

Date: August 1, 2013

ATTN: Medical Health Officers and Branch Offices
Public Health Nursing Administrators and Assistant Administrators
Holders of Communicable Disease Control Manuals

RE: Revisions to the Communicable Disease Control Manual, Chapter II Immunization Program, Section VII, Biological Products, 2013/2014 Influenza Season Product Pages

The following changes have been made to update the manual pages for the 2013/4 influenza vaccine season:

Section VII:

Page 31

The recommended strains by the World Health Organization for this season's vaccine have been updated.

The following changes have been made to the 'Recommended and provided free to the following groups' list:

- Addition of morbidly obese children and accompanying child BMI parameter, in keeping with NACI recommendations
- Updated current season indication for Aboriginal peoples (on and off reserve) pending completion of review by First Nations lead, as per Communicable Disease Policy Advisory Committee recommendation
- Updated recommendation in pregnancy to reflect that vaccine is indicated at any stage of pregnancy during the influenza season, as per Communicable Disease Policy Advisory Committee recommendation

'TIV' is used to denote 'trivalent inactivated influenza vaccine' as distinct from 'quadrivalent inactivated influenza vaccine' which is anticipated to come into use in Canada in the 2014/5 season.

Page 31a

The section on Egg Allergic Individuals has been updated to reflect anticipated changes to the NACI Influenza Statement for 2013/4. Only those who have experienced a prior severe reaction require special management, which may include allergy testing, but such individuals should be immunized only in a setting such as a medical clinic or hospital capable of managing anaphylaxis.

The section on febrile seizures following concomitant receipt of TIV and PCV13 has been removed as this signal in the data based on US surveillance of adverse events has not consistently been observed and has not resulted in recommendations for precautions.

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Page 31b

This is a title page to highlight that while the influenza vaccine pages cover all products marketed in Canada in the 2013/4 season, only the first 4 products are expected to be used in the publicly funded program in BC: FLUVIRAL®, FLUAD®, AGRIFLU®, FLUMIST®. These 4 are listed first, in the order of highest to lowest proportion of total doses expected to be distributed in BC.

The NACI Statement on Influenza Vaccine for the 2013-2014 Season has not yet been posted, but it will be available at the link(s) contained in these pages, on the PHAC NACI web site, under Recent Statements.

The vaccine –specific pages have been reformatted using our new template used since the issuance of the rabies product pages earlier in 2013, and includes the same headings in the same order on every page(s), including ‘Not applicable’ when there is no particular product specific information beyond that contained in the general recommendations for immunization section of the manual.

The following same changes have been made to all vaccine product pages:

- Included a prior episode of Guillain-Barré syndrome (GBS) with 8 weeks of receipt of a previous dose of influenza vaccine under **CONTRAINDICATIONS** instead of PRECAUTIONS for all vaccines (in 2012/3 it was listed as a precaution for FLUMIST®), and added that this is for persons ‘without another cause of GBS being identified’. We recognize that prior GBS could be considered a relative rather than an absolute contraindication. In specific circumstances, providers may, following discussion with a patient at high risk of influenza-related morbidity or mortality, choose to re-administer influenza vaccine in such circumstances. The risk of a recurrent episode of GBS in such persons is unknown. These are rare circumstances.
- Under **PRODUCT COMPONENTS**, potential allergens are listed first. Non allergenic components are listed under ‘Other components’.
- Under **PRECAUTIONS**, changed: “Those who only experience hives or gastro-intestinal symptoms after eating lightly cooked egg or egg-containing foods’ in last year’s pages to: ‘Individuals who have a severe allergic reaction to eggs should be immunized in a controlled medical setting (e.g., hospital) using inactivated influenza vaccine.’
- Under **ADVERSE EVENTS** list local events first, then systemic.
- Minimized the use of footnotes, and inserted important content into the body of the text. For instance, 2-dose recommendations for children under 9 are now listed consistently in the ‘Doses and Schedule’ sections for all products with paediatric age indications.
- Under **ADMINISTRATION** added relevant content if needed for that product, including specific details of intranasal administration for FLUMIST® and intradermal administration using the micro-injector for INTANZA®; inserted relevant content to shelf life after vial entry and short shelf life for FLUMIST®.

SPECIFIC REVISIONS TO FLUMIST® PAGE(S) 33a

Under **DOSES AND SCHEDULE** the following changes have been made given that this is the first season in which this product will be used province wide in BC with 80,000 doses planned for distribution and use in children and youth aged 2-17 years old; text is reflective of NACI and Communicable Disease Policy Advisory Committee recommendations:

2-8 years of age: 1 or 2 doses given as 0.2 mL (0.1 mL in each nostril) **intranasal spray**; this product should be preferentially offered to children in this age group.

Children under 9 years of age who have not previously received seasonal influenza vaccine require **2 doses** given 4 weeks apart. If the child has received 1 or more doses in any previous season, only a single dose is required. For children requiring 2 doses within the season, TIIV may be given interchangeably with LAIV with either product used for the 1st or 2nd dose if LAIV is not available.

9-17 years of age: 1 dose given as 0.2 mL (0.1 mL in each nostril) **intranasal spray**; this product is recommended for use in this age group and offers the advantage of needle-free administration.

18-59 years of age: 1 dose: 0.2 mL (0.1 mL in each nostril) **intranasal spray**; this product is approved for use in this age group but TIIV provides better protection against influenza; it is not provided free in the BC program for this age group.

Under **CONTRAINDICATIONS** to FLUMIST® egg allergic individuals have been added. Data supporting use of TIIV in egg allergic individuals including those with severe egg allergy do not exist for LAIV.

Under **SPECIAL CONSIDERATIONS** there are two points new from last year:

- As for other live vaccines, LAIV can be given concurrently with MMR and varicella vaccines to young children without reducing the immunogenicity or safety of any of the vaccines. If not given at the same visit, administration of live vaccines should be separated by at least four weeks to reduce or eliminate interference from the vaccine given first on the vaccine given later.

The above recommendation may differ from the NACI Statement on Influenza Vaccine for the 2013/4 Season because of lack of evidence to support that LAIV may be given any time before or after other live vaccines.

- Antiviral agents interfere with the immune response to FLUMIST®. FLUMIST® should not be administered to individuals while taking antiviral agents active against influenza (oseltamivir and zanamivir). Such individuals should receive inactivated influenza vaccine. If antiviral agents are administered from 48 hours before to 2 weeks after receipt of FLUMIST®, revaccinate when antiviral agents have been discontinued for at least 48 hours.

The above recommendation is similar to that related to antivirals effective against varicella-zoster virus and the administration of zoster vaccine, and is based on antiviral interference with replication of attenuated vaccine virus which is required to mount an effective immune response.

- No information on the effect of FLUMIST® on a TB skin test is available. It is prudent to do TB skin testing on the same day as FLUMIST® immunization, or delay TB skin testing ≥ 4 weeks, to avoid having a false negative TB skin test result. This advice is extrapolated from the experience with measles vaccine.

A similar recommendation was included in last year's FLUMIST® page but included BCG vaccine administration, which is not relevant to this issue.

Please remove and recycle the following pages from the Communicable Disease Control Manual, Chapter II Immunization Program, Section VII, Biological Products:

Dated October 2012, with the exception of FLUMIST® pages dated February 2013:

2012/2013 Seasonal Trivalent Influenza Vaccine	page 31
Safety Issues Applicable to Influenza Vaccines	page 31a-c
Influenza Vaccine (Inactivated Split Virion) (VAXIGRIP®)	page 32a
Influenza Vaccine (Inactivated Subunit, Adjuvanted with MF59C.1) (FLUAD®)	page 32b
Influenza Vaccine (Inactivated Subunit) (AGRIFLU®)	page 32c
Influenza Vaccine (Live, attenuated) (FLUMIST®)	page 33a-b
Influenza Vaccine (Inactivated Split Virion) (INTANZA®)	page 34a
Influenza Vaccine (Inactivated Subunit) (INFLUVAC®)	page 34b
Influenza Vaccine (Inactivated Split Virion) (FLUVIRAL®)	page 34c

Please insert the following pages in the Communicable Disease Control Manual, Chapter II Immunization Program, Section VII, Biological Products:

Page title and associated page number, dated August 2013

2013/2014 Seasonal Trivalent Influenza Vaccine (Inactivated and Live Attenuated).....	31
Safety Issues Applicable to Influenza Vaccines	31a
Influenza Vaccine (Inactivated Split Virion) FLUVIRAL®.....	32a
Influenza Vaccine (Inactivated Subunit, Adjuvanted with MF59C.1) FLUAD®.....	32b
Influenza Vaccine (Inactivated Subunit) AGRIFLU®	32c
Influenza Vaccine (Live attenuated influenza vaccine (LAIV)) FLUMIST®	33a
Influenza Vaccine (Inactivated Split Virion) VAXIGRIP®.....	34a
Influenza Vaccine (Inactivated Split Virion) INTANZA®.....	34b

Influenza Vaccine (Inactivated Subunit) INFLUVAC® 34c

If you have any questions or concerns, please contact me or Karen McColgan (and starting August 19th, Brittany Deeter), Public Health Resource Nurse, at telephone (604) 707-2577, fax (604) 707-2515 or by email at monika.naus@bccdc.ca, karen.mccolgan@bccdc.ca or brittany.deeter@bccdc.ca

Sincerely,



Monika Naus, MD MHS Sc FRCPC FACPM
Medical Director
Immunization Programs and Vaccine Preventable Diseases Service
BC Centre for Disease Control

cc: BC Ministry of Health:

Dr. Perry Kendall
Provincial Health Officer

Dr. Eric Young
Deputy Provincial Health Officer

Craig Thompson
Director, CD Prevention – Immunization

Warren O'Briain
Executive Director
Communicable Disease and Addiction Prevention