



Is this an initial or a follow-up report?

Initial report

Follow-up report

1a. Unique episode #:

1b. Region #:

2. Pediatric surveillance ref #:

Reporting form for adverse events following immunization (AEFI)

Instructions

The instructions for the AEFI reporting form are available at:

<https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization.html>

For complete instructions and definitions, refer to the user guide at:

<https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/user-guide-completion-submission-ae-fi-reports.html>

Note: Discuss with vaccinee or their parent/caregiver reason for reporting and confidentiality of information.

3. Patient identification

First name:

Last name:

Health number:

Address of usual residence and community:

Province/territory:

Postal code:

Phone number:

Phone number extension:

Information source

First name:

Last name:

Relation to patient:

4. Information at time of immunization and AEFI onset

4a. At time of immunization

Province/territory of immunization:

Date vaccine administered (DVA) (yyyy-mm-dd):

Time:

am

pm

Date of birth (yyyy-mm-dd):

Age (units in days, months, years):

Sex at birth:

Male

Female

Other

Gender (refer to user guide for categories):

Pregnant at time of immunization

Gestation:

Weeks

Days

Breastfeeding at time of immunization

Race (refer to user guide for categories):

Indigenous status (refer to user guide for categories):

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4b. Vaccines

Immunizing agent(s)	Trade name	Manufacturer	Lot number	Expiry date (yyyy-mm-dd)	Dose number	Dosage / unit	Route	Site

4c. Medical history (up to the time of AEFI onset)

Please indicate the patient's medical history prior to AEFI onset and check all that apply. Provide details and descriptions including medical investigations, dates and timing prior to time of AEFI onset in section 10:

Concomitant medication(s) (e.g., prescription/ over the counter/ herbal supplements/ traditional medicines)

Known medical condition(s) (e.g., immunocompromised/ chronic conditions)

Allergies and reactions (e.g., medications/ foods/ previous vaccinations)

Acute illness/injury (e.g., animal bite/ skin puncture injury)

Recent immunization history: Please indicate below any other vaccine(s) received within 30 days prior to the "date vaccine administered" reported in section 4a.

Immunizing agent(s)	Trade name	Manufacturer	Lot number	Dose number	DVA (yyyy-mm-dd)

5. Previous AEFI

Did an AEFI follow a previous dose of any of the immunizing agents listed in section 4b? (Choose one of the following and provide details in section 10):

Yes No Unknown Not applicable (no prior doses)

6. Immunization errors

Did this AEFI follow an incorrect immunization?

Yes No Unknown

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If this AEFI follows an incorrect immunization, choose all that apply and provide details in section 10:

Vaccine administered at inappropriate site Inappropriate route of vaccination Wrong vaccine administered
 Inappropriate age at vaccine administration Other, specify:

7. Impact of AEFI, outcome, and level of care obtained

7a. Highest impact of AEFI

Indicate the highest perceived impact of the AEFI. Choose one of the following:

Did not interfere with daily activities Prevented daily activities
 Interfered with but did not prevent daily activities Unknown

7b. Outcome at time of report

Indicate the outcome of the AEFI at the time of completion of the report. Choose one of the following (provide details in section 10 for items with †):

Death † (date of death (yyyy-mm-dd): Persistent or significant disability/incapacity †
 Congenital anomaly/birth defect Not yet recovered †
 Fully recovered Unknown

7c. Highest level of care obtained

Indicate the highest level of care obtained for the reported AEFI. Choose one of the following:

None Telephone/virtual consultation with health care provider
 Non-urgent visit Emergency visit (no hospitalization)
 Unknown Required hospitalization (days):
 Resulted in prolongation of existing hospitalization (days):

Date of hospital admission (yyyy-mm-dd):

Date of hospital discharge (yyyy-mm-dd):

7d. Treatment received

Indicate whether the patient received any treatment, including self-treatment, for the reported AEFI. Choose one of the following (provide details in section 10):

Yes No Unknown

8. Reporter information

Work setting (choose one of the following):

Long-term care home Physician office Community nursing station
 Public health Pharmacy School/student clinic
 Hospital Workplace clinic Local vaccination campaign clinic
 CISSS/CIUSSS CANVAS Other, specify:

Name:

Phone number:

Phone number extension:

Fax:

Address:

Postal code:

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City:	Province/territory:
Please indicate your professional status or affiliation: MD RN Active pediatric surveillance hospital Pharmacist CANVAS Other, specify:	
Signature:	Date reported (yyyy-mm-dd):

9. AEFI details

Complete all the appropriate sections; for each, check all signs/symptoms that apply. Item(s) with a double dagger (‡) should be diagnosed by a physician or nurse practitioner, except in the case of anaphylaxis where objective signs can be reported by any other health care practitioner. If not, provide sufficient information to support the selected item(s). Use Section 10 for additional information, including clinical details, type of treatment, test results, and prior infections with the pathogen(s) being vaccinated against in section 4b.

9a. Local reaction at or near vaccination site

Infected abscess	Lymphadenitis	Sterile abscess	Cellulitis	Nodule
Reaction joint-to-joint/crosses joint(s), specify:				
Other, specify:				

For the indicated local reaction, specify the time to onset and duration below.

Time to onset (in minutes, hours, days):	Duration (in minutes, hours, days):
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For any local reaction indicated above, check all signs/symptoms that apply below and provide details in section 10:

Swelling	Pain	Tenderness	Erythema	Warmth	Induration	Rash
Largest diameter of vaccination site reaction (cm):			Site(s) of reaction (e.g., LA):			
Palpable fluctuance		Fluid collection shown by imaging technique (e.g., MRI, CT, ultrasound)				
Spontaneous/surgical drainage		Microbial results				
Lymphangitic streaking		Regional lymphadenopathy				

9b. Allergic and allergic-like events

Choose one of the following allergic and allergic-like events:

Anaphylaxis	Oculo-Respiratory Syndrome (ORS)	Other allergic events
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For the indicated local reaction, specify the time to onset and duration below.

Time to onset (in minutes, hours, days):	Duration (in minutes, hours, days):
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For any allergic and allergic-like event selected above, check all that apply below and provide details in section 10.

Treatment (epinephrine administered):	Yes	No
Laboratory test (mast cell tryptase measured):	Yes	No
Mast cell tryptase elevated (>upper normal limit or 1.2 X baseline + 2 ng/L):		

Reference range:

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For cases of **suspected anaphylaxis**, was more than one body system (skin/mucosal, cardiovascular, respiratory, gastrointestinal) involved within the first hour after onset of signs or symptoms?

Yes

No

Unknown

Respiratory (select any signs/symptoms)

Expiratory wheezing †

Inspiratory stridor †

Upper airway swelling †:

tongue pharynx uvula larynx

Tachypnea † Cyanosis † Grunting †

Measured hypoxia with O₂ saturation <90% †

Chest wall retractions †

Increased use of accessory respiratory muscles †

Chest tightness Hoarse voice

Sore throat Difficulty swallowing

New onset and persistent:

dry cough sneezing runny nose

Skin/mucosal (select any signs/symptoms)

Urticaria (not at vaccination site)

Generalized erythema with pruritus

Generalized erythema without pruritus

Bilateral red itchy eyes (new onset)

Bilateral red eyes without itching

Angioedema of skin at a site other than vaccination site (may include lip swelling)

Cardiovascular (select any signs/symptoms)

Measured hypotension † (mmHg):

Loss of consciousness (excluding vasovagal syncope)

Gastrointestinal (select any signs/symptoms)

New onset (≥2 episodes if <12 months old; otherwise ≥1 episode):

Vomiting

Diarrhea

9c. Neurological events

Neurological event	Time to onset (minute/hour/day)	Duration (minute/hour/day)
Meningitis †		
Encephalopathy †		
Encephalitis †		
Meningoencephalitis †		
Guillain-Barré Syndrome (GBS) †		
Bell's palsy †		
Other paralysis †, specify:		
Seizure(s)		
Acute disseminated encephalomyelitis (ADEM) †		
Myelitis/Transverse myelitis †		
Other neurologic diagnosis †, specify:		

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For any neurologic events selected above, check all that apply below and provide details in section 10:

Depressed/altered level of consciousness

Lethargy

Personality change lasting ≥ 24 hrsFever ($\geq 38.0^{\circ}\text{C}$)

Focal or multifocal neurologic sign(s)

Formication

Anaesthesia (numbness)/Paraesthesia (prickling or tingling)/Burning

CSF abnormality

Other, specify:

EEG abnormality

EMG abnormality

Neuroimaging abnormality

Brain/spinal cord histopathologic abnormality

Decreased or absent reflexes

Type of seizure (specify the type of seizure below):

Partial

Generalized

Specify the type of seizure:

Tonic

Clonic

Tonic-Clonic

Atonic

Absence

Myoclonic

Select seizure details below.

Sudden loss of consciousness:

Yes

No

Unknown

Witnessed by healthcare professional:

Yes

No

Unknown

Previous history of seizures (specify):

Febrile

Afebrile

Unknown

9d. Other events

Other event	Time to onset (minute/hour/day)	Duration (minute/hour/day)
Hypotonic-hyporesponsive episode (age <2 years)		
Persistent crying (continuous and unaltered crying for ≥ 3 hours)		
Intussusception †		
Arthritis		
Parotitis		
Multisystem inflammatory syndrome in children (MIS-C) †		
Multisystem inflammatory syndrome in adults (MIS-A) †		
Thrombosis/Thromboembolism †		
Thrombosis with Thrombocytopenia syndrome (TTS) †		
Single organ cutaneous vasculitis †		
Syncope with injury		
Rash (elsewhere than at vaccination site)		
Kawasaki disease †		
Thrombocytopenia †		
Severe vomiting		
Severe diarrhea		
Erythema multiforme †		
Myocarditis †		
Pericarditis †		
Fever $\geq 38^{\circ}\text{C}$		
Shoulder injury related to vaccine administration (SIRVA)		
Other serious or unexpected event(s) not listed in the form		

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Check all signs and symptoms that apply based on other events:

Limpness Pallor Cyanosis Petechial rash Joint redness Joint warm to touch
 Joint pain Joint swelling Inflammatory changes in synovial fluid Decreased responsiveness/
 unresponsiveness

Platelet count <150 x 10⁹/L (specify number of platelet count):

Clinical evidence of bleeding (specify clinical evidence of bleeding):

10. Supplementary information

Please indicate the section number when providing details. Please provide details of any investigation or treatment for the recorded AEFI. This can include clinical details, types of treatment, test results, and prior infections with the pathogen(s) being vaccinated against reported in section 4b. If additional space is required, please attach a separate sheet.

11. Recommendations for future immunization(s) according to the federal / provincial / territorial best practices

Indicate recommendations for the patient regarding future immunizations by selecting all that apply below. Provide more details in section 10 as needed.

No change to immunization schedule

Determine protective antibody level

No further immunizations with, specify:

Expert referral, specify:

Active follow up for AEFI recurrence after next vaccine

Other, specify:

Controlled setting for next immunization

Comments

Name:

Phone number:

Phone number extension:

Professional status:

MOH/MHO

MD

RN

Other, specify:

Signature:

Date (yyyy-mm-dd):

12. Follow up information for a subsequent dose of same vaccine(s)

Choose one of the options that apply to the patient. Provide more details in section 10 as needed.

Vaccine not administered

Vaccine administered with recurrence of AEFI

Vaccine administered without AEFI

Vaccine administered, other AEFI observed

Vaccine administered without information on AEFI