# STANDARD NURSE PROTOCOLS FOR PREVENTION OF SEASONAL INFLUENZA

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#### STANDARD NURSE PROTOCOL FOR PREVENTION OF SEASONAL INFLUENZA

**DEFINITION** Seasonal Influenza is a contagious respiratory illness caused by influenza viruses. It can cause mild to severe illness, and at times can lead to death. Every year in the United States, on average:

- 5% to 20% of the population gets seasonal influenza;
- more than 200,000 people are hospitalized from influenzarelated complications; and
- about 36,000 people die from influenza-related causes.

Influenza viruses cause disease among persons in all age groups. Rates of infection are highest among children, but the risks for complications, hospitalizations, and deaths from influenza are higher among persons aged 65 years and older, young children, and persons of any age who have medical conditions that place them at increased risk for complications from influenza. Flu Complications include; pneumonia bronchitis and sinus and ear infections. The flu can make chronic health problems worse. For example, people with asthma may experience asthma attacks while they have the flu, and people with chronic congestive heart failure may have worsening of this condition that is triggered by the flu.

#### ETIOLOGY

There are two main types of influenza (flu) virus: Types A and B. There is also a C type; however it causes only mild upper respiratory illness, and is not associated with flu epidemics. Influenza A and B viruses are responsible for seasonal flu epidemics each year. Influenza A viruses can be broken down into sub-types. Over the course of a flu season, different types (A & B) and subtypes of influenza A viruses can circulate and cause illness. Influenza A viruses are divided into subtypes based on two proteins on the surface of the virus: the hemagglutinin (H) and the neuraminidase (N). There are 16 different hemagglutinin subtypes and 9 different neuraminidase subtypes, Influenza A viruses can be further broken down into different strains. The current subtypes of influenza A viruses of influenza A viruses found in people are A (H1N1) and A (H3N2).

In addition, influenza viruses are constantly changing through a process called "antigenic drift." These are small changes in the virus that happen continually over time. Antigenic drift produces new virus strains that may not be recognized by the body's immune system. This process works as follows: a person infected with a particular flu virus strain develops antibody against that virus. As newer virus strains appear, the antibodies against the older strains no longer recognize the "newer" virus, and re-

infection can occur. This is the primary reason that people can get the flu more than once. In most years, one or two of the three virus strains in the influenza vaccine are updated to keep up with the changes in the circulating flu viruses. Therefore, in order to be protected from flu, individuals need to have a flu shot every year.

The other type of change that occurs in influenza viruses is called "antigenic shift." Antigenic shift is an abrupt, major change in the influenza A viruses, resulting in new hemagglutinin and/or new hemagglutinin and neuraminidase proteins in those influenza viruses that infect humans. Shift results in a new influenza A subtype. When shift happens, most people have little or no protection against the new virus. While influenza viruses are changing by antigenic drift all the time, antigenic shift happens only occasionally. Type A viruses undergo both kinds of changes; influenza type B viruses change only by the more gradual process of antigenic drift.

Influenza B viruses are not divided into subtypes. Influenza B viruses also can be further broken down into different strains.

# 2013-14 U.S. trivalent influenza vaccines will contain an A/California/7/2009 (H1N1)-like virus, an H3N2 virus antigenically like the cell-propagated prototype virus A/Victoria/361/2011, and a B/Massachusetts/2/2012-like virus. Quadrivalent vaccines will include an additional vaccine virus, a B/Brisbane/60/2008-like virus.

Influenza viruses are spread from person to person primarily through large-particle respiratory droplet transmission (e.g., when an infected person coughs or sneezes near a susceptible person). Transmission via large-particle droplets requires close contact between source and recipient persons, because droplets do not remain suspended in the air and generally travel only a short distance (less than or equal to 1 meter) through the air. Contact with respiratory-droplet contaminated surfaces is another possible source of transmission. Airborne transmission (via small-particle residue [less than or equal to  $5\mu$ m] of evaporated droplets that might remain suspended in the air for long periods of time) also is thought to be possible, although data supporting airborne transmission are limited.

In the United States, annual epidemics of influenza typically occur during the fall or winter months, but the peak of influenza activity can occur as late as April or May.

#### SUBJECTIVE/ OBJECTIVE

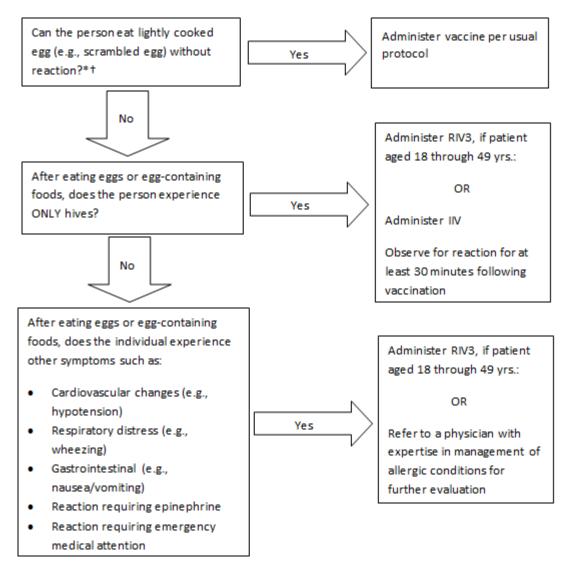
- 1. May or may not report history of exposure to an individual known to have seasonal influenza.
- 2. Denies any contraindications to flu vaccine (Refer to Figure 2).

- 3. Denies severe reaction to an influenza vaccination or components in vaccine such as thimerosal or any antibiotic used in the formulation.
- 4. Denies anaphylactic reaction to latex. Latex in some pre-filled syringes flu presentations (e.g., Fluvirin®, Fluarix®, Fluarix Quadrivalent® and Flucelvax®)
- 5. Denies any allergies to eggs or egg products. (Refer to Figure 1).

Note on abbreviations: This document includes revised abbreviations to refer to currently available influenza vaccines. Specifically:

- The former abbreviation TIV (Trivalent Inactivated Influenza Vaccine, previously used for inactivated influenza vaccines) has been replaced with the new abbreviation IIV (Inactivated Influenza Vaccine). For 2013-14, IIVs as a class will include:
  - egg-based and cell culture-based trivalent inactivated influenza vaccines (IIV3), and
  - egg-based quadrivalent inactivated influenza vaccine (IIV4).
- RIV refers to recombinant hemagglutinin influenza vaccine, available as a trivalent formulation (RIV3) for 2013-14;
- LAIV refers to live-attenuated influenza vaccine, available as a quadrivalent formulation (LAIV4) for 2013-14.
- LAIV, IIV, and RIV denote vaccine categories; numeric suffix specifies the number of antigens in the vaccine.
- Where necessary to refer specifically to cell culture-based vaccine, the prefix "cc" is used (e.g., "ccllV3").

### Figure 1. Recommendations regarding influenza vaccination of persons who report allergy to eggs: Advisory Committee on Immunization Practices, United States, 2013-14 Influenza season.



IIV=Inactivated Influenza Vaccine; RIV3=Recombinant Influenza Vaccine, Trivalent

\*Individuals with egg allergy may tolerate egg in baked products (e.g. bread, cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy.

† For individuals who have no known history of exposure to egg, but who are suspected of being egg-allergic on the basis of previously performed allergy testing, consultation with a physician with expertise in the management of allergic conditions should be obtained prior to vaccination. Alternatively, RIV3 may be administered if the recipient is aged 18 through 49 years.

#### Influenza Vaccination of Persons with a History of Egg Allergy

- 1. Persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine. Because relatively little data are available for use of LAIV in this setting, IIV or RIV should be used. RIV is eggfree and may be used for persons aged 18-49 years who have no other contraindications. However, IIV (egg- or cell-culture based) may also be used, with the following additional safety measures (Figure 1):
  - 1. Vaccine should be administered by a healthcare provider who is familiar with the potential manifestations of egg allergy; and
  - 2. Vaccine recipients should be observed for at least 30 minutes for signs of a reaction after administration of each vaccine dose.
- 2. Persons who report having had reactions to egg involving such symptoms as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention may receive RIV3, if aged 18 through 49 years and there are no other contraindications. If RIV3 is not available or the recipient is not within the indicated age range, such persons should be referred to a physician with expertise in the management of allergic conditions for further risk assessment before receipt of vaccine (Figure 1).
- 3. All vaccines should be administered in settings in which personnel and equipment for rapid recognition and treatment of anaphylaxis are available.
- 4. Some persons who report allergy to egg might not be egg-allergic. Those who are able to eat lightly cooked egg (e.g., scrambled egg) without reaction are unlikely to be allergic. Egg-allergic persons might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy (2). Egg allergy can be confirmed by a consistent medical history of adverse reactions to eggs and egg-containing foods, plus skin and/or blood testing for immunoglobulin E antibodies to egg For individuals who have no known history of exposure to egg, but who are suspected of being egg-allergic on the basis of previously performed allergy testing, consultation with a physician with expertise in the management of allergic conditions should be obtained prior to vaccination (Figure 1). Alternatively, RIV3 may be administered if the recipient is aged 18 through 49 years.
- 5. A previous severe allergic reaction to influenza vaccine, regardless of the component suspected to be responsible for the reaction, is a contraindication to future receipt of the vaccine.

### Figure 2. CONTRAINDICATIONS/ PRECAUTIONS to Seasonal Influenza Vaccine 2013-2014

2013-2014		I
Vaccine	Contraindications	Precautions
IIV (includes IIV3, IIV4, and ccIIV)	History of severe allergic reaction to any component of the vaccine, including egg protein, or after previous dose of any influenza vaccine.	Moderate to severe illness with or without fever. History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.
RIV	History of severe allergic reaction to any component of the vaccine.	Moderate to severe illness with or without fever. History of Guillain- Barré syndrome within 6 weeks of receipt of influenza vaccine.
LAIV	<ul> <li>History of severe allergic reaction to any component of the vaccine, including egg protein, gentamicin, gelatin, and arginine, or after a previous dose of any influenza vaccine;</li> <li>Concomitant Aspirin therapy in children and adolescents. In addition, ACIP recommends against use in the following: <ul> <li>Children aged 24 years whose parents or caregivers report that a health-care provider (HCP) has told them during the preceding 12 months that their child had wheezing or asthma or whose medical record indicates a wheezing episode has occurred during the preceding 12 months;</li> <li>Persons with asthma;</li> <li>Children and adults who have chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic/neuromuscular, hematologic, or metabolic disorders;</li> </ul> </li> </ul>	Moderate to severe illness with or without fever. History of Guillain- Barré syndrome within 6 weeks of receipt of influenza vaccine.

<ul> <li>immunosuppression (including immunosuppression caused by medications or by HIV);</li> <li>Persons with egg allergy;</li> <li>Close contacts and caregivers of severely immunosuppressed persons who require a protected environment;</li> <li>Pregnant women</li> </ul>	
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IIV=Inactivated Influenza Vaccine; IIV3=Inactivated Influenza Vaccine, Trivalent; IIV4=Inactivated

Influenza Vaccine, Quadrivalent; RIV=Recombinant Influenza Vaccine LAIV=Live-Attenuated

Influenza Vaccine; IM=intramuscular; ID=intradermal; IN=intranasal.

\* Immunization providers should check Food and Drug Administration--approved information for

2013--14 influenza vaccines for the most complete and updated information, including (but not limited

to) indications, contraindications, and precautions. Package inserts for US-licensed vaccines are available at

http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm.

#### ASSESSMENT No contraindications Candidate for seasonal influenza vaccine

PLAN The plan is focused on prevention of seasonal influenza

#### MATERIALS NEEDED

- Needles
- Seasonal Influenza Vaccine
- Syringes
- Alcohol swabs
- Gloves
- Biohazard disposal container
- Hand hygiene supplies
- Emergency drugs, supplies and protocols
- Certified calibrated thermometer
- Cooler and cold packs
- VIS for influenza vaccine
- Patient Consent Forms
- Patient education materials

#### **DIAGNOSTIC STUDIES**

Rapid Test is not recommended. The focus should be on prevention.

#### THERAPEUTIC PHARMACOLOGIC Vaccination (Proventio

#### Vaccination (Prevention)

The primary option for reducing the effect of influenza is immunoprophylaxis. Vaccinating persons at high risk for complications and their contacts each year before seasonal increases in influenza virus circulation is the most effective means of reducing effects of influenza. It is associated with reduction in influenza-related respiratory illness, hospitalization and death.

Administer seasonal influenza vaccine in accordance with the tables:

- Recommended Influenza Vaccine Schedule;
- Recommended Dosages & Intervals; and
- Recommended Dosage and Route.

#### Primary Changes and Updates in the Recommendations

- Routine annual influenza vaccination of all persons aged 6 months and older continues to be recommended.
- Several new, recently-licensed vaccines will be available for the 2013-14 season, and are acceptable alternatives to other licensed vaccines indicated for their respective age groups when otherwise appropriate:
  - A quadrivalent live attenuated influenza vaccine (LAIV4; Flumist® Quadrivalent [MedImmune]) is expected to replace the trivalent (LAIV3) formulation. FluMist® Quadrivalent is indicated for healthy, nonpregnant persons aged 2 through 49 years;
  - A quadrivalent inactivated influenza vaccine (IIV4; Fluarix® Quadrivalent [GlaxoSmithKline]) will be available, in addition to the previous trivalent formulation. Fluarix® Quadrivalent is indicated for persons aged 3 years and older;
  - A quadrivalent inactivated influenza vaccine (IIV4; Fluzone® Quadrivalent [Sanofi Pasteur]) will be available in addition to the previous trivalent formulation. Fluzone® Quadrivalent is indicated for persons aged 6 months and older;
  - A trivalent cell culture-based inactivated influenza vaccine (ccIIV3; Flucelvax® [Novartis]), which is indicated for persons aged 18 years and older; and
  - A recombinant hemagglutinin (HA) vaccine (RIV3; FluBlok® [Protein Sciences]), which is indicated for persons aged 18 through 49 years.
- Within approved indications and recommendations, no preferential recommendation is made for any type or brand of licensed influenza vaccine over another.

Recommended Doses & Intervals <sup>1</sup>					
Vaccine	Age Group	Dosage & Route	Number of Doses	Minimum Interval from dose 1 to 2	Pregnancy Category
	Inactivat	ted Influenza v	accine, Triva		
Fluzone®	6-35 months	0.25 mL IM	1 or 2	28 days	
	3 through 8 years	0.5 mL IM	1 or 2	28 days	
	Greater than or equal to 9 years	0.5 mL IM	1		С
Fluzone <sup>®</sup> High Dose	Greater than or equal to 65 years	0.5 mL IM	1		
Fluzone® Intradermal	18 through 64 years	Intradermal 0.1 mL	1		В
	4 through 8 years	0.5 mL IM	1 or 2	28 days	
Fluvirin®	Greater than or equal to 9 years	0.5 mL IM	1		С
	3 through 8 years	0.5 mL IM	1 or 2	28 days	
Fluarix <sup>®</sup>	Greater than or equal to 9 years	0.5 mL IM	1		В
FluLaval®	3 through 8 years	0.5 mL IM	1 or 2	28 days	
	Greater than or equal to 9 years	0.5 mL IM	1		В
Afluria <sup>®6</sup>	9 years of age and older	0.5 mL IM	1		В
Flucelvax <sup>®</sup>	18 years of age and older	0.5 mL IM	1		В

Vaccine Age Group	Dosage & Route	Number of Doses	Minimum Interval from dose 1 to 2	-
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	Inactivate	Inactivated Influenza Vaccine, Quadrivalent (IIV4)					
eurosia ®	3 through 8 years	0.5 mL IM	1 or 2	28 days			
Fluarix <sup>®</sup> Quadrivalent	Greater than or equal to 9 years	0.5 mL IM	1		В		
FluLaval®	3 through 8 years	0.5 mL IM	1 or 2	28 days			
Quadrivalent	Greater than or equal to 9 years	0.5 mL IM	1		В		
	6months through 35 months	0.25 mL IM	1 or 2	28 days			
Fluzone <sup>®</sup> Quadrivalent	36 months through 8 years	0.5 mL IM	1 or 2		с		
	Greater than or equal to 9 years and older	0.5 mL IM	1				

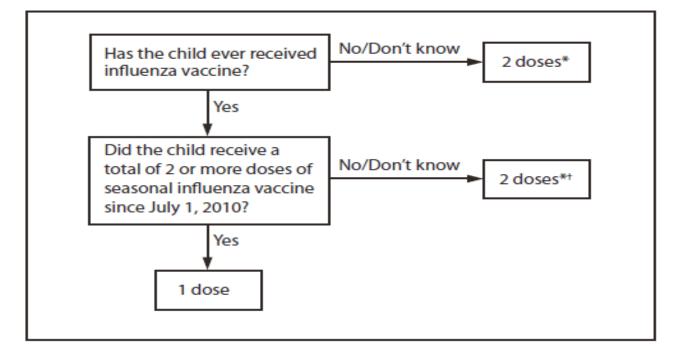
		Dosage &	Number of	Minimum interval	Pregnancy
Vaccine	Age Group	Route	Doses	from dose 1 to 2	Category
Recombinant Influenza Vaccine Trivalent (RIV3)					
Flublok <sup>®</sup>	18 through 49 years	0.5mL IM	1		В
	Live /	Attenuated Infl	uenza Vaccin	e (LAIV4)	
FluMist <sup>® 3</sup>	Greater than or equal to 24 months through 8 years	0.2 mL Intranasal	1 or 2	28 days	Do not use
FluMist <sup>® 5</sup>	Greater than or equal to 9 years through 49 years of age	0.2 mL intranasal	1		in pregnancy
IIV=Inactivate	d Influenza Vaccine;	IIV3=Inactivated	d Influenza Vac	cine, Trivalent; IIV4=Ina	ictivated
Influenza Vac	cine, Quadrivalent; R	IV=Recombinar	it Influenza Vac	cine LAIV=Live-Attenua	ited Influenza
Vaccine; IM=ir	ntramuscular; ID=intr	adermal; IN=intr	anasal.		
infants and you length for intran	ng children is the anter nuscular administration	olateral aspect of may be found in	the thigh. Specif the ACIP Generation	ne deltoid muscle. The pre ic guidance regarding site al Recommendations on Ir administered using the del	and needle nmunization [4].
included with th			y intradermaris a	administered using the dei	ivery system
<sup>3</sup> FluMist® is shipped refrigerated and stored in the refrigerator at 35°F46°F (2°C8°C) after arrival in the vaccination clinic. The dose is 0.2 mL divided equally between each nostril. Health-care providers should consult the medical record, when available, to identify children aged 24 years with asthma or recurrent wheezing that might indicate asthma. In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving LAIV, parents or caregivers of children aged 24 years should be asked: "In the past 12 months, has a health-care provider ever told you that your child had wheezing or asthma?" Children whose parents or caregivers answer "yes" to this question and children who have asthma or who had a wheezing episode noted in the medical record within the past 12 months should not receive FluMist®.					
<sup>5</sup> Flumist® is indicated for healthy, non-pregnant persons aged 2-49 years. Individuals who care for severely immunosuppressed persons who require a protective environment should not receive FluMist given the theoretical risk of transmission of the live attenuated vaccine virus.					
aged 6 months 2010 Southern available for a c complications,	through 8 years becau Hemisphere IIV3. If no child aged 58 years w Afluria® can be used; h uenza vaccination with	se of increased rig other age-approp ho has a medical nowever, providers	sk of febrile react priate, licensed in condition that inc s should discuss	nmends Afluria® not be us tions noted in this age gro activated seasonal influen creases the child's risk for with the parents or caregi vaccine. Afluria® may be	up with CSL's za vaccine is influenza vers the benefits

CDC, Summary\* Recommendations: Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices— (ACIP)—United States, 2013-14

<a href="http://www.cdc.gov/flu/professionals/acip/2013-summary-recommendations.htm">http://www.cdc.gov/flu/professionals/acip/2013-summary-recommendations.htm</a> (8/30 2013).

Pregnancy Risk Categories				
А	Controlled studies in pregnant women fail to demonstrate a risk to the fetus in the first trimester with no evidence of risk in later trimesters. The possibility of fetal harm appears remote.			
В	Either animal-reproduction studies have not demonstrated a fetal risk but there are not controlled studies in pregnant women, or animal-reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester and there is no evidence in later trimesters.			
С	Either studies in animals have revealed adverse effects on the fetus and there are no controlled studies in women, or studies in women and animals are not available. Drugs should be given only if the potential benefits justify the potential risk to the fetus.			
D	There is positive evidence of human fetal risk, but the benefits from use in pregnant may be acceptable despite the risk (e.g., if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective).			
x	Studies in animals or humans beings have demonstrated fetal abnormalities or there is evidence of fetal risk based on human experience, or both, and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit. The drug is contraindicated in women who are or may become pregnant.			

Figure 3. Influenza vaccine dosing algorithm for aged children 6 months through 8 years — Advisory Committee on Immunization Practices, United States, 2013–14 influenza season



\* Doses should be administered at least 4 weeks apart.

+ For simplicity, this algorithm takes into consideration only doses of seasonal influenza vaccine received since July 1, 2010. As an alternative approach in settings where vaccination history from before July 1, 2010, is available, if a child aged 6 vaccine (i.e., 2010–11, 2011–12, or 2012-13 seasonal vaccine or the monovalent 2009[H1N1] vaccine), then the child needs only 1 dose for 2013–14. Using this approach, children aged 6 months through 8 years need only 1 dose of vaccine in 2013–14 if they have received any of the following: 1) 2 or more doses of seasonal influenza vaccine since July 1, 2010; 2) 2 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of monovalent 2009(H1N1) vaccine; or 3) 1 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of seasonal influenza vaccine since July 1, 2010. Children in this age group for whom one of these conditions is not met require 2 doses in 2013–2014.

#### Recommended Dosage and Route

0.25 mL or 0.5 mL administered intramuscularly for IIV. For adults and older children, the recommended site of vaccinations is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh. \*

0.1mL administered intradermally for IIV\*\* 0.2 mL administered intranasally for LAIV\*\*\*

\*Please refer to the Georgia Immunization Program Manual Chapter 13 (Quality Assurance-Attachment D) on vaccine administration recommendations for appropriate site and needle size.

\*\*See package insert on Fluzone Intradermal Influenza Vaccine at <u>http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM195479.p</u> <u>df</u> For administration instructions.

\*\*\* **NOTE:** Before using the nasal spray, gently blow your nose to clear the nostrils. If the vaccine recipient sneezes after administration, the dose should not be repeated. However, if nasal congestion is present that might impede delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration should be considered until resolution of the illness, or TIV should be administered instead.

#### Simultaneous Vaccine Administration

May be administered simultaneously with any of the following routinely recommended vaccines: DTaP, Tdap, Td, RV, MMR, Varicella, Hib, Hepatitis A, Hepatitis B, IPV, PPSV23, PCV13, HPV, Zoster, MCV4, and MPSV4

**NOTE**: See current ACIP statement regarding FluMist® and simultaneous administration with other vaccines. See package insert for the safety and immunogenicity of this practice.

#### PATIENT EDUCATION/COUNSELING

- 1. Provide the current Vaccine Information Sheet to the patient, guardian, or caretaker prior to immunization and answer any questions related to the vaccine prior to giving the immunization.
- 2. Emphasize that inactivated influenza vaccine contains noninfectious killed viruses and cannot cause influenza.
- 3. Coincidental respiratory disease unrelated to influenza vaccination can occur after vaccination.
- 4. If two doses are required to achieve immunity, arrange for information about need for second dose and stress importance of second dose of vaccine.
- 5. Stress the importance of hand hygiene.
- 6. Support staying at home if ill.
- 7. Pregnant and postpartum women do not need to avoid contact with persons recently vaccinated with LAIV
- 8. Persons receiving antiviral drugs within the period 2 days before to 14 days after vaccination with LAIV should be revaccinated at a later date with any approved vaccine formulation
- 9. Individuals who care for the severely immunocompromised (those living in a protective environment) should receive either IIV or RIV3.

#### FOLLOW UP

Patients who do not have regularly scheduled visits during the fall should be reminded by mail, telephone or other means of the need for vaccination. Use the reminder recall system on GRITS immunization registry.

#### CONSULTATION/REFERRAL

Refer to physician for complications of influenza, and/or history of Guillain-Barré Syndrome.

#### REFERENCES

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- 2. CDC, Key Facts About Seasonal Influenza (Flu), <a href="http://www.cdc.gov/flu/keyfacts.htm">http://www.cdc.gov/flu/keyfacts.htm</a>> (September 26, 2013).
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- 9. Intradermal Influenza (Flu) Vaccination <<u>http://www.cdc.gov/flu/protect/vaccine/ga\_intradermal-vaccine.htm</u>>
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- 12. Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)-United States, 2013-2014 Influenza Season September 20, 2012, Vol. 62 (RR07)
- 13. CDC. ACIP adult immunization schedule, United States, 2013 (available at <<u>http://www.cdc.gov/vaccines/schedules/hcp/adult.html</u>>)

#### INTERIM STANDARD NURSE PROTOCOL AGREEMENT AND SIGNATURE PAGE FOR THE 2014 - 2015 PREVENTION OF SEASONAL INFLUENZA

**NOTE:** This protocol agreement and signature page should be used as a template by health districts for administering new Advisory Committee on Immunization Practices recommended vaccine presentations for the 2014-2015 Influenza season. As the Department of Public Health, Immunization Program awaits the Advisory Committee on Immunization Practices recommendations and guidance to develop the 2014-2015 Prevention of Seasonal Influenza nurse protocol, health districts may use this template to develop a nurse protocol based on the manufacturer's drug information (i.e., package inserts) to expedite the process of immunizing individuals against influenza.

This interim protocol indicates a mutual agreement and understanding between the delegating physician(s) and the registered professional nurse(s) (RNs) and/or advanced practice registered nurses (APRNs) that the undersigned individuals are authorized to administer, order, and dispense Seasonal Influenza vaccine as listed below in accordance with the Advisory Committee on Immunization Practices recommendations and manufacturer's drug information attached to this signature page for each of the vaccines listed:

VACCINES TO BE ADMINISTERED:

For the following populations (i.e., adult, children greater than 5 years of age, pregnant women):

1.\_\_\_\_\_

For the following indications listed:

1.\_\_\_\_\_ 2.\_\_\_\_\_

(List the Specific Vaccine to be administered and attach the Drug Manufacturer's Insert and the Advisory Committee on Immunization Practices recommendations for each):

1.\_\_\_\_\_ 2.\_\_\_\_\_

VACCINES TO BE ORDERED AND DISPENSED

For the following populations (i.e., adult, children greater than 5 years of age, pregnant women):

1.\_\_\_\_\_ 2.\_\_\_\_\_

For the following indications listed:

1.\_\_\_\_\_ 2.\_\_\_\_\_ (List Vaccines to be Ordered and Dispensed and Attach the Drug Manufacturer's Insert and the Advisory Committee on Immunization Practices recommendations for each):

1.\_\_\_\_\_ 2.

NOTE: The Advisory Committee on Immunization Practices recommends that vaccine recipients be observed for at least 15 minutes for signs of reaction after administration of each seasonal influenza vaccine dose. For those vaccine recipients with a history of egg allergy a 30 minute observation time is recommended.

The delegating physician, RNs and APRNs whose signatures appear on this signature page agree that the RNs and APRNs:

- 1. Have been adequately trained and are prepared to perform the delegated medical acts contained in the designated nurse protocols; such training is documented in the nurses' personnel/supervisory files.
- 2. Have read and understand all statutes, rules and regulations pertaining to nursing practice under nurse protocol and have read and understand the drug dispensing procedure.
- 3. Have been given an opportunity to have questions answered.
- 4. Record reviews by the delegating physician(s) must be completed at least once annually. Ideally, it is preferred that record reviews be completed on a quarterly basis throughout each year in order to identify strengths and opportunities for improvement a in a timely manner.
- 5. This authorization/agreement shall terminate upon release of the 2014- 2015 Prevention of Seasonal Influenza Nurse Protocol by the Department of Public Health.

Signature of Delegating Physician	Date
Signature of RN or APRN	Date
Signature of RN or APRN	Date
Signature of RN or APRN	Date
Signature of RN or APRN	Date

## STANDARD NURSE PROTOCOLS FOR PERINATAL HEPATITIS B

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#### 2013-2014 PERINATAL HEPATITIS B CONTACTS CLINICAL REVIEW COMMITTEE

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#### STANDARD NURSE PROTOCOL FOR PERINATAL HEPATITIS B CONTACTS

DEFINITION Hepatitis B is a contagious liver disease that results from infection with the hepatitis B virus. When first infected, a person can develop an "acute" infection, which can range in severity from a very mild illness with few or no symptoms to a serious condition requiring hospitalization. Acute hepatitis B refers to the first 6 months after someone is infected with the hepatitis B virus. Some people are able to fight the infection and clear the virus. For others, the infection remains and leads to a "chronic," or lifelong, illness. Chronic hepatitis B refers to the illness that occurs when the hepatitis B virus remains in a person's body. Over time, the infection can cause serious health problems.

> Hepatitis B is usually spread when blood, semen, or other body fluids from a person infected with the hepatitis B virus enter the body of someone who is not infected. This can happen through sexual contact with an infected person or sharing needles, syringes, or other injection drug equipment. Hepatitis B can also be passed from an infected mother to her baby at birth.

> Hepatitis B is not spread through breastfeeding, sharing eating utensils, hugging, kissing, holding hands, coughing, or sneezing. Unlike some types of hepatitis, hepatitis B is not spread by contaminated food or water.

- ETIOLOGY Hepatitis B virus (HBV)
- SUBJECTIVE 1. May have a history of exposure at birth to a HBV-infected mother
  - 2. May have a history of close (household/sexual) contact with a HBV-infected person
  - 3. May have experienced or is experiencing symptoms listed below. Not everyone has symptoms with acute Hepatitis B, especially young children. Symptoms usually appear within 2 to 3 months (Range: 45-180 days) of exposure. Symptoms can last from a few weeks to several months and include:
    - a. Fever
    - b. Fatigue
    - c. Loss of appetite

- d. Nausea
- e. Vomiting
- f. Abdominal pain
- g. Grey-colored stools
- h. Dark urine
- i. Joint and/or muscle pain
- j. Jaundice
- OBJECTIVE History of exposure to an HBV-infected mother at birth or through close household contact.
- ASSESSMENT Exposure to hepatitis B viral infection
- PLAN MANAGEMENT OF EXPOSED INFANTS

For infants that were exposed to HBV at birth:

- Ensure that Hepatitis B Immune Globulin (HBIG) and hepatitis B vaccine were given to the child prior to hospital discharge if the child is less than 7 days old.
- Verify child's hepatitis B immunization record in GRITS. Administer any needed doses using the current year's Advisory Committee on Immunization Practices (ACIP) schedule.
- Conduct post-vaccination serologic testing (HBsAg & anti-HBs) at 9 months of age. The child must be at least 9 months and have not received a hepatitis B vaccine in the previous 30 days.

#### **DIAGNOSTIC STUDIES**

For infants and children born to a HBV-infected mother, order hepatitis B surface antigen (HBsAg) and hepatitis B surface antibody (anti-HBs) serology. Infants must be at least 9 months of age and have not received hepatitis B immunization less than 30 days prior to lab testing. NOTE: Draw blood before administering the dose of hepatitis B vaccine and hepatitis B immune globulin (HBIG) to avoid a temporary HBsAgpositive result (transient antigenemia).

#### **Specimen Collection**

Refer to the most current version of the Georgia Public Health Laboratory (GPHL) Manual at <u>http://dph.georgia.gov/lab</u>. Hepatitis B testing is performed by the Microbial Immunology Unit. GPHL can be contacted at 404-327-7970.

• Obtain the specimen via venipuncture using the appropriate

gauge needle (e.g. 23-25 gauge butterfly needle)

- Hepatitis B testing requires approximately six milliliters (one tube) of whole blood (for serum) in a red-top tube (no additive) or serum separator tube (SST).
- Centrifugation of specimen is requested.
- Invert specimen in serum separator tube (SST) 5 times to ensure distribution of the clot activator within sample, and allow it to clot for 30 minutes in vertical position before centrifugation.
- Red-top tubes (non-SST) should be allowed to clot for 60 minutes in vertical position before centrifugation.

#### Laboratory Requisition Form

Refer to the most current version of the Georgia Public Health Laboratory (GPHL) Manual to obtain the current laboratory requisition form. This information is available online at <u>http://dph.georgia.gov/lab</u> (see Infectious Disease Serology section).

NOTE: Hepatitis Testing is located under Immunology. Select Hep B (Routine Screen) under the hepatitis testing section. The panel consists of hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (anti-HBs) and hepatitis B core antibody (anti-HBc).

#### Test Result Interpretation

Hepatitis B surface antigen (HBsAg) is a protein on the surface of the hepatitis B virus. It can be detected in the blood during acute or chronic hepatitis B virus infection. The body normally produces antibodies to HBsAg as part of the normal immune response to infection, unless chronic infection occurs.

- Positive/Reactive test result means: The person has an acute or chronic hepatitis B virus infection and can pass the virus to others.
- Negative/Non-Reactive test result means: The person does not have the hepatitis B virus in his or her blood.

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Hepatitis B surface antibody (anti-HBs) is an antibody that is produced by the body in response to the hepatitis B surface antigen.

• Positive/Reactive test result means:

The person is protected or immune from the hepatitis B virus for one of two reasons: he or she was successfully vaccinated against hepatitis B. OR he or she recovered from an acute infection (and cannot get

he or she recovered from an acute infection (and cannot get hepatitis B again)

 Negative/Non-Reactive test result means: A person does not have immunity against hepatitis B virus.

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Hepatitis B core antibody (anti-HBc) is an antibody that does not provide any protection or immunity against HBV.

- Positive/Reactive test result means: The person may have current or past infection with the hepatitis B virus. A positive result does NOT mean the person is protected from HBV.
- Negative/Non-Reactive test result means: The person does not have current or past infection with the hepatitis B virus.

NOTE: The anti-HBc result should be disregarded for children less than 24 months of age who were exposed to HBV at birth. The mother's maternal antibody can be detected in the child's blood up to 24 months after birth.

#### THERAPEUTIC

#### POST-EXPOSURE PROPHYLAXIS (PEP)

- 1. Infants born to hepatitis B surface antigen-positive women should receive Hepatitis B Immune Globulin (HBIG) and hepatitis B vaccine within 12 hours of birth.
- 2. Infants that are discharged from the delivery hospital prior to hepatitis B immune globulin (HBIG) administration should be referred to the delivery hospital for immediate HBIG administration. HBIG can be administered up to 7 days after birth.

- 3. HBIG may be administered simultaneously with hepatitis B vaccine but in a different injection site.
- 4. HBIG is administered by intramuscular injection. For infants, HBIG should be administered intramuscularly in the anterolateral thigh using a 22--25-gauge needle that is <sup>7</sup>/<sup>8</sup>"--1" in length. For older children and adolescents, an appropriate muscle mass (i.e., deltoid gluteal) should be chosen in which to deliver the larger volumes of HBIG required for these age groups by using a needle length appropriate for the person's age and size.
- 5. Vaccination with certain live-virus vaccines (measles, mumps, rubella, and varicella) should be deferred for at least 3 months after administration of HBIG because HBIG can inhibit the response to these vaccines.

#### PHARMACOLOGIC

Formulation	Dose	Route	Frequency	Duration
Infant (birth-12 months)	0.5 mL	Intramuscularly in vastus lateralis (anterolateral thigh)	One time	N/A
Children ≥ 12 months	0.06 mL/kg	Intramuscularly	One time	N/A

Drug Name: Hepatitis B Immune Globulin (HBIG) Trade Name(s): HepaGam B®, HyperHEP B®, Nabi-HB®

#### Drug Name: Hepatitis B Vaccine

Trade Name(s): Comvax®, Engerix-B®, Pediarix®, Recombivax HB®

Formulation	Dose	Route	Frequency	Duration
Pediatric/adolescen	0.5	Intramuscularly	One time	N/A
t	mL			

#### **IMMUNIZATION**

1. Infants and children of hepatitis B-infected mothers should follow

the Advisory Committee on Immunization Practices (ACIP) Recommended Immunization Schedule for Persons 0 Through 6 Years for the current year.

NOTE: Infants whose mothers are HBsAg-positive should receive the last (third or fourth) dose by 6 months of age (12 to 15 months if Comvax is used).

- 2. The anterolateral thigh muscle is the recommended site of administration for the hepatitis B vaccine for neonates (aged <1 month) and infants (aged 1--12 months). For toddlers (aged 1--2 years) and older children, either the anterolateral thigh or the deltoid muscle may be used if the muscle mass is adequate. The deltoid muscle is the preferred site of administration for adolescents.
- Infants and children who do not develop adequate antibody (HBsAg-Negative/Non-Reactive and anti-HBs-Negative/Non-Reactive) to the first series of hepatitis B vaccine should complete a second three-dose vaccine series. The second vaccine series schedule should be given at a 0, 1, 6-month schedule. Post-vaccination serologic testing should occur at least

30 days after completion of the second hepatitis B vaccine series. NOTE: Persons who fail to respond after two appropriately administered three-dose series should be counseled regarding precautions to prevent HBV infection. No additional vaccine needed.

#### PATIENT EDUCATION/COUNSELING

- 1. Ensure that the client's parent or legal guardian knows the ways HBV can be transmitted.
- 2. Teach the client's parent or legal guardian ways to reduce disease transmission.
- 3. Explain the importance of completing the hepatitis B series using the recommended time intervals.
- 4. Explain the importance of completing post-vaccination serologic testing. Post-vaccination testing is recommended at age 9 through 18 months (after hepatitis B series completion).
- 5. Explain the client's status of immunity based on the laboratory findings.

#### CONSULTATION/REFERRAL

1. Repeat hepatitis B series and post-vaccination serologic testing for hepatitis B vaccine non-responders. Testing should be conducted at least 30 days after last dose of vaccine to avoid a transient antigenemia result.

- 2. Refer clients that test positive for hepatitis B virus to a gastroenterologist or hepatologist (liver specialist) for further evaluation.
- 3. Notify your district's Perinatal Hepatitis B Program Case Manager of the laboratory results for any clients tested.
- 4. Contact the Georgia Perinatal Hepatitis B Prevention Program for consultation or additional information at 404-651-5196.

#### REFERENCES

- 1. Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases.* Atkinson W, Hamborsky J, Wolfe S, eds. 12<sup>th</sup> ed., second printing. Washington DC: Public Health Foundation, 2012.
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- 3. Centers for Disease Control and Prevention, "Hepatitis B General Information," 2010; Publication No. 21-1073; June 2010. (http://www.cdc.gov/hepatitis/hbv/pdfs/hepbgeneralfactsheet.pdf)
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