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Universal Influenza Immunization Program (UIIP) 2012-2013. Welcome Participating Pharmacies

Attention: Pharmacists Participating in UIIP 2012-2013

Date: October 22, 2012

The following information is being provided to assist you with the provision of flu vaccine to your clients.

Influenza Immunization Recommendations for the 2012-2013 Season

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There have been two NACI Statements published this year with recommendations for the 2012-2013 season:

- The National Advisory Committee on Immunization (NACI) Statement on Influenza Vaccination for the 2012-2013 Season
- A Supplemental Statement of Seasonal Influenza Vaccine for 2012-2013: New Evidence review for children 24-59 months of age.

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

Influenza Surveillance

Between September 2011 and January 2012, influenza activity was reported in Africa, the Americas, Asia, Europe and Oceania. Influenza A (H3N2) viruses were predominant in Europe, in many countries in the Americas and northern Africa and Asia. Influenza A (H1N1) pdm09 viruses circulated at very low levels in general with the exception of some countries in Asia and the Americas (including Mexico). Influenza B viruses circulated in many parts of the world and predominated in some countries including China.

While most of the viruses characterized early in 2011-12 season were antigenically related to the virus in the vaccine in the 2011-12 trivalent vaccine, there was evidence of increasing antigenic and genetic drift in the more recently circulating influenza A (H3N2) viruses and the proportion of influenza B viruses that were from the Yamagata lineage had been increasing relative to those from the Victoria lineage. The WHO therefore recommended a change in the formulation of the 2012-2013 influenza season to include an A/Victoria/361/2011 (H3N2)-like virus and a B/Wisconsin/1/2010-like virus of the Yamagata lineage, and to continue the inclusion of the an A/California/7/2099 (H1N1)pdm09-like virus.

Recommended Recipients of Influenza Vaccine for the 2012-2013 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).

***New this year - NACI has expanded the high risk groups to include children 6-59 months (rather than just 6-24).

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 2012/2013 UIIP

There are eight seasonal trivalent influenza vaccines authorized for use in Canada. For the 2012-2013 influenza season, the following vaccines are available publicly funded (free) in Ontario:

Vaccine Products	Vaxigrip® - manufactured by Sanofi Pasteur (10 dose vial)
	Agriflu® - manufactured by Novartis (single dose prefilled syringe)
	Fluad® - manufactured by Novartis (for Long Term Care Residents ≥65 years)
	Fluviral® – manufactured by GlaxoSmithKline (10 dose vial)

Vaxigrip®, Agriflu® and Fluad® contain trace amounts of neomycin. All four products are latex free. Vaxigrip® is provided in a multi-dose format (therefore contains trace amount of thimerosal as a preservative) and must be discarded 7 days after puncturing the vial. Fluviral® is also provided in a multi-dose format (therefore contains trace amount of thimerosal as a preservative) and must be discarded in 28 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), and Influvac® (single use, thimerosal free), Fluzone®, and Intanza® (intradermal delivery) are not available publicly funded through the UIIP for the 2012/2013season.

Scheduling and Dosage

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 through 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.

Individuals with an Egg Allergy

Prior to 2011-2012, 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. (Refer to this year's NACI Statement for more detailed information).

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 dose** of flu vaccine. The **two-step graded dosing** protocol is recommended for individuals who are at higher risk for severe allergic reaction. These two protocols are outlined as follows in the NACI Statement:

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.

Guillain-Barre Syndrome (GBS)

In previous NACI Statements, it was recommended that flu vaccine not be given to individuals who had developed **GBS** within 8 weeks of receiving a previous dose of influenza vaccine. This timeframe has been revised in this year's NACI Statement to within 6 weeks of receiving a previous dose of influenza vaccine.

Vaccine Ordering & Availability

Influenza vaccine will be available for pick up, from the Health Unit office nearest to your location once you have met all of the prequalification requirements. 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.

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

<u>www.simcoemuskokahealth.org</u> – information for health care providers can be found in the *Just for You* section <u>www.ontario.ca/flu</u> - 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**.

Reminder: The Health Unit also offers UIIP clinics every Wednesday and Saturday, across the County and District, in November, starting November 3. The HU has moved 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 go 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.

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 extension 8806.

Recommended Recipients of Influenza Vaccine for the 2012-2013 Season

People at high risk of influenza-related complications:

- Adults and children with underlying health conditions
- People of any age who are residents of nursing homes and other chronic care facilities
- People ≥65 years of age
- Healthy children 6 to 59 months of age
- All pregnant women
- Aboriginal peoples

People capable of spreading 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 child care to children ≤59 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 5 to 64 years without contraindication are also encouraged to receive influenza vaccine even if they are not in one of the priority groups.

Influenza Vaccine Order Form page 5

Report of Adverse Event Following Immunization Form – pages 6 -9



Pharmacy:	
Phone #:	
Fax #:	
Contact Person:	

TEL: 705-721-7520 1-877-721-7520 Fax: 705-721-1495 ATTENTION: Vaccine Order Desk

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

Please order in doses. 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 Doses
Influenza (10 doses/box)	

Location to be picked up from (please check):

□ Barrie Office □ Gravenhurst Office

- □ Orillia Office
- Collingwood Office
 Huntsville Office
 Midland Office

Cookstown Office

South Muskoka Memorial Hospital

BIOS Order # (for office use only): ____

Barrie: Collingwood: Huntsville: Midland: Cookstown: Gravenhurst: Orillia: 34 Chaffey St. 15 Sperling Drive 280 Pretty River Pkwy. 2-25 King Street S. 2-5 Pineridge Gate B-865 Hugel Ave. 120-169 Front St. S. Barrie, ON Collingwood, ON Orillia, ON Cookstown, ON Gravenhurst, ON Huntsville, ON Midland, ON L4M 6K9 L9Y 4J5 LOL 1LO P1P 1Z3 P1H 1K1 L4R 1X8 L3V 4S8 705-721-7520 705-445-0804 705-458-1103 705-684-9090 705-789-8813 705-526-9324 705-325-9565 FAX: 705-721-1495 FAX: 705-445-6498 FAX: 705-458-0105 FAX: 705-684-9887 FAX: 705-789-7245 FAX: 705-526-1513 FAX: 705-325-2091

Your Health Connection



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 <u>INITIAL</u> or <u>FOLLOW UP</u> report. For all follow up reports, please specify the <u>Unique Episode number</u>.
- 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 <a>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) British Columbia (BC) Manitoba (MB) New Brunswick (NB) Newfoundland and Labrador (NL)

Northwest Territories (NT) Nova Scotia (NS) Nunavut (NU) Ontario (ON) Prince Edward Island (PE) Quebec (QC) Saskatchewan (SK) Yukon (YT) Public Health Agency of Canada (PHAC)





O Initial report

O 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 num				
Address of usual residence: Province/Territory:		Postal code:		Phone	e:()	- (e)	<t #:<="" td=""><td>)</td></t>)
Information Source: First	name:	Last name:			Relation to	patient:		
Contact info, if different:								
4. Information at Time of I	mmunization 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: O Male O Female O 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	Manufacture	r Lot nun	nber	Dose #	Dosage/unit	Route	Site
						1		
						/		
						/		
						/		
						1		
5. Immunization Errors				6. Previo	ous AEFI			
Did this AEFI follow an incorrect immunization? O No O Unknown O Yes (If Yes, choose all that apply and provide details in section 10) Did an AEFI follow a previous dose of any of the above immunizing agents (Table 4c)? Given outside the recommended age limits Product expired Wrong vaccine given Incorrect route Dose exceeded that recommended for age Other, specify:				the				
7. Impact of AEFI, Outcom	ne, and Level of Care Ob	otained						
7a. Highest impact of AEFI: (Choose one of the following) 7b. Outcome at time of report: O Did not interfere with daily activities O Death * Date: YYYY / MM / DD O Permanent disability/incapacity * O Interfered with but did not prevent daily activities O Not yet recovered * O Fully recovered O Unknown O Prevented daily activities (Provide details in section 10 for items with *)								
7c. Highest level of care obtained: (Choose one of the following) O Unknown O None O Telephone advice from a health professional O Non-urgent visit O Emergency visit O Required hospitalization (days) OR O Resulted in prolongation of existing hospitalization (bydays) Date of hospital admission YYYY I MM I DD								
7d. Treatment received: O No O Unknown O Yes (Provide details of all treatments including self treatment, in section 10)								
8. Reporter Information								
Setting : O Physician office O Public health O Hospital O Other, specify: Name: Phone: () - (ext #:) Fax: () -								
Address: Prov/Terr: Postal code: Date reported: YYYY I MM I DD								
Signature: O MD O RN O IMPACT O Other, specify:								

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



Unique episode #	e episode #: 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 near injection					
□ Infected abscess □	Sterile a	bscess 🗅 Cellulitis 🗅 Nodule 🛛 Reaction	crosses joint Dymphadenitis DOther, specify:		
□ Swelling □ Pain Site(s) of reaction	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	s	·	n immunization to onset of 1 st symptom or sign n onset of 1 st symptom/sign to resolution of all symptoms/signs		
		aphylaxis 〇 Oculo-Respiratory Syndron I that apply below and provide details in s			
Skin /mucosal Urticaria Erythema Pruritis Prickle sensation Rash (For these events, specify site of reaction) Skin /mucosal ANGIOEDEMA: Tongue Throat Uvula Larynx Lip EYE(S): Red bilateral Eyelids Face Limbs Other, specify: Image: Constraint of the second s					
Cardio-vascular	Cardio-vascular □ Measured hypotension □ ↓central pulse volume □ Capillary refill time >3 sec □ Tachycardia □ ↓ or loss of consciousness (<i>Duration</i>)				
Respiratory	Sneezing Rhinorrhea Hoarse voice Sensation of throat closure Stridor				
Gastrointestinal		hea 🛛 Abdominal pain 🖓 Nausea 🔾			
□ 9c. Neurologic events Interval: →MinHrsDays from immunization to onset of 1 st symptom or sign Duration: →MinHrsDays from onset of 1 st symptom/sign to resolution of all symptoms/signs					
	-	lopathy/Encephalitis ❑ * Guillain-Barre Sy eurologic diagnosis, <i>specify:</i>	yndrome (GBS) □ * Bell's Palsy □ * Other Paralysis 		
		icated above, check all that apply below a	-		
□ Fever (≥38.0°C)		consciousness, lethargy or personality change □ CSF abnormality □ EEG ab			
 Neuroimaging abn 	ormality	□ Brain/spinal cord histopathologic abnorm			
•••			O Unknown		
□ Sudden loss of consciousness					
9d. Other defined	d	Interval:MinHrsDays from im			
events of interes			set of 1 st symptom/sign to resolution of all symptoms/signs		
For all selected defined events of interest below, provide details in section 10:					
	-	ve Episode (age <2 years)	□*Thrombocytopenia □ Platelet count <150x10 ⁹ /L		
		s □↓responsiveness/unresponsiveness	Petechial rash Other clinical evidence of bleeding		
■ Persistent crying (Continuous and unaltered crying for ≥3 hours)			□ Anaesthesia/Paraesthesia (□ Numbness □ Tingling		
Intussusception			□ Burning □ Formication □ Other, <i>specify</i> :) ○ Generalized ○ Localized (<i>Site</i>)		
□ Arthritis □ Joint redness □ Joint warm to touch □ Joint swelling □ Inflammatory changes in synovial fluid □ Fever >38 0°C (Note: report ONU V if fever occurs in					
		lling with pain and/or tenderness)	□ 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)		
□ Rash (Non-allergic) ○ Generalized ○ Localized (Site)			Other severe or unusual event(s) not listed above		

Unique episode #:	Region #:	IMPACT LIN:	
10. Supplementary information (<i>Please i the recorded AEFI</i>).	ndicate the section # when providing	g details. Please provide details of any investiga	ntion or treatment for
11. Recommendations for future immun (<i>Provide comments, use section 10 if extra space</i>)		cial/Territorial best practices.	
 No change to immunization schedule Expert referral, <i>specify:</i> 	 Controlled setting for next imm No further immunizations with: 		ify:
Determine protective antibody level	Active follow up for AEFI recur		
Name:		○ ○ MD ○ RN ○ Other, <i>specify:</i>	
Comments:			
Phone: () - (e	ext #:) Date: YYYY / MM	/ DD Signature:	
12) Follow up information for a subsequ	ent dose of same vaccine(s) (Pro	ide details in section 10)	
 Vaccine administered without AEFI Vaccine administered without information 			AEFI observed