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

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2014-2015 IMMUNIZATION CLINICAL REVIEW TEAM

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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 influenza-related 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 found in people are A (H1N1) and A (H3N2).

Influenza viruses can change in two different ways.

One is 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 reinfection can occur. This is one of the main reasons why people can get the flu more than one time. 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. So, people who want to be protected from flu need to get a flu shot every year.

The other type of change 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 influenza viruses that infect humans. Shift results in a new influenza A subtype or a virus with a hemagglutinin or a hemagglutinin and neuraminidase combination that has emerged from an animal population that is so different from the same subtype in humans that most people do not have immunity to the new (e.g., novel) virus. Such a “shift” occurred in the spring of 2009, when a new H1N1 virus with a new combination of genes emerged to infect people and quickly spread, causing a pandemic. 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.

All of the 2014-2015 influenza vaccine is made to protect against the following three viruses:

- an A/California/7/2009 (H1N1)pdm09-like virus**
- an A/Texas/50/2012 (H3N2)-like virus**
- a B/Massachusetts/2/2012-like virus.**

Some of the 2014-2015 flu vaccine also protects against an additional B virus (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 5µm] 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 allergies to eggs or egg products. (Refer to Figure 1).
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 Fluclelvax®)
5. Denies any contraindications to flu vaccine (Refer to Figure 2).

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

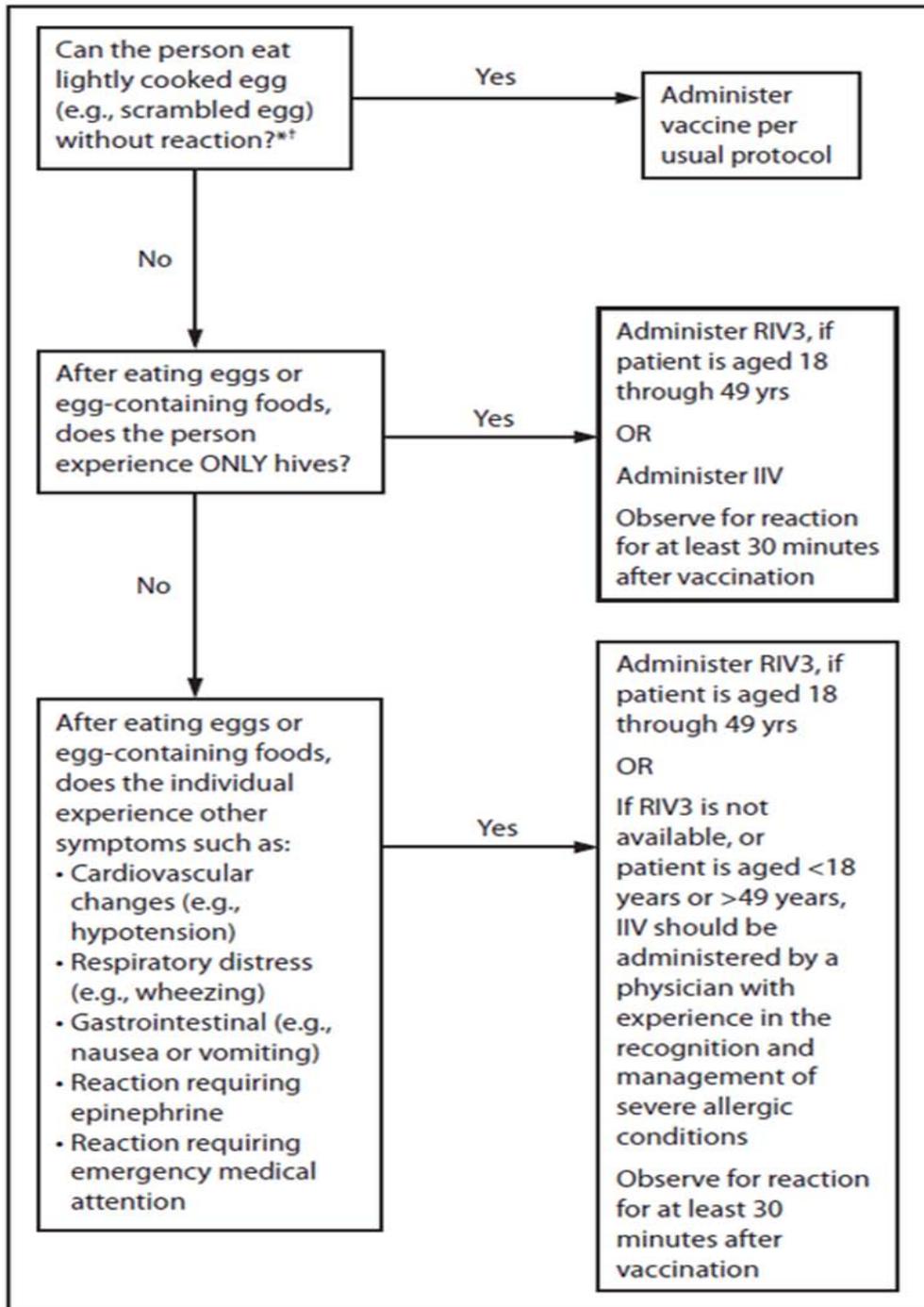
- **The former abbreviation TIV (Trivalent Inactivated Influenza Vaccine, previously used for inactivated influenza vaccines) has been replaced with the new abbreviation IIV (Inactivated Influenza Vaccine). For 2014-15, IIVs as a class will include:**
 - **egg-based and cell culture-based trivalent inactivated 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 2014-15;**
- **LAIV refers to live-attenuated influenza vaccine, available as a quadrivalent formulation (LAIV4) for 2014-15.**
- **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., “ccIIV3”).

FIGURE 1. Recommendations regarding influenza vaccination of persons who report allergy to eggs — Advisory Committee on Immunization Practices, United States, 2014–15 influenza season

CDC Advisory Committee on Immunization Practices, United States, 2014–15 influenza season egg allergy assessment

Refer to Figure 1 for egg allergy assessment or refer to a physician



Refer to Figure 1 on previous page

Abbreviations: IIV = inactivated influenza vaccine; RIV3 = recombinant influenza vaccine, trivalent.

*** Persons with egg allergy might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy (Erlewyn-Lajeunesse M, Brathwaite N, Lucas JS, Warner JO. Recommendations for the administration of influenza vaccine in children allergic to egg. *BMJ* 2009;339:b3680).**

† For persons 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 before vaccination. Alternatively, RIV3 may be administered if the recipient is aged 18 through 49 years.

Alternate Text: The figure above is a flow chart detailing recommendations regarding influenza vaccination of persons who report allergy to eggs in the United States for the 2014-15 influenza season. Persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine. Because relatively few data are available for use of live attenuated influenza vaccine in this setting, inactivated influenza vaccines (IIV), or trivalent recombinant influenza vaccine (RIV3) should be used. RIV3 may be used for persons aged 18 through 49 years who have no other contraindications. However, IIV (egg- or cell-culture based) may also be used, with certain additional safety measures

Influenza Vaccination of Persons with a History of Egg Allergy

With the exceptions of trivalent recombinant influenza vaccine (RIV3 [FluBlok], Protein Sciences) and cell culture-based inactivated influenza vaccine (ccIIV3 [Flucelvax], Novartis), currently available influenza vaccines are prepared by propagation of virus in embryonated chicken eggs. A review of published data (including data on 4,172 patients, 513 of whom were reported to have a history of severe allergic reaction to egg) noted that no occurrences of anaphylaxis were reported, although some milder reactions did occur, suggesting that severe allergic reactions to egg-based influenza vaccines are unlikely. On this basis, some guidance recommends that no additional measures are needed when administering influenza vaccine to egg-allergic persons. However, occasional cases of anaphylaxis in egg-allergic persons have been reported to the Vaccine Adverse Event Reporting System (VAERS) after administration of influenza vaccine (25,26). In published studies, vaccines containing as much as 0.7 µg/0.5 mL of ovalbumin have been tolerated (27,28); however, a threshold below which no reactions would be expected is not known (27). Among IIVs for which ovalbumin content was disclosed during the 2011–12 through 2013–14 seasons, the reported maximum amounts were ≤1 µg/0.5 mL dose. Ovalbumin is not directly measured for Flucelvax; it is estimated by calculation from the initial content in the reference virus strains to contain less than 5×10^{-8} µg of total egg protein per 0.5 mL dose, of which ovalbumin is a fraction (Novartis, personal communication, 2013). FluBlok is considered egg-free. However, neither Flucelvax nor FluBlok are licensed for use in children aged <18 years.

Primary Changes and Updates in the Recommendations

1. **Persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine. Because relatively few data are available for use of LAIV in this setting, IIV or trivalent recombinant influenza vaccine (RIV3) should be used. RIV3 may be used for persons aged 18 through 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 2):**
 - **Vaccine should be administered by a health care provider who is familiar with the potential manifestations of egg allergy; and**
 - **Vaccine recipients should be observed for equal to or greater than 30 minutes for signs of a reaction after administration of each vaccine. Although very rare, advise patient to seek immediate medical attention if a delayed reaction occurs.**
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 they are 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, IIV should be administered by a physician with experience in the recognition and management of severe allergic conditions (Figure 2).**
3. **Regardless of allergy history, all vaccines should be administered in settings in which personnel and equipment for rapid recognition and treatment of anaphylaxis are available.**
4. **Persons 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.**
5. **For persons with 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 before vaccination (Figure 2). Alternatively, RIV3 may be administered if the recipient is aged 18 through 49 years.**
6. **A previous severe allergic reaction to influenza vaccine, regardless of the component suspected of being responsible for the reaction, is a contraindication to future receipt of the vaccine.**

Figure 2. Contraindications/Precautions to Seasonal Influenza Vaccine 2014-2015

Vaccine	Contraindications	Precautions
IIV (includes IIV3, IIV4, and cIIV3)	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	<p>Severe allergic reaction to any component of the vaccine, including egg protein, or after previous dose of any influenza vaccine.</p> <p>Concomitant use of aspirin or aspirin-containing medications in children and adolescents.</p> <p>In addition, ACIP recommends LAIV4 not be used for pregnant women, immunosuppressed persons, persons with egg allergy, and children aged 2–4 years who have asthma or who have had a wheezing episode noted in the medical record within the past 12 months, or for whom parents report that a health care provider stated that they had wheezing or asthma within the last 12 months.</p> <p>LAIV should not be administered to persons who have taken influenza antiviral medications within the previous 48 hours. Persons who care for severely immunosuppressed persons who require a protective environment should not receive LAIV, or should avoid contact with such persons for 7 days after receipt.</p>	<p>Moderate to severe illness with or without fever. History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.</p> <p>Asthma in persons aged 5 years and older.</p> <p>Medical conditions which might predispose to higher risk for complications attributable to influenza.</p>

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 2014-2015 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 (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.

Vaccine	Age Group	Dosage & Route	Number of Doses	Number of Doses	Pregnancy Category
Inactivated Influenza vaccine, Trivalent (IIV3)					
Fluzone [®]	6-35 months	0.25 mL IM	1 or 2	28 days	C
	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	-----	
Fluzone ^{®1} High Dose	Greater than or equal to 65 years	0.5 mL IM	1	-----	
Fluzone ^{®2} Intradermal	18 through 64 years	Intradermal 0.1 mL	1	-----	B
Fluvirin [®]	4 through 8 years	0.5 mL IM	1 or 2	28 days	C
	Greater than or equal to 9 years	0.5 mL IM	1	-----	
Fluarix [®]	3 through 8 years	0.5 mL IM	1 or 2	28 days	B
	Greater than or equal to 9 years	0.5 mL IM	1	-----	
FluLaval [®]	3 through 8 years	0.5 mL IM	1 or 2	28 days	B
	Greater than or equal to 9 years	0.5 mL IM	1	-----	
Afluria ^{®3}	9 years of age and older	0.5 mL IM	1	-----	B

Inactivated Influenza Vaccine, Quadrivalent (IIV4)					
Vaccine	Age Group	Dosage & Route	Number of Doses	Number of Doses	Pregnancy Category
Fluarix® Quadrivalent	3 through 8 years	0.5 mL IM	1 or 2	28 days	B
	Greater than or equal to 9 years	0.5 mL IM	1	-----	
FluLaval® Quadrivalent	3 through 8 years	0.5 mL	1 or 2	28 days	B
	Greater than or equal to 9 years	0.5 mL	1	-----	
Fluzone® Quadrivalent	6 months Through 35 months	0.25 mL	1 or 2	28 days	C
	36 months through 8 years	0.5 mL IM	1 or 2	28 days	
	Greater than or equal to 9 years	0.5 mL IM	1	-----	

Vaccine	Age Group	Dosage & Route	Number of Doses	Minimum interval from dose 1 to 2	Pregnancy Category
Recombinant Influenza Vaccine Trivalent (RIV3)					
Flublok [®]	18 through 49 years	0.5 mL IM	1	-----	B
Inactivated Influenza Vaccine, Trivalent, Cell Culture-based (ccIV3)					
Flucelvax ^{® 4}	18 years of age and older	0.5 mL IM	1	-----	B
Live Attenuated Influenza Vaccine (LAIV4)					
FluMist ^{® 5 6}	Greater than or equal to 24 months through 8 years	0.2 mL Intranasal	1 or 2	28 days	Do not use in pregnancy
FluMist ^{® 5}	Greater than or equal to 9 years through 49 years of age	0.2 mL intranasal	1	-----	

Abbreviations: IM = intramuscular; ID = intradermal; IN = intranasal; ACIP = Advisory Committee on Immunization Practices.

*** Immunization providers should check Food and Drug Administration–approved prescribing information for 2014–15 influenza vaccines for the most complete and updated information, including (but not limited to) indications, contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at <http://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm>.**

† For adults and older children, the recommended site of vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh. Specific guidance regarding site and needle length for intramuscular administration can be found in ACIP's General Recommendations on Immunization (available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm>).

¹ Trivalent inactivated vaccine, high-dose: A 0.5-mL dose contains 60 µg of each vaccine antigen (180 µg total).

² Trivalent inactivated vaccine, intradermal: A 0.1-mL dose contains 9 µg of each vaccine antigen (27 µg total). ** The preferred site is over the deltoid muscle. Fluzone Intradermal is administered using the delivery system included with the vaccine.

³ Age indication per package insert is greater than or equal to 5 years; however, ACIP recommends Afluria not be used in children aged 6 months through 8 years because of increased risk for febrile reactions noted in this age group with bioCSL's 2010 Southern Hemisphere IIV3. If no other age-appropriate, licensed inactivated seasonal influenza vaccine is available for a child aged 5 through 8 years who has a medical condition that increases the child's risk for influenza complications, Afluria can be used; however, providers should discuss with the parents or caregivers the benefits and risks of influenza vaccination with Afluria before administering this vaccine. Afluria may be used in persons aged greater than or equal to 9 years.

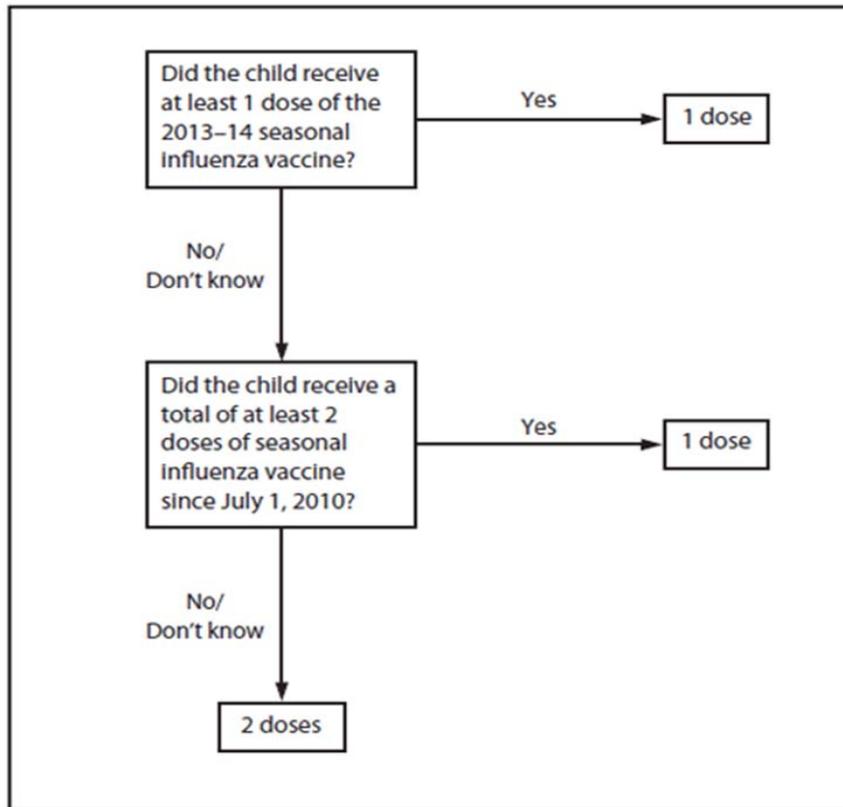
⁴ Information not included in package insert. Estimated to contain less than 50 femtograms (5x10⁻⁸ µg) of total egg protein (of which ovalbumin is a fraction) per 0.5 mL dose of Flucelvax.

⁵ FluMist is shipped refrigerated and stored in the refrigerator at 35°F–46°F (2°C–8°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 2 through 4 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 2 through 4 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.

⁶ Starting in 2014-2015, CDC recommends use of the nasal spray vaccine for healthy* children 2 through 8 years of age when it is immediately available and if the child has no contraindications or precautions to that vaccine. If the nasal spray vaccine is not immediately available and the flu shot is, vaccination should not be delayed and a flu shot should be given.

Pregnancy Risk Categories	
A	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.
B	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.
C	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 children aged 6 months through 8 years — Advisory Committee on Immunization Practices, United States, 2014–15 influenza season*



* For simplicity, this algorithm takes into consideration only doses of seasonal influenza vaccine received since July 1, 2010, to determine the number of doses needed for the 2014–15 season. As an alternative approach in settings where vaccination history from before July 1, 2010, is available, if a child aged 6 months through 8 years is known to have received either 1) at least 1 dose of 2013–14 seasonal influenza vaccine, or 2) at least two seasonal influenza vaccines during any previous season, and at least 1 dose of a 2009(H1N1)–containing vaccine (i.e., seasonal vaccine since 2010–11 or the monovalent 2009[H1N1] vaccine), then the child needs only 1 dose for 2014–15. Using this approach, children aged 6 months through 8 years need only 1 dose of vaccine for 2014–15 if they have received any of the following: 1) at least 1 dose of 2013–14 seasonal influenza vaccine; or 2) 2 or more doses of seasonal influenza vaccine since July 1, 2010; or 3) 2 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of monovalent 2009(H1N1) vaccine; or 4) 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 for 2014–15.

Refer to Figure 3 on previous page

† Doses should be administered at least 4 weeks apart.

Alternate Text: The figure above is a flow chart detailing the influenza vaccine dosing algorithm for children aged 6 months through 8 years in the United States for the 2014-15 influenza season. Two approaches are recommended for determination of the necessary doses for the 2014-15 season; both are acceptable. The first approach considers only doses of seasonal influenza vaccine received since July 1, 2010. Where adequate vaccination history from before the 2010-11 season is available, the second approach may be used.

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**

0.2mL 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 <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM195479.pdf> 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

1. **Refer individuals who have ever had a severe allergic reaction to eggs to medical doctor with experience in management of severe allergic conditions.**
2. Refer to physician for complications of influenza, and/or history of Guillain-Barré Syndrome.

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**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 HBsAg-positive result (transient antigenemia).

Specimen Collection

Refer to the most current version of the Georgia Public Health Laboratory (GPHL) Manual at <http://dph.georgia.gov/lab>. 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 <http://dph.georgia.gov/lab> (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.
-

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 hepatitis B again)

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

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 5/8"--1" in length. For older children and adolescents, an appropriate muscle mass (e.g. deltoid muscle or anterolateral thigh) 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

Drug Name: Hepatitis B Immune Globulin (HBIG)

Trade Name(s): HepaGam B®, HyperHEP B®, Nabi-HB®

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 Vaccine

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

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

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.

3. 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.

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