Setting	Setting in which the reporter is employed (i.e., 'Physician Office', 'Public Health', 'Hospital', 'Pharmacy', 'Workplace Health', 'Other').
Reporter	Name and title of the reporter. Reporter refers to the health care provider who received and reported the AEFI information to the Yukon Immunization Program. This may or may not be the same person as the user who enters the information. *In Panorama: This field is labelled "Provider". If the reporter is not indexed, identification information must be provided in the 'non-indexed provider' fields. When the non-indexed provider option is selected, the lower level fields will be enabled. Proceed to complete the prompted fields.*
Source of Information or **Client Information**	Source of information can be the client, the immunizer (nurse, physician, pharmacist), or a secondary source such as parent of a child recipient. If source of information is different than the reporter or client, provide their name, relation to the patient and contact information. *In Panorama: If 'Other' is selected, demographic and identification questions will be asked (name, email, and address are required questions).*

6.0 IMMUNIZATION DATA SECTION

Provide all information pertaining to the vaccine(s) administered prior to the onset of the reported AEFI. Any concomitant passive immunizing and/or diagnostic agent(s) should be reported in medical history not the immunization data section.
When completing this section, provide all information as outlined below:

Field	Description
Date vaccine administered	Indicate the date of vaccine administration.
Immunizing agent(s)	Please record the proper name or abbreviation as outlined in Section 8 of the Yukon Immunization Manual
Trade name	Indicate the trade name of all vaccine(s) received.
Manufacturer	Specify the name of the manufacturer as indicated on the product label.
Lot number	Document the complete lot number including all letters and numbers. This information is essential for conducting future risk assessments.
Dose number	Provide the number in series (1, 2, 3, 4, or 5), if known. For the Influenza vaccine, the Dose Number should ordinarily be recorded as one, unless the client receives more than one dose in one season, which is then recorded accordingly.
Dosage/unit	Indicate the quantity administered for each vaccine, usually in units of volume (i.e., milliliter or ml).
Route	Specify the route of administration for each vaccine received.
Site	Indicate the site of injection for each vaccine administered.

All of the immunizations given at the same appointment may be associated with the reported event(s). If it was a local reaction at the site where only 1 or 2 vaccines were given, select the appropriate agent(s) accordingly. If the client had a systemic reaction and a specific vaccine cannot be definitively associated with the event, then all vaccines administered at that appointment should be selected (even if client also had a local reaction associated with only one of the vaccines).

If multiple episodes of an adverse event are reported at one time that occurred following multiple prior immunization appointments (e.g., after 2, 4, and 6 month vaccines), separate AEFI reports should be created for each episode.

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

7.0 INFORMATION AT TIME OF IMMUNIZATION AND AEFI ONSET SECTION

Field	Description
Did an AEFI follow a previous dose of any of the immunizing agents associated with this AEFI report?	Indicate whether the client had ever experienced an AEFI following a previous dose of any of the vaccines associated with this AEFI report. Choose one of the values listed below. • **'No':** Previously immunized with one or more of the vaccines associated with this report and had not experienced a subsequent AEFI. • **'Not applicable (No prior dose)':** Never previously immunized with any of the vaccines associated with this report. • **'Unknown':** It is unknown if the client previously received any of the associated vaccines and/or if an AEFI followed. • **'Yes':** Previously immunized with one or more of vaccines associated with this report and experienced a subsequent AEFI. o If the answer is yes, provide as much detail of the prior AEFI in the comment box including onset and duration, AEFI details, severity of AEFI, whether event was less or more severe than the event following the current dose, dose number, and date of vaccination. If a comment is recorded, record the response which it accompanies, e.g. "Unknown. Client does not recall whether previously received this vaccine." Once a comment is added, it cannot be updated or deleted.
Did this AEFI follow an incorrect immunization?	Indicate whether the AEFI followed an incorrect immunization by choosing one of 'No', 'Unknown', or 'Yes'. If yes, choose all of the following options that apply and provide details in the comment box. • **'Given outside the recommended age limits':** The vaccine was administered to an individual who was not within the recommended age limits for a specific vaccine. • **'Dose exceeded that recommended for age':** A larger dose of vaccine was administered than is recommended for the patient's age group. • **'Incorrect route':** The vaccine was administered via a route not recommended for its administration (e.g., subcutaneous vs. intramuscular). • **'Wrong vaccine given':** An unintended vaccine was administered. • **'Product expired':** The vaccine was administered after the expiry date as indicated on the vaccine label by the manufacturer and/or after the recommended amount of time elapsed between the first use of a multi-dose vial and the last use. • **'Other':** An error has occurred that is not accurately reflected in the list of provided errors (e.g. shoulder injury related to vaccine administration – SIRVA). Provide all details in the corresponding comment box.

Field	Description
Medical history (up to time of AEFI onset)	Indicate the client's medical history prior to the time of AEFI onset by choosing all of options that apply in the list below and provide details in the comment box. • **'Concomitant medication(s)':** Provide name of all medications, including prescription, over the counter and herbal supplements, which the client had been taking immediately prior to the time of AEFI onset. When available, provide the dose, frequency, route of administration and reason for taking each concomitant medication. If a passive immunizing agent or TB skin test was administered at the same visit as the vaccine(s) provide the details of the passive immunizing agent or TB skin test, including lot number when available. • **'Known medical conditions/allergies':** Indicate all known medical conditions and/or allergies, including pregnancy, that the client experienced prior to the time of immunization with a corresponding date/month/or year of onset. Include any conditions for which the client is taking a concomitant medication including chronic conditions with intermittent symptoms such as migraine headaches. • **'Acute illness/injury':** Indicate if client had an acute illness and/or injury immediately prior to the time of immunization and specify a corresponding date/month/or year of onset. • **'No known medical condition(s)':** Client's medical history prior to time of AEFI onset was assessed and no concomitant medications or medical conditions/allergies were identified. Do not select any other options if this selected. • **'Unknown at time of report':** Client's medical history prior to time of AEFI onset is unknown. Do not select any other options if this selected. *In Panorama: Requires details in the comment box when a value from this list is selected. If 'No known medical condition(s)' or 'Unknown at time of report' is reported, copy and paste the value in the comment box.*

8.0 AEFI DETAILS SECTION

Indicate the details of the AEFI being reported by checking all that apply. Include pertinent details (results of medical investigations, laboratory test results, etc.) in the corresponding comment box.

Events with an asterisk (*) or "(MD)" in Panorama must be diagnosed by a physician, or where appropriate and based on current scope of practice, the diagnosis may be made by a nurse practitioner. If not diagnosed by a physician or nurse practitioner, provide sufficient information to support the selected event(s).

For more in depth information around Clinical Management Guidelines, please refer to Section 13 of the Yukon Immunization Manual.

For all AEFIs, indicate the time to onset (time from immunization to onset of first symptom/sign) and the duration (time from onset of first symptom/sign to resolution of all signs and symptoms). If the AEFI is not yet resolved at the time of the report, do not document any duration, and check 'Unresolved'.

Field	Description
Onset	• Interval of time between administration of the vaccine(s) associated with the event and the onset of the first symptoms or signs of the event. • Record minute or hour or day parameter. It is not necessary to record more than one time parameter. • Record minutes if event onset < 1 hour post-vaccination, hours if event onset < 24 hours post-vaccination, and days if event onset 1 or more days post-vaccination. If hours or days are recorded, record the number of complete hours or days between vaccine administration and onset of event.
Duration	• Interval of time from the onset of the first symptom until all the symptoms resolved. If unresolved, leave this blank and must check 'Unresolved' on the right. Record minute or hour or day parameter.

8.1 Local reaction at or near vaccination site

(For non-allergic local reactions only)

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

Field	Description
Reactions	Indicate the local reactions by choosing all that apply. Refer to Section 13 of the Yukon Immunization Manual for definitions and reporting criteria. • **'Infected abscess*':** Must be diagnosed by a physician. • **'Sterile abscess*':** Must be diagnosed by a physician. • **'Cellulitis*':** Must be diagnosed by a physician. • **'Nodule'** • **'Rash'** • **'Pain or redness or swelling extends past the nearest joint'** • **'Pain or redness or swelling persisting for 10 days or more'** • **'Adenopathy/Lymphadenitis*':** Must be diagnosed by a physician. • **'Other':** Examples of "other" local reactions that may be reported here include necrosis, papule, etc. Specify details of the 'other' local reaction being reported in the comment box. *In Panorama: specify the other reaction in the general local reaction comment box in the following format "Other local reaction: [Describe reaction here]".*
Descriptors	For all local reactions at or near the vaccination site, describe the signs and symptoms by selecting all that apply from the list below. At least one local reaction must be selected before selecting any corresponding signs or symptoms. • **'Swelling'** • **'Pain'** • **'Tenderness'** • **'Erythema'** • **'Warmth'** • **'Induration'** • **'Largest diameter of vaccination site reaction':** Indicate the diameter (in centimetres) of the largest vaccination site reaction that is present. • **'Site(s) of reaction':** Site(s) of the local reaction if known. • **'Palpable fluctuance':** Wavelike motion on palpation due to presence of liquid content. • **'Fluid collection shown by imaging technique'** • **'Spontaneous/surgical drainage'**

Field	Description
	• **'Microbial results':** Select "Microbial results" only if the result is positive. Record the laboratory result in the comments field associated with this section (e.g., positive for S. aureus). • **'Lymphangitic streaking'**: Red streaks below the skin's surface that follows the path of lymph draining from the site of infection via lymphatic vessels to regional lymph nodes. • **'Regional lymphadenopathy':** Abnormal enlargement of the lymph nodes closest to the vaccination site.
Comments	Provide any additional pertinent details in the comment box for this section.

If an event is selected in the local section, Panorama requires either a sign/symptom or comment to be in this section to save the record. If signs/symptoms are unknown, or none of the options apply, users can report "No additional details", or describe the signs/symptoms, in the local comment box, as applicable. In Panorama, once a comment is added, it cannot be modified or deleted.

8.2 Anaphylaxis and other allergic events

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

Field	Description
Event Type	Choose one of the following events: • **'Anaphylaxis':** Any event managed as anaphylaxis following immunization, regardless of how or whether it meets the facility criteria, should be reported as anaphylaxis. • **'Ocular-Respiratory Syndrome (ORS)':** Bilateral red eyes AND respiratory symptoms following influenza vaccine. • **'Other allergic events':** Encompasses all allergic reactions that are neither anaphylaxis nor ocular-respiratory syndrome.
For the allergic event reported, describe the signs and symptoms by selecting all that apply from the list below:	

Field	Description
1. *Skin/Mucosal*	• **'Generalized':** A reaction involving in two or more body locations (e.g., both arms) and cannot only affect the injection site. User must select 'Non-injection site' alone or 'At injection site' AND • **'Non-injection site',** but not **'At injection site'** only. If the event occurred only at the injection site, it should be reported as 'Localized'. • **'Localized':** An event occurring in only one body location. User must select 'Non-injection site' only or 'At injection site' only, but not both. • If client has both 'Generalized' and 'Localized' skin/mucosal symptoms, use 'Generalized'. Users should select at least one of the following signs and symptoms: • **'Urticaria' (hives):** Localized swelling of superficial layers of skin that is itchy, raised, sharply demarcated, and transient (usually <12 hours). • **'Erythema':** Abnormal redness of the skin without any raised skin lesions. • **'Pruritus':** An unpleasant skin sensation that provokes the desire to rub and/or scratch to obtain relief. • **'Prickly sensation':** Tingling or smarting (stinging) sensation. • **'Rash'** • **'Eyes':** Select 'Red bilateral', 'Red unilateral', or 'Itchy' if applicable. • **'Angioedema':** Areas of deeper swelling of the skin and/or mucosal tissues in either single or multiple sites which may not be well circumscribed and is usually not itchy. Typical sites in anaphylaxis include tongue, lips, around the eyes (periorbital), eyelids. Do not include hereditary angioedema. o Angioedema should not be reported unless this was a visible objective sign, i.e., provider-observed skin or mucosal swelling. If these are experienced as symptoms (subjective descriptions by the client such as "my tongue feels thick") but not observable as signs, do not report 'angioedema'. o Check all the locations where angioedema is seen 'Tongue', 'Throat', 'Uvula', 'Larynx', 'Lip', 'Eyelids', 'Face', 'Limbs', 'Other', if applicable. If 'Other' is checked, provide details.