New Nouveau Brunswick

ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) REPORT FORM

INSTRUCTIONS:

Please complete this form to 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.

Please indicate what type of event is reported with an "√":

- ❑ **Serious** (*death, life-threatening, hospitalization, disability, congenital anomaly, medically important)*
- ❑ **Require an urgent medical attention** *(not resulted in hospitalization)*
- ❑ **Unusual or unexpected** *(not consistent with product information / labeling);* regardless of its seriousness
- ❑ **Other** (*non-serious and expected*)

An AEFI is a reportable event in New Brunswick and should be reported to a Medical Officer of Health in writing **within one week of identification** (Public Health Act- Charter P-22.4; New Brunswick regulation 2009-141).

NOTE: ***The numbers below correspond to the numbered sections of the form.***
Please indicate if this report is initial or follow up (top right corner of the 2nd page of the form)

3. Provide all information as requested in the table. For the "Dose #", provide the number in series (1, 2, 3 or 4) if known. For the influenza vaccine, unless a client receives two doses in one season, the "Dose #" should be recorded as "1".
6. Provide details of level of care obtained, outcome and all investigations in section 9. If a client had recovered at the time of reporting, provide the date. If the reaction lasted >1 hour, but <1 day also provide the exact time of recovery. For all hospitalizations, indicate the date of admission and discharge.
8. Choose, from section 8 (AEFI details), the description that best fits the AEFI being reported. Make sure to record the onset date and time of the 1st symptom or sign.
9. Use section 9 to provide additional information relevant to the event such as duration of all symptoms, results of investigations, comments and other information as appropriate.
10. This section is to be completed by the MOH or their designate who provides public health recommendations.
MOH: Medical Officer of Health; MD: Medical Doctor; PHN: Public Health Nurse.

Any item marked on the form with asterisk (*) must be diagnosed by a physician.

For more complete instructions, please refer to the AEFI report form user guide and AEFI interpretation and clinical definitions guide at:
http://www.gnb.ca/0053/public_health/health_professionals-e.asp

Return the completed form to your local Public Health Office:

Zone 1	Zone 2	Zone 3	Zone 4	Zone 5	Zone 6	Zone 7
Moncton 81 Albert Street, Suite 300, NB, E1C 1B3 T: 506-856-2401 F: 506-856-2623	**Saint John** 55 Union Street, PO Box 93, NB, E2L 3X1 T: 506-658-5188 F: 506-643-7894	**Fredericton**, 300 St. Mary's St., Suite 1200, NB, E3B 5H1 T: 506-453-5200 F: 506-444-4877	**Edmundston** 121 Church St., Suite 330, NB, E3V 1J9 T: 506-735-2065 F: 506-735-3142	**Campbellton** 6 Arran Street, 1st Floor, NB, E3N 1K4 T: 506-789-2266 F: 506-789-2349	**Tracadie-Sheila** 3520 Main Street, Place Tracadie NB, E1X 1C9 T: 506-394-3888 F: 506-394-3858	**Miramichi** 1780 Water St, Suite 300, NB, E1N 1B6 T: 506-778-6102 F: 506-778-6611

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❑ **Initial report**

❑ **Follow up report**

REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

1. Province case #:

2. Client Identification

First name: **L**ast name: Medicare number: **Date of birth**: YYYY / MM / DD

Sex: ❑ Male ❑ Female

Address of residence: **City/Town:** **Postal code:** Phone #:

Information source Name: Relation to client:

Contact info, if different:

Name of client's physician: Address: Phone #:

3. Vaccine Information

Province of Immunization: _____ **Date vaccine administered:** YYYY / MM / DD (hr: am/pm)

Immunizing agent	Trade name	Manufacturer	Lot number	Dose #	Dosage/unit	Route	Site
					/		
					/		
					/		

4. Immunization Errors

Did this AEFI follow an incorrect immunization? ○ **Yes** ○ No ○ Unknown

(If **Yes,** *choose all that apply and provide detail in section 9)*

❑ Given outside the recommended age limits ❑ Product expired ❑ Wrong dose

❑ Wrong vaccine given ❑ Incorrect route ❑ Other, *specify:*

5. Previous AEFI

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

○ No ○ **Yes** *(Provide details in section 9)*

○ Unknown ○ Not applicable (no prior doses)

6. Level of care and outcome *(Provide details in section 9)*

6a. Highest level of care obtained:

❑ Unknown ❑ None ❑ Telephone advice from a health professional

❑ Non-urgent visit ❑ Emergency visit

❑ Required hospitalization: ○ **Yes** ○ No

Date of hospital admission YYYY / MM / DD

Date of hospital discharge YYYY / MM / DD

6b. Outcome at time of report:

❑ ***Death** Date: YYYY / MM / DD ❑ Unknown

❑ ***Not yet recovered** ❑ ***Permanent disability/incapacity**

❑ Recovered Date: YYYY / MM / DD (hr: am/pm)

(Provide details in section 9 for items with ***)***

6c. Treatment received: ○ **Yes** *(If yes, provide details below)* ○ No ○ Unknown

6d. Medical history (up to the time of AEFI onset) *(Choose all that apply and provide details below or enclose a print out)*

❑ Concomitant medication(s) ❑ Known medical conditions/allergies ❑ Acute illness/injury

7. Reporter Information

Setting : ○ Physician office ○ Public Health ○ Hospital ○ Pharmacy ○ Other, *specify:*_____

Name: **Phone**: ( ) - (ext:) Fax: ( ) -

Address: **Date reported to Service Provider**: YYYY / MM / DD

City: Province: Postal code: **Date reported to Public Health**: YYYY / MM / DD

Signature: _____ ○ MD ○ RN ○ Other, *specify:*_____

Province case #:

8. AEFI Details: *for each section check all signs/symptoms that apply. Use section 9 to provide clinical details and test results.*
Any item marked with asterisk (*) must be diagnosed by a physician.

❑ 8a. LOCAL REACTION around injection site | **Onset date and time of the 1st symptom or sign:** YYYY / MM / DD (hr: am/pm)

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

For any injection site reaction indicated above, check all that apply below and provide details in section 9

❑ Swelling ❑ Pain ❑ Tenderness ❑ Erythema ❑ Warmth ❑ Induration ❑ Rash ❑ Largest diameter of injection site reaction: ____ cm

Site(s) of reaction _____ (e.g. LA, RA) ❑ Palpable fluctuance ❑ Fluid collection shown by imaging technique (e.g. MRI, CT, ultrasound)

❑ Spontaneous/surgical drainage ❑ Microbial results ❑ Lymphangitic streaking ❑ Regional lymphadenopathy

❑ 8b. ALLERGIC and ALLERGIC-LIKE EVENTS | **Onset date and time of the 1st symptom or sign:** YYYY / MM / DD (hr: am/pm)

Chose one of the following: **❑ *Anaphylaxis ❑ Other allergic events ❑ Oculo-Respiratory Syndrome (ORS)**

For a chosen event, check all that apply below and provide details in section 9

Skin /mucosal	❑ Urticaria ❑ Erythema ❑ Pruritus ❑ Prickle sensation ❑ Rash *(For these events, specify site of reaction)*	
	ANGIOEDEMA: ❑ Tongue ❑ Throat ❑ Uvula ❑ Larynx ❑ Lip ❑ Eyelids ❑ Face ❑ Limbs ❑ Other, *specify:*	EYE(S): ❑ Red bilateral ❑ Red unilateral ❑ Itchy
Cardio-vascular	❑ Measured hypotension ❑ ↓central pulse volume ❑ Capillary refill time >3 sec ❑ Tachycardia ❑ ↓ or loss of consciousness (*Duration*) _____	
Respiratory	❑ Sneezing ❑ Rhinorrhea ❑ Hoarse voice ❑ Sensation of throat closure ❑ Stridor ❑ Dry cough ❑ Tachypnea ❑ Wheezing ❑ Indrawing/retractions ❑ Grunting ❑ Cyanosis ❑ Sore throat ❑ Difficulty swallowing ❑ Difficulty breathing ❑ Chest tightness	
Gastrointestinal	❑ Diarrhoea ❑ Abdominal pain ❑ Nausea ❑ Vomiting	

❑ 8c. NEUROLOGIC EVENTS | **Onset date and time of the 1st symptom or sign:** YYYY / MM / DD (hr: am/pm)

❑ *Meningitis ❑ *Encephalopathy/Encephalitis ❑ *Guillain-Barre Syndrome (GBS) ❑ *Bell's Palsy ❑ *Other Paralysis
❑ Seizure ❑ *Other neurologic diagnosis, *specify:*

For any neurologic event indicated above, check all that apply below and provide details in section 9

❑ Depressed/altered level of consciousness ❑ Lethargy ❑ Personality change lasting ≥24hrs ❑ Focal or multifocal neurologic sign(s)

❑ Fever (≥ 38.0^{0}C) ❑ CSF abnormality ❑ EEG abnormality ❑ EMG abnormality

❑ Neuroimaging abnormality ❑ Brain/spinal cord histopathologic abnormality

***Seizure details**:* ❑ Witnessed by healthcare professional: ○ Yes ○ No ○ Unknown

❑ Sudden loss of consciousness: ○ Yes ○ No ○ Unknown

❑ Generalized (*Specify*: ○ Tonic ○ Clonic ○ Tonic-Clonic ○ Atonic ○ Absence ○ Myoclonic) **OR** ❑ Partial

❑ Previous history of seizures (*Specify*: ○ Febrile ○ Afebrile ○ Unknown type)

❑ 8d. OTHER EVENTS | **Onset date and time of the 1st symptom or sign:** YYYY / MM / DD (hr: am/pm)

For all selected defined events of interest below, provide details in section 9

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

❑ Persistent crying (C*rying which is continuous and unaltered for ≥ 3h*)

❑ *Intussusception

❑ Arthritis: ❑ Joint redness ❑ Joint warm to touch ❑ Joint swelling ❑ Inflammatory changes in synovial fluid

❑ Parotitis *(Parotid gland swelling with pain and/or tenderness)*

❑ Rash (*Non-allergic*): ❑ Generalized ❑ Localized (site)_____

❑ *Thrombocytopenia: ❑ Platelet count <150x10^9/L ❑ Petechial rash ❑ Other clinical evidence of bleeding

❑ Anaesthesia/Paraesthesia (❑ Numbness ❑ Tingling ❑ Burning ❑ Formication ❑ Other, *specify:* *)*
❑ Generalized **OR** ❑ Localized (*Site*) _____

❑ Fever ≥38.0^{0}C *(Note: report **ONLY** if fever occurs in conjunction with a reportable event. For fever in a neurological event, use section 8c)*

❑ Other serious or unusual/unexpected event(s) not listed elsewhere on the form

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Province case #:

9. Supplementary information *(Please use this section to provide any additional information relevant to the event, please indicate the appropriate section # of the form when providing details)*

For local Public Health Office use only:

10. Recommendations for future immunizations (*check all that apply below and provide comments in section 9 if extra space is needed*)

❑ No change to immunization schedule	❑ Controlled setting for next immunization	❑ Other, *specify:*
❑ Expert referral, *specify:*	❑ No further immunizations with, *specify*:	
❑ Determine protective antibody level	❑ Active follow-up for AEFI recurrence after next vaccine	

Name: Professional status: ○ MOH ○ PHN ○ Other, *specify:*_____

Comments:

Phone: ( ) - (ext:) **Date:** YYYY / MM / DD **Signature**: _____