LOUISIANA DEPARTMENT OF HEALTH AND HOSPITALS

OFFICE OF PUBLIC HEALTH

2009 INFLUENZA A (H1N1) STRIKE TEAM

REFERENCE MANUAL

OCTOBER 2009

OPH Strike Team Reference Manual

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Appendices

Louisiana Department of Health and Hospitals
Office of Public Health

GENERAL PROTOCOLS FOR H1N1 VACCINATION CAMPAIGN

I. Requirements for Administration of All Vaccines

A. Persons Administering Vaccines

Health care providers who administer vaccine must have the legal authority to do so and shall be directly accountable for the safe and effective administration of immunizing agents. Furthermore, they must be appropriately trained in all aspects of vaccine administration including:

a. Proper storage and handling of vaccines;
b. Information to be elicited from patient or parent/legal representative before vaccination;
c. Information to be given to patient or parent/legal representative before vaccination;
d. Techniques for vaccine administration; and
e. Ability to handle adverse reactions

B. *Screening Patients Prior to Vaccination*

1. Screen for patient for eligibility for vaccination. Eligibility is based on:
   a. The patient's age;
   b. The patient's vaccination status (e.g. persons previously unvaccinated or due for vaccination according to the recommended schedule); and
   c. The presence of a medical condition that puts them at high risk.

2. Screen for contraindications:
   a. At minimum, obtain information regarding vaccines previously received, preexisting health conditions, allergies, and adverse events that occurred after previous vaccinations.
   b. Latex allergies

   A person with a history of an anaphylactic reaction to latex should be referred to a health care provider for evaluation and safe administration of vaccines. For the most up-to-date information, please refer to package inserts.

C. *Patient Education Requirement*

1. Provide patient, parent or legal representative with adequate information regarding the risks and benefits of a vaccine, and answer any questions. CDC-developed Vaccine Information Statements (VISs), which provide this information, must be used for all vaccines for which they have been developed (42 U.S.C. Section 300aa-26). The most current version of the appropriate VIS **must** be used for **each dose** of vaccine administered. Each patient, or the parent/legal representative, must receive a copy of the form prior to administration of the vaccine. Copies of the most recent VISs are available at your Louisiana Immunization Program (LIP). They are also available on the CDC website: www.cdc.gov/nip/publications/VIS. Provide non-English speakers with a VIS in their own language, if available. VIS's in many languages for all vaccines are available at www.immunize.org/vis.

2. Appropriate materials and information may be substituted **only** if VISs are unavailable. This information should be culturally and linguistically appropriate and written at a

reading level that can be easily understood.

3. Address questions and concerns posed by the patient or parent/legal representative.
4. Maintain the original consent signature(s).
5. For additional information, please see the LIP Immunization Manual.

E. Vaccine Storage and Handling

1. Store all vaccines in a refrigerator at 2ºC to 8ºC (35ºF to 46ºF). Maintain a log (available from the LIP) of daily temperatures recorded twice daily (AM and PM) for all vaccine storage units. Vaccines should **not** be stored on the refrigerator door.
2. Multi-dose vials that contain a bacteriostatic agent, usually thimerosal, can be used until the date of expiration once they are opened, unless the vial becomes visibly contaminated or is not stored at the correct temperature. Label opened multi-dose vials with the date and time it was opened.
3. Store vaccines separate from other medication and biologics. Do not store food or beverages in the same refrigerator or freezer as vaccines.

F. General Administration Guidelines

1. Administer immunization(s) **per the vaccine-specific standing order.** Remember to always read the vaccine package insert(s) prior to administration.
2. Hands should be washed before each new patient is immunized. Alcohol-based hand rubs or gels may be used. Gloves are **not** required when administering vaccines unless there is potential for exposure to blood and body fluids, or the health care provider has open hand lesions.
3. Syringes and needles must be sterile and preferably disposable, to minimize the chances of contamination. Changing needles between drawing up the vaccine into the syringe and injecting it is not necessary, unless indicated in the package insert. After use, needles should not be recapped, detached, bent, cut, or broken. Used needles and syringes should be disposed of as medical waste in specially labeled puncture-proof "sharps" containers to prevent accidental inoculation or theft. A separate needle and syringe should be used for each injection. Different vaccines should not be mixed in the same syringe unless specifically licensed and labeled for such use.

Occupational Safety and Health Administration (OSHA) Regulations:
In order to reduce the incidence of needle-stick injuries among healthcare workers and the consequent risk for bloodborne diseases acquired from patients, federal regulations now require that safer injection devices (e.g., needle-shielding syringes or needle-free injectors) be used for parenteral vaccination in all clinical settings when such devices are appropriate, commercially available, and capable of achieving the intended clinical purpose. Additional information is available on the OSHA website: www.osha.gov.

1. The person who prepares the vaccination should be the same person who administers the vaccination. Pre-drawing of immunizations in a non-mass vaccination clinic setting is discouraged. If syringes are pre-filled in a non-mass vaccination clinic setting, they should be stored in the refrigerator, used on the same day they are filled, and they should be labeled for identification purposes.
2. If aspiration results in blood in the needle hub, remove and discard the syringe. Begin the vaccination procedure again.
3. A brief period of bleeding at the injection site is common and can usually be controlled by applying gentle pressure for several minutes.

4. Whenever possible, patients should be observed for an allergic reaction for 15 to 20 minutes after receiving immunizations. Facilities and personnel should be available to treat immediate hypersensitivity reactions. For additional information, please see the Department of Health and Hospital's *Standing Orders for Emergency Treatment (PM 119).*

G. *Documentation Requirements (LINKS)*

1. Document the following information required for each dose of vaccine administered:
   a. Patient's name,
   b. Patient's age,
   c. Type of vaccine,
   d. Dose of vaccine,
   e. Site and route of administration,
   f. Date of administration of vaccine,
   g. Manufacturer and lot number of vaccine,
   h. Name and address of health care provider administering the vaccine (the address should be the address where the record is kept).
2. Provide the patient or parent/legal representative with a vaccine card / form documenting the vaccines given and the date the next doses are due.

H. ***Post-Vaccination Adverse Event Reporting Requirements***

Any post-vaccination adverse event(s) **must** be reported to the Vaccine Adverse Event Reporting System (VAERS). The appropriate VAERS forms and contact information should be readily available. Report all clinically significant events to the Vaccine Adverse Event Reporting System (VAERS), regardless of whether or not you believe the events are caused by the vaccine. Encourage patients or their parents/legal representatives to report any post-vaccination adverse event that occurs after they leave your facility to their primary care provider.

I. *Additional Documentation Requirements for Mass Immunization Clinics*

1. Maintain a data sheet for patients attending each clinic. Include, at a minimum, the number of clients vaccinated and the date of clinic.
2. Establish a system for central storage of all documentation relating to vaccine administration. This will include any vaccine administration records or data sheets.
3. If more than one type of vaccine is administered to a patient, a separate vaccine administration record **must** be used for each type of vaccine.

II. Recommendations for Drawing Up Vaccine

When drawing up vaccine in preparation for mass immunization clinics, three issues must be considered:

1. Viability of the vaccine;
2. Ability to identify the vaccine in the syringes; and
3. Avoiding vaccine wastage.

1. Viability of vaccine

a. Vaccines should be drawn up as close to the time of administration as possible. Once the vaccine is drawn up, it should be placed in the refrigerator or in containers with cold packs. Environmental conditions, such as heat and light, can affect the viability of the vaccines, and vaccines vary as to their stability.

b. If there are any questions about the viability of a vaccine, consult your regional immunization nurse, or the vaccine manufacturer. Mishandled or expired vaccine administered should not be counted as valid doses.

2. **Ability to identify vaccine in the syringes**
   In order to reduce the risk of medication administration errors, the CDC strongly discourages pre-filling syringes. In situations where pre-filling syringes is inevitable, medication administration errors may be avoided by:
   a. Storing syringes with vaccines of the same type and same lot number in separate or divided containers or trays.
   b. Label each syringe with:
      (i) type of vaccine;
      (ii) lot number;
      (iii) date and time vaccine was drawn up;
      (iv) initials of the person who drew up the vaccine.
   c. Label each container or tray with:
      (i) type of vaccine;
      (ii) date and time vaccine was drawn up;
      (iii) initials of the person who drew up the vaccine.
   d. Syringes other than those filled by manufacturer **must** be discarded at the end of the day.

3. **Avoiding vaccine wastage**
   In order to avoid wastage:
   a. Do not draw up more vaccine than will be used at the clinic or session.
   b. Ensure the cold chain is maintained until the vaccine is administered.
   c. Adhere to sterile technique when drawing up the vaccine.

References

Recommendations of the Advisory Committee on Immunization Practices (ACIP)
CDC. Adult immunizations programs in nontraditional settings: quality standards and guidance for program evaluation: a report of the National Vaccine Advisory Committee. MMWR 2000;49(No. RR-1):1-13.

CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians (AAFP). MMWR 2002; 51 (No. RR-2):1-35.

State of Louisiana

Department of Health and Hospitals

Office of Public Health

S*TANDING ORDERS*
Influenza A (H1N1) 2009 Monovalent Vaccine (MIV)

These standing orders are current as of September 2009. They should be reviewed carefully against the most current recommendations and may be revised by the Medical Director of the Louisiana Office of Public Health Immunization Program.

Influenza A (H1N1) 2009 Monovalent Vaccine is an inactivated influenza virus vaccine indicated for active immunization of persons against influenza disease caused by the pandemic (H1N1) 2009 virus. Administer Influenza A (H1N1) 2009 Monovalent Vaccine to any person without contraindications who wishes to reduce the likelihood of becoming ill with influenza or of transmitting influenza to others should they become infected.

Influenza A (H1N1) 2009 Monovalent Vaccine is especially recommended for persons in the following groups:

I. Target Group for H1N1 InfluenzaVaccine:

1. Persons aged 6 months - 24 years;
2. Pregnant women;
3. Persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and
   daycare providers),
4. Healthcare and emergency medical services personnel;
5. Persons aged 25-64 years who have medical conditions that put them at higher risk for influenza-related complications

ORDER:

1. Provide patient, parent or legal representative with a copy of the Vaccine Information Statement (VIS) and answer any questions. VIS's in English and other languages are available from the Louisiana Immunization Program (LIP) and online at http://www.immunize.org/vis.
2. Screen for contraindications according to Table 1.
3. Inspect Influenza A (H1N1) 2009 Monovalent Vaccine syringes and vials for particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.

4. Shake the syringe and single–dose vials well before administering the vaccine. Shake the multi-dose vial each time before withdrawing a dose of vaccine.
5. Administer MIV intramuscularly (IM), according to the recommended age-specific dose and schedule (Table 2). Administer IM vaccines at a 90^{o} angle with a 22-25 gauge needle. The needle length for IM injections depends upon the age, gender, and/or weight of the vaccine recipient (see Table 2 below). **Always check the package insert prior to administration of any vaccine.**
6. Influenza A (H1N1) 2009 Monovalent Vaccine should not be mixed with any other vaccine in the same syringe or vial. If Influenza A (H1N1) 2009 Monovalent Vaccine is to be given at the same time as another injectable vaccine(s), the vaccine(s) should always be administered at different injection sites.
7. If possible, observe patient for an allergic reaction for 15 - 20 minutes after administering vaccine.
8. Appropriate facilities and medical personnel must be available to manage possible anaphylactic reactions following administration of the vaccine.
9. Report clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or http://www.vaers.hhs.gov/.
10. See the document *General Protocols for Standing Orders* for further recommendations and requirements regarding vaccine administration, documentation and consent.

Table 1. Contraindications and Precautions to Inactivated Influenza Vaccine

<table>
<tr><th>Valid Contraindications for

Inactivated Influenza Vaccine</th><th>Invalid Contraindications

(Give Inactivated Influenza Vaccine)</th></tr>
<tr><td rowspan="4">Known severe hypersensitivity to eggs[1] or chicken proteins or any component of the vaccine or life-threatening reactions after previous administration of any influenza vaccine (see package insert for specific components)[2]</td><td>Mild illness with or without fever</td></tr>
<tr><td>Non-anaphylactic allergy to any component of the vaccine</td></tr>
<tr><td>HIV infection[4]</td></tr>
<tr><td rowspan="2">Pregnancy [3]or breast feeding</td></tr>
<tr><td rowspan="3">Precaution to influenza vaccine:

The immune response of immunocompromised persons may be decreased after receiving Influenza A (H1N1) 2009 Monovalent Vaccine

Guillain-Barré Syndrome (GBS) ≤ 6 weeks of receiving dose of influenza vaccine.[3]</td><td>Treatment with warfarin (Coumadin), theophylline, phenytoin, or aminophylline[6]</td></tr>
<tr><td>Anticoagulation or bleeding disorder[7]</td></tr>
</table>

Table 2. Needle Length and Injection Site for IM Injection

Gender and Weight	Needle Length	Injection Site	Injection Technique
Infants (< 12 months)	1”	Anterolateral thigh	Bunch subcutaneous and muscle tissue
Toddlers (12 months – 24months)	≥ 1”	Anterolateral thigh (preferred)	Depends on body mass
	5/8”	Deltoid	Stretch skin flat between thumb and forefinger
Children (3 – 18 y/o)	5/8” – 1”	Deltoid	Depends on body mass
Male and female < 60 kg (< 130 lbs)	5/8”	Deltoid	Do not bunch subcutaneous and muscle tissue
Male and female (130 – 152 lbs)	1”		
Female 70 – 90 kg (152 - 200 lbs)	1” – 1½”		
Male 70 – 118 kg (152 – 260 lbs)			
Female > 90 kg (200 lbs)	1½”		
Male > 118 kg (260 lbs)			

[1] Asking persons if they can eat eggs without adverse effects is a reasonable way to determine who might be at risk for an allergic reaction.

[2] Refer persons with a history of anaphylaxis to a vaccine component, but who are at risk for complications from influenza, to their health care provider for evaluation, desensitization and possible administration of influenza vaccine. Protocols have been developed for safely administering influenza vaccine to persons with egg allergies.

[3] It may be prudent to avoid influenza vaccination of persons who are not at high risk of complications from influenza and who have experienced GBS within 6 weeks of a previous dose of influenza vaccine. As an alternative, consider antiviral chemoprophylaxis for these persons.

[4] Because influenza can result in serious illness, *vaccination will benefit many HIV-infected patients, including HIV-infected pregnant women*. Vaccine may not induce protective antibodies in patients with advanced disease. A second dose during the same flu season *does not* improve immune response in these patients.

[5] Pregnant women have an increased risk for hospitalization due to complications from influenza.

[6] Although flu vaccine can inhibit the clearance of warfarin, theophylline, phenytoin, and aminophylline, studies show no adverse clinical effects. High-risk patients who take these medications *should* receive flu vaccine.

[7] Minimize the risk of bleeding after an IM injection in these patients by administering the vaccine immediately after the patient’s receipt of replacement factor. Use a 23-gauge (or smaller) needle and immediately apply direct pressure to the vaccination site for ≥ 2 minutes.

Table 2. Inactivated influenza vaccine dosage, by age group - United States

Age Group	Dose	No. of Doses	Preservative (Thimerosal)
6 – 35 months	0.25 mL	2[1]	Thimerosal- Free[2]
3 – 9 years	0.5 mL	2[1, 3]	
≥ 10 years	0.5 mL	1	

[1] Children < 10 years of age should receive 2 doses, ≥ 1 month apart. Administer the 2nd dose before the onset of flu season, if possible.

[2] If available, pregnant women and children under 10 yrs should receive Thimerosal-free vaccine.

[3] Existing recommendations are that two inactivated vaccines can be administered at any time before, after, or at the same visit as each other. Existing recommendations also state that an inactivated and live vaccine may be administered at any time before, after or at the same visit as each other. Consequently, providers can administer seasonal and 2009 H1N1 inactivated vaccines, seasonal inactivated vaccine and 2009 H1N1 LAIV, or seasonal LAIV and inactivated 2009 H1N1 at the same visit, or at any time before or after each other.

Patient Counseling Information

- Inform vaccine recipient or guardian that Influenza A (H1N1) 2009 Monovalent Vaccine contains killed viruses and cannot cause influenza.
- Inform vaccine recipient or guardian that there are two influenza vaccine formulations for this influenza season, the monovalent vaccine against H1N1 pandemic virus and seasonal trivalent influenza vaccine.
- Instruct vaccine recipient or guardian to report any severe or unusual adverse reactions to their health care provider.

Table 3. Approved Influenza A (H1N1) 2009 Monovalent Vaccines

Proper Name / Type	Manufacturer	Dose/ Presentation	Dosage	Age Group
Influenza A (2009) H1N1 Monovalent Vaccine Inactivated virus; Intramuscular injection	CSL Limited 1-888-435-8633	- 0.5 mL prefilled single-dose syringe - 5.0 mL multi-dose vial containing 10 doses (with thimerosal)	- Single 0.5 mL dose	Adult 18 years of age and older
Influenza A (2009) H1N1 Monovalent Vaccine Inactivated virus; Intramuscular injection	Novartis 1-800-244-7668	- 0.5 mL prefilled single-dose syringe (trace thimerosal) - 5.0 mL multi-dose vial (with thimerosal)	- Two 0.5 mL doses approx. 1 month apart for children 4 to 9 - Single 0.5 mL dose for children 10 – 17 - Single 0.5 mL dose for adults 18 and older	Persons 4 yrs of age and older

Proper Name / Type	Manufacturer	Dose/ Presentation	Dosage	Age Group
Influenza A (2009) H1N1 Monovalent Vaccine Inactivated virus; Intramuscular injection	Sanofi Pasteur Inc. 1-800-822-2463	- 0.25 mL prefilled single-dose syringe (thimerosal free) distinguished by pink syringe plunger rod - 0.5 mL prefilled single-dose syringe (thimerosal free) - 0.5 mL single-dose vial (thimerosal free) - 5.0 mL multi-dose vial (with thimerosal)	- Two 0.25 mL doses approx. 1 month apart for children 6 – 35 months of age - Two 0.5 mL doses approx. 1 month apart for children 36 months – 9 years - Single 0.5 mL dose for children 10 years and older - Single 0.5 mL dose for adults 18 and older	Persons 6 months and older
Influenza A (2009) H1N1 Monovalent Vaccine	GlaxoSmithKline	Awaiting FDA licensure		

Dr. Frank Welch, MD
Medical Director
Immunization Program

10/16/09
Date

This document expires on June 30, 2010.

Bobby Jindal
GOVERNOR

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State of Louisiana

Department of Health and Hospitals

Office of Public Health

STANDING ORDERS
Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal

These standing orders are current as of September 2009. They should be reviewed carefully against the current recommendations and may be revised by the Medical Director of the Louisiana Office of Public Health Immunization Program.

Influenza A (H1N1) 2009 Monovalent Vaccine Live, **Intranasal** is indicated for the active immunization of healthy individuals 2 – 49 years of age against influenza disease caused be pandemic (H1N1) 2009 virus.

ORDER:

1. Provide patient, parent or legal representative with a copy of the Vaccine Information Statement (VIS) and answer any questions. VIS's in English and other languages are available from the Louisiana Office of Public Health Immunization Program (LIP) and online at http://www.immunize.org/vis.
2. Screen for contraindications according to Table 1.

Table 1. Contraindications to Influenza A (H1N1) Monovalent Vaccine, Live

Valid Contraindications for Live influenza A (H1N1) 2009 Vaccine
Hypersensitivity to eggs[1], egg proteins, gentamicin, gelatin or arginine or life threatening reactions to previous influenza vaccination or any components of the LAIV
Children receiving aspirin therapy or aspirin-containing therapy because of the association with Reye's Syndrome with aspirin and wild-type influenza infection
Age < 2 and > 50 years of age
Adults and children who have chronic pulmonary, cardiovascular, renal, hepatic, neurological/neuromuscular disorders (including diabetes mellitus)
Pregnant women

WARNINGS AND PRECAUTIONS
Individuals with asthma or children < 5 years of age with recurrent wheezing (potential for increased risk of wheezing post vaccination) or whose parents or caregivers report that a medical provider has told them during the preceding 12 months that their child had wheezing or asthma
If Guillain-Barré Syndrome has occurred with any prior influenza vaccination
Individuals with known immunodeficiency diseases or immunosuppressed states[2]
Individuals with underlying medical conditions predisposing them to wild-type influenza infection complications
Children who have received any other live vaccines within the past 30 days such as MMR, Varicella or Yellow Fever should defer until sufficient time has elapsed between vaccine doses

[1] Asking persons if they can eat eggs without adverse effects is a reasonable way to determine who might be at risk for an allergic reaction.

[2] Use of inactivated influenza vaccine is recommended over LAIV for health care workers, household contacts and anyone coming in close contact with severely immunocompromised individuals during periods when such patients require care in a protected environment (typically described as a specialized patient-care area with a positive – airflow relative to the corridor, high-efficiency air filtration and frequent air changes).

3. Administer 0.2 mL Influenza A (H1N1) 2009 Monovalent Vaccine Live intranasally (0.1 mL in each nostril) according to the age-specific dose and schedule (Table 2).

    - Check expiration date. Product must be used before the date on the sprayer label.
    - Remove rubber tip protector. **Do not** remove dose-divider clip at the other end of the sprayer.
    - With the patient in an upright position, head tilted back, place the tip just inside the nostril to ensure the vaccine is delivered into the nose.
    - With a single motion, depress plunger **as rapidly as possible** until the dose-divider clip prevents you from going further.
    - Pinch and remove the dose-divider clip from the plunger.
    - Place the tip just inside the other nostril and with a single motion, depress the plunger **as rapidly as possible** to deliver the remaining vaccine.
    - If the vaccine recipient sneezes after administration, the dose should **not** be repeated.

    Note: Active inhalation (i.e., sniffing) is not required by the patient during vaccine administration.

4. Influenza A (H1N1) 2009 Monovalent Vaccine Live can be given on the same day as any other live virus vaccine **EXCEPT** seasonal influenza LAIV.

5. If possible, observe the patient for an allergic reaction for 15 – 20 minutes after administering vaccine.

6. Appropriate facilities and medical personnel must be available to manage possible

8. See the document *General Protocols for Standing Orders* for further recommendations and requirements regarding vaccine administration, documentation and consent.

Table 2. Live Attenuated Influenza A (H1N1) Monovalent Vaccine Live Dosage, by Age Group

Age Group	Dose/ Schedule
Children (2 – 9)	**2 doses (0.2 mL each*), approx. 1 month apart**
Children, adolescents and adults (10 – 49)	**1 dose (0.2 mL**

*Each 0.2 mL dose is administered as 0.1 mL per nostril

Storage and Handling

- Store Influenza A (H1N1) 2009 Monovalent Vaccine Live in a refrigerator between 2 – 8° C (35 - 46° F) upon receipt and until use. Keep at that temperature until the expiration date is reached. **Do not freeze.**

Patient Counseling Information

- Inform vaccine recipient or guardian of the benefits and risks of Influenza A (H1N1) 2009 Monovalent Vaccine.
- Inform vaccine recipient or guardian that there are two influenza vaccine formulations for this influenza season, the monovalent vaccine against H1N1 pandemic virus and seasonal trivalent influenza vaccine.
- Instruct vaccine recipient or guardian to report any severe or unusual adverse reactions to their health care provider.

Table 3. Approved Live Influenza A (H1N1) 2009 Monovalent Vaccine

Proper Name / Type	Manufacturer	Dose/ Presentation	Dosage	Age Group
Influenza A (2009) H1N1 Monovalent Vaccine Live virus (LAIV); Intranasal spray	MedImmune, LLC 1-877-633-4411	- 0.2 mL prefilled single dose intranasal spray (Each 0.2 mL dose is administered as 0.1 mL per nostril)	- Two 0.2 mL doses approx. 1 month apart for children 2 to 9 - Single 0.2 mL dose for persons 10-49	Persons 2 to 49 years of age

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Immunization Program

09/16/09
Date

This document expires on June 30, 2010.

H1N1 Vaccination Strike Team Schematic

Department Of Education

OPH Command Center Strike Team Coordinator (CCSTC)

Non-DOE Schools

Submit # of students/ staff to be immunized
Submit # of nurses to participate in vaccination efforts
Coordinate vaccination awareness & consent form dissemination and collection pre-event
Maintain communication with OPH CCSTC

Oversee vaccination campaign
Maintain active communication with partners
Route staffing/client info to Regional Strike Team Coordinator
Evaluate processes to enhance future immunization efforts

Submit # of students/ staff to be immunized
Submit # of nurses to participate in vaccination efforts
Coordinate vaccination awareness & consent form dissemination and collection pre-event
Maintain communication with OPH CCSTC

Local School Vaccination Contact Person

REGIONAL H1N1 STRIKE TEAM COORDINATOR

Local School Vaccination Contact Person

Parental consent form & information dissemination and collection
Participate in scheduling (date, time)
Facility set-up & process assistance

Coordinate Strike Team activities with local partners
Ensure Strike Team readiness

Parental consent form & information dissemination and collection
Participate in scheduling (date, time)
Facility set-up & process assistance

STRIKE TEAMS

INTRANASAL INFLUENZA VACCINE ADMINISTRATION COMPETENCY ASSESSMENT

Patient Population Served: Child (2 – 5 yrs) School Age (5 – 12 yrs) Adolescents (13 – 17 yrs) Adults (18 yrs +)

Required Competency or Skill	* Self Assessment	Orientation (Preceptor initials & date)	+ Evaluation Method	Competency Validated by Supervisor (Signature & date)	Comments/Additional Resources
Patient Screening	CRITICAL THINKING: *Recognizes normal and abnormal values for all age groups and takes appropriate action in a timely manner. Documents findings appropriately. Recognizes unique age and language appropriate communication needs of patients and responds appropriately. Assures the confidentiality of patient information and their rights to privacy (i.e., auditory and visual privacy).*				
A. Understands the actions, implications, precautions and age groups for administration of the live, attenuated influenza vaccine(LAIV):					
(1) Vaccine screening sheet is reviewed for vaccine contraindications a. Age (younger than 2 yrs, older than 49 yrs) b. Hypersensitivity to eggs, egg proteins, gentamicin, gelatin, arginine or a previous life threatening reaction to the influenza vaccine c. Pregnancy d. Immunocompromised e. Guillan-Barre History f. Individuals with a history of asthma, children older than 5 yrs with recurrent wheezing g. Children and adolescents on concomitant aspirin therapy h. Vaccination with live virus in last 28 days					
(2) Familiarity with the FluMist package insert for this flu season					
B. Verbalizes understanding of the standing order for the administration of the intranasal influenza vaccine to adults and pediatric patients					
C. Provides patient/guardian a LAIV Vaccination Information Statement (VIS) sheet to read prior to administration of immunization					
D. Clinic policy regarding beneficiary children under age 18 must be accompanied by parent or legal guardian					
Patient Care Procedures for RN, LPN, Medic, Corpsman	CRITICAL THINKING: *Recognizes unique needs of patients of age groups 2-49 and performs FluMist administration accordingly. Gathers age appropriate supplies and equipment. Explains all procedures in an age appropriate manner according to the level of understanding of the child and the parent/guardian. Approaches child in non-threatening manner and comforts at completion.*				
A. Understands importance of the care and handling of the live, attenuated influenza virus vaccine					

*** Self Assessment:** 1=Experienced 2=Needs Practice/Assistance 3=Never Done N/A= Not Applicable

+ Evaluation / Validation Methodologies: T=Tests D=Demonstration/Observation V=Verbal I=Interactive Class *Updated 21 Jul 09*

INTRANASAL INFLUENZA VACCINE ADMINISTRATION COMPETENCY ASSESSMENT

Patient Population Served: Child (2 – 5 yrs) School Age (5 – 12 yrs) Adolescents (13 – 17 yrs) Adults (18 yrs +)

Required Competency or Skill	* Self Assessment	Orientation (Preceptor initials & date)	+ Evaluation Method	Competency Validated by Supervisor (Signature & date)	Comments/Additional Resources
(1) Must be stored in a refrigerator (2-8°C) upon arrival, during transportation and until use. DO NOT FREEZE.					
(2) Must be used by labeled expiration date					
(3) Uses gloves and washes hands between each procedure					
(4)Verbalizes procedures to protect vaccine after temperature compromise is noted (segregate product, label as "potentially compromised", place in functioning refrigerator, contact DSCP, USMMA or manufacturer to verify stability. Prepare EXUM for loss as necessary.)					
B. Demonstrates proper technique for administration of FluMist *(Self administration by the patient is not authorized)*					
(1) Remove rubber tip protector					
(2) Patients sits upright, tilt head back, place tip just inside nostril , as rapidly as possible depress plunger until clip prevents you from going further					
(3) Pinch and remove dose divider clip and repeat procedure in opposite nostril					
(5) Do **NOT** have the patient actively inhale (i.e., sniff) the mist					
(6) Dispose of sprayer in rigid sharps container					
(7) All children 6mo-8yrs who are receiving the influenza vaccine for the first time should receive two 0.2mL doses separate by 4 weeks					
(8) Documentation of vaccine, dose, manufacturer, lot number, provider and VIS date in ITS system					
C. Demonstrates ability to recognize signs and symptoms of a patient experiencing an anaphylactic reaction and responds appropriately					
(1) Verbalizes understanding of the standing order for the medical management of vaccine adverse events.					
(2) Positions patient on litter/ floor					
(3) Calls for assistance and administers epinephrine per protocol					
(3) Monitors vital signs / assess breathing					

*** Self Assessment: 1=Experienced 2=Needs Practice/Assistance 3=Never Done N/A= Not Applicable**

+ Evaluation / Validation Methodologies: T=Tests D=Demonstration/Observation V=Verbal I=Interactive Class ***Updated 21 Jul 09***

INTRANASAL INFLUENZA VACCINE ADMINISTRATION COMPETENCY ASSESSMENT

Patient Population Served: Child (2 – 5 yrs) School Age (5 – 12 yrs) Adolescents (13 – 17 yrs) Adults (18 yrs +)

Required Competency or Skill	* Self Assessment	Orientation (Preceptor initials & date)	+ Evaluation Method	Competency Validated by Supervisor (Signature & date)	Comments/Additional Resources
(5) Proper documentation of event a. Documents a Medical Temp (MT) in MODS/MRRS/AFCITA b. Document incident in AHLTA c. Completes and submits a VAERS form					
D. Demonstrates ability to recognize signs and symptoms of a patient experiencing a vasovagal reaction and responds appropriately					
(1) Verbalize signs and symptoms of a vasovagal reaction					
(2) Position patient on litter/ floor and elevate legs					
(3) Monitor vital signs / assess breathing					
(4) Administer ammonia inhalant as needed					
E. Explains policy and procedure for waiting at least 15 min after vaccination for monitoring of possible adverse event					

Preceptor's Initials: _____ Printed Name: _____ Signature: _____

I understand the topics listed, I will be allowed to perform only those for my skill level/scope of practice and only after I have successfully demonstrated competency.

Employee Signature: _____ **Date:** _____

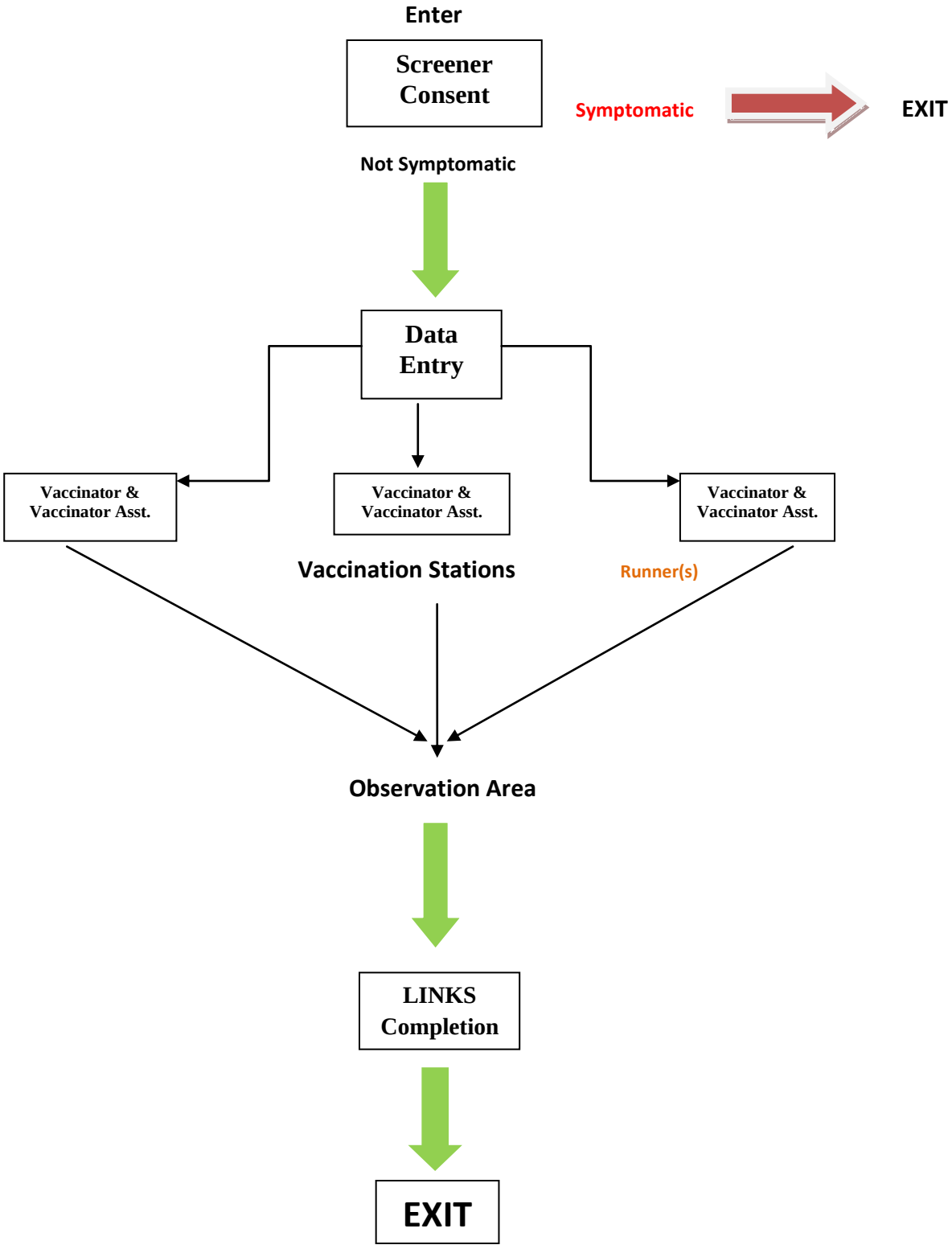
*** Self Assessment: 1=Experienced 2=Needs Practice/Assistance 3=Never Done N/A= Not Applicable**

+ Evaluation / Validation Methodologies: T=Tests D=Demonstration/Observation V=Verbal I=Interactive Class *Updated 21 Jul 09*

RECOMMENDED SUPPLIES AND EQUIPMENT

Ammonia inhalants
Band-Aids
Biohazard bags
Blood pressure cuffs
Blue pads
Cotton balls
Clipboards
Diphenhydramine 50 mg IM
Disinfectant solution
Emergency phone numbers
Epinephrine 1:1000 SQ
Gloves
Hand sanitizer
Ice chest/cooler/ insulated container
Ice packs
ID badges for team members
Internet access
Laptop computers
PPE (surgical masks; gowns)
Pads of paper
Paper clips/binder clips
Paper towels
Pediatric and adult oral airways
Pencils
Pens
Pocket CPR masks
Sharps Containers
Staples/stapler
Stethoscopes
Syringes
Tables/ chairs
Tackle box
Telephone/cell phone
TB syringes with needles
Tissues
Tongue depressors
5/8" needles
7/8" needles
1" needles

VACCINATION SITE FLOW PLAN



POLICY NUMBER:	0015-09
SUBJECT:	Bloodborne Pathogen Policy
CONTENT:	DHH Bloodborne Pathogen Plan
EFFECTIVE DATE:	Issued: 09/01/2009
INQUIRIES TO:	Department of Health & Hospitals Security Coordinator 628 N. 4th Street P. O. Box 91030 Baton Rouge, LA 70821-9030 (225) 342-3501 Fax (225) 342-2467

BLOODBORNE PATHOGEN POLICY

I. STATEMENT OF POLICY

It is the policy of the Department of Health and Hospitals (DHH) to provide a policy to control employee exposure to bloodborne pathogens. Each department employee must willingly assist management in accomplishing this goal, which cannot be achieved without safe work practices. This policy, with certain procedural requirements, will serve as a guide to Offices in developing internal procedures to fit their particular operations. It is our objective to follow federal, state and local codes, and our own polices to maintain safe and healthy conditions.

Bloodborne pathogens are disease-causing microorganisms that are carried and transmitted through human blood and other bodily fluids. The pathogens of primary concern are the human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV).

II. APPLICABILITY

This policy applies to all Offices of the Department of Health and Hospitals.

III. IMPLEMENTATION

This policy will be effective September 1, 2009

IV. DEFINITIONS

Blood – human blood, human blood components, and products made from human blood.

Bloodborne Pathogen – pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to HBV, HVC and HIV.

Bodily Fluids – includes by not limited to saliva, urine, blood, semen, vaginal secretions and any bodily fluids that may or may not be contaminated with blood.

Contaminated Sharps – any contaminated object that can penetrate the skin includes, but not limited to, needles, scalpels, broken glass, and broken capillary tubes.

Decontamination – the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

High-Risk – a professional health care provider who provides invasive procedures, such as injection of vaccines or medications to and for patients on a daily basis or any employee who handles the disposal of waste or provides clean-up and janitorial services in any health care facility.

Occupational Exposure – reasonably anticipated skin, eye, mucus membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

Parenteral – piercing mucous membranes or the skin barrier through such events as needle sticks, human bites, cuts, and abrasions on any part of the body.

Personal Protective Equipment – specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes are not intended to function as protection against a hazard and are not considered to be personal protective equipment.

Work Practice Controls – controls that reduce the likelihood of exposure by altering the manner in which a task is performed.

V. TRANSMISSION OF BLOODBORNE PATHOGENS

Bloodborne pathogens are transmitted when contaminated blood or bodily fluids enter the body of another person. In the workplace setting, transmission is most likely to occur through:

- An accidental puncture by a sharp object, such as a needle, broken glass, or other "sharps", contaminated with the pathogen.
- Contact between broken or damaged skin and infected bodily fluids
- Contact between mucous membranes and infected bodily fluids.

Unbroken skin forms an impervious barrier against bloodborne pathogens. However, infected blood or bodily fluids can enter your system percutaneously through:

- Open sores
- Cuts
- Abrasions
- Acne
- Any sort of damaged or broken skin such as sunburn or blisters

Bloodborne pathogens can also be transmitted through the mucous membranes of the eyes, nose, or mouth. For example, a splash of contaminated blood to your eye, nose, or mouth could result in transmission.

There are also many ways that bloodborne pathogens are not transmitted. For example, bloodborne pathogens are not transmitted by:

- touching an infected person
- coughing or sneezing
- using the same equipment, materials, toilets, water fountains or showers as an infected person

It is important that you know which ways are viable means of transmission for the bloodborne pathogens in your workplace, and which are not.

VI. RESPONSIBILITIES

Employees are responsible for safe work practices, and must follow the procedures and practices for bloodborne pathogens established by the department and comply with this policy.

Supervisors are responsible for identifying employees with occupational exposure and shall develop, within the framework of this guide, a written exposure control plan to minimize or eliminate occupational exposure to bloodborne pathogens. Supervisors must ensure that eligible employees follow the safety practices and receive required training.

Each Office shall develop internal procedures to this policy in accordance with the departmental guidelines. Each Office's internal bloodborne pathogen procedures shall reflect the commitment of management to safety and the philosophy that safety is a management directed program.

VII. EXPOSURE DETERMINATION

Employers must perform an exposure determination concerning which employees may incur occupational exposure to blood or other potentially infectious materials. This determination, specific to DHH, includes the following:

Category 1 employees: All job classifications in which employees in those job classifications have occupational exposure to blood or potentially infectious materials. Many DHH employees associated with healthcare programs have occupational exposure at clinical affiliation sites. Clinical affiliation sites have the responsibility of providing site-specific training, personal protective equipment, and controlling of potential exposure conditions.

Category 2 employees: All job classifications in which some employees have occupational exposure to blood and potentially infectious materials. Occupational exposure is unlikely, but may occur in office type settings.

VIII. GOOD SAMARITAN ACTS

Employees exposed to blood or other potentially infectious materials while helping members of the public or fellow employees shall report the incident promptly to their supervisor. All organizational parts of the Department of Health and Hospitals shall make provision for medical evaluation and treatment, if necessary, available to these employees. Employees performing "Good Samaritan Acts" are usually employees who are not members of a first-aid team or who are not expected to render medical assistance as a job duty.

IX. UNIVERSAL PRECAUTIONS

Universal precautions are intended to prevent transmission of infection, as well as decrease the risk of exposure for employees. It is impossible to identify all infected persons, so it is necessary to treat every person as potentially infected with a bloodborne pathogen. Employees must protect themselves from blood or other bodily fluids that are not their own. Employees should anticipate possible exposures both in emergency situations and routine tasks they perform in a normal workday. Employees must be knowledgeable about the use of personal protective equipment such as latex or non-latex gloves, mask/eye protection, gowns, prevention of injuries by sharp instruments, proper handwashing

techniques, mouthpieces and ventilation bags, proper disposal and cleanup techniques, and other important skills.

Universal precautions pertain to blood and other potentially infectious materials containing blood. When differentiation of types of bodily fluids is difficult or impossible, all bodily fluids are to be considered as potentially infectious.

When dealing with spilled blood/other bodily fluids, disposal of infectious waste or potentially infectious waste, universal precautions should be utilized as follows:

1. Gloves

    - Contact with blood/bodily fluids
    - Contact with items soiled with blood/bodily fluids
    - Contact with mucous membranes
    - Contact with nonintact skin
    - Wash hands and skin with soap & water immediately after contamination and/or between examining patients.

2. Mask/Eye Protection

    - Any procedure likely to generate aerosols of blood/bodily fluids

3. Prevention of Injuries by Sharp Instruments

    - Never recap, bend or break needles
    - Never remove needles from disposable syringes
    - Immediately place sharps in puncture resistant sharps containers

4. Wash hands/skin

    - Immediately if contaminated with blood/bodily fluids
    - With soap and water or skin sanitizer, if soap and water are not readily available.

5. Health care workers with skin lesions or dermatitis

- Should refrain from all direct patient contact and handling patient care equipment with unclothed parts of their body, e.g. hands, until the condition resolves.

X. ENGINEERING CONTROLS

Engineering controls are designed to isolate or remove the bloodborne pathogens hazards from the workplace so that employee exposure is limited. Where occupational exposure remains after institution of these controls, personal protective equipment must be used. Engineering controls may include sharps disposal containers, the use of plastic containers for blood specimens instead of glass safety needle systems, and in certain situations, ultraviolet lights to sanitize the air, and negative pressure airflow systems, when warranted.

XI. WORK PRACTICE CONTROLS

Work practice controls reduce the likelihood of exposure by altering the manner in which a task is performed. Many times they work with engineering controls to provide maximum protection for the employee. Work practice controls include handwashing practices, avoiding recapping of needles, using the proper personal protective equipment and refraining from eating or storing food in restricted areas.

Handwashing

Handwashing facilities which are readily accessible must be provided to employees in clinical affiliation sites. These handwashing stations must have hot and cold running water, a germicidal handwashing detergent, and paper towels. In addition, each building must have public rest rooms that are available to all staff.

When the provision of handwashing facilities is not feasible, DHH shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleanser or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

DHH shall ensure that exposed personnel wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment. Employees wash hands and any other skin with soap and water, or flush with

water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

Needles and Sharps

Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted below. Shearing or breaking of contaminated needles is prohibited.

Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

- Puncture resistant
- Labeled or color-coded in accordance with the Bloodborne Pathogen standard
- Leak proof on the sides and bottom

Work Area Restrictions

Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.

Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertop or bench tops where blood or other potential infectious materials are present.

All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

Specimens

Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

- The container for storage, transport, or shipping shall be labeled or color-coded and closed prior to being stored, transported, or shipped. When a

facility utilizes standard precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary, provided containers are recognizable as containing specimens and containers remain within the facility. Labeling or color-coding is required when such specimens/containers leave the facility.

- If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.
- If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture resistant in addition to the above characteristics.

Equipment Servicing or Shipping

Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless a demonstration that decontamination of such equipment or portions of such equipment is not feasible.

- A readily observable label shall be attached to the equipment stating which portions remain contaminated.
- DHH shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

XII. PERSONAL PROTECTIVE EQUIPMENT

Personal protective equipment (PPE) is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be PPE.

Program coordinators and supervisors or their designees are responsible for ensuring that PPE is readily accessible in all areas where it may be needed and that it is properly used. The effectiveness of the required PPE should be periodically reviewed and appropriate changes made if necessary.

Gloves should always be used for cleaning blood or other bodily fluids that are spilled on a work surface. In addition, plastic goggles, a surgical-type mask, and a gown should be worn if the situation is such that there is a large amount of potentially infectious material present and splashing is likely to occur in the clean-up process.

XIII. HOUSEKEEPING

Contaminated surfaces must be cleaned and decontaminated with an appropriate disinfectant. In order to be effective, it is important that disinfectants be used according to all label instructions. Protective coverings can be used on surfaces, but they must be replaced when they become contaminated.

In handling and disposal of blood specimens and disposal of infectious waste and potentially infectious waste, emergency responders and staff of DHH Administrative Offices/Facilities must use the following precautions for the protection of both clients and personnel.

If blood or other bodily fluids are spilled on a work surface, the blood should be wiped up carefully with absorbent paper towels and the surface cleaned with a 1:10 solution of sodium hypochlorite (one part household bleach mixed with nine parts water, no older than one day).

The absorbent paper towels, after use, are not considered infectious waste: the bleach solution disinfects the blood. The bloodied towels, however, should be placed in a heavy corrugated paper container (cardboard box) and taped shut. The package may then be disposed of with the regular trash or garbage. The nearest parish health unit may be called for advice or instructions about this. If the facility has 'routine' provision for storing, handling and disposing of potentially infectious waste, the bloodied towels, for example, may be discarded into the potentially infectious was container, until disposal of the entire container occurs.

If glass is broken and has blood or other bodily fluids on it, the broken glass should be carefully disinfected by carefully pouring a solution of 1:10 sodium hypochlorite, as stated above, on the glass fragments. The glass fragments should then be carefully picked up with a dust pan and brush and placed in a heavy corrugated paper container and disposed of as stated above, or, if an approved sharps container is used 'routinely' in the facility, the broken glass, for example, should be placed in that sharps container. Of course, cuts on employees or office

visitors should be immediately given proper care either by "first aid" or by a professional health care provider.

XIV. VACCINATION

DHH must make available within 10 working days of initial assignment the hepatitis B vaccine and vaccination series to all employees who may in any way have an occupational exposure.

XV. POST-EXPOSURE EVALUATION/FOLLOW-UP

When an employee has an exposure incident, they should immediately wash the exposed skin with soap and water and flush the other areas such as mucous membranes of the eyes, nose or mouth with copious amounts of cool water. The employee should report the incident to their supervisor immediately after washing. The supervisor is responsible for assuring that all applicable provisions of this policy are effectively carried out and for maintaining all records related to the exposure.

Following a report of an exposure incident, DHH shall make immediately available to the exposed employee a confidential medical evaluation and follow-up.

DHH shall obtain and provide the employee with a copy of the evaluating professional health care person's written opinion.

XVI. TRAINING

Low risk DHH employees must complete the CareerMap bloodborne pathogen training on the DHH Intranet at http://dhhinet01.dhh.la.gov/humanr/webtrain.htm within 1 year after the date of hire. Training shall occur once every five years thereafter. High risk health care providers must complete the training within 90 days after date of hire and annually thereafter.

POLICY ON TRANSPORTING VACCINE

Policy:
All vaccine transported by OPH personnel (or for use in OPH-sponsored vaccination clinics) will be transported in a way that assures proper temperature control.

Rationale:
Improper temperature control during transport can result in a loss of vaccine potency.

Guidelines:
In all instances vaccine should be packed in the bottom of the container with ice packs on top. A cloth or non-heat conducting material should prevent the vaccine from coming into direct contact with the ice pack. Specific instructions (also review specific vaccine package inserts for "Storage/Handling" requirements) for vaccines are as follows:

All vaccine must be transported in an insulated container and cold packs must be used to maintain the proper temperature:

Influenza

General Handling:

a. In clinic situations where a refrigerator is located in the clinic room, the vaccine should be kept in the refrigerator until it is needed.

b. If a refrigerator is not in the clinic room, then the vaccines must be kept in an insulated container or storage tray with ice packs and vaccine removed as needed.

c. Labeling specifications previously outlined must be closely followed.

SPECIAL NOTE: Vaccines must not be stored with food items. Refrigerators more than 10 years of age should not be used for vaccine storage.

TEMPERATURE LOG

Month/Year ______________________________

Refrigerator needs to be +35° to 46° F (2° - 8°C). Freezer needs to be +5° F (-15° C) or colder for varicella vaccine, 0° F or colder is ideal.

IF TEMPERATURES FALL OUTSIDE OF DESIRED RANGES, CONTACT VFC AT 504-838-5300 IMMEDIATELY!

Date	Morning Temp		Time	Initials	Afternoon Temp		Time	Initials
	Refrigerator	*Freezer*			*Refrigerator*	*Freezer*		

Excerpted from
Immunization Program of Louisiana Rev. 04/09

2009 H1N1 Influenza Vaccine Screening and Consent Form

Section 1: Information about the Patient to Receive Vaccine (please print)

PATIENT'S NAME (Last)	(First)	(M.I.)	**PATIENT'S DATE OF BIRTH** **month_____ day_____ year _____**	
PARENT/GUARDIAN'S NAME , if applicable (Last)	(First)	(M.I.)	**PATIENT'S AGE**	**PATIENT'S GENDER** **M / F**
ADDRESS			**DAYTIME PHONE NUMBER:**	
CITY	**STATE**	**ZIP**		

Section 2: Screening for Vaccine Eligibility

If the patient has already been vaccinated with 2009 H1N1 influenza vaccine, indicate the number of doses and dates of vaccination.

☐ Dose 1 Date received: month ____day____year_____ Form (please circle): nasal spray shot

☐ Dose 2 Date received: month ____day____year_____ Form (please circle): nasal spray shot

The following questions will help us to know if the patient can get the 2009 H1N1 influenza vaccine. Please mark YES or NO for each question.

A. If you answer "NO" to all four of the following questions, the patient can probably get the influenza vaccine. If you answer "YES" to one or more of the following four questions, the patient may be able to get the 2009 H1N1 vaccine, but we would like discuss your options.

	YES	**NO**
1. Does the patient have a serious allergy to eggs?	☐	☐
2. Does the patient have any other serious allergies? Please list: _____	☐	☐
3. Has the patient ever had a serious reaction to a previous dose of flu vaccine?	☐	☐
4. Has the patient ever had Guillain-Barré Syndrome (a type of temporary severe muscle weakness) within 6 weeks after receiving a flu vaccine?	☐	☐

B. There are two kinds of 2009 H1N1 influenza vaccine. Your answers to the following questions will help us know which of the two kinds of vaccine to provide.

	YES	**NO**
1. Has the patient been vaccinated with any vaccine (not just flu) within the past 30 days? Vaccine: _____ Date given: month_____day_____year_____	☐	☐
2. Does the patient have any of the following: asthma, diabetes (or other type of metabolic disease), or disease of the lungs, heart, kidneys, liver, nerves, or blood?	☐	☐
3. Is the patient on long-term aspirin or aspirin-containing therapy (for example, does your child take aspirin every day)?	☐	☐
4. Does the patient have a weak immune system (for example, from HIV, cancer, or medications such as steroids or those used to treat cancer)?	☐	☐
5. Is the patient pregnant?	☐	☐
6. Does the patient have close contact with a person who needs care in a protected environment (for example, someone who has recently had a bone marrow transplant)?	☐	☐

Section 3: Consent

CONSENT FOR VACCINATION:

I have read or had explained to me the 2009-2010 Vaccine Information Statement for the 2009 H1N1 influenza vaccine and understand the risks and benefits.

I GIVE CONSENT for me or my child named at the top of this form to be to be vaccinated with this vaccine.

Signature of Patient/Parent/ Guardian _____

Date: month_____day_____year_____

Section 5: Vaccination Record

FOR ADMINISTRATIVE USE ONLY

Vaccine	**Date Dose Administered**	**Route**	**Dose Number (1st or 2nd)**	**Vaccine Manufacturer**	**Lot Number**	**Name and Title of Vaccine Administrator**
2009 H1N1	/ /	☐ IM ☐ Intranasal				
2009 H1N1	/ /	☐ IM ☐ Intranasal				

School Name: _____ **School Parish**: _____

COMFORTING RESTRAINT

FOR IMMUNIZATIONS

• The method:

This method involves the parent in embracing the child and controlling all four limbs. It avoids "holding down" or overpowering the child, but it helps you steady and control the limb of the injection site.

• For infants and toddlers:

Have parent hold the child on parent's lap.

1. One of the child's arms embraces the parent's back and is held under the parent's arm.
2. The other arm is controlled by the parent's arm and hand. For infants, the parent can control both arms with one hand.
3. Both legs are anchored with the child's feet held firmly between the parent's thighs, and controlled by the parent's other arm.

• For kindergarten and older children:

Hold the child on parent's lap or have the child stand in front of the seated parent.

1. Parent's arms embrace the child during the process.
2. Both legs are firmly between parent's legs.

IMMUNIZATION TECHNIQUES

Safe • Effective • Caring

Gary Davis, Governor — State of California
Health and Human Services Agency
Diana M. Bonta, R.N., Dr.P.H., Director — Department of Health Services
Immunization Branch • 1616 Capitol Avenue • P.O. Box 997426, MS 7320 • Sacramento, CA 95899-7426
dhs
IM-770 (12/01)

APPENDICES

Patient name: _____ Date of birth: ____/____/____
(mo.) (day) (yr.)

Screening Questionnaire for Injectable Influenza Vaccination

For adult patients as well as parents of children to be vaccinated: The following questions will help us determine if there is any reason we should not give you or your child injectable influenza vaccination today. If you answer "yes" to any question, it does not necessarily mean you (or your child) should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	Yes	No	Don't Know
1. Is the person to be vaccinated sick today?	☐	☐	☐
2. Does the person to be vaccinated have an allergy to eggs or to a component of the vaccine?	☐	☐	☐
3. Has the person to be vaccinated ever had a serious reaction to influenza vaccine in the past?	☐	☐	☐
4. Has the person to be vaccinated ever had Guillain-Barré syndrome?	☐	☐	☐

Form completed by: _____ Date: _____

Form reviewed by: _____ Date: _____

Technical content reviewed by the Centers for Disease Control and Prevention, September 2009.

www.immunize.org/catg.d/p4066.pdf • Item #P4066 (9/09)

Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org

Information for Health Professionals about the Screening Questionnaire for Injectable Influenza Vaccination

Are you interested in knowing why we included a certain question on the Screening Questionnaire? If so, read the information below. If you want to find out even more, consult the sources listed at the bottom of this page.

1. Is the person to be vaccinated sick today?
There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. Persons with an acute febrile illness usually should not be vaccinated until their symptoms have improved. Minor illnesses with or without fever do not contraindicate use of influenza vaccine. Do not withhold vaccination if a person is taking antibiotics.

2. Does the person to be vaccinated have an allergy to eggs or to a component of the vaccine?
Allergic reactions to any vaccine component can occur. The majority of reactions probably are caused by residual egg protein. Although current influenza vaccines contain only a limited quantity of egg protein, this protein can induce immediate allergic reactions among persons who have severe egg allergy. If a person can eat eggs, they can receive inactivated influenza vaccine. However, persons who have experienced an anaphylactic reaction (e.g., hives, swelling of the lips or tongue, acute respiratory distress, or collapse) after eating eggs should consult a physician for appropriate evaluation to help determine if vaccine should be administered. Persons who have documented immunoglobulin E (IgE)-mediated hypersensitivity to eggs, including those who have had occupational asthma or other allergic responses to egg protein, might also be at increased risk for allergic reactions to influenza vaccine. Consultation with a physician should be considered. Protocols have been published for safely administering influenza vaccine to persons with egg allergies (see source 3).

FluZone (sanofi pasteur) contains gelatin as a stabilizer; therefore a history of anaphylactic reaction to gelatin is a contraindication. Some inactivated influenza vaccines contain thimerosal as a preservative. Most persons with sensitivity to thimerosal, such as that found in contact lens solution, do not experience reactions to thimerosal administered as a component of vaccines. Check the package insert at www.immunize.org/packageinserts for a list of the vaccine components (i.e., excipients and culture media) used in the production of the vaccine, or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

3. Has the person to be vaccinated ever had a serious reaction to influenza vaccine in the past?
Patients reporting a serious reaction to a previous dose of inactivated influenza vaccine should be asked to describe their symptoms. Immediate—presumably allergic—reactions are usually a contraindication to further vaccination against influenza.

Fever, malaise, myalgia, and other systemic symptoms most often affect persons who are first-time vaccinees. These mild-to-moderate local reactions are not a contraindication to future vaccination. Also, red eyes or mild upper facial swelling following vaccination with inactivated injectable influenza vaccine is most likely a coincidental event and not related to the vaccine; these persons can receive injectable vaccine without further evaluation.

4. Has the person to be vaccinated ever had Guillain-Barré syndrome?
It is prudent to avoid vaccinating persons who are not at high risk for severe influenza complications but who are known to have developed Guillain-Barré syndrome (GBS) within 6 weeks after receiving a previous influenza vaccination. As an alternative, physicians might consider using influenza antiviral chemoprophylaxis for these persons. Although data are limited, the established benefits of influenza vaccination for the majority of persons who have a history of GBS, and who are at high risk for severe complications from influenza, justify yearly vaccination.

Sources:
1. CDC. *Epidemiology & Prevention of Vaccine-Preventable Diseases*, W. Atkinson et al., editors, at www.cdc.gov/vaccines/pubs/pinkbook.
2. CDC. "General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)" at www.cdc.gov/vaccines/pubs/ACIP-list.htm.
3. CDC. "Prevention and Control of Influenza—Recommendations of ACIP" at www.cdc.gov/flu/professionals/vaccination.

Patient name: _____ Date of birth: ____/____/____ (mo.) (day) (yr.)

Screening Questionnaire for Intranasal Influenza Vaccination

For adult patients as well as parents of children to be vaccinated: The following questions will help us determine if there is any reason we should not give you or your child intranasal influenza vaccine (FluMist) today. If you answer "yes" to any question, it does not necessarily mean you (or your child) should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	Yes	No	Don't Know
1. Is the person to be vaccinated sick today?	☐	☐	☐
2. Does the person to be vaccinated have an allergy to eggs or to a component of the influenza vaccine?	☐	☐	☐
3. Has the person to be vaccinated ever had a serious reaction to intranasal influenza vaccine (FluMist) in the past?	☐	☐	☐
4. Is the person to be vaccinated younger than age 2 years or older than age 49 years?	☐	☐	☐
5. Does the person to be vaccinated have a long-term health problem with heart disease, lung disease, asthma, kidney disease, neurologic or neuromuscular disease, liver disease, metabolic disease (e.g., diabetes), or anemia or another blood disorder?	☐	☐	☐
6. If the person to be vaccinated is a child age 2 through 4 years, in the past 12 months, has a healthcare provider ever told you that he or she had wheezing or asthma?	☐	☐	☐
7. Does the person to be vaccinated have a weakened immune system because of HIV/AIDS or another disease that affects the immune system, long-term treatment with drugs such as high-dose steroids, or cancer treatment with radiation or drugs?	☐	☐	☐
8. Is the child or teen to be vaccinated receiving aspirin therapy or aspirin-containing therapy?	☐	☐	☐
9. Is the person to be vaccinated pregnant or could she become pregnant within the next month?	☐	☐	☐
10. Has the person to be vaccinated ever had Guillain-Barré syndrome?	☐	☐	☐
11. Does the person to be vaccinated live with or expect to have close contact with a person whose immune system is severely compromised and who must be in a protective isolation (such as in a hospital room with reverse air flow)?	☐	☐	☐
12. Has the person to be vaccinated received any other vaccinations in the past 4 weeks?	☐	☐	☐

Form completed by: _____ Date: _____

Form reviewed by: _____ Date: _____

Technical content reviewed by the Centers for Disease Control and Prevention, September 2009.

www.immunize.org/catg.d/p4067.pdf • Item #P4067 (9/09)

Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org

Information for Health Professionals about the Screening Questionnaire for Intranasal Influenza Vaccination

Are you interested in knowing why we included a certain question on the Screening Questionnaire? If so, read the information below. If you want to find out even more, consult the sources listed at the bottom of this page.

1. Is the person to be vaccinated sick today?
There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. Persons with an acute febrile illness usually should not be vaccinated until their symptoms have improved. Minor illnesses with or without fever do not contraindicate use of influenza vaccine. Do not withhold vaccination if a person is taking antibiotics.

2. Does the person to be vaccinated have an allergy to eggs or to a component of the influenza vaccine?
History of anaphylactic reaction—such as hives, wheezing, or difficulty breathing, or circulatory collapse or shock (not fainting)—after eating eggs or receiving any component of the intranasal live attenuated influenza vaccine (LAIV, tradename FluMist) is usually a contraindication for further doses. Check the package insert (at www. immunize.org/packageinserts) for a list of the vaccine components (i.e., excipients and culture media) used in the production of the vaccine, or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf.

3. Has the person to be vaccinated ever had a serious reaction to intranasal influenza vaccine (FluMist) in the past?
Patients reporting a serious reaction to a previous dose of LAIV should be asked to describe their symptoms. Immediate—presumably allergic—reactions are usually a contraindication to further vaccination with LAIV.

4. Is the person to be vaccinated younger than age 2 years or older than age 49 years?
LAIV is not licensed for use in persons younger than age 2 years or older than age 49 years.

5. Does the person to be vaccinated have a long-term health problem with heart disease, lung disease, asthma, kidney disease, neurologic or neuromuscular disease, liver disease, metabolic disease (e.g., diabetes), or anemia or another blood disorder?
Persons with any of these health conditions should not be given the LAIV. Instead, they should be vaccinated with the inactivated injectable influenza vaccine.

6. If the person to be vaccinated is a child age 2 through 4 years, in the past 12 months, has a healthcare provider ever told you that he or she had wheezing or asthma?
LAIV is not recommended for a child this age if their parent or guardian answers yes to this question or if the child has a history of asthma or recurrent wheezing. Instead, they should be given the inactivated injectable influenza vaccine.

7. Does the person to be vaccinated have a weakened immune system because of HIV/AIDS or another disease that affects the immune system, long-term treatment with drugs such as high-dose steroids, or cancer treatment with radiation or drugs?
Persons with weakened immune systems should not be given the LAIV. Instead, they should be given the inactivated injectable influenza vaccine.

8. Is the child or teen to be vaccinated receiving aspirin therapy or aspirin-containing therapy?
Because of the theoretical risk of Reye's syndrome, children and teens on aspirin therapy should not be given LAIV. Instead they should be vaccinated with the inactivated injectable influenza vaccine.

9. Is the person to be vaccinated pregnant or could she become pregnant within the next month?
Pregnant women or women planning to become pregnant within a month should not be given LAIV. All pregnant women should, however, be vaccinated with the inactivated injectable influenza vaccine.

10. Has the person to be vaccinated ever had Guillain-Barré syndrome?
It is prudent to avoid vaccinating persons who are not at high risk for severe influenza complications but who are known to have developed Guillain-Barre syndrome (GBS) within 6 weeks after receiving a previous influenza vaccination. As an alternative, physicians might consider using influenza antiviral chemoprophylaxis for these persons. Although data are limited, the established benefits of influenza vaccination for the majority of persons who have a history of GBS, and who are at high risk for severe complications from influenza, justify yearly vaccination.

11. Does the person to be vaccinated live with or expect to have close contact with a person whose immune system is severely compromised and who must be in a protective isolation (such as in a hospital room with reverse air flow)?
Inactivated injectable influenza vaccine is preferred for persons who have close contact with severely immunosuppressed persons during periods in which the immunosuppressed person requires care in protective isolation (e.g., an isolation room of a bone marrow transplant unit). Either the inactivated injectable influenza vaccine or LAIV may be used in persons who have close contact with persons having lesser degrees of immunosuppression.

12. Has the person to be vaccinated received any other vaccinations in the past 4 weeks?
Persons who were given an injectable live virus vaccine (e.g., MMR, MMRV, varicella, yellow fever) in the past 4 weeks should wait 28 days before receiving LAIV. Separate the seasonal LAIV and H1N1 LAIV vaccines by at least 4 weeks because of concerns about competition between the 2 vaccine viruses. There is no reason to defer giving LAIV if persons were vaccinated with an inactivated vaccine or if they have recently received blood or other antibody-containing blood products (e.g., IG).

Sources:
1. CDC. *Epidemiology & Prevention of Vaccine-Preventable Diseases*, W. Atkinson et al., editors, at www.cdc.gov/vaccines/pubs/pinkbook.
2. CDC. "General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)" at www.cdc.gov/vaccines/pubs/ACIP-list.htm.
3. CDC. "Prevention and Control of Influenza—Recommendations of ACIP" at www.cdc.gov/flu/professionals/vaccination.

Medication Administration Techniques

Injections

Intramuscular (IM)

- Review medication orders, and check for drug allergies.
- Wash hands, and put on gloves.
- Identify client.
- Use appropriate syringe and needle. Maximum amount of fluid should be determined by client's muscle mass and site to be injected. Use 2 inch needle with obese client to ensure that medication is injected into a large muscle.
- Position client, and locate site using appropriate anatomical landmarks.
- Wipe site with alcohol in a circular motion to cleanse. Allow to dry.
- Spread skin taut, and insert needle at 90° angle with quick, dartlike action.

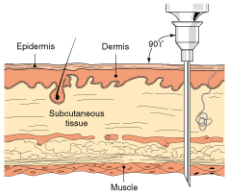


Figure 1: Insert needle at 90° angle for intramuscular injections.
Source: Smith et al., 2000, p. 394.

- Aspirate, and observe for blood. (If blood appears, remove and discard needle).
- Inject medication slowly, remove needle quickly, and gently apply pressure to site with dry, sterile 2 x 2 gauze. Do not massage injection site.

Deltoid (Upper Arm)

- Use appropriate syringe and needle.
- Client may be positioned sitting or standing.
- Locate site by measuring 2 - 3 fingerbreadths below the acromion process on the lateral midline of the arm.
- Administer in nondominant arm when possible.

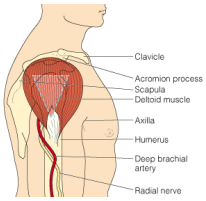


Figure 2: The deltoid muscle of the upper arm, used for intramuscular injections.
Source: Kozier et al., 2000, p. 785.

Anterolateral Thigh (Vastus Lateralis)

- Use 22 - 25 gauge, 5/8 - 1 inch needle.
- This is the preferred site for infants and children < 7 mo.
- Position client in supine or sitting position.
- Locate by identifying the greater trochanter and lateral femoral condyle. Injection site is the middle third and anterior lateral aspect of the thigh.

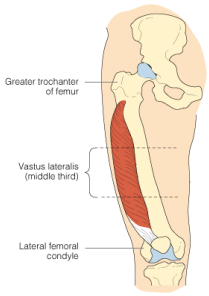
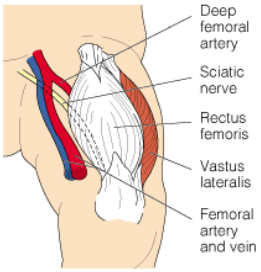
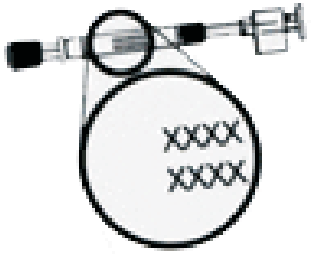


Figure 3: The vastus lateralis site of the right thigh, used for intramuscular injections.
Source: Kozier et al., 2000, p. 785.

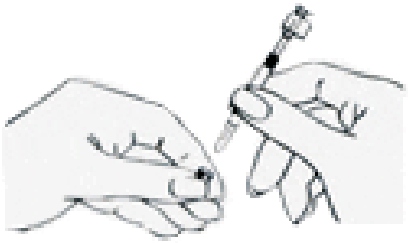


1



Check expiration date. Product must be used before the date on sprayer label.

2



Remove rubber tip protector. Do not remove dose-divider clip at the other end of the sprayer.

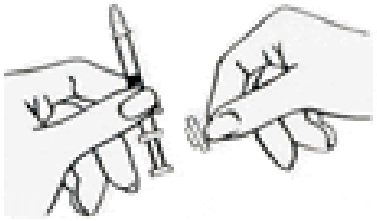
3

With the patient in an upright position, place the tip just inside the nostril to ensure FluMist is delivered into the nose.

4

With a single motion, depress plunger **as rapidly as possible** until the dose-divider clip prevents you from going further.

5



Pinch and remove the dose-divider clip from plunger.

6

Place the tip just inside the other nostril and with a single motion, depress plunger **as rapidly as possible** to deliver remaining vaccine.

DO NOT INJECT. DO NOT USE A NEEDLE

Skills Checklist for Immunization

The Skills Checklist is a self-assessment tool for health care staff who administer immunizations. To complete it, review the competency areas below and the clinical skills, techniques and procedures outlined for each of them. Score yourself in the Self-Assessment column. If you check **Need to Improve** you indicate further study, practice or change is needed. When you check **Meets or Exceeds** you indicate you believe you are performing at the expected level of competence, or higher.

Supervisors: Use the Skills Checklist to clarify responsibilities and expectations for staff who administer vaccines. When you use it for performance reviews, give staff the opportunity to score themselves in advance. Next observe their performance as they provide immunizations to several patients and score in the Supervisor Review columns. If improvement is needed, meet with them to develop a Plan of Action (over) that will help them achieve the level of competence you expect; circle desired actions or write in others. In 30 days, observe their performance again. When all competency areas meet expectations, file the Skills Checklist in their personnel folder. At the end of the probationary period and annually thereafter, observe them again and complete the Skills Checklist.

		Self-Assessment		Supervisor Review		
Competency	**Clinical Skills, Techniques, and Procedures**	**Need to Improve**	**Meets or Exceeds**	**Need to Improve**	**Meets or Exceeds**	**Plan of Action***
A. Patient/Parent Education	1. Welcomes patient/family, establishes rapport, and answers any questions.					
	2. Explains what vaccines will be given and which type(s) of injection will be done.					
	3. Accommodates language or literacy barriers and special needs of patient/parents to help make them feel comfortable and informed about the procedure.					
	4. Verifies patient/parents received the Vaccine Information Statements for indicated vaccines and had time to read them and ask questions.					
	5. Screens for contraindications. (MA: score NA–not applicable–if this is MD function.)					
	6. Reviews comfort measures and after care instructions with patient/parents, inviting questions.					
B. Medical Protocols	1. Identifies the location of the medical protocols (i.e. immunization protocol, emergency protocol, reference material).					
	2. Identifies the location of the epinephrine, its administration technique, and clinical situations where its use would be indicated.					
	3. Maintains up-to-date CPR certification.					
	4. Understands the need to report any needlestick injury and to maintain a sharps injury log.					
C. Vaccine Handling	1. Checks vial expiration date. Double-checks vial label and contents prior to drawing up.					
	2. Maintains aseptic technique throughout.					
	3. Selects the correct needle size. 1"-1 1/2" for IM (DTaP, Td, Hib, HepA, HepB, Pneumo Conj., Flu); 5/8" for SC (MMR, Var); IPV and Pneumo Poly depends on route to be used.					
	4. Shakes vaccine vial and/or reconstitutes and mixes using the diluent supplied. Inverts vial and draws up correct dose of vaccine. Rechecks vial label.					
	5. Labels each filled syringe or uses labeled tray to keep them identified.					
	6. Demonstrates knowledge of proper vaccine handling, e.g. protects MMR from light, logs refrigerator temperature.					

		Self-Assessment		Supervisor Review		
Competency	**Clinical Skills, Techniques, and Procedures**	**Need to Improve**	**Meets or Exceeds**	**Need to Improve**	**Meets or Exceeds**	**Plan of Action***
D. Administering Immunizations	1. Rechecks the physician's order or instructions against prepared syringes.					
	2. Washes hands and if office policy puts on disposable gloves.					
	3. Demonstrates knowledge of the appropriate route for each vaccine. (IM for DTaP, Td, Hib, HepA, HepB, Pneumo Conj, Flu; SC for MMR, Var; Either SC or IM for IPV and Pneumo Poly).					
	4. Positions patient and/or restrains the child with parent's help; locates anatomic landmarks specific for IM or SC.					
	5. Preps the site with an alcohol wipe using a circular motion from the center to a 2" to 3" circle. Allows alcohol to dry.					
	6. Controls the limb with the non-dominant hand; holds the needle an inch from the skin and inserts it quickly at the appropriate angle (45° for SC or 90° for IM).					
	7. Injects vaccine using steady pressure; withdraws needle at angle of insertion.					
	8. Applies gentle pressure to injection site for several seconds with a dry cotton ball.					
	9. Properly disposes of needle and syringe in sharps container. Properly disposes of live vaccine vial.					
	10. Encourages comfort measures before, during and after the procedure.					
E. Records Procedures	1. Fully documents each immunization in patient's chart: date, lot number, manufacturer, site, VIS date, name/initials.					
	2. If applicable, demonstrates ability to use IZ registry or computer to call up patient record, assess what is due today, and update computer immunization history.					
	3. Asks for and updates patient's record of immunizations and reminds them to bring it to each visit.					

Plan of Action:

Circle desired next steps and write in the agreed deadline and date for the follow-up performance review. **a.** Watch video on immunization techniques. **b.** Review office protocols. **c.** Review manuals, textbooks, wall charts or other guides. **d.** Review package inserts. **e.** Review vaccine handling guidelines or video. **f.** Observe other staff with patients. **g.** Practice injections. **h.** Read Vaccine Information Statements. **i.** Be mentored by someone who has these skills. **j.** Role play with other staff interactions with parents and patients, including age-appropriate comfort measures. **k.** Attend a skills training or other courses or training. **l.** Attend health care customer satisfaction or cultural competency training. **m.** Renew CPR certification. **Other:**_____

Employee Signature _____ Date _____

Supervisor Signature _____ Date _____

Plan of Action Deadline _____

Date of Next Performance Review _____

IMMUNIZATION TECHNIQUES

Safe • Effective • Caring

California Department of Health Services • Immunization Branch • 2151 Berkeley Way • Berkeley, CA 94704

IMM-694B (9/01)

IMM-694 (12/11/00)

Skills Checklist for Pediatric Immunization

Goal: To assure clinical staff has the skills and competencies needed for safe, effective and caring administration of pediatric immunizations.

Purpose: The Skills Checklist can be used for self-assessment or for annual performance reviews by physician or supervisor. It also can be used for new employees, to identify what they will need in orientation and what knowledge or skills they should attain during their probationary period.

Instructions: Prior to annual review, staff should score themselves (self-assessment) on the items below. After their self-assessment, the medical director or supervisor should observe their skills and techniques with several patients. Score by checking in the appropriate column. Discuss in private any scoring differences and recommend a plan of action for any scores of **"Needs Review"**.

Scoring:

Needs Review: Needs improvement. Institute a corrective plan of action to develop appropriate skills level. Review again in 30 days, followed by 3 months review if needed.
Meets or Exceeds: Demonstrates competencies and skills required for safe, effective and caring pediatric immunization administration. File in personnel folder. Review again at end of probationary period and annually thereafter.

		Self Assessment		Supervisor Review		
Competency	**Clinical Skills, Techniques, and Procedures**	**Needs Review**	**Meets or Exceeds**	**Needs Review**	**Meets or Exceeds**	**Plan of Action***
A. Parent Education	1. Welcomes child and family, establishes rapport, and answers parents questions.					
	2. Explains what vaccines will be given and which type(s) of injection will be done.					
	3. Accommodates language or literacy barriers and special needs of parents to help make them feel comfortable and informed about the procedure.					
	4. Verifies parents received the Vaccine Information Statements for all vaccines the child is to receive and had time to read them and ask questions.					
	5. Screens for contraindications. (MA: score NA–not applicable–if this is MD function.)					
	6. Reviews comfort measures and after care instructions with parent, inviting questions.					
B. Medical Protocols	1. Identifies the location of the medical protocols (i.e. immunization protocol, emergency protocol, reference material).					
	2. Identifies the location of the epinephrine, its administration technique, and clinical situations where its use would be indicated.					
	3. Maintains up-to-date CPR certification.					
C. Vaccine Handling	1. Checks vial expiration date. Double-checks vial label and contents prior to drawing up.					
	2. Maintains aseptic technique throughout.					
	3. Selects the correct needle size. 1"-1 1/2" for IM (DTaP, Hib, HepA, HepB, Pneumo Conj); 5/8" for SC (MMR, Var); IPV depends on route to be used.					
	4. Reconstitutes and/or draws vaccine into syringe correctly.					
	5. Labels each filled syringe or uses labeled tray to keep them identified.					
	6. Demonstrates knowledge of proper vaccine handling, e.g. protects MMR from light, logs refrigerator temperature.					

		Self Assessment		Supervisor Review		
Competency	**Clinical Skills, Techniques, and Procedures**	**Needs Review**	**Meets or Exceeds**	**Needs Review**	**Meets or Exceeds**	**Plan of Action***
D. Administering Immunizations	1. Rechecks the physician's order or instructions against prepared syringes.					
	2. Washes hands and if office policy puts on disposable gloves.					
	3. Demonstrates knowledge of the appropriate route for each vaccine. [Intramuscular (IM) for DTaP, Hib, HepA, HepB, Pneumo Conj;Subcutaneous (SC) for MMR, Var; Either SC or IM for IPV].					
	4. Positions and restrains the patient; locates anatomic landmarks specific for IM or SC.					
	5. Preps the skin, cleaning the site and a 2" to 3" circle around it. Allows alcohol to dry.					
	6. Inserts the needle at the appropriate angle to skin (45° for SC or 90° for IM); if office policy, aspirate.					
	7. Injects vaccine using steady pressure; withdraws needle at angle of insertion.					
	8. Applies gentle pressure to injection site for several seconds with a dry sterile pad.					
	9. Properly disposes of needle and syringe in sharps container. Properly disposes of live vaccine vial.					
	10. Understands the need to report any needlestick injury and to maintain a sharps injury log.					
	11. Encourages comfort measures before, during and after the procedure.					
E. Records Procedures	1. Fully documents each immunization in patient's chart: date, lot number, manufacturer, site, VIS date.					
	2. If applicable, demonstrates ability to use IZ registry or computer to call up patient record, assess what is due today, and update computer immunization history.					
	3. Asks for and updates parents' record of their child's immunizations and reminds them to bring it to each visit.					

***Plan of Action:** Might include: Review manual or textbook section on injections; review package insert; review office protocols or other references; watch video on administration techniques or vaccine handling; observe proper technique, practice injections; read Vaccine Information Statements; mentor with someone who has these skills; do role playing with other staff; attend an update, skills training or refresher course; attend cultural competency training; etc. Plan of action must include a deadline and date for a 30-day and a 3-month follow-up review.

Performance Review Acknowledgement:

Employee	Date	Plan of Action Time Frame
Supervisor	Date	Date for Follow-up Review

California Department of Health Services • Immunization Branch • 2151 Berkeley Way • Berkeley, CA 94704

IMM-694 (12/11/00)

P.M. NO. 119 (Revision 6)

DEPARTMENT OF HEALTH AND HOSPITALS
OFFICE OF PUBLIC HEALTH

POLICY MEMORANDUM NO. 119 (Revision 6) **October 16, 2009**

FROM: M. Rony Francois, MD, MSPH, PhD Assistant Secretary **mrf** and Jimmy Guidry, M.D. State Health Officer **jg**

SUBJECT: **EMERGENCY PROTOCOL FOR DEPARTMENT OF HEALTH AND HOSPITALS OFFICE OF PUBLIC HEALTH FACILITIES**

PURPOSE: Update the procedure for handling of medical emergencies by OPH personnel within the OPH clinics and in non-medical facilities. This Policy replaces P.M. No. 119 (Revision 5) dated June 1, 2009.

EFFECTIVE DATE: Policy will be in effect upon receipt

POLICY STATEMENT: The staff of clinical facilities of the Department of Health and Hospitals Office of Public Health must be prepared and knowledgeable in handling medical emergencies, which may result from the professional medical and related health services provided in the facilities.

R E M E M B E R - **TRUE EMERGENCIES ARE RARE. NOT ALL FAINTING AND ANXIETY ATTACKS ARE MEDICAL EMERGENCIES.**

Professional judgment in handling emergencies must be exercised at all times and the plan for handling any emergency must be known by all personnel in your unit. Call immediately for emergency transport at the same time that you are starting emergency treatment in your unit. If deemed necessary, a member of your professional staff should accompany the emergency patient to the hospital.

Any patient who may have experienced an emergency, not requiring medication, and the situation has been taken care of in the Health Unit, may be discharged home with assistance. Family of the patient must be notified if the patient has been sent to the emergency room alone or accompanied. A follow-up call regarding the patient's condition should be made within 24 hours, whether or not patient was sent home or to the emergency room.

Proper documentation of the entire episode should be made by the appropriate personnel. An allergic tag should be placed on the patient's chart if this has been an allergic reaction.

An allergic reaction to a vaccine must be reported to the Central Office Immunization Program on the adverse reaction form (Form VAERS-1) and recorded for the patients record In LINKS.

Public Health Nurses may administer authorized medication provided the following described emergency supplies (page 4) are available.

THE TELEPHONE NUMBER FOR THE LOCAL EMERGENCY SERVICES SHOULD BE CONSPICUOUSLY POSTED AND KNOWN BY ALL CLINIC PERSONNEL.

POLICY

Before administering any vaccine or medication, a thorough and complete history of allergic reactions to drugs, any other known allergies, and any history of syncopal episodes should be elicited from the patient or client. Whether or not to proceed with giving an injectable vaccine or any medication in view of the history of allergies or allergic reactions as related by the patient or client must be the physician's decision.

Health Unit Nurses may administer the following medications by injection provided the described emergency Supplies (page 4) are available:

1. Routine immunizations for children and adults.
2. Travel immunizations
3. Seasonal immunizations (e.g. influenza)
4. Individualized short term medications (Separate arrangements should be made according to Health Unit Personnel)
5. Streptomycin or other anti-tuberculosis drugs
6. Injectable antibiotics
7. Medications for Children Special Health Services (CSHS)
8. Medications under standing orders or by individual physicians' orders in the OPH clinics.

Patients receiving penicillin or ceftriaxone injections must be advised prior to being injected that they should be observed for at least thirty minutes after the injection is given. The time the injection is given and this verbal advisory given to the patient should be documented on the chart. A patient not cooperating with this requirement and leaving prior to being given permission to leave by the physician or nurse in the health unit or regional facility clinic must have the action documented in his or her clinic chart.

The names of all medications and equipment included in and on the emergency cart must be posted conspicuously next to or on the cart. A Registered Nurse must be assigned to check all medications, equipment and availability of oxygen at least monthly. This must be documented through a "sign-off" procedure.

EMERGENCY PROTOCOL

F A C T S A B O U T A N A P H Y L A X I S

Definition:
An acute systemic allergic reaction that occurs in a previously sensitized patient when he/she again receives the sensitizing antigen. Immediate appropriate treatment is mandatory to prevent laryngeal edema leading to fatal asphyxia and/or hypotensive shock leading to anoxia of the central nervous system and brain damage or death.

Causes of Anaphylaxis:
There are many causes of anaphylaxis, including drugs, foods, insect bites, allergy extracts, and other allergies. Severe and acute allergic reactions to drugs are very rare, occurring in about 1 in 10,000 and the risk of a fatal reaction is probably 1 in 100,000 cases.

Signs and Symptoms:
The clinical manifestations of anaphylaxis occur typically in 1 to 15 minutes following exposure to the precipitating agent. The more immediate the reaction, the greater the severity. Most commonly, the patient complains of uneasiness and apprehension. A diffuse erythema, facial flushing, pruritic and generalized urticaria occur next and may precede the more severe involvement of the respiratory and cardiovascular systems.

- **Dermatologic:**
  pruritis, diffuse erythema, urticaria, angioedema

- **Respiratory:**
  dyspnea, hoarseness, stridor, respiratory failure, chest tightness, coughing, wheezing, sneezing, nasal congestion, rhinorrhea

- **Cardiovascular:**
  diaphoresis, hypotension, rapid weak pulse, arrythmia, cardiac arrest

- **Neurologic:**
  apprehension, seizures

All OPH clinical facilities should have an emergency cart with drawers, to which the following chart is applicable. If there is no cart, then all emergency supplies must be otherwise easily available and accessible by the medical and nursing staff. All emergency equipment and supplies are mandated to be available, with the exception of endotracheal tubes and laryngoscopes. The availability of this equipment should be based on the clinical needs and the availability of trained personnel, as determined by the Regional Medical Director and/or the Regional Nurse Manager.

E M E R G E N C Y C A R T
C O N T E N T S*

TOP OF CART

Box of Gloves (latex and non-latex) (1 each)
Clip Board with papers for documentation and pen (1 each)

SIDE OF CART (HANGING)

Oxygen (Ready to administer) (1 tank)

DRAWER ONE

Alcohol swabs (one box of swabs)
Atropine sulfate injectable 0.4 mg/ml vial (2 vials)
Benadryl 50mg/ml (1 vial)
Epinephrine 1:1000 (3 ampules)
Needles 1 in. and 1 ½ in., 21 and 23 gauge (5 each)
Syringes TB, 2, 3, 5, and 10ml (5 each)
"Combivir" tablets (10 each)

DRAWER TWO

Angiocaths Nos. 18,20,22,24 gauge (2 each)
Butterflies (Pediatric IV Needles) 23 Gauge (2 each)
Infusion sets and tubing (2 each)
IV Starter kits (2 each)
Normal Saline solution for IV (500ml) (1 pack)
Tape, scissors, 4"x4" sterile gauze pads package (1 each)
Tourniquets (latex and non-latex) (1 each)

DRAWER THREE

Optional: Endotracheal tubes (Adult, Pediatric) (1 each)
Optional: Laryngoscope (adult and pediatric, curved, straight) with batteries and extra bulb (1 each)
CPR mouth-to-mask emergency resuscitator (1 resuscitator)
Tube of Water-soluble lubricant (1 tube)
Oral airways, Adult (small, medium, large) and Pediatric (Infant, Child) (1 each)
Blood pressure cuff (pediatric, adult, and large adult sizes) (1 each)

DRAWER FOUR (LARGE AREA)

Bag-valve masks (various sizes-adult and pediatric, disposable) (1 each)
Emergency Delivery Kit (1 kit)
Heavy Duty Extension Cord (50ft) (1 cord)
Oxygen cannula and masks (disposable masks, large, medium and small sizes) (1 each)
Suction Machine [and tubing and tips (1 each), if needed]

*numbers of items indicated are suggested only for minimum number to keep in stock

S T A N D I N G O R D E R S
TREATMENT FOR ANAPHYLAXIS

1. **CALL FOR HELP. NOTIFY EMERGENCY MEDICAL SERVICES.**
2. Place patient in recumbent (lying on back) position.
3. Evaluate Airway, Breathing, Circulation, Vital Signs and start Basic Life Support, if necessary.
4. **BEGIN DOCUMENTATION**
5. **** EPINEPHRINE IS THE TREATMENT OF CHOICE FOR ANAPHYLAXIS**. **Give subcutaneously every 10 MINUTES, UP TO A TOTAL OF THREE DOSES as needed.**
   Give epinephrine 1:1000 S.Q. according to weight
   Epinephrine 1:1000 at 0.005 ml/lb/dose or 0.01 ml/kg/dose

WEIGHT	DOSE, millimeters
< 10 lbs.	0.05 ml
10 - 20 lbs.	0.05 - 0.1ml
21 - 40 lbs.	0.1 - 0.2ml
41 - 60 lbs.	0.2 - 0.3ml
61 - 80 lbs.	0.3 - 0.4ml
81 - 100 lbs.	0.4 - 0.5ml
> 100 lbs.	0.5ml

6. Administer oxygen at 4-6 liters per minute by mask or cannula.
7. Start I.V. of Normal Saline at circulatory support (Keep Open) rate.
8. **IF NO RESPONSE TO FIRST** Epinephrine AFTER 10 MINUTES:
   Give the second dose of Epinephrine SQ as above.
9. **REASSESS**. Obtain Vital Signs at least every 5 min.
   Ensure that Emergency Medical Services have been called.
10. **IF NO RESPONSE TO SECOND EPINEPHRINE AFTER 10 MINUTES:**
    Give Third Dose of Epinephrine as Above.

11.****Give Benadryl, if ordered by physician, I.V.(slowly) or I.M. according to the weight of the patient, known or estimated, as for epinephrine. Benadryl may be given earlier in the protocol. The Benadryl (50 mg/ml) dosage is based on about 1 mg/kg or 0.5 mg/lb of body weight per dose. For the stocked parenteral formulation of diphenhydramine, this equals about 0.01 ml/lb of body weight per dose.** This guide indicates approximate dosage to be used when estimating weight of patient; the lower dose should be used for the lower weight and the higher dose for the higher weight given in the table.

Benadryl (50 mg/ml)

WEIGHT	DOSE
< 10 lbs.	0.08ml
10 - 20 lbs.	0.1- 0.2ml
21 - 40 lbs.	0.2- 0.4ml
41 - 60 lbs.	0.4- 0.6ml
61 - 80 lbs.	0.6- 0.8ml
81 - 100 lbs.	0.8- 1.0ml
> 100 lbs.	1.0ml

12. Give copy of documentation to EMS upon arrival.

E M E R G E N C Y R E P O R T
(PASSPORT Label May Be Used)

NAME_____ **ID#**_____

ADDRESS_____**PHONE**_____

AGE_____ **WEIGHT**_____ **ALLERGIE(S)**_____

DATE: _____ EMERGENCY START TIME_____ **TIME EMS CALLED**_____

HISTORY (Pertinent to this incident, i.e. known allergies previous reactions to medications or injections)

_____

_____

PHYSICAL ASSESSMENT (Pertinent to this incident, i.e. airway, circulation, temp.)

_____

_____

VITAL SIGNS (q 5 min)					**MEDICATIONS**					
TIME	**P**	**R**	**BP**		**TIME**	**NAME**	**DOSE**	**ROUTE**	**SIGN**	

INTERVENTIONS: OXYGEN: [ ] BLS: [ ] IV: [ ]
DISCHARGED TO: Hospital _____ Home _____

CONDITION: Stable _____ Unstable_____

Clinic Personnel_____ _____
(Print Name) (Signature)

EMS Personnel _____ _____
(Print Name) (Signature)

TIME EMS assumes care _____

										Date
										Oxygen (full, regulator working)
										Suction working (extension cord)
										Epinephrine 1:1000
										Benadryl (Diphenhydramine) 50 mg/ml
										Atropine sulfate
										Stethoscope, Sphygmomanometer and appropriate size cuffs
										Angiocaths (I-V needles) (sizes 18, 20, 22, 24)
										Syringes (sizes TB, 2 ml, 3 ml, 5 ml, 10 ml), IV Start Kits
										IV Solution, IV Sets
										Tourniquets
										Optional: Laryngoscopes, Endotracheal Tubes
										Oral Airways, Suction Tubing
										CPR mouth-to-mask emergency resuscitator
										Oxygen Masks, Cannulas (tubing)
										Emergency Delivery Kits
										Combivir capsules
										COMMENTS
										NURSE'S SIGNATURE

Special Considerations of Vaso-vagal Reactions

I. Keep patient in supine (lying on back with face upward) or recumbent position, if shock present
II. Maintain airway
III. Support ventilation with oxygen
IV. Monitor blood pressure and pulse
V. Consider giving atropine sulfate 0.4 mg IM, if clinically indicated

These reactions (very rarely associated with insertion of intra-uterine devices) must be handled by the attending physician and/or an advanced practice registered nurse in accord with the OPH-approved Collaborative Practice Protocol. The protocol is essentially repeated above.

SPECIAL CONSIDERATION FOR EMERGENCY PROTOCOL TO BE FOLLOWED IN A NON-MEDICAL FACILITY:

PURPOSE: This section will clarify the emergency protocol to be followed when OPH nursing personnel are administering immunizations in a non-medical facility and should anaphylaxis occur in a patient following administration of a vaccine.

POLICY STATEMENT: The Office of Public Health strongly encourages its medical, nursing and other allied health professional staff to participate in all community events, such as health fairs, where the opportunity will be presented to offer immunizations to the public, especially children, even though these events may be held in a non-medical facility. Although anaphylaxis may occur for the first time in any patient receiving a vaccine (even a repeat dose of a vaccine received in the past with no problem experienced by the patient), the occurrence of anaphylaxis following "routine" vaccinations is extremely rare.

Vaccinations which may be given to those needing them by OPH nursing personnel at special events at non-medical facilities are: Diphtheria, Tetanus and Acellular Pertussis (DTaP), Diphtheria and Tetanus - pediatric (DT), Tetanus and Diphtheria - adult (Td), TdaP, Meningococcal Vaccine (MCV4), Polio Vaccine, Measles, Mumps and Rubella (MMR), Varicella (VAR), Haemophilus influenza, type b (Hib), Hepatitis B Virus (HBV), Pneumococcal Vaccine, Influenza Vaccine, Hepatitis A Vaccine, and Human Papilloma Virus (HPV) vaccine (in those designated areas where this vaccine is given routinely). Indications for giving each vaccine and dosage are per existing OPH policy and protocol.

Emergency supplies brought to the site by the OPH nursing personnel must be, as a minimum requirement: A sufficient quantity of injectable aqueous epinephrine solution, 1:1000 strength; a sufficient quantity of injectable diphenhydramine ("Benadryl") solution, 50 mg/ml strength (if the physician is expected to be present); sufficient numbers of syringes and needles; stethoscopes. Sphygmomanometers and oral airways and cardiopulmonary resuscitation (CPR) masks in case CPR is needed. The facility being used must be equipped with a telephone, readily accessible and usable by the OPH personnel in the event of an emergency. The Office of Public Health regional medical director or his or her physician designee must be the general supervisor of the immunizations and be available for consultation, either in person or by telephone, regarding contraindications and adverse reactions during the time of administration of immunizations. **The Emergency Protocol and Standing Orders contained in this policy remain the same, <u>except for the standing orders related to administration of oxygen and the starting of an intravenous drip, which will not be done in a non-medical facility. The "Call for Help" means calling the local emergency number by telephone, 911 in most of the state. The local number must be known to the personnel in areas where 911 is not available.</u>**

It is also suggested that the latest OPH immunization schedules and the protocol for handling anaphylaxis be brought to the immunization site for reference as needed. The sheets may be laminated for durability! Questions regarding this memorandum may be addressed to Dr. Erin Brewer (504) 219-4402 or Ms. Clair Millet (225) 342-7880.

Approved for redirection or redistribution

_____

Regional Administrator Date

Standing Orders for the Treatment of Hemorrhagic Shock

Definition: Hemorrhagic shock is a clinical state that is caused from inadequate tissue perfusion due to acute or sudden loss of blood. The blood loss may be external as manifested by severe vaginal bleeding or internal manifested by hemorrhage into peritoneal (abdominal) cavity.

Causes: Perforation of the Uterus, Ruptured Ectopic Pregnancy, Incomplete Abortion (Miscarriage), or Trauma

Clinical Findings:

***Mental Status**:* Alterations in sensorium: anxiety, restlessness, fear, apathy, stupor
Skin: Cold, clammy, pale, mottled, easily blanched
Respiratory: Tachypnea-Rapid Breathing. Breath sounds may be clear to auscultation
***Heart*:** Tachycardia; Arrhythmias
Extremities: collapse of the peripheral veins
Other: Thirst

Intervention:

***Please ensure that all Emergency Supplies and Equipment are current and available.**

1. CALL FOR HELP. CALL 911-NOTIFY EMERGENCY SERVICES TO TRANSPORT PATIENT TO THE APPROPRIATE EMERGENCY FACILITY.
2. Place patient in the recumbent position and elevate the legs.
3. Start large bore I.V. (18-20 Gauge) of Normal Saline and administer at wide open rate. *Upon arrival of EMS, if hemorrhage is extremely severe and/or worsening, a second large bore I.V. can be started.*
4. Administer oxygen at 4-6 liters per minute per mask or nasal cannula.
5. Monitor vital signs every 5 minutes.
   Begin documentation using the* ***Emergency Report* *form included in Policy Memorandum 119 (Revision 5).*
6. Once vital signs are stable, I.V. rate may be slowed to 200-250 cc per hour.
7. Upon arrival of EMS, Medical or Nursing staff will assist with the transfer of patient to EMS care.
8. Provide as much history as possible to EMS along with copies of documentation of this incident and appropriate medical information. Follow-up of the patient's condition should be documented in the patient's chart.

DEPARTMENT OF HEALTH AND HOSPITALS

OFFICE OF PUBLIC HEALTH

POLICY MEMORANDUM NO. 205 (REVISED) December 12, 2005

From: Erin Brewer, M.D., M.P.H.
Medical Director and Assistant State Health Officer

Subject: Protocol for Managing Needle Stick Injuries and Other Unintentional Exposures to Blood or Potentially Infectious Body Fluids

This policy updates and amends the first five pages of Policy Memorandum No. 205 (REVISED) issued October 29, 2001. This updated and amended policy updated in accordance with the Centers for Disease Control and Prevention's updated Guidelines issued September 30, 2005. Note that this revision and the updated guidelines pertain only to human immuno-deficiency virus (HIV) exposure in an occupational setting. These updates are contained in the following narrative and in Tables 1-6.

As in the previous policy, reference may also be made to Policy Memorandum No. 170 (December 1, 1990) "Hepatitis B Vaccine Recommendations for Office of Public Health Employees" and Policy Memorandum No. 128 Addendum 2 Revised (October 13, 1997) "Policy on Blood Specimen Collection and Infectious Waste Management in Office of Public Health Facilities."

Form Epi-31 is included in this policy and, if needed, should be photocopied as necessary. Forms referenced in Ms. Janet Merritt's memorandum of December 20, 1999 are included in this policy memorandum and are available from the Regional or Central Office Safety Administrator. Laboratory forms needed are available by ordering in the usual way.

This Policy Memorandum must also be included in the Employee Health and Safety Index in your facility. Questions regarding this memorandum may be addressed to the HIV/AIDS Program, (504) 568-7524, Dr. Louis Trachtman or Ms. Roma Oliveri via GroupWise or at (225) 763-3593.

Approved for Redirection or Redistribution

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Regional Administrator Date

I. Evaluation of Exposure and Exposure Source

Health care workers (HCW) are at risk for occupational exposures to Human Immuno-deficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) through injuries involving needle sticks and other unintentional exposure to blood and body fluids. The most important response to this risk is prevention by strict adherence to guidelines, the "universal precautions," which minimize the likelihood of such exposures. The guidelines that follow are meant to be used when an exposure of this type does occur in an Office of Public Health (OPH) facility.

Following national guidelines issued by the United States Public Health Service Centers for Disease Control and Prevention (CDC), exposure is contact with blood or body fluids, for which universal precautions apply, from a known or unknown patient source, through percutaneous inoculation (such as injury with a hypodermic needle or other "sharps") or through contact with an open wound, non-intact skin or mucous membranes (splatter into eyes, nose or mouth). The body fluids for which universal precautions apply are: blood, amniotic fluid, pericardial fluid, peritoneal fluid, pleural fluid, synovial fluid, cerebrospinal fluid, semen, and vaginal secretions. Feces, nasal secretions, saliva, sputum, sweat, tears, urine and vomitus are not considered potentially infectious for HIV, HBV, or HCV unless they contain blood. The purpose of this protocol is to guide employees, who have had such exposure through the appropriate procedures in assessing risk, taking appropriate prophylaxis, follow-up and reporting the incident.

Evaluation of Occupational Exposure Sources

Known Sources

-Test known sources for HBsAg, anti-HCV and HIV antibody

-Consider using a rapid HIV antibody test

-If the source person is not infected with a blood-borne pathogen, baseline testing or further of the exposed person is not necessaryfollow-up

-For source patients whose infection status remains unknown, e.g. the source pateint refuses testing, consider medical diagnoses, clinical symptoms and history of risk behaviors

- Do not test discarded needles for blood-borne pathogens

Unknown Sources

-For unknown sources, evaluate the likelihood of exposure to a source at high risk of infection

- Consider likelihood of blood-borne pathogen infection among patients in the exposure setting

II. Immediate Wound Care

Immediately following percutaneous exposure the site should be washed with soap and water, following a mucous membrane exposure flush with copious amounts of water, and following exposure to the eye irrigate with copious amounts of saline solution or other sterile irrigants. There is no data to suggest that use of other antiseptic agents is of additional benefit.

III. Risk Assessment and Prophylaxis

A. HIV

The risk of HIV infection after exposure depends on (1) the nature of the exposure, and (2) the HIV status or risk of HIV infection in the source patient. CDC has developed national guidelines for evaluating this risk. These guidelines are to be used as follows:

1. The Nature of the Exposure

- **The average risk of infection from a percutaneous (e.g. needle stick) exposure to HIV is 0.3%.**
- **The risk of infection from a mucous membrane exposure to HIV is 0.9%.**

The risk of infection from non-intact skin exposure is estimated to be less than that for mucous membrane exposure. Employees should assess the type of exposure and amount of blood or fluid involved in the exposure.

2. Determining the HIV Status of the Source Patient

This may be done by searching medical records (e.g. STD, Prenatal or Family Planning charts or clinic records) or by requesting a blood sample for an HIV antibody test from a source patient. In most circumstances the source patient will be willing to provide consent for testing. If the source patient refuses and his or her blood has already been drawn for other purposes, under certain circumstances that blood may be used to test for HIV after it is used for the reason for which it was originally drawn. Consult with central office if this situation occurs. If it is not possible to determine the HIV status of the source patient, it is useful to remember that, in general, patients in OPH clinics are at very low risk for HIV infection, because of their being children or adults lacking the risk factors for infection.

For those rare instances in which the source patient is known to be HIV+, it is useful to check medical records to estimate his or her severity of disease (presence of AIDS [Acquired Immuno-deficiency Syndrome]) and the drugs, including the anti-retroviral drugs, being used to treat the disease.

3. Combine the information about the status of the source patient and the nature of the exposure to estimate the risk of infection. It should then be determined whether or not post-exposure prophylaxis (PEP) should be considered or is recommended by national guidelines. Most source patients in OPH clinics have an unknown HIV status. *If the OPH source patient's HIV status cannot be determined, the guidelines would not suggest nor recommend that PEP for HIV infection for an OPH employee after an occupational exposure be started.*

4. Determine whether or not prophylactic measures will be taken. These are drugs that are felt to decrease the risk of HIV infection following an actual occupational HIV exposure. *The drugs involved can cause side effects or serious toxicity; toxic effects from an attempt to prevent infection are often far more likely than the risk of HIV infection!* The decision regarding whether these medications should be taken or not should be made by the exposed person after reviewing this information and after consultation with other medical professional persons. Employees and supervisors considering the use of prophylactic drugs should consult immediately with the regional medical director, their private physician and/or the medical director of the HIV/AIDS Program in OPH. Additionally the advice of an infectious disease medical specialist should be sought. The following must be considered:

- **If prophylactic drugs are used, they should be started as soon as possible after exposure, preferably within 1 to 2 hours.**
- **The drugs should continue to be taken for four weeks.**

NOTE: PLEASE SEE ACCOMPANYING TABLES 1-6

IN THE PREVIOUS PUBLIC HEALTH SERVICE (PHS) GUIDELINES, A COMBINATION OF STAVUDINE (D4T) AND DIDANOSINE (DDI) WAS CONSIDERED ONE OF THE FIRST-CHOICE POSTEXPOSURE PROPHYLAXIS (PEP) REGIMENS; HOWEVER, THIS REGIMEN IS NO LONGER RECOMMENDED BECAUSE OF CONCERNS ABOUT TOXICITY (ESPECIALLY NEUROPATHY AND PANCREATITIS) AND THE AVAILABILITY OF MORE TOLERABLE ALTERNATIVE REGIMENS.

PREVIOUSLY, INDINAVIR (IDV), NELFINAVIR (NFV), EFAVIRENZ (EFV), OR ABACAVIR (ABC) WERE RECOMMENDED AS FIRST-CHOICE AGENTS FOR INCLUSION IN AN EXPANDED PEP REGIMEN.

PHS NOW RECOMMENDS THAT EXPANDED PEP REGIMENS BE PROTEASE-INHIBITOR (PI) BASED. THE PI PREFERRED FOR USE IN EXPANDED PEP REGIMENS IS LOPINAVIR/RITONAVIR (LPV/RTV). OTHER PI'S ACCEPTABLE FOR USE IN EXPANDED PEP REGIMENS INCLUDE ATAZANAVIR (ATV), FOSAMPRENAVIR (FOSAPV), RTV-BOOSTED IDV, RTV-BOOSTED SAQUINAVIR (SQV), OR NFV. ALTHOUGH SIDE EFFECTS ARE COMMON WITH NNRTIS, EFV MAY BE CONSIDERED FOR EXPANDED PEP REGIMENS, ESPECIALLY WHEN RESISTANCE TO PI'S IN THE SOURCE PERSON'S VIRUS IS KNOWN OR SUSPECTED. REMEMBER, CAUTION IS ADVISED WHEN EFV IS USED IN WOMEN OF CHILDBEARING AGE BECAUSE OF THE RISK OF TERATOGENICITY.

Combivir will continue to be the PEP stocked in OPH clinical facilities' emergency carts. If exposed employees choose to take these medications, they or their supervisors should contact the regional medical director and/or the HIV/AIDS Prevention Program Medical Director to help obtain the drugs. The initial five-day supply is available on the emergency cart in each OPH clinical site. The Office of Public Health pharmacy can supply the remainder of the prophylactic drug Combivir to complete the usual 28-day prophylactic regimen. This combination drug is also generally available at local pharmacies. Additional drugs, if needed, may be supplied on an individual need basis, if expanded PEP is needed, as indicated in the updated guidelines.

If the regional medical director or HIV/AIDS program medical director is not immediately available, the employee and/or supervisor should contact their own physician or a physician at the regional HIV/AIDS clinic, which is located in each regional state-run (Charity) hospital. In all instances, the employee must seek medical consultation from their own physician as soon as possible regarding continuing prophylaxis.

All OPH clinical sites must replenish their stock of Combivir on the emergency cart as soon as the initial package is used. The OPH clinical facilities must always be stocked with a five-day supply of Combivir. As mentioned above, in all instances staff using these drugs must consult with their own physician as soon as possible regarding medical follow-up and continuation of the drugs.

<u>Pregnancy</u> in an exposed person is not a contraindication to starting PEP for HIV. The decision to use any anti-retroviral drug during pregnancy should involve discussion between the pregnant woman and her physician regarding the potential benefits and risks to her and her fetus. Certain drugs should be avoided in pregnant women. Because teratogenic effects were observed in primate studies, as mentioned above, efavirenz is not recommended during pregnancy. Reports of fatal lactic acidosis in pregnant women treated with a combination of didanosine and stavudine have prompted warnings about these drugs during pregnancy. Because of risk of hyperbilirubinemia in newborns, indinavir should not be administered to pregnant women shortly before delivery.

5. Have a baseline HIV antibody test done. All exposed persons who have experienced an exposure serious enough to consider PEP (regardless of whether or not drugs were actually taken) should be tested for HIV antibodies at the time of exposure. The blood sample for this test should be sent to the OPH Laboratory.

September 18, 2009

OPH REGIONAL STRIKE TEAM COORDINATOR

Job Action Sheet

Reports to: OPH Command Center Strike Team Coordinator (CCSTC)

Mission: Organize and facilitate Strike Team orientation, assignment and deployment.

Immediate:

- Receive appointment from OPH Command Center Strike Team Coordinator
- Read this entire Job Action Sheet
- Obtain briefing from OPH CCSTC and participate in planning meetings and conference calls and evaluate the operation
- Develop the Strike Team Action Plan
- Identify Strike Team "team" leader for each Strike Team
- Identify and obtain resources needed for the vaccination activity
- Coordinate IT and data entry needs (i.e. LINKS, daily reporting, etc.) with OPH Immunization Program Consultants and IT personnel
- Verify licenses of nurse volunteers and ensure adequate training is done for nurses needing refresher courses

Intermediate:

- Brief OPH CCSTC routinely on the status of the Strike Team Operations.
- Coordinate and monitor/evaluate Strike Team Operations and available resources needed to achieve mission and request resources as needed.

Extended:

- Maintain documentations of all actions and decisions on a continual basis.
- Forwards completed reports, as requested, to the OPH CCSTC
- Report issues to CCSTC
- Prepare the end of shift report and present to oncoming Strike Team Coordinator and OPH CCSTC if necessary
- Prepare final report, if requested, for CCSTC

STRIKE TEAM MEMBERS (NURSING/Medical)

Job Action Sheet

Reports to: Strike Team Leader

Mission: Provide immunizations and emergency care as directed and assigned by the Strike Team Leader.

Immediate:

- Receives assignment from OPH Strike Team Leader
- Read this entire Job Action Sheet and review organizational chart and Strike Team Action Plan
- Obtain briefing from OPH Strike Team Leader
- Review Strike Team Procedures prior to deployment

Intermediate:

- Brief OPH Strike Team Leader daily on status of strike team operation
- Monitor resources and report needs to OPH Strike Team Leader

Extended:

- Maintain documentations of all vaccinations and services provided (Written and verbal reports shall be given daily on the number of vaccinations given).
- Document and maintain all patient recordings
- Observe all staff for signs of stress. Report issues to Strike Team Leader. Take breaks when necessary after reporting off to Team Leader.

STRIKE TEAM MEMBERS (NON-MEDICAL)

Job Action Sheet

Reports to: Strike Team Leader as identified by the OPH Regional Strike Team Coordinator

Mission: Provides ancillary support to the medical strike team as directed by the Strike Team Leader

Immediate:

- Receive assignment from Strike Team Leader
- Read this entire Job Action Sheet and review organizational chart and Strike Team Action Plan
- Obtain briefing from Strike Team Leader
- Review Strike Team Procedures prior to deployment
- Work with medical Strike Team members as appropriate

Intermediate:

- Work with clerical, LINKS, or other personnel as appropriate
- Maintain resources as appropriate

Extended:

- Observe all staff for status and signs of stress
- Take breaks as needed after reporting off to Strike Team Leader

STRIKE TEAM LEADER

Job Action Sheet

Reports to: OPH Regional Strike Team Coordinator

Mission: Coordinates vaccination strike team efforts. Coordinates personnel and supplies.

Immediate:

- Read this entire Job Action Sheet
- Obtain a full briefing of the Regional Strike Team Coordinator
- Provide just in time refresher training for team members as needed.
- Request resources as needed for /Strike Team operation
- Keep OPH Regional Strike Team Coordinator aware of Operation status

Intermediate:

- Design routine briefings with OPH Regional Strike Team Coordinator in regards to resources and strike team operations
- Maintain documentations of all actions and decisions on a continual basis
- Report issues to OPH Regional Strike Team Coordinator

Extended:

- Prepare end of shift report and update, and strike team operations and present to oncoming Strike Team Leader as requested
- Maintain a list of emergency phone number listings in your area
- Maintain telephone contact availability

2009 H1N1 INFLUENZA VACCINE

INACTIVATED WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 What is 2009 H1N1 influenza?

2009 H1N1 influenza (which was earlier called Swine Flu) is a type of flu caused by a new strain of influenza virus. Because it has spread to many countries, it has been declared a pandemic influenza strain.

Like other flu viruses, 2009 H1N1 spreads from person to person through coughing, sneezing, nasal secretions, and sometimes through handling objects contaminated with the virus.

Signs of 2009 H1N1 can include:
- Fatigue
- Fever
- Sort Throat
- Muscle Aches
- Chills
- Coughing
- Sneezing

Some people also have diarrhea and vomiting.

Most people recover within a week. But some people get pneumonia or other serious illnesses. Some people have to be hospitalized and some die.

2 How is 2009 H1N1 different from regular (seasonal) flu?

Seasonal flu viruses change from year to year, but they are closely related to each other.

People who have had prior flu infections usually have some immunity to seasonal flu viruses.

The 2009 H1N1 flu virus is a new virus strain. It is very different from seasonal flu viruses.

Most people have little or no immunity to 2009 H1N1 flu.

3 2009 H1N1 influenza vaccine

Vaccines are being made to protect against 2009 H1N1 influenza.

- These vaccines are produced just like seasonal flu vaccines.
- They are expected to be as effective as seasonal flu vaccines.
- They will not prevent "influenza-like" illnesses caused by other viruses.
- They will not prevent seasonal flu. ***You should also get seasonal influenza vaccine, if recommended.***

Inactivated (killed) vaccine is injected into the muscle, like the annual flu shot. **This statement describes the inactivated vaccine.**

A **live, intranasal** vaccine is also available. It is described in a separate statement.

Some inactivated H1N1 vaccine contains a preservative called thimerosal. While some people have suggested that thimerosal may be related to developmental problems in children, that theory has not been supported by research. Thimerosal-free vaccine is also available.

4 Who should get 2009 H1N1 influenza vaccine and when?

WHO

Groups recommended to receive 2009 H1N1 vaccine first are:

- Pregnant women
- People who live with or care for infants younger than 6 months of age
- Health care and emergency personnel
- Anyone from 6 months through 24 years of age
- Anyone from 25 through 64 with certain chronic medical conditions or a weakened immune system

These groups should also be vaccinated:
- Healthy 25-64 year olds
- Adults 65 and older

WHEN

Get vaccinated as soon as the vaccine is available.

Recommendations may change if we learn that other groups of people are at particularly high risk.

Some people may need two doses of vaccine.

5 Some people should not get the vaccine or should wait

You should not get 2009 H1N1 flu vaccine if you have a **severe (life-threatening) allergy** to **eggs**, or to **any other substance in the vaccine**. *Tell the person giving you the vaccine if you have any severe allergies.*

Also tell them if you have ever had:
- a life-threatening allergic reaction after a dose of seasonal flu vaccine,
- Guillain Barré Syndrome (a severe paralytic illness also called GBS).

These may not be reasons to avoid the vaccine, but the medical staff can help you decide.

If you are moderately or severely ill, you might be advised to wait until you recover before getting the vaccine. If you have a mild cold or other illness, there is usually no need to wait.

Pregnancy or breastfeeding are *not* reasons to avoid getting 2009 H1N1 flu vaccine.

2009 H1N1 vaccine may be given at the same time as other vaccines, including seasonal influenza vaccine.

6 What are the risks from 2009 H1N1 influenza vaccine?

A vaccine, like any medicine, could cause a serious problem, such as a severe allergic reaction. But the risk of any vaccine causing serious harm, or death, is extremely small.

The virus in inactivated 2009 H1N1 vaccine has been killed, so you cannot get influenza from the vaccine.

The risks from 2009 H1N1 vaccine are expected to be similar to those from seasonal flu vaccine:

Mild problems:
- soreness, redness, tenderness, or swelling where the shot was given • fainting (mainly adolescents)
- headache, muscle aches • fever • nausea

If these problems occur, they usually begin soon after the shot and last 1-2 days.

Severe problems:
- Life-threatening allergic reactions to vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.
- In 1976, an earlier type of swine flu vaccine was associated with cases of Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS.

7 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?
- **Call** a doctor, or get the person to a doctor right away.
- **Tell** the doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

8 Vaccine injury compensation

The Federal government is providing this vaccine for receipt on a voluntary basis. However, state law or employers may require vaccination for certain persons.

If you or your child has a reaction to the vaccine, your ability to sue is limited by law.
However, a federal program has been created to help pay for the medical care and other specific expenses of certain persons who have a serious reaction to this vaccine. For more information about this program, call **1-888-275-4772** or visit the program's website at: **www.hrsa.gov/countermeasurescomp/default.htm**.

9 How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/h1n1flu** or **www.cdc.gov/flu**
- Visit the web at **www.flu.gov**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Vaccine Information Statement (Pre-Licensure)
2009 H1N1 Influenza Vaccine 8/26/09

2009 H1N1 INFLUENZA VACCINE

LIVE, ATTENUATED (the nasal spray vaccine) WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 What is 2009 H1N1 influenza?

2009 H1N1 influenza (sometimes called Swine Flu) is caused by a new strain of influenza virus. It has spread to many countries.

Like other flu viruses, 2009 H1N1 spreads from person to person through coughing, sneezing, and sometimes through touching objects contaminated with the virus.

Signs of 2009 H1N1 can include:
• Fatigue • Fever • Sore Throat • Muscle Aches
• Chills • Coughing • Sneezing

Some people also have diarrhea and vomiting.

Most people feel better within a week. But some people get pneumonia or other serious illnesses. Some people have to be hospitalized and some die.

2 How is 2009 H1N1 different from regular (seasonal) flu?

Seasonal flu viruses change from year to year, but they are closely related to each other.

People who have had flu infections in the past usually have some immunity to seasonal flu viruses (their bodies have built up some ability to fight off the viruses).

The 2009 H1N1 flu virus is a new virus strain. It is very different from seasonal flu viruses.

Most people have little or no immunity to 2009 H1N1 flu (their bodies are not prepared to fight off the virus).

3 2009 H1N1 influenza vaccine

Vaccines are available to protect against 2009 H1N1 influenza.

- These vaccines are made just like seasonal flu vaccines.
- They are expected to be as safe and effective as seasonal flu vaccines.
- They will not prevent "influenza-like" illnesses caused by other viruses.
- They will not prevent seasonal flu. *You should also get seasonal influenza vaccine, if you want protection from seasonal flu.*

Live, attenuated intranasal vaccine (or **LAIV**) is sprayed into the nose. **This sheet describes the live, attenuated intranasal vaccine.**

An **inactivated** vaccine is also available, which is given as a shot. It is described in a separate sheet.

The 2009 H1N1 LAIV does not contain thimerosal or other preservatives. It is licensed for people from 2 through 49 years of age.

The vaccine virus is attenuated (weakened) so it will not cause illness.

4 Who should get 2009 H1N1 influenza vaccine and when?

WHO

LAIV is approved for people from 2 through 49 years of age who are not pregnant and do not have certain health conditions (see number 5 below). Groups recommended to receive 2009 H1N1 LAIV first are healthy people who:

- are from 2 through 24 years of age,
- are from 25 through 49 years of age and
  - live with or care for infants younger than 6 months of age, or
  - are health care or emergency medical personnel.

As more vaccine becomes available, other healthy 25 through 49 year olds should also be vaccinated.

> Note: While certain groups should not get LAIV – for example pregnant women, people with long-term health problems, and children from 6 months to 2 years of age – it is important that they be vaccinated . They should get the flu shot.

The Federal government is providing this vaccine for receipt on a voluntary basis. However, state law or employers may require vaccination for certain persons.

WHEN

Get vaccinated as soon as the vaccine is available.

Children through 9 years of age should get **two doses** of vaccine, about a month apart. Older children and adults need only one dose.

5 Some people should not get the vaccine or should wait

You should not get 2009 H1N1 LAIV if you have a **severe (life-threatening) allergy to eggs, or to any other substance in the vaccine**. *Tell the person giving you the vaccine if you have any severe allergies.*

2009 H1N1 LAIV should not be given to the following groups.

- children younger than 2 and adults 50 years and older
- pregnant women,
- anyone with a weakened immune system,
- anyone with a long-term health problem such as
  - heart disease
  - kidney or liver disease
  - lung disease
  - metabolic disease such as diabetes
  - asthma
  - anemia and other blood disorders
- children younger than 5 years with asthma or one or more episodes of wheezing during the past year,
- anyone with certain muscle or nerve disorders (such as cerebral palsy) that can lead to breathing or swallowing problems,
- anyone in close contact with a person with a *severely* weakened immune system (requiring care in a protected environment, such as a bone marrow transplant unit),
- children or adolescents on long-term aspirin treatment.

If you are moderately or severely ill, you might be advised to wait until you recover before getting the vaccine. If you have a mild cold or other illness, there is usually no need to wait.

Tell your doctor if you ever had:

- a life-threatening allergic reaction after a dose of seasonal flu vaccine,
- Guillain-Barré syndrome (a severe paralytic illness also called GBS).

These may not be reasons to avoid the vaccine, but the medical staff can help you decide.

2009 H1N1 LAIV may be given at the same time as most other vaccines. Tell your doctor if you got any other vaccines within the past month or plan to get any within the next month. H1N1 LAIV and seasonal LAIV should not be given together.

6 What are the risks from 2009 H1N1 LAIV?

A vaccine, like any medicine, could cause a serious problem, such as a severe allergic reaction. But the risk of any vaccine causing serious harm, or death, is extremely small.

The risks from 2009 H1N1 LAIV are expected to be similar to those from seasonal LAIV:

Mild problems:

Some children and adolescents 2-17 years of age have reported mild reactions, including:

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- wheezing
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

Severe problems:

- Life-threatening allergic reactions to vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the vaccination.
- In 1976, an earlier type of inactivated swine flu vaccine was associated with cases of Guillain-Barré Syndrome (GBS). LAIV has not been linked to GBS.

7 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** the doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

8 Vaccine injury compensation

If you or your child has a reaction to the vaccine, your ability to sue is limited by law.

However, a federal program has been created to help pay for the medical care and other specific expenses of certain persons who have a serious reaction to this vaccine. For more information about this program, call **1-888-275-4772** or visit the program's website at:

www.hrsa.gov/countermeasurescomp/default.htm.

9 How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/h1n1flu** or **www.cdc.gov/flu**
  - Visit the web at **www.flu.gov**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Vaccine Information Statement
2009 H1N1 LAIV 10/2/09

FDA Approval of 2009 Novel H1N1 Vaccine: Summary

FDA approved four vaccines as a strain change to each manufacturer's seasonal influenza vaccine on September 15, 2009. The presentations, age, and dosage specifications listed in the chart below. For more information, as well as the package inserts, visit FDA's website at http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm.

Manufacturer	Presentations	Age	Dosage[1]	Type	Package Insert
CSL Limited	-0.5 mL prefilled single-dose syringe (thimerosal free) -5 mL multi-dose vial containing 10 doses (with thimerosal)	Adults 18 years of age and older	-Single 0.5 mL dose	Inactivated virus; intramuscular injection	Link
GlaxoSmithKline[2]	*Awaiting FDA licensure*				
Novartis Vaccines and Diagnostics Limited	-0.5 mL prefilled single-dose syringe (trace thimerosal) -5 mL multi-dose vial (with thimerosal)	Persons 4 years of age and older	-Two 0.5 mL doses approx. 1 month apart for children 4 to 9 -Single 0.5 mL dose for children 10-17 -Single 0.5 mL dose for adults 18 and older	Inactivated virus; intramuscular injection	Link
Sanofi Pasteur Inc.	-0.25 mL prefilled single-dose syringe (thimerosal free) distinguished by pink syringe plunger rod -0.5 mL prefilled single-dose syringe (thimerosal free) -0.5 mL single-dose vial (thimerosal free) -5 mL multi-dose vial (with thimerosal)	Persons 6 months and older	-Two 0.25 mL doses approx. 1 month apart for children 6-35 months of age -Two 0.5 mL doses approx. 1 month apart for children 36 months-9 years -Single 0.5 mL dose for children 10 years and older -Single 0.5 mL dose for adults 18 and older	Inactivated virus; intramuscular injection	Link
MedImmune, LLC	-0.2 mL prefilled single-dose intranasal sprayer	Persons aged 2 to 49 years	-Two 0.2 mL doses approx. 1 month apart for children 2 to 9 -Single 0.2 mL dose for persons 10-49	**LAIV; Intranasal spray**	Link

1 Based on currently available information, which suggests children 6 months to 9 years of age have little or no evidence of protective antibodies to the novel H1N1 virus. It is expected that children 9 years of age and younger should be administered two doses of the vaccine, and that children and adults 10 years of age and older will need one dose. Clinical studies are underway and will provide additional information about the optimal dosage for children.

2 The GlaxoSmithKline H1N1 vaccine has not yet been approved. Based on their licensure for 2009-2010 seasonal influenza vaccine, their H1N1 vaccine can be expected to be an inactivated virus vaccine for adults 18 and older with presentations of 0.5 mL prefilled single-dose syringes (thimerosal free).

ASTHO
September 18, 2009

VACCINATOR LIABILITY

VACCINATOR LIABILITY COVERAGE: Liability immunity for "activities related to administration and use of the vaccine" is provided as part of the Secretary's declaration under the Public Readiness and Emergency Preparedness (PREP) Act.

On June 15, 2009, Secretary Sebelius signed a declaration under the PREP Act to extend liability immunity against tort claims (except for willful misconduct) to individuals and entities involved in all stages of 2009 H1N1 influenza vaccine development, testing, manufacture, distribution, prescribing, administration, and use. Liability immunity means that there is no legal tort claim that can be pursued in state or federal court. Individuals and entities that receive liability immunity under the declaration include manufacturers, distributors, states, locals, tribes, and other entities that supervise or administer a vaccination program; and healthcare professionals or others authorized under state law to prescribe, administer, and dispense vaccines when they are carrying out activities in accordance with the conditions stated in the declaration. The declaration covers all vaccination activities related to present or future federal contracts, grants, cooperative agreements, interagency agreements, or memoranda of understanding, including all activities using vaccine procured by HHS. The PREP Act also authorizes HHS to establish a compensation program when a declaration is issued under the Act. The PREP Act liability protections under the declaration pertain to anything causally related to administration and use of the vaccine, but do not extend to general medical care rendered in emergencies.[11,12]

The Pandemic Influenza Vaccines Amendment to the January 26, 2007 Declaration under the PREP Act is available at: http://edocket.access.gpo.gov/2009/E9-14948.htm. Questions and answers on the PREP Act are available at: http://www.hhs.gov/disasters/emergency/manmadedisasters/bioterorism/medication-vaccine-qa.html.

Coverage under the Public Readiness and Emergency Preparedness (PREP) Act for H1N1 Vaccination

Q1: What is the PREP Act?

A1: The Public Readiness and Emergency Preparedness Act or PREP Act is a federal law that authorizes the Secretary of Health and Human Services to issue a declaration to provide tort liability immunity (except for willful misconduct) to individuals and organizations involved in the development, manufacture, distribution, administration and use of countermeasures against pandemics, epidemics and diseases and health threats caused by chemical, biological, radiological, or nuclear agents of terrorism.

Q2: How does the PREP Act work?

A2: On June 15, 2009, Secretary of Health and Human Services Kathleen Sebelius extended the PREP Act declaration for pandemic vaccines to H1N1 vaccines, and amended the declaration on (date) to add provisions that can help H1N1vaccination campaigns.

Q3: What is tort liability immunity?

A3: Tort liability immunity means that no legal tort claim related to activities described in the declaration that can be pursued in State or U.S. Federal court. The declaration provides legal liability protections for individuals or entities that are involved in the distribution and administration of H1N1 vaccine.

Q4: Who is immune from tort liability under H1N1 vaccine declaration?

A4: The H1N1 vaccine declaration provides tort liability immunity to a group named "program planners." Program planners include State and local governments, Tribes, other entities that supervise or administer a vaccination program, establish requirements, provide policy guidance, supply technical or scientific advice or assistance, or provide a facility to administer the vaccine. Program planners can include private sector individuals and organizations, community groups, schools, or businesses.

Government program planners only have tort liability immunity when the vaccines are provided to them voluntarily, such as when Federal Government provides vaccines from Federal stockpiles, or when the vaccines are donated or sold.

The H1N1 vaccine declaration also provides tort liability immunity to a group named "qualified persons." Qualified persons include healthcare professionals or others authorized under State law to prescribe, administer, and dispense vaccines.

The declaration also provides tort liability immunity to individuals or organizations that assist public officials with vaccination programs, even if they are not licensed healthcare professionals. Qualified persons also include individuals or organizations (including their officials, agents, employees, contractors and volunteers) that are part of the public health and medical emergency response of the "Authority Having Jurisdiction" for prescribing, administering, delivering, distributing, or dispensing the vaccine following a declaration of emergency issued by a federal, regional, State, or local official. The "Authority Having Jurisdiction" is the public agency or entity or its delegate with legal responsibility and authority to respond to the incident. These qualified persons can include any public or private person, entity, or organization – such as local
businesses, community groups and volunteer groups -- and their officials, agents, employees, contractors and volunteers, assisting in carrying out vaccine programs under agreements, plans, protocols, procedures, policies or other arrangements with any State, local or other public agency or its delegate that has legal responsibility and authority for public health and medical response. The Acting HHS Secretary's April 26 declaration of nationwide public health emergency caused by H1N1, which was renewed by the HHS Secretary on July 24, can be used by "Authorities Having Jurisdiction" to begin their public health and medical response.

The H1N1 vaccine declaration also provides tort liability immunity to the United States, to vaccine manufacturers, and vaccine distributors.
Officials, agents, and employees of program planners, qualified persons, the United States, manufacturers, and distributors are also immune from tort liability.

Q5: Which vaccines are covered under the H1N1 vaccine declaration?

A5: All of the H1N1 vaccine procured by the Department of Health and Human Services and distributed to the states is covered by the declaration.

Vaccines are covered only when they are administered and used as 1) licensed or approved by the Food and Drug Administration (FDA); 2) authorized for investigational use by the FDA; or 3) authorized under an Emergency Use Authorization (EUA) by the FDA. On September 15, 2008, the FDA approved four vaccines against H1N1 that are covered by the declaration.

Q6: What tort claims are prevented by the H1N1 vaccine declaration?

A6: The declaration prevents tort liability claims under U.S. Federal law and State law (except for willful misconduct) for losses caused by, arising out of, relating to, or resulting from administration or use by any individual of the vaccine, including any claim with a causal relationship to any stage of development, distribution, dispensing, prescribing, administration or use of the vaccine.

Types of loss include death; physical, mental, or emotional injury, illness, disability or condition; fear of physical, mental, or emotional injury illness, disability, or condition, including any need for medical monitoring; and loss of or damage to property, including business interruption. In addition, by defining "administration" to include "delivery, distribution, and dispensing activities... and management and operation of distribution and dispensing locations" the H1N1 vaccine declaration clarifies that "slip and fall" types of claims are also covered, not just injuries and illnesses arising from actually receiving the vaccine.

Q7: What types of claims are not prevented by the H1N1 vaccine declaration?

A7 The declaration does not prevent claims for willful misconduct. Willful misconduct is a term used in the PREP Act, and is beyond any standard of negligence or recklessness. Willful misconduct does not include acts or omissions by program planners and qualified persons who act consistently with the declarations, as long as they notify HHS or a State or local health authority within seven days of discovering any serious physical injury or death from the administration or use of the countermeasure.

The declaration also does not prevent other types of claims, such as claims for negligence in providing medical care unrelated to vaccine administration and use, claims brought under foreign law, or claims for civil rights or labor law violations.

Q8: What compensation is available for vaccine injuries?

A8: The U.S. Department of Health and Human Services is establishing a Countermeasures Injury Compensation Program for H1N1 vaccines. Under this program, compensation may be available to eligible individuals who suffer serious physical injuries or death from administration of the vaccine under the declarations. Eligibility, and the types of injuries for which compensation may be available, will be defined by regulations. Compensation can include medical benefits, lost wages and death benefits.

Q9: Where can I go for more information?

A9: For a copy of the PREP Act declaration for H1N1 vaccines, please go to: http://edocket.access.gpo.gov/2009/E9-14948.htm.

For more information about PREP Act liability protections, please go to http://www.hhs.gov/disasters/emergency/manmadedisasters/bioterorism/medication-vaccine-qa.html.

For more information about PREP Act Countermeasure Injury Compensation Program, please go to http://www.hrsa.gov/countermeasurescomp/default.htm.

For more information about the H1N1 vaccines approved by FDA, please go to http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm

H1N1 MASS VACCINATION REPORTING CATEGORIES

Three "**Reporting Category**" numbers have been set up in the ISIS accounting system to capture costs related to the recent CDC Grant Award (1H75TP000368-01) received by OPH for Public Health Emergency Response (PHER). They are:

0063 (***Focus Area 1****- Vaccination, Antiviral Distribution/Dispensing and Administration, Community Mitigation and Other Associated Pandemic Preparedness and Response Activities****)***

Headquarters, Administrative and non-direct services (No Lab/No Epi) should be charged to this reporting category

0163 *(**Focus Area 2** - Accelerated Planning and Enhancements relative to Laboratory, Epidemiology, Surveillance, and Other Associated Pandemic Preparedness and Response Activities)*.

Lab and Epi Only **should be charged to this reporting category**

0263 *(**Focus Area 3** –Implementation and administering and Other Associated Pandemic Preparedness and Response Activities)*.

Personnel preparing and responding to H1N1 (non- MVE regular clinic) temporary staff hired for H1N1 vaccination implementation and administering

This current grant award is for H1N1 related activities. As a result, you must notify anyone that utilizes these Reporting Category codes that they must also comply with the attached memorandum from the Division of Administration which requires all H1N1 related charges *(except routine salaries and leave taken)* to be coded to the ISIS "**Activity**" field as **SFLU**. Failure to comply may result in invoices not being processed for payment timely and may subject your office to later inquiries from the Division of Administration.

Anyone who is paid 100% by another federal grant is not eligible to charge to the H1N1 funding as it would be considered a duplication of services (co-mingling of funds). (Overtime only)

Please remember that the primary responsibility for coding lies at the point of purchase.
I have also attached a directive from Ms. Angele Davis Commission of Administration which must be implemented.

REPORTING OF ADVERSE VACCINE REACTIONS

Policy:

All adverse vaccine reactions reported to the OPH offices will be investigated and the Vaccine Adverse Event Reporting System form (VAERS-1) must be forwarded to the Immunization Program office in Metairie. Immediately (within 24 hours) upon a patient's report or occurrence of adverse events following vaccination, the vaccine provider must submit a VAERS report to the Program Office for further investigation and followup to be conducted. Once the VAERS report is submitted to the Program Office, the case report shall be assigned with a Louisiana ID number prior to submission to the VAERS system. This information is reported as part of the Centers for Disease Control and Prevention surveillance system.

Vaccine adverse events for vaccines administered in the public sector should be reported on the VAERS-1 form followed by submission of the original form to the Immunization Program. The information required on the form should be complete and not detained for further follow-up. Vaccine adverse events reported by the private sector should be reported directly to the VAERS system. Under no circumstances should public clinics report adverse events to the VAERS System.

Rationale:

Reporting of adverse vaccine reactions provides knowledge about rare side effects of vaccine, and allows OPH to better inform clients about the side effects of vaccine and ways to reduce reactions. Should it become necessary to withdraw a vaccine lot number, the information from the adverse event's lot number and expiration date becomes very important.

WEBSITE: www.vaers.org E-MAIL: info@vaers.org FAX: 1-877-721-0366

VACCINE ADVERSE EVENT REPORTING SYSTEM

VAERS

24 Hour Toll-Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number _____
Date Received _____

Patient Name:
_____
Last First M.I.

Address
_____
_____
_____
_____
City State Zip
Telephone no. (___) _____

Vaccine administered by (Name):
_____
Responsible Physician _____
Facility Name/Address
_____
_____
_____
_____
City State Zip
Telephone no. (___) _____

Form completed by (Name):
_____
Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other
Address *(if different from patient or provider)*
_____
_____
_____
_____
City State Zip
Telephone no. (___) _____

1. State	2. County where administered	3. Date of birth mm / dd / yy	4. Patient age	5. Sex ☐ M ☐ F	6. Date form completed mm / dd / yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
☐ Patient died (date mm / dd / yy)
☐ Life threatening illness
☐ Required emergency room/doctor visit
☐ Required hospitalization (_____days)
☐ Resulted in prolongation of hospitalization
☐ Resulted in permanent disability
☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

10. Date of vaccination mm / dd / yy
Time _____ AM PM

11. Adverse event onset mm / dd / yy
Time _____ AM PM

12. Relevant diagnostic tests/laboratory data

13. Enter all vaccines given on date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous Doses
a.					
b.					
c.					
d.					

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given
a.						
b.						

15. Vaccinated at:
☐ Private doctor's office/hospital ☐ Military clinic/hospital
☐ Public health clinic/hospital ☐ Other/unknown

16. Vaccine purchased with:
☐ Private funds ☐ Military funds
☐ Public funds ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)

20. Have you reported this adverse event previously? ☐ No ☐ To health department ☐ To doctor ☐ To manufacturer

Only for children 5 and under

22. Birth weight _____ lb. _____ oz.

23. No. of brothers and sisters

21. Adverse event following prior vaccination (check all applicable, specify)

	Adverse Event	Onset Age	Type Vaccine	Dose no. in series
☐ In patient				
☐ In brother or sister				

Only for reports submitted by manufacturer/immunization project

24. Mfr./imm. proj. report no.

25. Date received by mfr./imm.proj.

26. 15 day report? ☐ Yes ☐ No

27. Report type ☐ Initial ☐ Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

Form VAERS-1 (FDA)