Santé et Services sociaux Québec

REPORT OF CLINICAL MANIFESTATIONS OCCURING AFTER VACCINATION

(RESERVED SPACE) ESPRI NO :

IDENTIFICATION (OF PERSON VACCINATED)

HEALTH INS. NO. (NAM) :

LAST NAME, FIRST NAME	TELEPHONE #	DATE OF BIRTH	YEAR	MONTH	DAY	SEX	DATE OF VACCINE ADMINISTRATION	YEAR	MONTH	DAY
						☐1 Male ☐2 Female				

VACCINES

VACCINE(S) GIVEN	DOSE (1ST, 2ND, 3ND…)	SITE	ROUTE (IM, SD, ID)	DOSAGE ADMINISTERED	MANUFACTURER	LOT NUMBER

TIME BETWEEN VACCINATION AND ONSET OF PRINCIPAL CLINICAL EVENT THAT OCCASIONED THIS REPORT : MINS ____ HOURS ____ DAYS ____

CLINICAL EVENTS

Report only events which cannot be attributed to co-existing conditions.
Events marked with an asterisk (*) must be diagnosed by a physician.
All additional information, including duration and severity, should be provided in the "Supplementary Information" section on the reverse.

FEVER (Highest recorded temperature)

☐1 **≥ 40,5° C (105° F)**
☐2 **39,0-40,4° C (102,2-104,9° F)**
☐3 **Temperature believed to be very high but not recorded** (must be accompanied by other symptoms)

LOCAL REACTION AT INJECTION SITE

☐1 **INFECTED ABCESS** (tick one or two of the options below)
Positive gram stain or culture ☐1
Existence of purulent discharge with inflammatory signs ☐2
No discharge, with inflammatory signs ☐3

☐2 **STERILE ABCESS/NODULE** (no evidence of infection)
Lasting more than a month and measuring over 2.5 cm in diameter
No culture done ☐1 **Negative culture** ☐2

☐3 **SEVERE LOCAL REACTION**
(tick one or more of the options below)
Lasting 4 days or more ☐1
Extending past nearest joint ☐2
Other (describe in the "Supplementary Information" section) ☐3

☐4 **CELLULITIS ***
Cutaneous infection with prescription of antibiotics

SYSTEMIC CLINICAL EVENTS

☐1 **SEVERE ADENOPATHY** (tick one of the options below)
Enlarged lymph node(s), without discharge ☐1
Enlarged lymph node(s), with discharge ☐2
(please describe in the "Supplementary Information" section) (SEE OVER)

☐2 **ALLERGIC REACTION** (tick one or several of the options below)
Anaphylaxis (describe in the "Supplementary Information" section) (see OVER) ☐7
Respiratory difficulties due to bronchospasm ☐1
Swelling of mouth or throat ☐2
Facial or generalised edema ☐3
Pruriginous skin manifestations (describe in the "Supplementary Information" section)
Hives ☐4
Other skin itching ☐5
Other allergy (describe in the "Supplementary Information" section) (see OVER) ☐6

☐3 **RASH (NO APPARENT PRURITUS)**
Lasting 4 days or more (describe in the "Supplementary Information" section) (SEE OVER)
Generalised ☐1
Localised ☐2
Lasting < 4 days (describe in the "Supplementary Information" section) (SEE OVER)
Generalised ☐3
Localised ☐4

☐4 **ANAPHYLACTIC SHOCK ***
Occurring within 30 minutes after immunisation, usually associated with allergic reaction, and evolving rapidly towards cardiovascular collapse and requiring epinephrine injection.

☐5 **HYPOTONIC-HYPORESPONSIVE EPISODE** (children < 2 years only)
Characterised by <u>all the following features</u> :
i : generalised decrease/loss of muscle tone AND
ii : decreased level of awareness or loss of consciousness AND
iii : pallor or cyanosis. Should not be mistaken for fainting, vagal shock, post-convulsive state, anaphylaxis, or a lethargy due to fever.

☐6 **ARTHRALGIA/ARTHRITIS**
Joint pain/inflammation lasting at least 24 hours
If condition is an exacerbation of a pre-existing condition, give details in the "Supplementary Information" section (SEE OVER)

☐7 **SEVERE VOMITING AND/OR DIARRHOEA**
Must be severe enough to interfere with daily routine

☐8 **EPISODE OF SCREAMING OR PERSISTENT CRYING**
Inconsolable for 3 hours or more ; OR quality of cry definitely abnormal for child and not previously heard by parents

NEUROLOGICAL SIGNS

☐2 **SEIZURES ***
Febrile ☐1 **Afebrile** ☐2 **Don't know** ☐3
Do not include fainting, seizures occurring within 30 minute of immunisation, and seizures occurring as part of encephalopathy or meningitis/encephalitis
Personal history of seizures :
No ☐1 **Dont know** ☐2
Febrile ☐3 **Afebrile** ☐4 **Unknown type** ☐5

☐3 **ENCEPHALOPATHY ***
Acute onset of major neurological illness characterised by <u>at least two of the following signs</u> :
i : Seizures
ii : Distinct change in level of consciousness or mental status (behaviour and/or personality) lasting 24 hours or more
iii : Focal neurological signs which persist for more than 24 hours

☐4 **MÉNINGITIS AND/OR ENCEPHALITIS ***
Abnormal CSF findings and acute onset of :
i : Fever with neck stiffness or positive meningeal signs OR
ii : Signs and symptoms of encephalopathy (see ENCEPHALOPATHY above)
(Please provide results of CSF examination in the "Supplementary Information" section) (SEE OVER)

☐5 **ANESTHESIA/PARAESTHESIA ***
Lasting over 24 hours (describe in the "Supplementary Information" section) (SEE OVER)
Generalised ☐1
Localised ☐2

☐6 **PARALYSIS *** (Do not code if Guillain-Barré Syndrome is coded)
Limb paralysis ☐1
Facial or cranial nerve paralysis ☐2
(describe in the "Supplementary Information" section) (SEE OVER)

☐7 **GUILLAIN-BARRÉ SYNDROME ***
Progressive subacute weakness of more than one limb (typically symmetrical) **with hyporeflexial/areflexia**

VARIOUS

☐1 **PAROTIDITIS**
Painful or sensitive swollen parotid(s) gland(s)

☐3 **THROMBOCYTOPENIA ***
(provide analysis results in the "Supplementary Information" section) (SEE OVER)

☐4 **OCULO-RESPIRATORY SYNDROME (ORS)** (According to surveillance definitions)

☐5 **INTUSSUSCEPTION *** (According to surveillance definitions)

OTHER SERIOUS OR UNUSUAL CLINICAL EVENTS

☐ **Include any clinical event that may be related to immunisation, that does not fit any of the categories listed above, and for which no other cause is clearly established. Report events of clinical interest and which require medical attention, particularly events that (only one required) :**
i : are fatal
ii : are life-threatening
iii : require hospitalisation
iv : result in permanent disability

Describe diagnosis :

_____

_____

PARENT'S NAME : _____

TELEPHONE AT WORK : _____

NOTE : This form is based on the Canadian form (HC/SC 4229 (03-96)-PQ).

Adapted from : MSSS 24 nov 2003 / Groupe ESPRI Nov 2011

OUTCOME OF CLINICAL EVENTS AT TIME OF REPORT (PLEASE SUBMIT ALL SUBSEQUENT INFORMATION)

RECOVERE ☐[1]	SEQUELAE ☐[2]	DON'T KNOW ☐[4]	DEATH ☐[5]	NOT YET RECOVERED ☐[6]	DATE OF DEATH YEAR MONTH DAY

MEDICAL CONSULTATION (ER, outpatient clinic, medical clinic, etc.)

YES ☐[1] NO ☐[2] DON'T KNOW ☐[3] (IF YES, PROVIDE RELEVANT DETAILS OF TREATMENT IN THE "SUPPLEMENTARY INFORMATION" SECTION BELOW)

HOSPITALISATION BECAUSE OF CLINICAL EVENTS

YES ☐[1] NO ☐[2] DON'T KNOW ☐[3] A stay of under 24 hours is not a hospitalisation	DATE ADMITTED YEAR MONTH DAY	DATE DISCHARGED YEAR MONTH DAY

SUPPLEMENTARY INFORMATION

Provide all pertinent information in this section (e.g. duration of incident, laboratory results, medical history (see instruction #5 below) and list relevant medication, etc., and specify date of update (Year/Month/Day)

TOTAL DURATION OF EVENT :	MIN ☐ HRS ☐ DAYS ☐	SEVERITY OF THE CASE :	MILD ☐ MODERATE ☐ SERIOUS ☐

INSTRUCTIONS FOR COMPLETING REPORT OF CLINICAL EVENTS

1 Report only clinical events which occurred after administration of a vaccine and which cannot be clearly attributed to co-existing conditions and take into account the proposed definitions. **A causal relationship does not need to be proven. Submitting a report does not necessarily imply causality**. Report **all vaccines** administered during the vaccination session excepted when a local reaction is clearly related to one vaccine.

2 Clinical manifestations marked with an asterisk (*) must be diagnosed by a physician. Provide relevant details in the "SUPPLEMENTARY INFORMATION" section.

3 Report interval between vaccine administration and onset of the principal clinical event (in minutes, hours, or days) that occasioned this report. Include the duration of the main clinical event in the "SUPPLEMENTARY INFORMATION" section.

4 Provide all relevant information, when appropriate, in the "SUPPLEMENTARY INFORMATION" section, including information such as: details of events diagnosed by a physician (see 2 above), results of diagnostic or laboratory tests, hospital treatment, and discharge diagnoses where a vaccine was hospitalised because of reported clinical manifestations. If appropriate, or preferred, photocopies of original records may be submitted. Severity of the case will be noted (MILD : does not impair daily living activities ; MODERATE : impairs DLA ; SEVERE ; no DLA possible).

5 Provide pertinent details of medical history related to reported clinical events, such as history of allergies, previous episodes, or concurrent illnesses.

COMPLETED BY (PLEASE USE BLOCK LETTERS)

LAST NAME, FIRST NAME			TELEPHONE # ( )
INSTITUTION, ADDRESS (INSTITUTION, NUMBER, street, etc.)	CITY	PROVINCE	POSTAL CODE
PROFESSION NURSE ☐[1] MD ☐[2] OTHER ☐[3]	SIGNATURE	DATE YEAR MONTH DAY	

PERSON WHO RECEIVED THE VACCINE TOLD THE DSP MIGHT CALL : YES ☐ NO ☐

NOTES (To be completed by the public health department)

FOLLOW-UP : YES ☐[1] COMPLETED ☐[2] | DECISION-REGISTER : ☐[1] YES ☐[2] NO ☐[3] INACTIVATED

D.S.P. RESOURCE PERSON	SIGNATURE	DATE YEAR MONTH DAY