Public Health Agency of Canada | Agence de la santé publique du Canada

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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-aefi-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
○ Interfered with but did not prevent daily activities
○ Prevented 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):
○ Congenital anomaly/birth defect
○ Fully recovered
○ Persistent or significant disability/incapacity †
○ Not yet 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
○ Non-urgent visit
○ Unknown
○ Telephone/virtual consultation with health care provider
○ Emergency visit (no hospitalization)
○ 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
○ Public health
○ Hospital
○ CISSS/CIUSSS
○ Physician office
○ Pharmacy
○ Workplace clinic
○ CANVAS
○ Community nursing station
○ School/student clinic
○ Local vaccination campaign clinic
○ 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):

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

For the indicated allergic event, specify the time to onset and duration below.

Time to onset (in minutes, hours, days):	Duration (in minutes, hours, days):

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 O_2 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
- ☐ Personality change lasting ≥24hrs
- ☐ Focal or multifocal neurologic sign(s)
- ☐ Anaesthesia (numbness)/Paraesthesia (prickling or tingling)/Burning
- ☐ Other, specify:
- ☐ EMG abnormality
- ☐ Brain/spinal cord histopathologic abnormality
- ☐ Lethargy
- ☐ Fever (≥38.0°C)
- ☐ Formication
- ☐ CSF abnormality
- ☐ EEG abnormality
- ☐ Neuroimaging 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 ≥38°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 10^9/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

☐ No further immunizations with, specify:

☐ Active follow up for AEFI recurrence after next vaccine

☐ Controlled setting for next immunization

☐ Determine protective antibody level

☐ Expert referral, specify:

☐ Other, specify:

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 without AEFI

○ Vaccine administered without information on AEFI

○ Vaccine administered with recurrence of AEFI

○ Vaccine administered, other AEFI observed

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