simcoe muskoka
DISTRICT HEALTH UNIT

Dr. Charles Gardner, Medical Officer of Health
Dr. Jim Pfaff, Associate Medical Officer of Health
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HealthFAX

Universal Influenza Immunization Program (UIIP) 2011-2012

Attention: **Physicians, Nurse Practitioners, Long-Term Care Facilities, Rest & Retirement Homes, Walk-in Clinics, Hospitals, Infection Control Practitioners, Community Care Access Centres, Correctional Facilities, Waypoint Centre for Mental Health Care**

Date: October 3, 2011

Influenza Immunization Recommendations for the 2011-2012 Season

There have been two NACI Statements published this year with recommendations for the 2011-2012 season:

- The *National Advisory Committee on Immunization (NACI) Statement on Influenza Vaccination for the 2011-2012 Season*
- A *Supplemental Statement of Seasonal Influenza Vaccine for 2011-2012: Recommendations on the use of MF59-Adjuvanted Trivalent Influenza Vaccine (Fluad®)*

These documents can be found on the Public Health Agency of Canada website at the following link http://www.phac-aspc.gc.ca/naci-ccni/index-eng.php.

Influenza Surveillance

The recent influenza season in the southern hemisphere (e.g. Australia, New Zealand, South Africa) overall is seeing low to normal levels of seasonal influenza activity. Most of the activity has been from pandemic A (H1N1) 2009 (also designated pH1N1) co-circulating with Influenza B, while there has been little seasonal A (H3N2) activity. All 3 strains are expected to be a good match to this year's influenza vaccine as indicated by surveillance data from the southern hemisphere. The three strains included in this year's vaccines are:

- A/California/7/2009(H1N1)-like
- A/Perth/16/2009 (H3N2)-like
- B/Brisbane/60/2008 (Victoria-lineage)-like antigens

Please note that although these are the same three strains that were used in the 2010-2011 influenza season, the 2011-2012 influenza vaccine is still recommended for everyone over 6 months of age as the flu vaccine does not provide long term protection. The seasonal influenza vaccine is still the most effective method to prevent influenza illness, particularly for persons who are at high risk for its complications.

Recommended Recipients of Influenza Vaccine for the 2011-2012 Season

Influenza vaccine is encouraged for everyone 6 months of age and older. Immunization with influenza vaccine is **not** recommended for infants less than 6 months of age. The priority groups for influenza vaccination continue to be those at high risk of influenza-related complications, those capable of transmitting influenza to individuals at high risk of complications and those who provide essential community services. (Refer to the table on page 4 for more detailed information about priority groups)

Pregnancy and Breastfeeding - Influenza vaccination is recommended for all pregnant women regardless of trimester and women who are breastfeeding.

Publicly Funded Influenza Vaccine Products for the 2011/2012 UIIP

There are currently eight seasonal trivalent influenza vaccines authorized for use in Canada. For the 2011-2012 influenza season the following products are available as publicly funded (free) vaccines:

Vaccine Products	**Vaxigrip®** - manufactured by Sanofi Pasteur
	Agriflu® - manufactured by Novartis
	Fluad® - manufactured by Novartis (**for Long Term Care Residents ≥65 years**)

Vaxigrip®, Agriflu® and Fluad® contain trace amounts of neomycin. All three products are latex free. Vaxigrip® is provided in a multi-dose format and must be discarded 7 days after puncturing the vial. Agriflu® and Fluad® are provided in single dose pre-filled glass syringes and do not contain thimerosal. For detailed information on each of the vaccine products, refer to their product monographs.

Flumist® (nasal delivery), Fluviral® and Influvac® (single use, thimerosal free), Fluzone®, and Intanza® (intradermal delivery) are not available publicly funded through the UIIP for the 2011/2012 season.

Scheduling and Dosage

*****NEW - Children 6 to 35 months of age should be given a full dose (0.5 mL) of influenza vaccine, not the previously recommended half dose (0.25 mL).** This NACI recommendation is based on evidence showing an improvement in antibody response without an increase in adverse effects. This recommendation applies whether the child is being given one dose of the influenza vaccine or a two dose series as per below.

AGE	DOSE (mL)	NUMBER OF DOSES	ROUTE
6 months-8 years	0.5	1 or 2*	IM
≥ 9 years	0.5	1	IM

***Children less than 9 years of age who are receiving seasonal influenza vaccine for the first time this year are recommended to receive 2 doses, with a minimum interval of 4 weeks between the first and second dose.** The second dose is not needed if the child has received one or more doses of the seasonal influenza vaccine during a previous influenza season.

*****NEW - Individuals with an Egg Allergy**

Previous NACI statements have advised that those with a known IgE-mediated hypersensitivity to eggs not be routinely immunized with influenza vaccine manufactured in eggs. However, after review of a number of studies that demonstrate most egg-allergic individuals can safely receive inactivated influenza vaccine and guidelines for vaccination that have been developed by a number of professional groups, NACI concluded that egg-allergic individuals may be vaccinated against influenza. More information can be located in the NACI statement.

The risk of severe allergic reaction or anaphylaxis in egg-allergic individuals can be determined by assessing the history of reactions to egg. The Canadian Society of Allergy and Clinical Immunology CSACI considers an egg-allergic individual to be at ***lower risk for severe allergic reactions*** if they have mild gastrointestinal or mild local skin reaction, can tolerate ingestion of small amounts of egg, or have a positive skin/specific IgE test to egg when exposure is unknown. An egg-allergic individual is considered to be at ***higher risk for severe allergic reactions*** if they have had a previous respiratory or cardiovascular reaction or generalized hives when exposed to egg, or have poorly controlled asthma.

Two vaccine delivery protocols can be used for egg-allergic individuals, depending on their level of risk for an allergic reaction. Egg-allergic individuals at lower risk for severe allergic reaction can be vaccinated for influenza using a single full vaccine dose. The two-step graded protocol is recommended for individuals who are at higher risk for severe allergic reaction. These protocols are as follows:

Full dose - A single vaccine dose without the use of a graded challenge. Individuals should be observed for 30 minutes following administration for symptom development.

Two-step graded dosing - A two-step graded process, whereby 10% of the age-appropriate dose is administered followed by 30 minutes of observation. If no symptoms develop, or symptoms are self-resolving, administer the remaining 90% with another 30 minute observation period. If sustained or severe reactions arise after the initial dose, the vaccine is withheld and the individual should be re-evaluated for receipt of the influenza vaccine.

Influenza vaccine will be available for pick up starting Tuesday, October 11th, 2011. The first orders should be directed to persons at high risk as per the table on page 4. All vaccine orders for influenza vaccine must be accompanied by the previous 4 week vaccine refrigerator temperature log. Orders received by Wednesday will be available for pick up on the following Tuesday. The vaccine order form is included on page 5.

Hospitals, Long-Term Care Facilities, Community Health Centres and Community Care Access Centres

The Ministry of Health and Long-Term Care requires that hospitals, Long-Term Care Facilities, Community Health Centres and Community Care Access Centres submit the *Vaccine Utilization Report Form for Non-reimbursable Clinics* (see page 6-7) for their staff and residents. This form must be faxed back to the Vaccine Preventable Disease team: **fax (705) 721-1495**.

NEW THIS YEAR: The Health Unit is moving to an online appointment booking system for our community flu clinics. People can visit the health unit's website, www.simcoemuskokahealth.org, and click on the hot button on the home page that will take you directly to the clinic booking system. People will be able to choose the clinic they would like to attend and then select a time for their appointment.

For more information, support materials and forms refer to the following websites:

www.simcoemuskokahealth.org – information for health care providers can be found in the *Just for You* section
www.ontario.ca/flu - Ministry of Health and Long-Term Care Universal Influenza Immunization Program Website.

Reporting of Adverse Events

The attached *Adverse Event Following Immunization (AEFI)* form must be filled out and faxed back to the Vaccine Preventable Disease team for follow-up immediately following an unexpected adverse event: **fax (705) 721-1495**.

Pneumococcal Immunization Recommendations

A one time dose of pneumococcal polysaccharide vaccine (Pneumovax® 23 or Pneumo® 23) is recommended for:

- all persons 65 years of age and older regardless of medical conditions
- all residents of nursing homes, homes for the aged and chronic care facilities or wards

A single revaccination with pneumococcal polysaccharide vaccine is only recommended for those 2 years of age and older with:

- Functional or anatomic asplenia or sickle cell disease;
- hepatic cirrhosis,
- chronic renal failure or nephrotic syndrome;
- HIV infection; and
- immunosuppression related to disease or therapy.

The timing for single revaccination when indicated is recommended as follows:

- 1 dose after 5 years for those 11 years of age or older at the time of initial immunization

or

- 1 dose after 3 years for those 10 years of age or less at the time of initial immunization

This vaccine can be given at the same visit as influenza vaccine, or at any time during the year. Pneumococcal polysaccharide vaccine should not be given at the same visit as Zostavax®. A minimum of one month interval between Zostavax® and pneumococcal polysaccharide vaccine is recommended.

If you have any questions or comments please contact the Vaccine Preventable Disease Program or Health Connection at 705-721-7520 or 1-877-721-7520 or extension 8806.

Recommended Recipients of Influenza Vaccine for the 2011-2012 Season

People at high risk of influenza-related complications or hospitalization

- Adults (including pregnant women) and children with the following chronic health conditions:
  - cardiac or pulmonary disorders (including bronchopulmonary dysplasia, cystic fibrosis and asthma);
  - diabetes mellitus and other metabolic diseases;
  - cancer, immune compromising conditions (due to underlying disease and/or therapy);
  - renal disease;
  - anemia or hemoglobinopathy;
  - conditions that compromise the management of respiratory secretions and are associated with an increased risk of aspiration;
  - morbid obesity (BMI≥40); and
  - children and adolescents with conditions treated for long periods with acetylsalicylic acid.
- People of any age who are residents of nursing homes and other chronic care facilities.
- People ≥65 years of age.
- Healthy children 6 to 23 months of age.
- Healthy pregnant women (the risk of influenza-related hospitalization increases with length of gestation, i.e. it is higher in the third than in the second trimester)
- Aboriginal peoples.

People capable of transmitting influenza to those at high risk

- Health care and other care providers in facilities and community settings who, through their activities, are capable of transmitting influenza to those at high risk of influenza complications.
- Household contacts (adults and children) of individuals at high risk of influenza-related complications (whether or not the individual at high risk has been immunized):
  - household contacts of individuals at high risk, as listed in the section above;
  - household contacts of infants <6 months of age as these infants are at high risk of complications from influenza but cannot receive influenza vaccine; and
  - members of a household expecting a newborn during the influenza season.
- Those providing regular child care to children <24 months of age, whether in or out of the home.
- Those who provide services within closed or relatively closed settings to persons at high risk (e.g. crew on a ship).

Others

People who provide essential community services.
People in direct contact during culling operations with poultry infected with avian influenza.

*Note: Healthy persons aged 2 to 64 years without contraindication are also encouraged to receive influenza vaccine even if they are not in one of the priority groups.

SMDHU Vaccine Order Form - page 5

Vaccine Utilization Report Form for Non-reimbursable Clinics - pages 6 - 7

Report of Adverse Event Following Immunization Form – pages 8 - 11

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DISTRICT HEALTH UNIT

TEL: 705-721-7520 1-877-721-7520

Fax: 705-721-1495

Facility/Physician: _____

Phone #: _____

Office Fax #: _____

Office Contact: _____

Date: _____

ATTENTION: Vaccine Order Desk

Vaccine Order Desk: Ext: 8808 **General Vaccine/Immunization Inquiries**: Ext. 8806

Please order in **Boxes** unless specified. Orders placed by **Wednesday** will be available for pick up the following **Tuesday**.

*****All orders must be accompanied by the temperature log for the previous four weeks*****

******Coolers must be between 2-8 Degrees Celsius for vaccine to be released******

Antigen	# of Boxes
Pediacel (5 doses/box) Diphtheria, Pertussis, Tetanus, Polio and Act HIB	
Quadracel (5 doses/box) Diphtheria, Pertussis, Tetanus, Polio	
Tdap (Adacel or Boostrix) (order in doses) Diphtheria, Tetanus, Pertussis	
Td Adsorbed (5 doses/box) Tetanus, Diphtheria	
Td Polio (5 doses/box) Tetanus, Diphtheria, Polio	
IPV (order in doses) Polio	
Act HIB (order in doses) Haemophilus influenzae b	
MMR (10 doses/box) Measles, Mumps, Rubella	
MMRV (order in doses) Measles, Mumps, Rubella, Varicella	
Varicella (order in doses) Varicella only	
Hepatitis A – Adult - must meet criteria for publicly funded vaccine **(order in doses)**	
Hepatitis A - Pediatric - must meet criteria for publicly funded vaccine **(order in doses)**	
Hepatitis B - Adult - must meet criteria for publicly funded vaccine **(order in doses)**	
Hepatitis B - Pediatric - must meet criteria for publicly funded vaccine **(order in doses)**	
Hepatitis B – for dialysis patients (order in doses)	
Pneumo 23 (order in doses) Pneumococcal Polysaccharide	
Influenza (10 doses/box)	
Prevnar 13 (10 doses/box) Pneumococcal Conjugate 13-Valent	
Menjugate (5 doses/box) Meningococcal C Conjugate	
TB Mantoux Test (10 doses/box)	
Rotavirus (order in doses)	

Location to be picked up from (please check):

□ Barrie Office □ Huntsville Office □ Collingwood Office □ Cookstown Office
□ Midland Office □ Orillia Office □ Gravenhurst Office □ South Muskoka Memorial Hospital

BIOS Order # (for office use only): _____

Ontario

Ministry of Health and Long-Term Care

Public Health Policy and Programs Branch

Vaccine Utilization Report
Non-reimbursable Clinic
Universal Influenza Immunization Program (UIIP)

Type or print clearly. Complete all fields, as appropriate.

Part A: Influenza Clinic Information		**Part B: Vaccine Provider Information**	
Facility Hosting Clinic		Agency Administering Vaccine	
Address (*Street No., Street Name, Suite, Unit No.*)		Address (*Street No., Street Name, Suite, Unit No.*)	
City/Town **ON**	Postal Code	City/Town **ON**	Postal Code
Contact person for Facility	Telephone No. (*incl. ext.*) ( )	Contact person for Agency	Telephone No. (*incl. ext.*) ( )

Part C: Vaccine Supply Source

☐ Health Unit (specify name of health unit)	☐ Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS) Client No.	▶

Part D: Clinic Category (*please check ☒ only one box from the list below*)

☐ Workplace - Health care (i.e. hospital, LTCH, etc.)	☐ Workplace - Non-health care (i.e. financial institutions, etc.)
☐ Educational Institution	☐ Group Home
☐ Retirement Home	☐ Other (specify):

Part E: Clinic Information

Clinic Location (if different than in Part A)	Clinic Date *(yyyy/mm/dd)*	Vaccine Lot Number(s) Used At Clinic	Vaccine Wastage (in Doses)	Total Doses Administered
		Total Vaccine Wastage for Clinic =		
		Total Doses Administered at Clinic =		

Part F: Vaccination Coverage Data for Clinic

Category	**Age (Years)**										**Sub-Totals**
	6 months to <2 yrs		2 to <5		5 to 18		19 to 64		65 or older		
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	
a) Risk Groups											a.
b) General Population											b.

Part G: Authorization, Terms and Conditions

Participation in the Universal Influenza Immunization Program (UIIP) and the receipt of the publicly funded influenza vaccine requires that all agencies and service providers report both vaccine doses administered and doses wasted to the Ministry of Health and Long-Term Care. Failure to report this may result in vaccine orders not being filled. All clinic reports must be submitted within ten working days of the immunization clinic. Only reimbursable clinic providers who are operating or sponsoring public clinics and are not compensated for these services may make payment claims. The clinic provider is responsible for protecting the privacy, security and confidentiality of personal information and personal health information in accordance with privacy laws. The clinic provider agrees to maintain such records for no less than five years. The clinic provider must disclose all relevant records within his or her control to the UIIP manager upon request. Report forms must be submitted as soon as possible after a community influenza immunization clinic is held, but not more than 10 working days after the clinic. Failure to report this information could result in future vaccine orders not being filled. Reports must be received by the Ministry before the 28th day of February, for that influenza season.

1a. Authorized Signing Officer at Facility Hosting Clinic

By signing below, I certify that I have read and agree to the terms and conditions as outlined above and that publicly funded influenza vaccine was administered free of charge to all persons who received an influenza immunization. I further certify that I have authority to bind my organization.

Name *(please print)* Signature

1b. Authorized Signing Officer of Agency Administering Vaccine

By signing below, I certify that I have read and agree to the terms and conditions as outlined above and that publicly funded influenza vaccine was administered free of charge to all persons who received an influenza immunization. I further certify that I have authority to bind my organization.

Name (*please print*) Signature

Forward completed form for signoff to the location where the vaccine was obtained *(see Part F instructions on reverse)*

2. Health Unit / OGPMSS Use Only

Health Unit Delegate or OGPMSS Designate Approval

Name (*please print*) Signature Date Submitted to Ministry *(yyyy/mm/dd)*

3. Ministry Use Only

Public Health Division Rep. Date *(yyyy/mm/dd)*

Fax: 416-327-0984
Attn: UIIP Coordinator

  Disponible en Francais

The *Vaccine Utilization Report* needs to be completed for each clinic held. Please ensure that the report is completely filled out, as incomplete reports will not be processed and could result in future influenza vaccine orders not being filled.

Part A: Influenza Clinic Information

Facility Hosting Clinic and Address
Refers to the name and location of the facility (site) where the clinic was held, e.g., the business corporation name, **NOT** the agency contracted to administer the vaccine.

Contact Person for Facility and Telephone No.
This is the person who will ensure the information on the form is complete and accurate.

Part B: Vaccine Provider Information

Agency Administering Vaccine and Address
Refers to the name and location of the agency that is administering vaccine at the clinic.

Contact Person for Agency and Telephone No.
This is the person who will ensure the information on the form is complete and accurate.

Part C: Vaccine Supply Source

Indicate whether the vaccine was obtained from a health unit (please specify the health unit), or from the Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS) (please specify your OGPMSS Client No.).

Note: It is required that the vaccine be obtained from the jurisdiction in which the clinic is held.

Part D: Clinic Category

Check the one (1) box from the list that identifies your clinic type.

Part E: Clinic Information

Completed *Vaccine Utilization Report* forms should be submitted to the vaccine supply source (i.e. health unit or OGPMSS) as quickly as possible, and **within 10 working days after the date of the influenza immunization clinic**. A separate *Vaccine Utilization Report* must be submitted for each clinic held.

Note: For health care agencies and workplaces, a copy of the completed report form **must be submitted to the location(s) where the vaccine was obtained as soon as possible after the clinic is held** for cross-checking total doses administered against the original vaccine orders **before additional vaccine can be ordered.**

Clinic Location
Identify the name of the facility location, including the address, where the clinic was held if different that in Part A.

Clinic Date
Follow date format provided. **For clinics lasting more than one day, enter each day on a separate *Vaccine Utilization Report* form.**

Vaccine Lot Number(s) Used At Clinic
Enter the vaccine lot number(s) associated with each clinic.

Vaccine Wastage
Enter the number of doses wasted (e.g. breaking cold chain conditions, <10 doses drawn up from vial, etc.) for each Vaccine Lot No. used.
Note: 1 vial = 10 doses at 0.5 ml/dose

Total Doses Administered
Enter the total doses administered for each vaccine lot number.

Total Vaccine Wastage for Clinic
Enter the SUM of wastage for all Vaccine Lot Nos. used for the clinic.

Total Doses Administered for Clinic
Enter the SUM of all doses administered for the clinic.

Part F: Vaccination Coverage Data for Clinic

As a condition of receiving publicly funded influenza vaccine to administer, all vaccine doses (administered and wasted) must be reported to the Ministry on the *Vaccine Utilization Report*.
For the clinic identified on the report, enter the **aggregate totals** for "Risk Groups" and "General Population" across the appropriate age group(s) and gender identified. Add each of the rows for a total sum.

a) **"Risk Groups"** refer to people at high risk of influenza-related complications **and** people capable of transmitting influenza to those at high risk of influenza-related complications.

b) **"General Population"** includes healthy persons aged 2 to 64 years, who should be encouraged to receive the vaccine, even if they are not in one of the aforementioned groups.

Note: The **Sub-totals** (by row) for the "Risk Groups" and "General Population" must add up to the **Total Doses Administered at Clinic**.

Part G: Authorization, Terms and Conditions

A signature of authorization is required from both the facility hosting the clinic and the agency administering the influenza vaccine at the clinic. If the facility hosting the clinic is the same as the agency administering the vaccine, only one signature is required (see 1a).

1a. Authorized Signing Officer at Facility Hosting Clinic

The Authorized Signing Officer at the facility hosting the clinic is responsible for ensuring that the *Vaccine Utilization Report* is complete and that all information reported is accurate. The name, signature of the Authorized Signing Officer and the date the report was submitted to the health unit or OGPMSS are required to validate the accuracy and completeness of the information provided.

1b. Authorized Signing Officer of Agency Administering Vaccine

If an agency has administered the vaccine on behalf of the facility hosting the clinic, then the Authorized Signing Officer of the agency administering vaccine should be a regulated health professional as defined under the *Regulated Health Professions Act, 1991*.

Forward form for signoff to the location where the vaccine was obtained:
a. **For clinics that received the vaccine from a health unit:**
Health Unit from which the vaccine was obtained

b. **For clinics that received the vaccine from OGPMSS:**
Fax: 416-327-0818

2. Health Unit / OGPMSS Use Only
A signature is required from either the health unit or OGPMSS, depending upon where the vaccine was obtained, verifying that the report form has been reviewed. Health units are responsible for contacting the facility hosting the clinic if information is incomplete.

3. Ministry Use Only
Health units or OGPMSS, as appropriate, will forward the report(s) to the Ministry for approval.

Note: Ministry staff will not process the form until the report is signed by either the health unit delegate or the OGPMSS designate

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REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

INSTRUCTIONS: ***For more complete instructions and definitions, refer to the user guide at:***
http://www.phac-aspc.gc.ca/im/aefi-form-eng.php

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.

Of particular interest are those AEFIs which meet one or more of the following criteria:

a. Are of serious nature
b. Require urgent medical attention
c. Are unusual or unexpected events

Refer to the user guide, Background Information and for additional clarification.

NOTE:

- **The numbers below correspond to the numbered sections of the form.**
- **All dates should be captured in the following format: YYYY/MM/DD.**
- **When reporting an AEFI, check one of the boxes on the top right hand corner of the first page of the AEFI form to indicate whether it is an INITIAL or FOLLOW UP report. For all follow up reports, please specify the Unique Episode number.**

1a. The **"Unique episode number"** is assigned by the Province/Territory. Leave it blank unless authorized to assign it.
1b. The **"Region number"** is a number that corresponds to a given health unit. Leave it blank if it doesn't apply to your locale.
2. The "IMPACT LIN" is assigned by IMPACT nurse monitors (LIN: Local Inventory Number).
3. The information provided in this section is confidential and should not be sent to the Public Health Agency of Canada.
4a. Indicate the Province/Territory where the vaccine was administered, abbreviations may be used.
4c. Provide all information as requested in the table. For the "Dose #", provide the number in series (1, 2, 3, 4, or 5) if known. For the Influenza vaccine, unless a patient receives two doses in one season, the "Dose #" should be recorded as "1".
7a. Indicate the highest impact of the AEFI on the patient's daily activities as assessed by the patient or the parent/caregiver.
7c. Provide details of any investigations or treatments in section 10. If the patient was already in hospital when immunized and the immunization resulted in a longer hospital stay, indicate "Resulted in prolongation of existing hospitalization" and provide the number of days by which the patient's hospital stay was prolonged. For all hospitalizations, indicate the date of admission and discharge.
8. MOH/MHO: Medical Officer of Health, MD: Medical Doctor, RN: Registered Nurse.
9. Choose, from section 9 (AEFI details), the description that best fits the AEFI being reported. Make sure to record the time of onset and duration of signs/symptoms using the most appropriate time unit:
- If the interval is <1 hour, indicate in minutes;
- If it is ≥ 1 hour but <1 day; indicate in hours;
- If it is ≥1 day; indicate in days.

Report the time in one time unit only. Provide additional details of any investigation, therapy, and other information as appropriate in section 10.
11. This section is to be completed by the MOH/MHO, MD, RN or their designate who are assigned to provide public health recommendations according to the P/T best practices.
12. Information in this section is not collected by all P/Ts.

Return completed form to your local public health unit address at:

Alberta (AB)	Northwest Territories (NT)	Quebec (QC)
British Columbia (BC)	Nova Scotia (NS)	Saskatchewan (SK)
Manitoba (MB)	Nunavut (NU)	Yukon (YT)
New Brunswick (NB)	Ontario (ON)	Public Health Agency of Canada (PHAC)
Newfoundland and Labrador (NL)	Prince Edward Island (PE)	

Canada

Date modified: 2010-10-04

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○ Initial report
○ Follow up report (Unique episode #)

REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

1a. Unique episode #: **1b. Region #:** **2. IMPACT LIN:**

3. Patient Identification

First name: Last name: Health number:

Address of usual residence:
Province/Territory: Postal code: Phone: ( ) - (ext #:)

Information Source: First name: Last name: Relation to patient:

Contact info, if different:

4. Information at Time of Immunization and AEFI Onset

4a. At time of immunization
Province/Territory of immunization: _____
Date vaccine administered: YYYY / MM / DD (hr: am/pm)
Date of birth: YYYY / MM / DD **Age:** _____
Sex: ○ Male ○ Female ○ Other

4b. Medical history (up to the time of AEFI onset)
(Check all that apply and provide details in section 10)
❑ Concomitant medication(s)
❑ Known medical conditions/allergies
❑ Acute illness/injury

4c. Immunizing agent	Trade name	Manufacturer	Lot number	Dose #	Dosage/unit	Route	Site
					/		
					/		
					/		
					/		
					/		

5. Immunization Errors

Did this AEFI follow an incorrect immunization? ○ No ○ Unknown ○ **Yes**
(If **Yes,** *choose all that apply and provide details in section 10)*
❑ Given outside the recommended age limits ❑ Product expired
❑ Wrong vaccine given ❑ Incorrect route
❑ Dose exceeded that recommended for age ❑ Other, *specify:* _____

6. Previous AEFI

Did an AEFI follow a previous dose of any of the above immunizing agents (Table 4c)?
(Choose one of the following)
○ No ○ **Yes** *(Provide details in section 10)*
○ Unknown ○ Not applicable (no prior doses)

7. Impact of AEFI, Outcome, and Level of Care Obtained

7a. Highest impact of AEFI: *(Choose one of the following)*
○ Did not interfere with daily activities
○ Interfered with but did not prevent daily activities
○ Prevented daily activities

7b. Outcome at time of report:
○ Death ♦ Date: YYYY / MM / DD ○ Permanent disability/incapacity ♦
○ Not yet recovered ♦ ○ Fully recovered ○ Unknown
(Provide details in section 10 for items with ♦)

7c. Highest level of care obtained: *(Choose one of the following)*
○ Unknown ○ None ○ Telephone advice from a health professional ○ Non-urgent visit ○ Emergency visit
○ Required hospitalization (____days) **OR** ○ Resulted in prolongation of existing hospitalization (by ____days)
Date of hospital admission YYYY / MM / DD Date of hospital discharge YYYY / MM / DD

7d. Treatment received: ○ No ○ Unknown ○ Yes *(Provide details of all treatments including self treatment, in section 10)*

8. Reporter Information

Setting : ○ **Physician office** ○ **Public health** ○ **Hospital** ○ **Other,** ***specify:*** _____
Name: Phone: ( ) - (ext #:) Fax: ( ) -
Address:
City: Prov/Terr: Postal code: Date reported: YYYY / MM / DD
Signature: _____ ○ MD ○ RN ○ IMPACT ○ Other, *specify*: _____

Note: Discuss with patient or his/her parent/caregiver reason for reporting and confidentiality of information

Canada

Unique episode #: **Region #:** **IMPACT LIN:**

9. AEFI Details: ***Complete all sections as appropriate; for each, check all signs/symptoms that apply. Item(s) with asterisk (*) should be diagnosed by a physician. If not, provide sufficient information to support the selected item(s). Use Section 10 for additional information including, clinical details and test results.***

❑ 9a. Local reaction at or near injection site

Interval: → __Min __Hrs __Days from immunization to onset of 1st symptom or sign
Duration: → __Min __Hrs __Days from onset of 1st symptom/sign to resolution of all symptoms/signs

❑ 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 10:

❑ 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

❑ 9b. Allergic and Allergic-like events

Interval: → __Min __Hrs __Days from immunization to onset of 1st symptom or sign
Duration: → __Min __Hrs __Days from onset of 1st symptom/sign to resolution of all symptoms/signs

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

For a chosen event, check all that apply below and provide details in section 10:

Skin /mucosal	❑ Urticaria ❑ Erythema ❑ Pruritis ❑ 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	❑ Diarrhea ❑ Abdominal pain ❑ Nausea ❑ Vomiting	

❑ 9c. Neurologic events

Interval: → __Min __Hrs __Days from immunization to onset of 1st symptom or sign
Duration: → __Min __Hrs __Days from onset of 1st symptom/sign to resolution of all symptoms/signs

❑ * **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 10:

❑ Depressed/altered level of consciousness, lethargy or personality change lasting ≥24hrs ❑ Focal or multifocal neurologic sign(s)
❑ Fever (≥38.0°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
○ Focal **OR** ○ Generalized (*Specify*: ○ Tonic ○ Clonic ○ Tonic-Clonic ○ Atonic)
❑ Previous history of seizures (*Specify*: ❑ Febrile ❑ Afebrile ❑ Unknown type)

❑ 9d. Other defined events of interest

Interval: → __Min __Hrs __Days from immunization to onset of 1st symptom or sign
Duration: → __Min __Hrs __Days from onset of 1st symptom/sign to resolution of all symptoms/signs

For all selected defined events of interest below, provide details in section 10:

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

❑ Persistent crying (*Continuous and unaltered crying for ≥3 hours*)

❑ * 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 ○ Localized (*Site*) _____

❑ Fever ≥38.0°C *(Note: report **ONLY** if fever occurs in conjunction with a reportable event. For fever in a neurological event, use section 9c)*

❑ Other severe or unusual event(s) not listed above

Unique episode #: **Region #:** **IMPACT LIN:**

10. Supplementary information *(Please indicate the section # when providing details. Please provide details of any investigation or treatment for the recorded AEFI).*

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11. Recommendations for future immunization(s) according to the Provincial/Territorial best practices.
(*Provide comments, use section 10 if extra space 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/MHO ○ MD ○ RN ○ Other, *specify:* _____

Comments:

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

12) Follow up information for a subsequent dose of same vaccine(s) (*Provide details in section 10)*

❑ Vaccine administered without AEFI ❑ Vaccine administered with recurrence of AEFI ❑ Vaccine administered, other AEFI observed
❑ Vaccine administered without information on AEFI ❑ Vaccine not administered