Immunization Policies and Procedures Manual

Louisiana Department of Health
Office of Public Health

Immunization Program

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I. POLICY AND GENERAL CLINIC POLICY

PURPOSE

One of the major goals of the Office of Public Health (OPH) is to promote health through the prevention of illness and death. Immunization has proven to be a safe and effective way of preventing the morbidity and mortality of many infectious diseases. The low cost and high efficacy of vaccination ensures that every dollar spent on vaccination is repaid many times over because of reduced hospital costs, in addition to lives that remain productive. Accordingly, the Office of Public Health has made immunization of every child in Louisiana a high priority. The Louisiana Legislature supported this philosophy by requiring immunization for all children in schools and child care facilities in Louisiana.

Immunization is a complicated subject. It requires knowledge about numerous vaccines, preparation for the rare side effects, and effective communication with people. This immunization manual is published so that Office of Public Health personnel will have clear guidelines regarding immunization policies for clinics conducted by OPH, and will always have access to the latest information about vaccination. The authors have organized this section of the manual into:

I. Policy and General Clinic Policy

II. Policy Regarding Clinic Organization

III. General Policy Regarding Immunization

IV. OPH Program Vaccine Policies

V. Policies Regarding Specific Immunizations

VI. Miscellaneous Immunization Information

It is hoped that this Immunization Manual will provide quick and simple answers to the many questions that arise during immunization clinics.

POLICY ON CLINIC SCHEDULING

Policy:

1. The scheduling of times and places for immunization clinics is a local and regional responsibility.

2. Clinics shall be held at times and places that effectively promote vaccination and make efficient use of staff time and facilities.

3. Scheduling shall be periodically reviewed to ensure that the schedule still fulfills program goals.

4. During power outage and/or Louisiana Immunization Network for Kids Statewide (LINKS) system failure individuals should bring their personal immunization record to the clinic. Individuals without their personal immunization record shall be given age appropriate vaccinations.

5. Individuals being served at the time of power or system failure would have their vaccinations recorded in the Vaccine Administration Record, Vaccine for Children (VFC) Patient Eligibility Screening, AND Registry Authorization (Imm-5, Revised). A copy of the record brought by the parent should be attached to the Imm-5 form. Providers should be aware that this is the only form that is mandated by the Vaccine Injury Act of 1986. To obtain a blank copy of the VFC VAR form in LINKS, sign-onto LINKS registry, go to 'REPORTS' and scroll down to 'STATE REPORTS' and then select 'VFC VAR BLANK' to print copies.

6. A copy of the patient's updated immunization record will be mailed no later than a week after system becomes operational.

Rationale:

The goal of the OPH Immunization Program is to provide immunization services and education in the most effective and efficient manner. Effective immunization clinics promote high vaccination coverage levels by being held in locations and at times that provide access to the individuals and families who need vaccinations. Effective clinics promote vaccination by providing prompt service in a pleasant atmosphere. Efficient immunization clinics correctly vaccinate a maximum number of children with limited staff time and resources. Because of tremendously varying conditions in this large and diverse state, immunization clinics are best scheduled by staff most familiar with local conditions using clinic audit results and assessments to identify local needs.

Clinic scheduling to promote access is encouraged. Clinics are expected to provide immunizations to walk-in clients during all business hours whenever possible. Clinics are also

encouraged to provide regularly scheduled extended hours on weekends or evenings. This improves access for working families and can improve immunization coverage.

VACCINE ADMINISTRATION RECORD,
VACCINE FOR CHILDREN (VFC) PATIENT ELIGIBILITY SCREENING, AND REGISTRY AUTHORIZATION

Information About Person Receiving Vaccine:				
Last Name:	First:	Middle:	DOB:	Age:
Name (Parent or Guardian, if applicable):			Phone Number:	
Address:	City:		State:	Zip:

I agree to allow information about all vaccinations given to me or to the person for whom I am authorized to consent to be released to other medical care providers, schools, child care, or head start centers to avoid the administration of unnecessary vaccinations and to determine immunization status. I understand that this will remain in effect until canceled by me in writing.

Signature of Parent/Guardian or adult vaccine receipient_____

FOR CLINIC USE ONLY		
This child qualifies for vaccination through the VFC program because he/she (check only one box); or .....is not qualified		
(a) is enrolled in Medicaid	(b) does not have health insurance	(c) is American Indian or Alaskan Native
I certify that the Important Information Statement(s) for the vaccines(s) indicated as administered below were presented to the person or parent /guardian named above at this clinic and on the date shown here.		
Clinic:	Date Vaccinated:	Signature and title of the Vaccine Administrator

DTaP DT Td DTaP-Hib	IPV	MMR	HIB
Manufacturer and Lot#:	Manufacturer and Lot#:	Manufacturer and Lot#:	Manufacturer and Lot#:
Expiration Date: Site of Injection:	Expiration Date: Site of Injection:	Expiration Date: Site of Injection:	Expiration Date: Site of Injection:
VIS Pub Date:	VIS Pub Date:	VIS Pub Date:	VIS Pub Date:
Immunization & Dose DT Td DTaP DTaP-Hib 1 2 3 4 5	Immunization & Dose IPV 1 2 3 4 5	Immunization & Dose MMR 1 2 3	Immunization & Dose HIB 1 2 3 4

HBV	HAV	VARICELLA	FLU
Manufacturer and Lot#:	Manufacturer and Lot#:	Manufacturer and Lot#:	Manufacturer and Lot#:
Expiration Date: Site of Injection:	Expiration Date: Site of Injection:	Expiration Date: Site of Injection:	Expiration Date: Site of Injection:
VIS Pub Date:	VIS Pub Date:	VIS Pub Date:	VIS Pub Date:
Immunization & Dose HBV 1 2 3 4	Immunization & Dose HAV 1 2 3	Immunization & Dose VARICELLA 1 2 3	Immunization & Dose FLU 1 2 3 4

PPV	PCV-7	OTHER	OTHER
Manufacturer and Lot#:	Manufacturer and Lot#:	Manufacturer and Lot#:	Manufacturer and Lot#:
Expiration Date: Site of Injection:	Expiration Date: Site of Injection:	Expiration Date: Site of Injection:	Expiration Date: Site of Injection:
VIS Pub Date:	VIS Pub Date:	VIS Pub Date:	VIS Pub Date:
Immunization & Dose PPV 1 2 3 4 5	Immunization & Dose PCV-7 1 2 3 4 5	Immunization & Dose 1 2 3 4	Immunization & Dose 1 2 3 4

POLICY ON PUBLICITY FOR IMMUNIZATION ACTIVITIES

Policy:

Local and regional staff will have primary responsibility for public information regarding parish health unit immunization clinics as prescribed by the Department of Health and Hospitals/Office of Public Health (DHH/OPH) policy. Assistance may be requested from the Immunization Program Office in New Orleans.

Rationale:

Local public events such as immunization clinics are best publicized through the local media and other sources of local public information through the DHH Office of Public Health Media Communications Section. In addition to the local news media (newspaper, radio and TV, if available), there are many sources of local public information such as school, church, and voluntary organizations. OPH staff should maintain an effective liaison with these groups to ensure adequate public knowledge of local OPH activities. Public information campaigns are also carried out by the state "Shots for Tots" activities and the United States Centers for Disease Control and Prevention.

POLICY ON EDUCATIONAL ACTIVITIES (HEALTH EDUCATION IN IMMUNIZATION CLINICS)

Policy:

1. A concentrated effort shall be made by local and regional offices to provide health education and information regarding immunization at every opportunity.

2. The design and implementation of health education programs is the responsibility of local and regional personnel. Assistance and materials may be requested from the Immunization Program in New Orleans.

3. On a regular basis, every regional and parish health unit will review its efforts in health education, and strive to improve this component of the immunization program.

Rationale:

Education strengthens a patient's / parent's ability to act on their own behalf in the prevention of disease, by giving the patient or parent knowledge-- the most powerful of all tools. Health education is a dynamic process, which enlists the many skills, interests, and the resourcefulness of the persons involved. Health information is a passive approach using printed or audio-visual materials. There are many opportunities to present educational material regarding immunization.

Some examples are:

- Pre-Clinics: Media publicity, activity in schools, speakers for community groups.

- During Clinic: In the waiting room; coloring books, posters for walls, pamphlets for distribution, use of audio-visual presentations such as immunization video tapes and small conferences.

- With the nurse: this is the best time for person-to-person educational process (health education); the potential benefits are highest during this time.

- After Clinic: Printed information on immunizations and side effects given to parents; availability of personnel in the event if problems or questions arise.

POLICY ON CHECKING IMMUNIZATION STATUS OF ALL CHILDREN RECEIVING SERVICES THROUGH THE HEALTH DEPARTMENT

Policy:

The Immunization status of all children receiving services through the health department shall be reviewed at every visit; this includes private care WIC patients.

The following steps should be taken in regards to determining immunization status and immunizing private care WIC patients in the parish health units:

- Each private care WIC patient's status of immunization shall be checked at each visit by use of the LINKS immunization registry or assessing the patient's immunization record. The immunization record shall be checked to see if it has been entered in the LINKS registry with documentation of the most current immunizations received. Encourage the parent or guardian to bring the immunization record at each clinic visit.

- If the patient has no immunization record, urge the parent or guardian to obtain one from the private physician or obtain a signed Release of Information form that allows for the exchange of immunization records between the private physician and the Health Department.

- For the child who is up to date, the parent or guardian should be so informed, and also told when the next immunizations are due.

- For the child who is behind in the immunization schedule, the parent or guardian should be so informed, and offered the option of having the immunizations at the parish health unit at that visit, or seeing the private physician as soon as possible to have the immunizations.

- If the child is not present at the visit to the parish health unit, the parent or guardian should be urged to have the child immunized as soon as possible at the parish health unit or at the private physician's office.

For further information on the linkage of Immunization and WIC services see MMWR 1996; 45(10): 217-218 or www.cdc.gov/mmwr/preview/mmwrhtml/00040658.htm on the internet.

POLICY ON MAXIMIZING TIME SPENT WITH PARENTS DURING IMMUNIZATION CLINICS

Policy:

1. It is the policy of the Office of Public Health to maximize the time that parents/patients and the health professional spend together.

2. The health professional will continuously review practices and procedures so that adequate time may be spent with each parent/patient, according to specific circumstances involved.

Guidelines:

The following guidance is provided to help accomplish this policy of using time to maximum mutual advantage.

The Setting:

A. Establish the setting in the most efficient manner possible, assuring that needed supplies and their layout are completed before patients enter the clinic area.

B. Establish a setting conducive to interaction by eliminating to the highest degree possible, other activities, conversations, and non-essential personnel from the immediate clinic area.

Interaction-System:

A. A routine sequence of actions that is followed rigorously should be developed by each health professional to facilitate problem identification and to use the time available to educate the patient about the importance of keeping their children immunized on schedule.

Health Education:

A. Develop a systematic approach to allow inclusion of time to provide health education during all parent/patient contacts.

B. The following sequence of health education may be useful:

1. Review importance of immunization and how immunizations work.

2. Review details of specific vaccines including important information statements or vaccine information pamphlets and other materials presented in writing.

3. Review importance and need for boosters, and remind parents/patients to return

for the next immunization appointment.

4. Remind parents/patients to report an adverse event following immunization.

C. Continuously review and assess the many ways in which a health professional can make maximum use of time spent with parent/patient during the immunization process.

D. Continue to search for the desirable flexibility in individual approach to allow fulfillment of this policy.

POLICY ON ASSISTANCE TO FOREIGN TRAVELERS

Policy:

The Office of Public Health provides the following services for international travelers:

1. Advice to travelers, or their physicians, on the need for certain immunizations, biologics, medications, or other precautions that may be necessary to maintain their health when traveling overseas (Refer to the yellow book – CDC Health Information for International Travel – current version to provide foreign travel information specific to visiting countries or check the CDC website).

2. Clinics conducted by the Office of Public Health shall not provide immunizations or biologics to international travelers except those designated as International Travel or yellow fever vaccination centers with the exception of bringing children "up-to-date" for their normal childhood immunizations and giving adults Td boosters as appropriate for their immunization status. Only those health unit clinics designated as approved yellow fever vaccination centers shall provide yellow fever vaccinations.

Guidelines:

Inquiries made to the regional office or parish health unit for information on requirements and recommendations involving immunizations for international travel should be referred to the Infectious Disease Epidemiology Section at (504) 219-4563 or visit the Centers for Disease Control and Prevention website under Travelers' Health at http://www.cdc.gov.

Persons requesting immunizations not included in the above policy statement (i.e., typhoid, immune serum globulin, polio vaccine for adults) shall be referred to their private physicians. Persons needing yellow fever vaccinations shall be referred to the nearest yellow fever vaccination center.

II. POLICY REGARDING CLINIC ORGANIZATION

PROTOCOL FOR IMMUNIZATION CLINIC ORGANIZATION

Objectives:

1. To assure that all needed equipment, orders, and forms are readily available in the clinic room.

To make recommendations that will assist OPH staff in providing immunizations to Louisiana children in an efficient and effective manner.

Equipment	Educational Materials
Syringes – Needles	Pamphlets
Alcohol sponges (cotton balls)	Posters
Dry cotton balls	"Guide to True/False Contraindications to Vaccination"
Band Aids	
Emergency Tray	
Vaccines	
Ice chest w/ ice packs for clinic area vaccine storage	
Sharps disposal container	
Alcohol-based hand cleansers	
Space	
Waiting Area	
Clinic Room	
Forms/Orders	
Current Important Information Pamphlets/Statements	Immunization Policy Manual, Access to: "Pediatric Red Book", "Control of Preventable Diseases in Man", and current copy of “Epidemiology & Prevention of Vaccine Preventable Diseases” course book.
Orders from Medical Consultants	
Emergency Management protocol	
Immunization Record entry in LINKs Patient Education Materials Child's Immunization Records	

Staff

Sufficient staff is needed to cover expected attendance at clinic and knowledge in the handling of emergency reactions to vaccine.

Procedure

1. Assess needs - pre-plan and estimate how many children will attend the immunization clinic.

2. Publicize the clinic schedule.

3. Coordinate with school nurses.

4. Order enough vaccine and supplies for a one month period.

Set up the immunization site with sufficient vaccine (properly stored), related supplies, and with provisions for safe waste disposal.

Assign appropriate personnel to clinic activities. See Chart below for suggested duties and responsibilities.

Suggested Duties/Responsibilities	**Clerk**	**Volunteer**	**Public Health Nurse**
Greeting patients on arrival	√	√	
Determining purpose of visit	√		√
Pulling Old Records	√		
Making New Records/LINKs data entry	√		
*Giving Information Statements or Vaccine Information Pamphlets	√	√	√
Review Information Statements or Vaccine Information Pamphlets			√
Reviewing Immunizations Needed			√
Providing Pre-Immunization Education			√
Interviewing Individual Patients			√
Reviewing Contraindications			√
Administering Immunizations			√
Providing Post-Immunization & Side-Effects Information			√
Giving Return Appointments	√		√
Filling Out Patient LINKs Record	√		√
Completing Nurses Time Report			√

Note: In some cases it will be necessary to determine which specific immunizations are needed before important information statements or vaccine information pamphlets are handed out. In those situations, a nurse will instruct the clerk as to the appropriate information statements or vaccine information pamphlets needed.

The nurse in the clinic shall be responsible for:

1. Administering all of the appropriate immunizations;

2. Instructing parents about and assisting in positioning or restraining of children;

3. Maintaining aseptic technique during clinic;

4. Assuring that the vaccine cold chain (use of ice packs) is maintained;

5. Proper disposal of syringes, needles and other waste supplies after clinic;

6. Explaining any possible side effects and recommendations regarding immunizations received.

RECOMMENDATIONS

1. If two nurses are giving immunizations, arrange separate or screened areas for each nurse to provide privacy for discussion and vaccine administration.

2. Have one nurse complete the entire sequence of events for a given patient, i.e., contraindications, precautions, questions/answers, immunizations, reactions, and next appointment.

3. Take advantage of waiting room time to provide educational activity.

4. When possible as parent/child leave immunization room/space, have the clerk or a volunteer send in the next person (this may help maximize efficiency of nursing time).

5. If there is an obvious communication problem due to a language barrier and someone is available in the office that can help, bring them into the setting early to avoid disruption and confusion on the part of the parent or child as to what is going to happen. Contact the Language Line for assistance with language interpretation (e.g., Latino/Hispanic population) at 1-800-367-9559.

ORDERING OF IMMUNIZATION SUPPLIES

Policy:

1. Each parish health unit/clinic facility must have a designated nurse (preferably the supervisory nurse) whose responsibilities include:

A. maintaining adequate inventories of vaccines and related supplies

B. ordering/receiving vaccines and related supplies and compare vaccine received with vaccine invoice

C. proper storage of vaccines and related supplies immediately upon arrival

D. checking expiration dates and taking appropriate action with outdated vaccines/supplies and any discrepancies with vaccine shipment order

2. There must be a designated alternate nurse (in offices with more than one nurse) to serve when the designated nurse is absent from duty. It is recommended that a protocol be posted for all staff regarding vaccine deliveries and whom to contact regarding vaccine shipments in conjunction with storage and handling requirements.

Procedure:

The designated nurse is responsible for maintaining the designated ordering schedule for vaccines and supplies based on past usage, anticipated need, and storage capability. The order submitted by the parish health unit should allow for at least two weeks between submission of the requisition and receipt of the materials.

The designated nurse will compile a list of all needed vaccines -to be submitted through the Vaccine Ordering Management System (VOMS) in LINKS. All other biologics and supplies, such as PPD, infant formula, syringes, etc., should be ordered using the form AC-23. AC-23 requisitions will be signed and forwarded to the Pharmacy for processing.

The procedure for ordering is as follows:

VOMS must be used to order all vaccines.

The AC-23 requisition must be used when ordering other biologics and supplies.

The designated nurse shall submit the vaccine order through VOMS. The AC-23 requisition should be completed by the nurse/clerk and approved by the cost center manager.

The Immunization Program will approve the requisition after it is received and reviewed and

then submit the order to McKesson Specialty Distribution for processing and packing.

All vaccine shipments will be handled by McKesson Distribution to the recipients.

Upon receipt of the vaccine shipment, the designated nurse or alternate will make sure that the order is complete and ensure proper storage and refrigeration. All vaccines received shall be received through VOMS to populate the inventory. Discrepancies in vaccine orders should be directed to the Immunization Program at (504) 838-5300. Discrepancies in biologic or supply orders should be directed to Pharmacy Services at (504) 568-5022.

The designated nurse or alternate should place all immunization materials (i.e., biologics, vaccines, etc) in the proper refrigeration for storage and inventory.

VACCINE STORAGE REQUIREMENTS

The success of efforts against vaccine-preventable diseases is attributable in part to proper storage and handling of vaccines. Exposure of temperatures outside the recommended ranges can affect potency adversely, thereby reducing protection from vaccine-preventable diseases. Good practices to maintain proper vaccine storage and handling can ensure that the full benefit of immunization is realized.

NOTE: Each facility should post the Vaccine Storage and Handling Plan on or near the vaccine storage equipment and ensure all staff is trained regarding plan.

Policy:

1. Vaccines are to be stored in parish health units and regional laboratories according to the manufacturers' recommendation as given in the package insert.

2. Vaccines should be stored centrally in the refrigerator or freezer, not in the door or on the bottom of the storage unit or vegetable bins (crisper), and sufficiently away from walls to allow air to circulate. Post warning signs (i.e., Do Not Unplug) on the refrigerator and freezer to prevent inadvertent unplugging of the unit.

3. Vaccines that have been improperly stored will be removed from the clinic area to prevent accidental use, and returned to the Immunization Program in New Orleans. The regional Immunization Consultant must be notified of the return.

4. Calibrated certified thermometers must be used to monitor temperatures for each freezer and refrigerator compartments that are used to store vaccine or biologics. Temperatures must be logged twice a day on a daily basis and the log should be maintained for at least 3 years per unit. Please see the log sheet. Calibration must be traceable to standards provided by the National Institute of Standards and Technology (NIST) – a U. S. government agency within the Department of Commerce or a laboratory recognized by NIST. Calibration can be traceable to NIST using American Society for Testing and Materials (ASTM) methods for the calibration process.

5. Rotate stock and ensure that vaccines with the earliest expiration dates are to be used first and are in front of vaccines with longer expirations dates. Check and rotate your stock weekly with a monthly review of rotation and documentation. The designated staff person should rotate stock when new vaccine is added to inventory.

6. Effective January 2009, dormitory style refrigerators are not acceptable for permanent or long-term storage of vaccines. Refrigerators and freezers used for vaccine storage must comply with the following requirements: a) be able to maintain required vaccine storage temperatures year-round; b) be large enough to hold the year's largest inventory; c) at minimum, have a working certified and calibrated thermometer inside each storage compartment; and d) be dedicated to the storage of vaccines.

7. Effective August 1, 2016, all school-based health centers (SBHCs) enrolled in the Vaccines for Children (VFC) program are required to use digital data-logger thermometers to monitor temperatures of refrigerators and freezers used to store VFC vaccine. Backup thermometers kept in these facilities must also be data loggers by the above effective date.

8. Effective January 1, 2018, all other, non-SBHC healthcare providers enrolled in the VFC program are required to use data-logger thermometers as mandated by the Centers for Disease Control and Prevention.

Rationale:

Vaccines and biologics that are not stored properly lose potency and are ineffective as immunizing agents.

Information:

The vaccine storage information given in the table on the next page is current as of the publication of this manual. Any questions on storage requirements and problems should be called to the Immunization Pogram at (504) 838-5300.

Proper temperature monitoring is the key to proper cold chain management. Thermometers should be placed in a central location in the storage compartments, adjacent to the vaccine. Temperatures should be read and documented on the temperature log. Immediate action must be taken to correct storage temperatures that are outside the recommended ranges. Mishandled vaccines should not be administered. Storage requirements for vaccines are as follows:

VACCINE TYPE	Freezer -15° to -2° C 0° TO 30° F	Refrigerator 2° to 8° C 36° to 46° F	Protect from Light	Do Not Freeze
POLIO (IPV)*		√		√
DTaP, DT, Td, Tdap*		√		√
MMR⊥		√	√	√
HIB*		√		√
VARICELLA	√		√	
MMR-VAR	√		√	
HAV		√		√

HBV*		√		√
INFLUENZA		√		√
HPV		√	√	√
PNEUMO (PPV23)		√		√
PNEUMO (PCV13)		√		√
MCV4		√		√
ROTAVIRUS		√	√	
RABIES		√		
YELLOW FEVER		√		

⊥ Measles, Mumps, and rubella vaccine (MMR), or any single antigen components are not damaged if stored at freezer temperatures but should not be routinely stored in the freezer compartment.

* Applies to combination vaccines with these antigens

Temperature Log for Refrigerator – Celsius

DAYS 1–15

Month/Year_____ VFC PIN or other ID #_____

Facility Name_____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the refrigerator's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above 8°C) or too cold (below 2°C).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)															
Danger! Temperatures above 8°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
TEMPERATURES 8°C															
7°C															
6°C															
Aim for 5° 5°C															
ACCEPTABLE 4°C															
3°C															
2°C															
Danger! Temperatures below 2°C are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
ACTION Write any out-of-range temps (above 8°C or below 2°C) here:															
Room Temperature															

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

Adapted with appreciation from California Department of Public Health

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Technical content reviewed by the Centers for Disease Control and Prevention
www.immunize.org/catg.d/p3037C.pdf • Item #P3037F (8/13)

Temperature Log for Refrigerator – Celsius

DAYS 16–31

Month/Year_____ VFC PIN or other ID #_____

Facility Name_____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the refrigerator's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above 8°C) or too cold (below 2°C).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)																
Danger! Temperatures above 8°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
TEMPERATURES 8°C																
7°C																
6°C																
Aim for 5° 5°C																
ACCEPTABLE 4°C																
3°C																
2°C																
Danger! Temperatures below 2°C are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
ACTION Write any out-of-range temps (above 8°C or below 2°C) here:																
Room Temperature																

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

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Vaccine Storage Troubleshooting Record (check one) ☐ Refrigerator ☐ Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.
A fillable troubleshooting record (i.e., editable PDF or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp.

Date & Time of Event If multiple, related events occurred, see Description of Event below.	**Storage Unit Temperature** at the time the problem was discovered		**Room Temperature** at the time the problem was discovered	**Person Completing Report**	
Date:	Temp when discovered:		Temp when discovered:	Name:	
Time:	Minimum temp:	Maximum temp:	Comment (optional):	Title:	Date:

Description of Event *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- General description (i.e., what happened?)
- Estimated length of time between event and last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer)
- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

Action Taken *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer(s).)
- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)
- **IMPORTANT:** What did you do to prevent a similar problem from occurring in the future?

Results

- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)

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www.immunize.org/catg.d/p3041.pdf • Item #P3041 (8/13)

Vaccine Storage Troubleshooting Record (check one) ☑Refrigerator ☐Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.
A fillable troubleshooting record (i.e., editable pdf or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp

Date & Time of Event If multiple, related events occurred, see Description of Event below.	**Storage Unit Temperature** at the time the problem was discovered		**Room Temperature** at the time the problem was discovered	**Person Completing Report**	
Date: (see below)	Temp when discovered: 7°C		Temp when discovered: 25°C	Name: Nancy Nurse	
Time: (see below)	Minimum temp: 3°C	Maximum temp: 12°F	Comment (optional): temp is approx.	Title: VFC Coordinator	Date: 6/24/13

Description of Event *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- General description (i.e., what happened?)
- Estimated length of time between event & last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer)
- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

At 8 am on Monday (6/24/13) morning when clinic opened, identified 3 temperature excursions over the weekend in refrigerator with readings as high as 12°, 10° & 9°C in primary vaccine storage unit #1. Recordings taken every 15 min on calibrated digital data logger overnight. Data logger probe in glycol located in middle of refrigerator with vaccines.

Total time out of range: approximately 3 hrs — maximum temp 12°F (see attached document of continuous temp readings)

Inventory of vaccines: see attached

Water bottles in refrigerator door. No vaccine stored in freezer. No problems with storage unit prior to Saturday night. Thunderstorms in area over weekend may have affected power.

Action Taken *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer(s).)
- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)
- IMPORTANT: What did you do to prevent a similar problem from occurring in the future?

Vaccines currently stored appropriately at 7°C. Refrigerator and vaccines labeled "Do Not Use."

My State Immunization Program contacted at 8:30 am. Spoke with Victor Vaccine. Provided Victor with details of event and list of vaccines. Vaccine to remain quarantined until we hear back from Victor.

Called electric company and confirmed 2 short power outages during weekend.

Checked refrigerator seals — called refrigerator maintenance company to replace seals.

Checked plug on unit — placed tape over plug to prevent inadvertent dislodging. Plan to purchase plug guard.

Plan to follow up with Immunization Program on data loggers with alarms that could be sent to coordinator and back-up phones.

Results

- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)

Late on Monday, I talked with Victor regarding continued use of vaccine. Victor had checked with manufacturers which confirmed that vaccine is acceptable for use. He told me that vaccine could therefore be removed from quarantine. I discussed the entire situation with Susie Supervisor and Dr. Director (clinic medical director) who agreed that we could put vaccine back in use.

Example

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Vaccine Storage Troubleshooting Record (check one) ☑Refrigerator ☐Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.
A fillable troubleshooting record (i.e., editable pdf or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp

Date & Time of Event If multiple, related events occurred, see Description of Event below.	**Storage Unit Temperature** at the time the problem was discovered		**Room Temperature** at the time the problem was discovered	**Person Completing Report**	
Date: 7/16/2013	Temp when discovered: -2°C		Temp when discovered: 25°C	Name: Nancy Nurse	
Time: 8:00 am	Minimum temp: -2°C	Maximum temp: 6°C	Comment (optional): temp is approx.	Title: VFC Coordinator	Date: 7/15/13

Description of Event *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- General description (i.e., what happened?)
- Estimated length of time between event & last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer)
- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

When checked main clinic fridge (in lab) at 8:00 am on Tuesday, 7/16/2013, digital readout on data logger read -2°C. Data logger located in center of fridge with probe in glycol. Review of computer readings (taken every 15 minutes) showed steady drop in temps from 6°C at 8:15 pm (7/15/2013) to -2°C reading discovered when arrived at clinic on Tuesday morning (7/16/2013). Readings hit 1°C at 11 pm (7/15) and 0°C at 2 am (7/16). Total time out of recommended storage temps = 9 hours, with 6 hours at freezing or below (see attached document of continuous temp readings). Inventory of vaccines attached.

Water bottles in refrigerator door and crisper area. No vaccines stored in freezer. No recent adjustments to temp controls and no previous temp excursions noted with this refrigerator before 7/15.

Action Taken *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer(s).)
- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)
- **IMPORTANT:** What did you do to prevent a similar problem from occurring in the future?

Upon discovery, vaccines marked "Do Not Use" and stored in 2nd clinic fridge (in exam room #3 at 5°C). Also placed "Do Not Use" note on main fridge in lab. Notified Susie Supervisor about the issue. Contacted Victor Vaccine at My State Immunization Program at 8:30 am. Provided Victor with details of event and list of vaccines in fridge. Victor said to maintain vaccines in 2nd fridge and that he would check with manufacturers to determine next steps.

Called Jim's Appliance Repair to examine fridge. Repairman found and replaced faulty thermostat in unit.

Reset data logger on center shelf in fridge with probe in glycol.

Results

- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)

After fridge thermostat repaired, monitored temps in empty fridge for 1 week, per state requirements. Fridge maintained 3° to 4°C temps for entire week. Submitted repair documentation and data logger readings to Victor Vaccine for approval and ordered replacement vaccines. Victor had checked with manufacturers who confirmed that all vaccines in fridge EXCEPT MMR were no longer viable and should be returned per state policy guidelines. MMR may be used because pkg insert allows storage down to -50°C. Discussed entire situation with Susie Supervisor and clinic director, Dr. Director, who agreed on continued use of MMR. Will continue to monitor fridge closely to watch for pattern of temp fluctuations indicating potential problem with thermostat. If problems, contact Victor Vaccine for advice on purchasing new fridge meeting criteria for appropriate vaccine storage.

Example

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Temperature Log for Refrigerator – Fahrenheit

DAYS 1–15

Month/Year_____ VFC PIN or other ID #_____

Facility Name_____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the refrigerator's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above 46°F) or too cold (below 35°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)															
Danger! Temperatures above 46°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
TEMPERATURES 46°F															
45°F															
44°F															
43°F															
42°F															
41°F															
Aim for 40° 40°F															
ACCEPTABLE 39°F															
38°F															
37°F															
36°F															
35°F															
Danger! Temperatures below 35°F are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
ACTION Write any out-of-range temps (above 46°F or below 35°F) here:															
Room Temperature															

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

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Temperature Log for Refrigerator – Fahrenheit

DAYS 16–31

Month/Year_____ VFC PIN or other ID #_____

Facility Name_____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the refrigerator's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above 46°F) or too cold (below 35°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)																
Danger! Temperatures above 46°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
TEMPERATURES 46°F																
45°F																
44°F																
43°F																
42°F																
41°F																
Aim for 40° 40°F																
ACCEPTABLE 39°F																
38°F																
37°F																
36°F																
35°F																
Danger! Temperatures below 35°F are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
ACTION Write any out-of-range temps (above 46°F or below 35°F) here:																
Room Temperature																

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

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Vaccine Storage Troubleshooting Record (check one) ☐ Refrigerator ☐ Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.
A fillable troubleshooting record (i.e., editable PDF or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp.

Date & Time of Event If multiple, related events occurred, see Description of Event below.	**Storage Unit Temperature** at the time the problem was discovered		**Room Temperature** at the time the problem was discovered	**Person Completing Report**	
Date:	Temp when discovered:		Temp when discovered:	Name:	
Time:	Minimum temp:	Maximum temp:	Comment (optional):	Title:	Date:

Description of Event *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- General description (i.e., what happened?)
- Estimated length of time between event and last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer)
- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

Action Taken *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer(s).)
- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)
- IMPORTANT: What did you do to prevent a similar problem from occurring in the future?

Results

- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)

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Vaccine Storage Troubleshooting Record (check one) ☑Refrigerator ☐Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.
A fillable troubleshooting record (i.e., editable pdf or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp

Date & Time of Event If multiple, related events occurred, see Description of Event below.	**Storage Unit Temperature** at the time the problem was discovered		**Room Temperature** at the time the problem was discovered	**Person Completing Report**	
Date: (see below)	Temp when discovered: 45°F		Temp when discovered: 77°F	Name: Nancy Nurse	
Time: (see below)	Minimum temp: 38°F	Maximum temp: 53°F	Comment (optional): temp is approx.	Title: VFC Coordinator	Date: 6/24/13

Description of Event *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- General description (i.e., what happened?)
- Estimated length of time between event & last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer)
- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

At 8 am on Monday (6/24/13) morning when clinic opened, identified 4 temperature excursions over the weekend in refrigerator with readings as high as 54°, 50°, 49° & 53°F in primary vaccine storage unit #1. Recordings taken every 15 min. on calibrated digital data logger overnight. Data logger probe in glycol located in middle of refrigerator with vaccines.

Total time out of range: approximately 3 hrs — maximum temp 53°F (see attached document of continuous temp readings)

Inventory of vaccines: see attached

Water bottles in refrigerator door. No vaccine stored in freezer. No problems with storage unit prior to Saturday night. Thunderstorms in area over weekend may have affected power.

Action Taken *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer(s).)
- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)
- IMPORTANT: What did you do to prevent a similar problem from occurring in the future?

Vaccines currently stored appropriately at 45°F. Refrigerator and vaccines labeled "Do Not Use."

My State Immunization Program contacted at 8:30 am. Spoke with Victor Vaccine. Provided Victor with details of event and list of vaccines. Vaccine to remain quarantined until we hear back from Victor.

Called electric company and confirmed 2 short power outages during weekend.

Checked refrigerator seals — called refrigerator maintenance company to replace seals.

Checked plug on unit — placed tape over plug to prevent inadvertent dislodging. Plan to purchase plug guard.

Plan to follow up with Immunization Program on data loggers with alarms that could be sent to coordinator and back-up phones.

Results

- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)

Late on Monday, I talked with Victor regarding continued use of vaccine. Victor had checked with manufacturers which confirmed that vaccine is acceptable for use. He told me that vaccine could therefore be removed from quarantine. I discussed the entire situation with Susie Supervisor and Dr. Director (clinic medical director) who agreed that we could put vaccine back in use.

Example

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Vaccine Storage Troubleshooting Record (check one) ☑Refrigerator ☐Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.
A fillable troubleshooting record (i.e., editable pdf or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp

Date & Time of Event If multiple, related events occurred, see Description of Event below.	**Storage Unit Temperature** at the time the problem was discovered		**Room Temperature** at the time the problem was discovered	**Person Completing Report**	
Date: 7/16/2013	Temp when discovered: 28°F		Temp when discovered: 77°F	Name: Nancy Nurse	
Time: 8:00 am	Minimum temp: 28°F	Maximum temp: 42°F	Comment (optional): temp is approx.	Title: VFC Coordinator	Date: 7/15/13

Description of Event *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- General description (i.e., what happened?)
- Estimated length of time between event & last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer)
- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

When checked main clinic fridge (in lab) at 8:00 am on Tuesday, 7/16/2013, digital readout on data logger read 28°F. Data logger located in center of fridge with probe in glycol. Review of computer readings (taken every 15 minutes) showed steady drop in temps from 42°F at 8:15 pm (7/15/2013) to 28°F reading discovered when arrived at clinic on Tuesday morning (7/16/2013). Readings hit 34°F at 11 pm (7/15) and 32°F at 2 am (7/16). Total time out of recommended storage temps = 9 hours, with 6 hours at freezing or below (see attached document of continuous temp readings). Inventory of vaccines attached.

Water bottles in refrigerator door and crisper area. No vaccines stored in freezer. No recent adjustments to temp controls and no previous temp excursions noted with this refrigerator before 7/15.

Action Taken *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer(s).)
- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)
- IMPORTANT: What did you do to prevent a similar problem from occurring in the future?

Upon discovery, vaccines marked "Do Not Use" and stored in 2nd clinic fridge (in exam room #3 at 41°F). Also placed "Do Not Use" note on main fridge in lab. Notified Susie Supervisor about the issue. Contacted Victor Vaccine at My State Immunization Program at 8:30 am. Provided Victor with details of event and list of vaccines in fridge. Victor said to maintain vaccines in 2nd fridge and that he would check with manufacturers to determine next steps.

Called Jim's Appliance Repair to examine fridge. Repairman found and replaced faulty thermostat in unit.

Reset data logger on center shelf in fridge with probe in glycol.

Results

- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)

After fridge thermostat repaired, monitored temps in empty fridge for 1 week, per state requirements. Fridge maintained 38°-40°F temps for entire week. Submitted repair documentation and data logger readings to Victor Vaccine for approval and ordered replacement vaccines. Victor had checked with manufacturers who confirmed that all vaccines in fridge EXCEPT MMR were no longer viable and should be returned per state policy guidelines. MMR may be used because pkg insert allows storage down to -58°F. Discussed entire situation with Susie Supervisor and clinic director, Dr. Director, who agreed on continued use of MMR. Will continue to monitor fridge closely to watch for pattern of temp fluctuations indicating potential problem with thermostat. If problems, contact Victor Vaccine for advice on purchasing new fridge meeting criteria for appropriate vaccine storage.

Example

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Technical content reviewed by the Centers for Disease Control and Prevention
www.immunize.org/catg.d/p3041.pdf • Item #P3041 (8/13)

Temperature Log for Freezer – Celsius

DAYS 1–15

Month/Year_____ VFC PIN or other ID #_____

Facility Name_____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the freezer's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)															
Danger! Temperatures above -15°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
ACCEPTABLE TEMPERATURES -15°C															
-16°C															
-17°C															
-18°C															
-19°C															
-20°C															
-21°C															
-22°C															
-50°C to -23°C															
ACTION Write any out-of-range temps (above -15°C or below -50°C) here.															
Room Temperature															

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

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Temperature Log for Freezer – Celsius

DAYS 16–31

Month/Year_____ VFC PIN or other ID #_____

Facility Name_____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the freezer's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)																
Danger! Temperatures above -15°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
ACCEPTABLE TEMPERATURES -15°C																
-16°C																
-17°C																
-18°C																
-19°C																
-20°C																
-21°C																
-22°C																
-50°C to -23°C																
ACTION Write any out-of-range temps (above -15°C or below -50°C) here.																
Room Temperature																

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

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www.immunize.org/catg.d/p3038c.pdf • Item #P3038C (9/13)

Vaccine Storage Troubleshooting Record (check one) ☐ Refrigerator ☐ Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.
A fillable troubleshooting record (i.e., editable PDF or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp.

Date & Time of Event If multiple, related events occurred, see Description of Event below.	**Storage Unit Temperature** at the time the problem was discovered		**Room Temperature** at the time the problem was discovered	**Person Completing Report**	
Date:	Temp when discovered:		Temp when discovered:	Name:	
Time:	Minimum temp:	Maximum temp:	Comment (optional):	Title:	Date:

Description of Event *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- General description (i.e., what happened?)
- Estimated length of time between event and last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer)
- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

Action Taken *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer(s).)
- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)
- IMPORTANT: What did you do to prevent a similar problem from occurring in the future?

Results

- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)

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Vaccine Storage Troubleshooting Record (check one) ☐ Refrigerator ☑ Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.
A fillable troubleshooting record (i.e., editable pdf or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp

Date & Time of Event If multiple, related events occurred, see Description of Event below.	Storage Unit Temperature at the time the problem was discovered		Room Temperature at the time the problem was discovered	Person Completing Report	
Date: 7/16/2013	Temp when discovered: 13°C		Temp when discovered: 25°C	Name: Nancy Nurse	
Time: 8:00 am	Minimum temp: -17°C	Maximum temp: 14°C	Comment (optional): temp is approx.	Title: VFC Coordinator	Date: 7/15/13

Description of Event *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- General description (i.e., what happened?)
- Estimated length of time between event & last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer)
- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

When checked vaccine freezer (in lab) at 8:00 am on Tuesday, 7/16/2013, discovered freezer door slightly ajar. Digital readout on data logger read 13°C. Data logger located in center of freezer with probe in glycol. Review of computer readings (taken every 15 minutes) showed steady rise in temps from -17°C at 5:30 pm (7/15/2013) to 13°C reading discovered when arrived at clinic on Tuesday morning (7/16/2013). Readings hit -14°C at 11 pm (7/15) and 7°C at 2 am (7/16). Total time out of recommended storage temp of -15°C or below = 9 hours. (See attached document of continuous temp readings.) Freezer contained Varivax, ProQuad, and Zostavax (inventory attached).

Frozen packs stored on freezer floor and shelves in door. No recent adjustments to temp controls and no previous temp excursions noted with this freezer before 7/15.

Action Taken *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer(s).)
- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)
- IMPORTANT: What did you do to prevent a similar problem from occurring in the future?

Upon discovery, vaccines marked "Do Not Use" and stored in 2nd clinic freezer (in exam room #3) at -17°C. Also placed "Do Not Use" note on main freezer in lab. Notified Susie Supervisor about the issue. Contacted Victor Vaccine at My State Immunization Program at 8:30 am. Provided Victor with details of event and list of vaccines in freezer. Victor said to maintain vaccines in 2nd freezer and that he would check with Merck (manufacturer of all the affected vaccines) to determine next steps. Called Jim's Appliance Repair to examine freezer. Repairman replaced freezer door gasket and recommended removal of ~½ of freezer packs in door because size and weight of packs potentially interfered with door closing completely. No problems identified with thermostat or other mechanical components.

Removed half of freezer packs located in shelf in door, per recommendation.. Reset data logger on center shelf of freezer with probe in glycol. All staff received refresher training on ensuring freezer door is closed after each use, and a reminder sign was placed prominently on freezer door.

Results

- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)

After repair, monitored temps in empty freezer for 1 week, per state requirements. Freezer maintained -18° to -17°C temps for entire week. Submitted repair documentation and data logger readings to Victor Vaccine for approval and ordered replacement vaccines. Victor had checked with manufacturer. After reviewing history and stability data, manufacturer stated vaccine was acceptable for continued use. Discussed entire situation with Susie Supervisor and clinic director, Dr. Immunize, who agreed on continued use of vaccine. Vaccine to be labeled as "use first."

Example

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Temperature Log for Freezer – Fahrenheit

DAYS 1–15

Month/Year_____ VFC PIN or other ID #_____ Page 1 of 3

Facility Name _____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the freezer's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above 5°F) or too cold (below -58°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)															
Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
ACCEPTABLE TEMPERATURES: 5°F															
4°F															
3°F															
2°F															
1°F															
0°F															
-1°F															
-2°F															
-3°F															
-4°F															
-58°F to -5°F															
ACTION: Write any out-of-range temps (above 5°F or below -58°F) here.															
Room Temperature															

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

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Temperature Log for Freezer – Fahrenheit

DAYS 16–31

Month/Year_____ VFC PIN or other ID #_____

Facility Name _____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the freezer's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above 5°F) or too cold (below -58°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the Immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)																
Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
ACCEPTABLE TEMPERATURES: 5°F																
4°F																
3°F																
2°F																
1°F																
0°F																
-1°F																
-2°F																
-3°F																
-4°F																
-58°F to -5°F																
ACTION: Write any out-of-range temps (above 5°F or below -58°F) here.																
Room Temperature																

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

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Vaccine Storage Troubleshooting Record (check one) ☐ Refrigerator ☐ Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.
A fillable troubleshooting record (i.e., editable PDF or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp.

Date & Time of Event If multiple, related events occurred, see Description of Event below.	**Storage Unit Temperature** at the time the problem was discovered		**Room Temperature** at the time the problem was discovered	**Person Completing Report**	
Date:	Temp when discovered:		Temp when discovered:	Name:	
Time:	Minimum temp:	Maximum temp:	Comment (optional):	Title:	Date:

Description of Event *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- General description (i.e., what happened?)
- Estimated length of time between event and last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer)
- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

Action Taken *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer(s).)
- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)
- IMPORTANT: What did you do to prevent a similar problem from occurring in the future?

Results

- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)

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Vaccine Storage Troubleshooting Record (check one) ☐ Refrigerator ☑ Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.
A fillable troubleshooting record (i.e., editable pdf or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp

Date & Time of Event If multiple, related events occurred, see Description of Event below.	Storage Unit Temperature at the time the problem was discovered		Room Temperature at the time the problem was discovered	Person Completing Report	
Date: 7/16/2013	Temp when discovered: 55°F		Temp when discovered: 77°F	Name: Nancy Nurse	
Time: 8:00 am	Minimum temp: 2°F	Maximum temp: 57°F	Comment (optional): temp is approx.	Title: VFC Coordinator	Date: 7/15/13

Description of Event *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- General description (i.e., what happened?)
- Estimated length of time between event & last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer)
- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

When checked vaccine freezer (in lab) at 8:00 am on Tuesday, 7/16/2013, discovered freezer door slightly ajar. Digital readout on data logger read 55°F. Data logger located in center of freezer with probe in glycol. Review of computer readings (taken every 15 minutes) showed steady rise in temps from 2°F at 5:30 pm (7/15/2013) to 55°F reading discovered when arrived at clinic on Tuesday morning (7/16/2013). Readings hit 6°F at 11 pm (7/15) and 45°F at 2 am (7/16). Total time out of recommended storage temp of 5°F or below = 9 hours. (See attached document of continuous temp readings.) Freezer contained Varivax, ProQuad, and Zostavax (inventory attached).

Frozen packs stored on freezer floor and shelves in door. No recent adjustments to temp controls and no previous temp excursions noted with this freezer before 7/15.

Action Taken *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer(s).)
- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)
- IMPORTANT: What did you do to prevent a similar problem from occurring in the future?

Upon discovery, vaccines marked "Do Not Use" and stored in 2nd clinic freezer (in exam room #3) at 1°F. Also placed "Do Not Use" note on main freezer in lab. Notified Susie Supervisor about the issue. Contacted Victor Vaccine at My State Immunization Program at 8:30 am. Provided Victor with details of event and list of vaccines in freezer. Victor said to maintain vaccines in 2nd freezer and that he would check with Merck (manufacturer of all the affected vaccines) to determine next steps. Called Jim's Appliance Repair to examine freezer. Repairman replaced freezer door gasket and recommended removal of ~½ of freezer packs in door because size and weight of packs potentially interfered with door closing completely. No problems identified with thermostat or other mechanical components.

Removed half of freezer packs located in shelf in door, per recommendation. Reset data logger on center shelf of freezer with probe in glycol. All staff received refresher training on ensuring freezer door is closed after each use, and a reminder sign was placed prominently on freezer door.

Results

- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)

After repair, monitored temps in empty freezer for 1 week, per state requirements. Freezer maintained 0–2°F temps for entire week. Submitted repair documentation and data logger readings to Victor Vaccine for approval and ordered replacement vaccines. Victor had checked with manufacturer. After reviewing history and stability data, manufacturer stated vaccine was acceptable for continued use. Discussed entire situation with Susie Supervisor and clinic director, Dr. Immunize, who agreed on continued use of vaccine. Vaccine to be labeled as "use first."

Example

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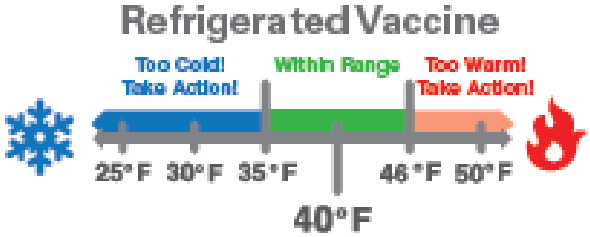
www.immunize.org/catg.d/p3041.pdf • Item #P3041 (8/13)

Vaccine Temperature Best Practices for Refrigerated Vaccines–Fahrenheit (F)

1 Store vaccine at ideal temperature: 40°F

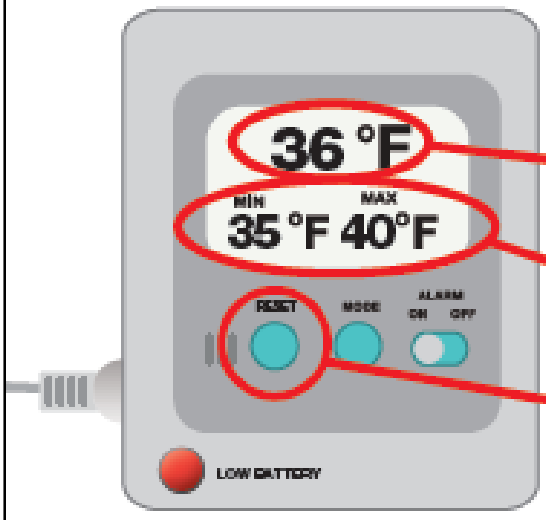
Never freeze refrigerated vaccine!

Exception: MMR can be stored in fridge or freezer



Report out of range temperatures immediately!

2 Record daily temperatures



Three Steps - Twice a Day: Temperatures should be checked and recorded first thing in the morning and before leaving at night.

1. **Current Temperature**: The temperature that the refrigerator is right now.
2. **Min/Max**: The coldest and warmest the refrigerator has been since you last reset the thermometer.
3. **Reset**: The button you push after you have checked the Min/Max.

Best Practices

- **Take your time** - Read and record temperatures accurately.
- **Make your mark!** Initial the log when recording temperatures.
- **Leave it blank** - if a temp was not recorded, leave the space blank!

3 Take action if out of range!

- Contact your state or local health department immediately. Or if private vaccine call the manufacturer directly.
- Tell them the total amount of time the refrigerator was out of range.

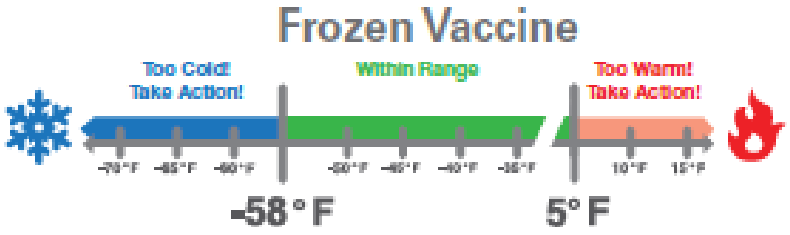
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Distributed by
Louisiana Department of Health and Hospitals
Office of Public Health
IMMUNIZATION PROGRAM

Visit www.cdc.gov/vaccines/SandH for more information, or your state health department.

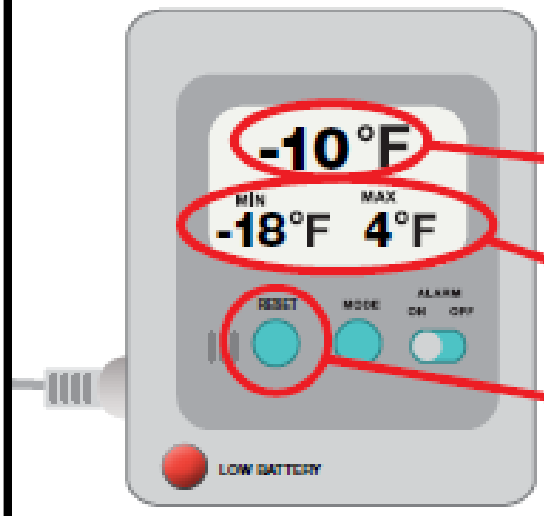
Vaccine Temperature Best Practices for Frozen Vaccines—Fahrenheit (F)

1 Store vaccine at ideal temperature



Report out of range temperatures immediately!

2 Record daily temperatures



Three Steps - Twice a Day: Temperatures should be checked and recorded first thing in the morning and before leaving at night.

1. **Current Temperature:** The temperature that the freezer is right now.
2. **Min/Max:** The coldest and warmest the freezer has been since you last reset the thermometer.
3. **Reset:** The button you push after you have checked the Min/Max.

Best Practices

- **Take your time** - Read and record temperatures accurately.
- **Make your mark!** Initial the log when recording temperatures.
- **Leave it blank** - if a temp was not recorded, leave the space blank!

3 Take action if out of range!

- Contact your state or local health department immediately. Or if private vaccine call the manufacturer directly.
- Tell them the total amount of time the freezer was out of range.

U.S. Department of Health and Human Services
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Version 8 Revision Jan 29, 2014

Visit www.cdc.gov/vaccines/SandH for more information, or your state health department.

Vaccine Storage Best Practices for Refrigerated Vaccines–Fahrenheit (F)

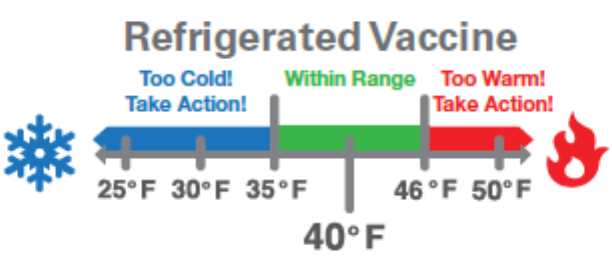
1 Unpack vaccines immediately

1. Place the vaccines in trays or uncovered containers for proper air flow.
2. Put vaccines that are first to expire in front.
3. Keep vaccines in original boxes with lid closed to prevent light exposure.
4. Separate and label by vaccine type and VFC/Public or private vaccine.

2 Store vaccine at ideal temperature: 40°F

Never freeze refrigerated vaccine!

Exception: MMR can be stored in fridge or freezer



Report out of range temperatures immediately!

3 Use vaccine storage best practices

DO

- Do make sure the refrigerator door is shut!
- Do replace crisper bins with water bottles to help maintain consistent temperature.
- Do label water bottles "Do Not Drink".
- Do leave 2-3 inches between all vaccines containers and refrigerator walls.
- Do post "Do Not Unplug" signs on refrigerator and by electrical outlet.

DON'T

- Don't use dormitory-style refrigerator.
- Don't use top shelf for vaccine storage.
- Don't put food or beverages in refrigerator.
- Don't put vaccines or diluent in doors or floor of refrigerator.
- Don't drink or remove water bottles.

CS243541-C Revision Jan 24, 2014

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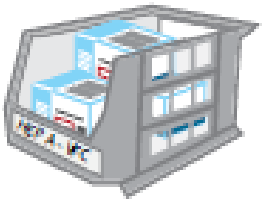
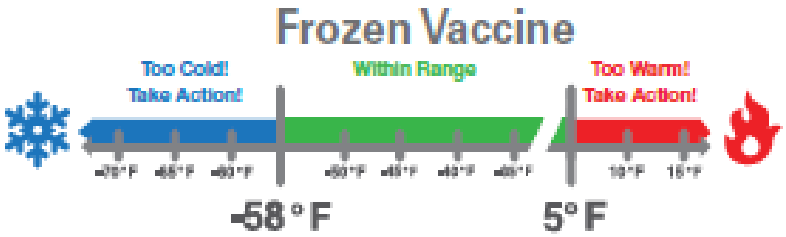
Vaccine Storage Best Practices for Frozen Vaccines–Fahrenheit (F)

1 Unpack vaccines immediately



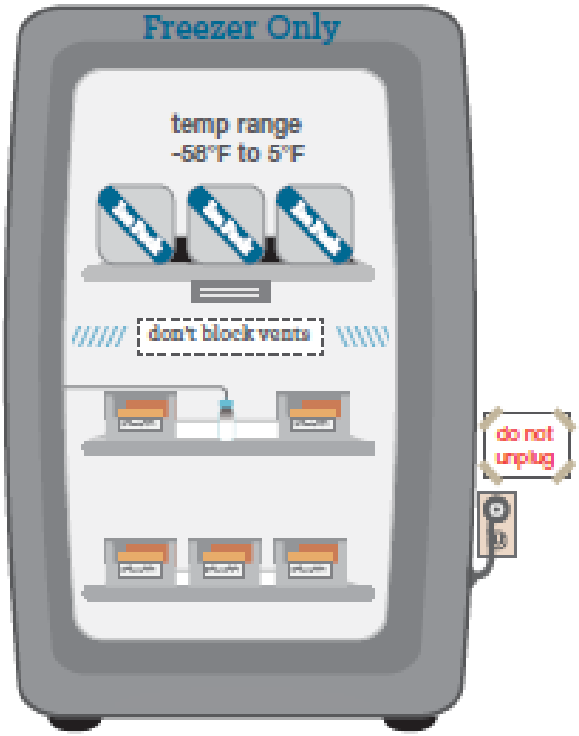
1. Place the vaccines in trays or uncovered containers for proper air flow.
2. Put vaccines that are first to expire in front.
3. Keep vaccines in original boxes with lid closed to prevent light exposure.
4. Separate and label by vaccine type and VFC/Public or private vaccine.

2 Store vaccine at ideal temperature range: -58°F to 5°F



Report out of range temperatures immediately!

3 Use vaccine storage best practices



DO

- Do make sure the freezer door is shut!
- Do use ice packs to help maintain consistent temperature
- Do leave 2 to 3 inches between all vaccines and freezer walls
- Do post "Do Not Unplug" signs on freezer and by electrical outlet

DON'T

- Don't use dormitory-style refrigerator/freezer
- Don't use combo fridge/freezer unit
- Don't put food in freezer
- Don't store vaccines in doors

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Visit www.cdc.gov/vaccines/SandH for more information, or your state health department.

POLICY ON POWER OUTAGES

Policy:

Recommendations regarding the use of vaccine after power outage or refrigerator/freezer failure should be referred to both the Immunization Program and specific vaccine manufacturers in managing potentially compromised vaccines. Vaccine exposed to temperatures outside the recommended range – either too warm or too cold – requires immediate corrective action! Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to:

Identify and isolate all potentially compromised vaccines and diluents. Label these "DO NOT USE" and store separately from uncompromised vaccines and diluents in the recommended temperature range.

Place the vaccine in the recommended storage between 36 F and 46 F (2 C and 8 C). For vaccines exposed to temperatures below -58F should be stored in a freezer between -58F and +5F (-50 C and -15C).

A clearly labeled paper bag can be used for this purpose. Do not automatically discard the vaccine or diluent. Follow your immunization program policy and contact the manufacturer and/or the Immunization Program for further guidance.

Do not discard vaccine unless directed by the Immunization Program and/or manufacturer.

NOTE: Contact the Immunization Program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Backup Supplies/Facility

If you do not have a backup generator, identify a location with one. Alternate storage sites include other health units, hospital pharmacies, fire station or police station or industrial facilities such as dairies with large refrigeration /freezing capacity. Make arrangements with the site to store your vaccine if your vaccine storage equipment malfunctions or there is a power outage. Train a designated person and backup person at the facility to accept your vaccine if it must be moved. Before moving your vaccine, call the location to ensure that their backup generator is working. In situations where a location with a backup generator can not be identified within a reasonable distance, preparations should be made to obtain use of a refrigerated truck or purchase coolers, frozen ice packs and/or portable freezers to temporarily store vaccine.

BACKUP FACILITIES CONTACT INFORMATION

Name of Facility	Primary & Backup Contact	Contact Phone Number Work/Home/Cell

EMERGENCY CONTACT LIST

List of emergency phone numbers, companies, and points of contact:

Electric Power Company:	Phone:
Refrigerator Repair Company:	Phone:
Temperature Alarm Monitoring Company:	Phone:
Transportation to Backup Storage:	Phone:
Dry Ice Vendor:	Phone:
Refrigerated Truck Company:	Phone:
Emergency Generator Repair Company:	Phone:
National Weather Service:	Phone:

HANDLING OF VACCINE IN THE CLINIC AREA

Policy:

Vaccines used in parish health unit clinics must be handled according to the recommendations made in the manufacturer's package insert. Vaccines for immediate use in the clinic room must be stored in suitable ice chests or in covered storage trays with ice packs.

Rationale:

Vaccines and biologics that are not handled properly lose potency and are ineffective as immunizing agents.

Guidelines:

The following information regarding handling procedures must be observed for these vaccines and is current at the time of publication. Questions and problems on vaccine handling should be directed to the Immunization Program at (504) 838-5300.

Labeling:

For labeling purposes, capital letters should be used to designate the following T-Thaw, F-Freeze, R-Reconstitution, O-Open. The date must include the month, day and year. The time must include the hour and minute and whether it is A.M. or P.M. On small vials an additional label should be used and attached if needed.

<u>Labeling is required for the following multi-dose vial vaccines</u>:

Polio (IPV)

Influenza

Pneumococcal – PPV23

Td

Immune Serum Globulin (ISG)

<u>No labeling is required for the following single-dose unit vaccines</u>:

DTaP, DT, Tdap, or any DTaP combination

HIB, HBV, HAV or any HIB or HBV combination

MCV4

Pneumococcal – PCV13

Rotavirus Vaccine

Measles/Mumps/Rubella

1. Once the vaccine has been reconstituted, the date and time must be recorded on the vial.

2. If the vaccine is not used immediately it must be stored at 36-46 degrees F (2 to 8 degrees C).

3. The reconstituted vaccine must be protected from light at all times.

4. The reconstituted vaccine must be destroyed if not used within 8 hours. (Vaccine should not be reconstituted until necessary.)

Varicella, MMR-VAR

1. Before reconstitution the product should be protected from light.

2. Once reconstituted the vaccine must be used within 30 minutes or should be discarded.

3. Unreconstituted Varicella vaccine (single antigen vaccine) may be stored at refrigerator temperature (2-8C /36-46 F) for up to 72 continuous hours. Vaccine stored at 36-46° F/2-8° C that is not used within 72 hours of removal from -15°C/5°F storage should be discarded. MMR-VAR should be stored continuously in the freezer at an average temperature of 5 F (-15 C) or colder at all times. MMR-VAR may not be stored at refrigerator temperature at any time and must be administered within 30 minutes after reconstitution.

4. No freeze thaw cycles are allowed with either vaccine.If a power outage or some other situation occurs that results in the vaccine storage temperature rising above the recommended storage temperature, the health care provider should contact the Immunization Program at (504) 838-5300 or Merck, the manufacturer at 1-877-829-6372 for a re-evaluation of the product's potency before using the vaccine. The manufacturer may determine that the product can be refrozen but given a shorter expiration date.

Yellow Fever

1. Once the vaccine has been thawed, it must be used within one (1) hour. After one hour, the subsequent loss of potency requires that the vaccine be destroyed.

2. Because health units designated as approved yellow fever vaccination centers use only a few doses during a clinic, it is recommended that only single dose vials be purchased to be cost efficient.

POLICY ON TRANSPORTING VACCINE

Policy:

All vaccine transported by OPH personnel (or for use in OPH 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:

- Polio
- Influenza
- Meningococcal Conjugate Vaccine (MCV)
- MenB
- Pneumococcal (PPV23 & PCV-13)
- DTaP, DT, Td, Tdap or any DTaP combination
- HIB, HBV, HAV or any HIB or HBV combination

All vaccine must be transported in an insulated container and cold packs must be used to maintain the proper temperature AND the vaccine should be protected from light at all times:

- MMR
- Rotavirus
- HPV

Specific instructions for transport of other vaccines:

Varicella, MMR-VAR

Reconstituted vaccine should not be transported. Varicella vaccine and MMR-VAR are to be administered immediately after reconstituting. If Varicella or MMR-VAR is not used within 30 minutes after reconstitution, the vaccine should be discarded. To minimize wasteful costs, neither vaccine should be reconstituted until ready for administration to the client.

Unreconstituted Varicella/MMR-VAR vaccine can be transported in an insulated container using frozen gel

packs to maintain a refrigerator temperature of 36-46 °F/2-8 °C for up to 72 continuous hours prior to reconstitution. Vaccine stored at 36-46° F/2-8 °C that is not used within 72 hours of removal from freezer storage (-15 °C/5° F) should be discarded.

Maintain in a continuously frozen state at -15° C (5° F) or colder. No freeze thaw cycles are allowed with this vaccine. Vaccine should only be stored in freezers or refrigerator/freezers with separate doors and compartments.

Special instructions for transporting varicella-containing vaccines are the following:

Place a certified calibrated thermometer in the container used for transport as close as possible to the vaccine. Record:

1. The time the vaccine was removed from the storage unit and placed in the container;

2. Temperature during transport;

3. Document the time and temperature at the beginning and end of transport.

Immediately upon arrival at the alternate storage facility:

1. Place the vaccine in the freezer between -58°F and +5° F (-50°C and -15°C). Any freezer that has a separate sealed freezer door and reliably maintains a temperature between -58°F and +5°F (-50 °C and -15° C) is acceptable for storage of Variella containing vaccines.

2. Document the time the vaccine was removed from the container and placed in the alternate storage unit.

3. Note that this is considered a temperature excursion, so contact the manufacturer at 1-800-637-2590 for further guidance

Do not discard vaccine without contacting the manufacturer and/or the Immunization Program for guidance. NOTE: Use of dry ice is not recommended, even for temporary storage or emergency transport. Dry ice may subject varicella-containing vaccine to temperatures colder than -58° F (-50° C).

Yellow Fever:

1. This vaccine MUST NOT be transported as declared by the LA Sanitary Code, Title 51, Chapter 9 - Section 905, No. 7.

General Handling:

In clinic situations where a refrigerator is located in the clinic room, the vaccine should be kept in the refrigerator until it is needed. Temperatures shall be recorded when stored in the refrigerator and upon removal. If vaccine will remain in this refrigerator, temperatures must be recorded twice daily at the beginning of clinic activity and at the end of clinic.

Varicella/MMR-VAR vaccine should only be stored in freezers or refrigerator/freezers with separate doors and compartments. Dormitory style refrigerators, usually smaller, often brown colored units are not acceptable for

the storage of Varicella/MMR-VAR vaccine or any vaccine for longer than 8 hours.

In order to maintain the -15 °C/5°F or colder needed to store Varicella/MMR-VAR vaccines it may be necessary in most refrigerator/freezer models to turn the temperature dial down to the coldest setting. This may result in the refrigerator compartment temperature being lowered as well. Careful monitoring of the refrigerator temperature to avoid freezing other vaccines will be necessary.

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.

MMR, MMR-VAR, HPV and Rotavirus vaccines must be protected from light at all times.

Syringes must not be pre-filled at any time prior to administration and left in a refrigerated location even for brief periods of time.

Labeling specifications previously outlined in Handling of Vaccines in the Clinic Area 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.

POLICY ON EXPIRATION OF VACCINES AND BIOLOGICS

Policy:

The Expiration Date on vaccines or biologics represents the last date on which the vaccine/biologic may be used. Vaccines or biologics will not be administered at any time after the expiration date.

Rationale:

The Food and Drug Administration requires that all vaccines and biologics have an expiration date printed on the label. This is designed to ensure that vaccines and biologics are of optimal potency.

Guidelines:

The following examples are illustrations of this policy:

1. A vaccine/biologic vial is labeled with an expiration date of January 15, l997. This means the product may be used on January 15, l997, but not on January 16, l997 or later.

2. A vaccine/biologic vial is labeled with an expiration date of October, l997. This means the product may be used during the entire month of October, l997, but may not be used on or after November 1, l997.

Vaccines or biologics which have expired should be removed from the refrigerator or freezer where vaccines or biologics are stored. This will help to avoid inadvertent confusion between expired and unexpired vaccines/biologics.

Expired vaccines or biologics must be returned to the Immunization Program. The regional Immunization Consultant must be notified. Refrigeration of expired vaccine during shipment is not necessary. Return of vaccines to the Immunization Program will assure recovery of applicable federal excise taxes, accountability, and proper disposal.

POLICY ON VACCINE TRANSFERS

Policy:

When any vaccine type (i.e. DTaP, HIB, DT (pediatric), Td (adult), Tdap, HBV, HAV, Polio, MMR, VAR, MMR-VAR, MCV4, MenB, Rotavirus, HPV, Influenza, Pneumococcal (PPV or PCV-7)) is transferred from one Parish Health Unit to another, or to the Immunization Program in New Orleans, an EPI-6 must be completed each time. The report is to be sent directly to the Immunization Program in New Orleans. All transfers of vaccine or shipping materials to the Immunization Program should be made through the courier service.

Rationale:

Because of the cost of vaccine it is necessary to maintain a formal protocol for the handling of vaccine that is being transferred between parish health units and/or branches of the Office of Public Health. This will enable the Immunization Program to maintain adequate supplies and to assure there is minimum loss.

Guidelines:

Prior to transporting unexpired vaccine to the Immunization Program, please contact us to make arrangements. The vaccine should only be shipped to our office on Monday through Wednesday. No vaccine should be shipped to our office on weeks containing a holiday. Absolutely no shipment of vaccine should be made to our office on Thursday or Fridays since it will arrive when the office is closed for the weekend and the shipment will have to be stored at the shipper's site over the weekend, which can render the vaccine inactive.

Unexpired vaccine must be shipped under refrigerated conditions as specified by individual vaccine handling and storage procedures. Please see Policy on Transporting Vaccine. Health Units should notify the Immunization Program immediately, if containers are not received intact. The courier should deliver everything intact and should not keep anything. Please do not return containers and ice packs. The Immunization Program is located at 1450 Poydras Street, Suite 1938, New Orleans, LA 70112-1938.

Persons picking up vaccine at our office must have an ice chest with frozen ice packs in order to transport any vaccine.

To obtain the Vaccine Transfer Form, login into the LINKS system and go to 'Reports'. Scroll down to 'State Reports' and click this selection. Then scroll down to Vaccine Transfer Report to obtain the EPI-6. Instructions for completing the EPI-6 are as follows:

Check the appropriate box:

- Transferred to: Name of the parish health unit or branch the vaccine is being transferred to including the facility's PIN number;

or:

- Expired: Vaccines that have expired and past expiration date;

or:

- Damaged: If Vaccine has been damaged OR if other than vaccine expiration; only after consultation from the Immunization Program in New Orleans.

Vaccine Type:	DTaP, HIB, DT, Td, Tdap,Varicella, Polio, MMR, Influenza, etc.
Number of Doses:	Doses in each vial.
Lot Number:	Manufacturer's lot number that appears on the vaccine package.
Expiration Date:	Date that appears on the vaccine package.
Remarks:	Self-explanatory
Parish health unit/ Clinic transferring:	Name of parish health unit or clinic that is transferring vaccine to another health unit or branch including the facility's PIN number
Signature:	Name of person transferring the vaccine.
Date of Transfer:	Date vaccine is released to another health unit/clinic.

NOTE: One copy of the Vaccine Transfer Report should accompany the vaccine and a second copy should be forwarded to the Immunization Program.

Questions concerning the Vaccine Transfer Report (EPI-6) should be directed to the Immunization Program at: (504) 838-5300 or Fax (504) 838-5255.

VACCINE TRANSFER REPORT IMMUNIZATION PROGRAM (EPI-6; rev 09/2012)

THE FOLLOWING VACCINE(S) WAS ☐ TRANSFERRED TO _____
VFC PIN # _____

☐ EXPIRED
☐ DAMAGED

Vaccine Type	Number of Doses	Lot #	Expiration Date

REMARKS:

TRANSFERRED FROM:
VFC PIN # Parish Health Unit or Clinic Name

WHEN TRANSFER TAKES PLACE
PLEASE SEND REPORT TO:

_____
Signature

State of Louisiana
Department of Health & Hospitals
Office of Public Health
Immunization Program
1450 Poydras St., Ste. 1938
New Orleans, LA 70112-1938
Phone: (504) 838-5300
Fax: (504) 838-5255

Date of Transfer

POLICY ON VACCINE USAGE AND INVENTORY

Policy:

All Vaccine Orders, Inventory, and Usage are to be recorded in LINKS through the use of the Vaccine Ordering Management System (VOMS) module. VOMS offers a complete vaccine management system for vaccine ordering/transferring, distribution, and accountability. In addition, VOMS achieves several objectives which include: a) decreasing staff time spent ordering and tracking inventory; b) increasing ability for facility to monitor orders and vaccine usage; c) enhanced inventory tracking may reduce vaccine wastage; and d) meets Centers for Disease Control and Prevention (CDC) requirement for "dose level" accountability of VFC vaccines.

Rationale:

The vaccine data collected in LINKS is used for the purposes of the budgetary process to justify and document the Immunization Program's funding requirements, in addition to evaluating the administration and usage of the vaccine antigens for age-specific groups and implement strategies for improving immunization coverage.

1. **Vaccine Ordering**:

Vaccine orders are to be created, submitted, and received in LINKS using the VOMS module by the designated health unit/clinic personnel. This person will have VOMS access in LINKS and will be responsible for ordering and inventory maintenance of all ordered vaccines. Instructions on the vaccine ordering/receiving process can be found on the LINKS home page or by going to the following URL:
http://linksweb.oph.dhh.louisiana.gov/linksweb/LINKS_VOMFAQ.html

2. **Vaccine Usage Section**:

The Vaccine Administered Report is available through LINKS and replaces the EPI-5 form. The LINKS network report will be generated automatically by tabulating the report according to the antigens used and specific age groupings. The age grouping column is further sub-divided to indicate the dose number given. (Dose number given refers to whether the immunization administered was either the first, second, third or fourth dose of the series).

To obtain the Vaccine Usage Report, log into the LINKS system and go to 'Reports'. Scroll down to 'Report module' and click this selection. Then select Vaccine administered under Vaccines for Children section and enter the appropriate information for the vaccine report compilation.

3. **Vaccine Inventory Section**:

Like the vaccine usage section the intention is to make vaccine inventory comprehensive and orderly. The vaccine inventory report is also available via the LINKS system which will generate an automatic report of the vaccine inventory for any given site. To obtain the Vaccine Inventory Form, log into the LINKS and go to 'Reports'. Scroll down to 'Report module' and click this selection. Then select lot number summary under Vaccinations section and enter the appropriate information for the vaccine report compilation.

In the event that the LINKS system is not operational, designated person can place the order as soon as LINKS

is operational. In the event LINKS system is not operational for a length of time, the designated person can contact Immunization Program Headquarters for direction.

POLICY ON MOBILE VACCINATION UNITS

Policy:

Healthcare providers operating mobile vaccinations units (e.g., buses, vans) shall implement vaccine transport and storage measures so as to maintain proper temperatures at all times and ensure vaccine viability while in the field.

Rationale:

As the efficacy of a vaccine is highly dependent on its being stored under the right temperature conditions, monitoring of stationary vaccine-storage units in offices or clinics has been an essential component of immunization-practices assessments by public-health agencies. The often-overlooked monitoring of portable storage units used by mobile-vaccination providers presents an additional challenge which may involve specialized measures different from those taken for stationary units.

Guidelines:

All providers administering federal vaccines must meet all program requirements including, but not limited to, eligibility screening and documentation; proper vaccine administration fee billing; and receiving required site visits including the assessment of where vaccine is stored prior to scheduled clinics and how vaccines are stored, handled and administered on site. The official VFC registered health care provider signing the agreement must be a practitioner authorized to administer pediatric vaccines under state law. In addition, this provider is also held responsible for the compliance of their entire organization and any provider administering vaccine under the agreement.

In addition, awardees and providers must:

1. Request, review and approve mass vaccination protocols to ensure that the outreach efforts meet all VFC requirements including how the provider is establishing vaccine need (provider profile) and oversee vaccine ordering for each clinic site to ensure proper amounts of public stock are transported on each clinic day.
2. Maintain a current listing of clinic dates and locations and vaccine amounts that will be transported that day.

To ensure vaccine is managed properly, the following storage and handling practices are required:

1. Vaccine must be ordered and shipped directly from CDC to a location within the awardee jurisdiction.

2. Vaccine received in one awardee jurisdiction must be administered within that awardee jurisdiction (state, city, and parish boundaries).

3. The vaccine may be transported, not shipped, to local schools or other community sites where the temporary clinics will be held.

4. Only amounts of vaccines that are appropriate, based on VFC need, should be transported to each scheduled clinic.

5. Vaccine must be transported to and from the scheduled clinic at appropriate temperatures and must be

monitored by a continuous monitoring and recording device with a probe in buffered material. Temperatures during transport must be documented.

6. Upon arrival at the clinic site, the mass vaccinator must ensure that vaccine is stored to maintain appropriate temperature throughout the clinic day:

A. Since the vaccine is at a temporary location, temperature data must be reviewed and documented every hour during the clinic day, using a continuous monitoring and recording device with a digital display and probe in buffered material.

B. Vaccines exposed to temperature excursions must be labeled "do not use" until further information can be gathered from the manufacturer(s) and awardee on the usability of the vaccine.

7. After each clinic day, the mass vaccinator must:

A. Assess temperature data temperatures prior to placing vaccine back into storage units to prevent inadvertent administration of vaccine that may have been compromised

B. Vaccines exposed to temperature excursions must be labeled "do not use" until further information can be gathered from the manufacturer(s) and awardee on the usability of the vaccine.

If the unit does not contain a stand-alone refrigerator or freezer, Louisiana requires the use of portable refrigerators/freezers for the storage of mobile vaccines.
Insulated containers are not allowed for mobile vaccination units.
Dormitory or bar-style refrigerator/freezers should not be used to store ANY vaccine.

Portable refrigerators/freezers must maintain the appropriate temperature ranges (36º to 46º F (2º to 8º C) for refrigerators, -58º to 5º F (-50º to -15º C) for freezers) for at least one week before mobile vaccines are stored in these units and administered in the field. During this one-week period, providers are required to monitor and document temperatures for their portable vaccine-storage units at least twice a day. Temperature documentation must contain:

- At least two temperature readings per day
- The time and date of each reading
- The name (or initials) of the person who assessed and recorded the readings
- The minimum and maximum temperatures of each unit once each workday (preferably in the morning)

Temperatures in portable storage units shall be monitored using a digital data-logger thermometer with the following features:

- Detachable probe in a buffered material (e.g., glycol) with continuous monitoring capabilities
- Easily-readable temperature from the outside of the unit
- Alarm for out-of-range temperatures
- Current, minimum, and maximum temperatures
- Reset button
- Low-battery indicator
- Accuracy of +/-1ºF (0.5ºC)

- Memory storage for at least 4,000 readings (the device must also not write over old data and stop recording when memory is full)
- User-programmable logging interval (or reading rate)

Information:

Further information on data loggers and vaccine storage may be obtained through the following documents found in the LINKS Document Center at https://linksweb.oph.dhh.louisiana.gov/linksweb/LINKS_DCNTR.html or by contacting the Immunization Program at (504) 838-5300.

- *2016 Louisiana VFC Thermometer Guide*
- *Vaccine Storage and Handling Toolkit – June 2016*
- *LA VFC Refrigerator and Freezer Guide 2016*

III. GENERAL POLICY REGARDING IMMUNIZATION

VACCINE ADMINISTRATION RECORD; VACCINE FOR CHILDREN (VFC) PATIENT ELIGIBILITY SCREENING RECORD; AND REGISTRY AUTHORIZATION

Policy:

The parent, legal guardian, patient, or other person, as appropriate, must read and understand an important information statement/vaccine information pamphlet prior to the administration of each dose of vaccine being given in any OPH parish health unit clinic and/or administered by OPH personnel. Under federal mandate, health care providers are not required to obtain the signature of the patient or parent or guardian acknowledging receipt of the vaccine information materials. To ensure that a record of the provision of the materials exists, the form requires the signature and title of the vaccine administrator. The health unit phone number where the individual receives the vaccine must be given in case the patient has follow up questions after receipt of the immunization. VFC patients must also be screened for eligibility at each clinic visit.

Rationale:

The courts, and Congress (with the enactment of the Vaccine Injury Act of 1986), have established legal requirement that the patient or other responsible person be informed of the benefits and risks involved in vaccination, however small those risks may be. OBRA93 provides vaccines (VFC) for eligible persons less than 19 years of age and requires screening at each clinic visit.

Procedure:

1. If the parent or legal guardian accompanies the child to the clinic or if vaccine is given to an adult, the important information statement/vaccine information pamphlet form for the vaccine(s) to be administered shall be given to the responsible adult or adult patient. The adult should take the opportunity to read the statement or to have it read to him, be able to ask questions relating to the form and request additional information or clarification regarding vaccination. In the same way, questions related to the VFC Program and LINKS can be discussed. If questions are raised, they must be answered to the satisfaction of the responsible adult or adult patient. Once questions have been answered and no further explanations are required, the nurse may then proceed with the immunization.

2. If the parent or legal guardian cannot accompany the child to be immunized, any one of the following persons is authorized and empowered under R.S. 40:1299.53 to consent to obtain vaccine or any medical treatment:

A. Any parent, whether an adult or a minor, for himself/herself and for his/her child.

B. Any married minor, for himself/herself.

C. Any person temporarily standing in loco parentis whether formally serving or not, for the minor under his/her care.

D. Any female regardless of age or marital status, for herself when given in connection with pregnancy or childbirth.

E. Any adult, for his/her minor brother or sister.

F. Any grandparent for his/her minor grandchild.

In addition, under compelling circumstance and after consulting the case with either the local or regional medical director, OPH medical consultants, or the Immunization Program in New Orleans, according to R.S. 40:1095, the consent of a parent shall not be necessary for any unaccompanied minor. In such a case the signature of the minor receiving the immunization should be obtained.

3. Storage and Retention: In accordance with VFC guidelines the Patient Eligibility Form must be retained for three years. The Vaccine Administration Record must be retained for a period of 10 years following the end of the calendar year in which the form is signed, as directed by the OPH Medical Record Retention Checklist, June, 2001. In addition, if a notice of a claim or lawsuit has been made, the Vaccine Administration Record/VFC Patient Eligibility Screening Record should be retained until after a final disposition of the claim or litigation (including appeals). The original signed copies are to be maintained in the respective parish health unit in boxes identified by year and month(s) to facilitate retrieval of a particular form when necessary. See IDM 711 dated November 19, 1993 for additional information.

Further inquiries on this subject may be addressed to the Immunization Program at (504) 838-5300, fax (504) 838-5206.

For a copy of the Vaccine Administration Record/VFC Patient Eligibility Screening Record see form at the end of this chapter or log into LINKS under ‘Reports’, go to ‘State Reports’ and scroll down to ‘Other’ and select ‘VFC VAR Blank’.

Special note: The Vaccine Administration Record/VFC Patient Eligibility Screening Record must be completely filled out at the time services are performed. This includes providing the telephone number of the health unit to the patient, parent, legal guardian, or other responsible adult to report any reactions.

POLICY ON ROUTE OF ADMINISTRATION

Policy:

DTaP, HIB, HBV, DT (pediatric), Td (adult), Tdap, MCV4, MenB, PCV13, HAV influenza and all other vaccines should be given by the intramuscular (IM) route and will be injected by that route and not subcutaneously.

MMR, VAR-MMR and Varicella should be given subcutaneously and not intramuscularly. IPV and PPV23 may be administered either intramuscularly or subcutaneously.

None of the vaccines recommended by the ACIP should be administered via gluteal route.

Rationale:

The incidence of sterile abscess and severe local reactions is increased when intramuscular (IM) vaccines, such as DTaP, HIB, HBV, DT (pediatric), Td (adult), Tdap, MCV4, MenB, PCV13 and influenza vaccines are injected into the subcutaneous tissue. Injections given in the gluteus site may risk damage to the nerve tissue.

TECHNIQUES FOR ADMINISTRATION OF INJECTIONS

Policy:

The technique outlined in the following pages will be used for administering injections by parish health unit nurses in the Office of Public Health.

Procedure:

There are four routes of injection, depending on the anatomic location in which the injection is given: intradermal, subcutaneous, intramuscular and intravenous.

1. The intradermal injection is given into the most superficial layers of the skin and is mainly used to give diagnostic skin tests (tuberculin test, coccidioidin skin test).

2. The subcutaneous injection is given beneath the skin into the fatty tissue which lies between the outer skin and the underlying muscle; this route is used for administration of medications and biologics such as measles and Varicella vaccines.

3. The intramuscular injection is given directly into the muscle mass, and is a common route for administration of biologics such as immune serum globulin (ISG) or DTaP vaccine, which requires a larger volume of muscle for slow absorption and to minimize local reactions.

4. The intravenous route is generally used for medical treatment, and is not relevant to immunization activities conducted through the parish health units of the Office of Public Health, except in treatment of emergency conditions.

Equipment:

1. Intradermal Injections

    A. Sterile disposable 1-cc tuberculin syringe with 26g - 3/8" needle.

    B. Prepackaged alcohol swabs.

    C. Vial of PPD tuberculin solution or other appropriate skin test material.

2. Subcutaneous Injection

    A. Sterile 3-cc syringe with 25g - 5/8" needle (for administration of insulin use disposable insulin syringe with 25g - 5/8" needle).

    B. Prepackaged alcohol swabs.

3. Intramuscular Injections

A. Sterile disposable 3cc syringe with needle, gauge and length appropriate for the patient's body habitus and stature, as below:

1. In most children ages 0-4 years old, a 23g - 1" needle will be necessary for administration of IM vaccine into the thigh (or deltoid site, if appropriate). (Infants born prematurely and who do not have sufficient subcutaneous tissue, may require a 25g – 5/8" needle.)

2. In children 5-11 years of age of small to average stature, a 25g 5/8" needle for the deltoid site will be adequate. Heavier children with a thick subcutaneous layer of tissue will require a 23g - 1" needle to reach the muscle. (To determine the thickness of the subcutaneous tissue lightly pinch movable skin between the thumb and index finger).

3. Children 12 years of age or older and adults of average stature should receive intramuscular injections in the deltoid site with a 23 gauge l" to 1 ¼ " needle to insure injection into the muscle (obese children and adults will require a 1 ¼ " needle for injection).

4. If the thigh is used on older children and adults, a 1" to 1 ¼ " needle should be used to insure injection into the muscle.

B. Prepackaged alcohol swabs.

Procedure:

1. Wash hands carefully.

2. Observe universal precautions.

3. Check vial(s) to be sure intended vaccine is being used.

4. Cleanse the rubber stopper of the vial with an alcohol swab.

5. Determine the proper dosage and ensure that the particular patient will receive the appropriate dosage and/or amount.

6. Using the proper syringe, draw amount of solution to be injected into the syringe and expel all air bubbles.

7. Inform the patient (and parent/guardian of child to be immunized) about the procedure and if necessary, instruct the parent/guardian on how to hold an infant or young child to avoid injury during the injection procedure. (See policy regarding unruly and resisting children).

8. Counsel the patient/parent on any side effects he/she may experience from the injection. Provide pertinent literature to the patient/parent and include the health unit telephone number to report reactions. Ask if there are any questions and answer the patient's or parent/guardian's questions.

9. Select the proper injection site, based on the size of the tissue available on the patient, and the volume of material to inject.

A. Intradermal injections: Ventral portion of forearm

B. Subcutaneous injections: option of two sites

1. outer aspect of the upper forearm at the insertion of the deltoid muscle

2. mid-antero-lateral surface of the thigh (rectus femoris muscle)

C. Intramuscular injections: options according to age of patient

1. infants and children

a) upper antero-lateral quadrant of thigh

2. children more than 4 years old and adults:

a) deltoid muscle of upper arm
b) upper antero-lateral quadrant of the thigh

Note: Because of the increased risk of injuring the sciatic nerve and poor antibody response. DO NOT use gluteal site on anyone regardless of age.

10. Cleanse the injection site with alcohol swab, and allow the site to dry.

11. Insert the needle into/beneath the skin at the appropriate angle.

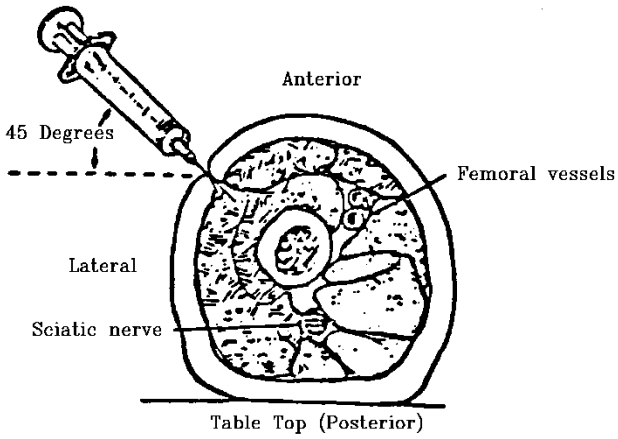
Note: When giving subcutaneous and intramuscular injections, lightly compress the skin so as to increase the penetrable subcutaneous or muscle mass.

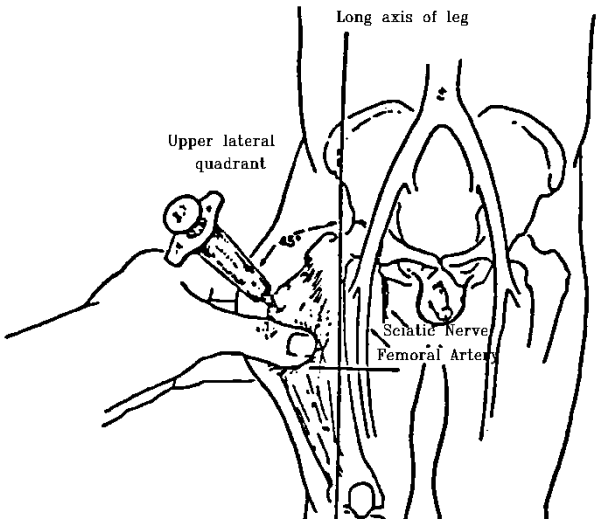
A. When giving an intradermal injection, spread the skin taut with thumb and index finger,
Intradermal injections: at 15 degrees or less

B. Subcutaneous injections: at 45-60 degrees.

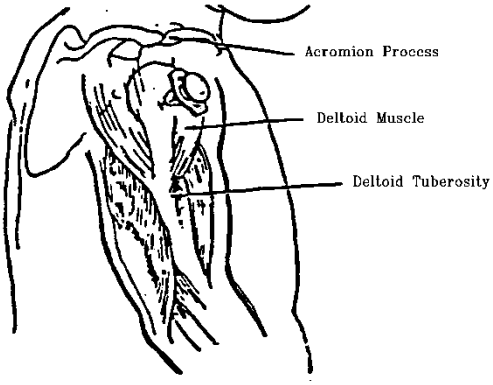
C. Intramuscular Injection:

1. In the upper antero-lateral quadrant of thigh -- insert needle inferiorly at an angle of 45o with the long axis of the leg and posteriorly at a 45o angle to the table top with the patient supine. (See picture below.)



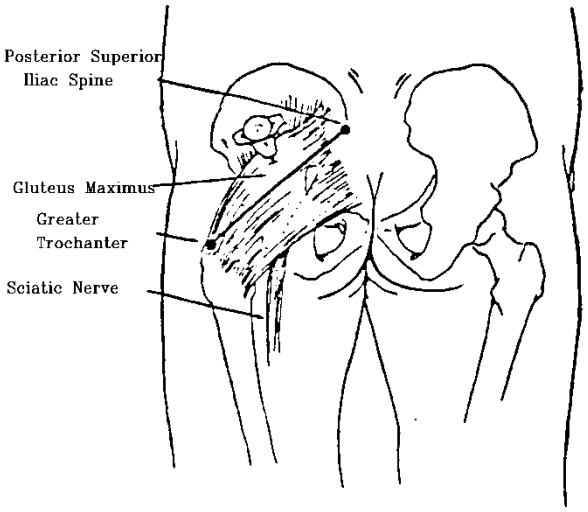


2. In the deltoid -- insert the needle at a point halfway from the acromion to the deltoid tuberosity. (See picture below.)



3. In the gluteal area -- insert the needle lateral and superior to a line between the posterior superior iliac spine and greater trochanter. The needle should be inserted at an angle of 90o to the table (rather than the skin) on which the individual is lying. (See picture below.)

NO VACCINE SHOULD BE GIVEN IN THE GLUTEAL AREA.



Reference
†Bergeson, Paul S., et al., Intramuscular Injections Pediatrics 70: 944, 1982.

4. When the needle is in the desired anatomic location (intradermal, subcutaneous, or intramuscular).

5. Inject the solution. (Intradermal injection will result in a visible bleb in the skin).

6. After injection is completed, withdraw the needle and place an alcohol swab over the injection site.

7. If the injection site bleeds slightly place a Band-Aid over it.

8. Place syringe into a sharps container for disposal.

9. Record the immunizations in the LINKs registry, type of vaccine, date of injection, site of injection, the manufacturer, lot number, the expiration date, and name of provider that administered the vaccine(s).

POLICY ON INFORMING PARENTS OF POTENTIAL VACCINE REACTIONS

Policy:

Nurses administering vaccines or biologics in OPH clinics will inform the patient, parent, legal guardian, or other responsible adult of common side-effects of the vaccine and steps that should be taken if these side-effects occur. According to General Recommendations on Immunization: Recommendations of the ACIP, all health-care personnel administering vaccinations should be aware of the potential for syncope after vaccination, especially among adolescents, and should take appropriate measures to prevent potential injuries. If syncope occurs, the vaccine recipient should be observed until symptoms resolve. Healthcare providers should strongly consider observing patients for 15 minutes after they are vaccinated.

The nurse must verify the patient, parent, legal guardian, or other responsible adult has been made aware of the rare side effects through assuring that the important information statement/vaccine information pamphlet has been read. In addition, in the event of an adverse event, the telephone number of the parish health unit must be recorded in the space provided at the end of the important information statement/vaccine information pamphlet so that the patient, parent, legal guardian, or other responsible adult will know where to call.

Rationale:

Informing the responsible person fulfills the legal requirement to provide an appropriate important information statement/vaccine information pamphlet.

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 New Orleans. 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.

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

VAERS

VACCINE ADVERSE EVENT REPORTING SYSTEM

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)

SIMULTANEOUS ADMINISTRATION OF VACCINES

Policy:

Any child seen in an OPH immunization clinic, who is not current with his immunizations, should be given a single dose of each vaccine or a licensed manufactured-FDA approved combination vaccine (ex. HBV/HiB) needed at that visit.

Rationale:

Serologic studies have shown no reduction in antibody response when multiple vaccines are given. Side effects are not increased by giving multiple vaccines simultaneously. Compliance with the recommended schedule is more likely to be achieved with a minimum number of required visits.

Example:

An 18 months old child present at a clinic with a history of having received a single DTaP and IPV. This child will be given an injection of DTaP, MMR, Varicella, HiB, HBV, PCV13, HAV and IPV. Combination vaccines appropriate for age may be given to reduce the number of injections to the child.

MIXING VACCINES

Policy:

OPH staff shall not mix different vaccines for administration in a single syringe. Each type of vaccine will be given by separate injection. Exceptions to this policy apply only when specifically described by the vaccine manufacturer.

Rationale:

Vaccines may require different stabilizers and preservatives and have different chemical compositions. Mixing vaccines may therefore inactivate vaccines or increase side effects.

Example:

A child is to receive MMR and PCV13. The vaccines are given as two separate injections at different injection sites. They are not mixed in a single syringe.

CHILDREN WITH INTERCURRENT ILLNESS

Policy:

1. Children with minor illnesses not accompanied by high fever shall be vaccinated when seen at OPH vaccination clinics.

2. Children with high fever shall not be vaccinated at OPH vaccination clinics.

3. Children taking antibiotics for intercurrent illnesses who are not febrile may be vaccinated.

Rationale:

Minor illnesses do not interfere with seroconversion following vaccination. Children who have frequent minor illnesses such as colds or ear infections may significantly delay their immunizations if they are not vaccinated while at the clinic during these illnesses. While reduced rates of seroconversion have not been shown to occur in children with fever, we do not wish to add possible febrile reaction to vaccination to an acute, severe illness. In addition, if a child is vaccinated during a severe illness, effects of the illness may be falsely attributed to vaccine.

Definition: Fever is defined for this policy is a temperature greater than 101 degrees.

- Normal temperature range: 96.6-100.9 then vaccinate patient
- Temperature <96.6, reassess temperature and if second assessment <96.6 refer to primary care provider
- Fever: >101 degrees, do not vaccinate and refer patient to primary care provider

POLICY ON IMMUNIZATIONS OF HIV-INFECTED INDIVIDUALS

Policy:

The following vaccines will be given to children and adults with HIV infection who are served in the parish health units. Whether a patient receives certain vaccines depends on the patient's degree of immunosuppression based upon the CD4 count and CD4 percentage. The administration intervals, as published in Louisiana's OFFICIAL IMMUNIZATION SCHEDULE, are the same as for other individuals.

The subsequent guidelines should be followed:

VACCINE	HIV INFECTION	
	CD4 Count >200	**CD4 Count <200**
DTaP	YES*	YES*
Td	YES*	YES*
Tdap	YES*	YES*
IPV **(**Never Oral Polio Vaccine)**	YES	YES
MMR	YES	NO
Hepatitis A	YES	YES
Hepatitis B	YES	YES
Hib	YES	YES
Varicella	YES	NO
MCV4	YES	YES
MenB	YES	YES
MMR-VAR	YES	NO
Pneumococcal (PPV)	YES	YES
Pneumococcal (PCV-13)	YES	YES
Influenza **(**Never give nasal inhalation influenza vaccine – Use IM injection vaccine only)**	YES	YES

Rotavirus	NO	NO
HPV	YES	YES

* Age appropriate vaccine and schedule used.

http://www.cdc.gov/vaccines/adults/rec-vac/health-conditions/hiv.html
(Updated March, 2014)

http://www.cdc.gov/vaccines/schedules/easy-to-read/adult-conditions-easyread.html
(Site Updated February, 2016

https://www.healthychildren.org/English/safety-prevention/immunizations/Pages/Weakened-Immune-Systems.aspx
(American Academy of Pediatrics Supported Site - Updated November, 2015)

POLICY ON IMMUNE GLOBULIN, BLOOD PRODUCTS AND ROUTINE VACCINATION

Policy:

1. Vaccination with Measles, Mumps, Rubella vaccine, and Varicella or MMR-VAR vaccine should be deferred after administration of Immune Globulin (IG) or after blood transfusions. Specific intervals depend on the product given.

2. Persons inadvertently given the above vaccines too soon after IG administration or blood products must be revaccinated after an appropriate interval has elapsed.

3. IG administration should preferably be delayed until 2 weeks after administration of measles, mumps, rubella vaccine, or Varicella/MMR-VAR vaccine.

4. Persons given IG or blood products less than 2 weeks after administration of measles, mumps and/or rubella vaccines must be revaccinated with the appropriate measles, mumps and/or rubella after the appropriate interval has elapsed.

Rationale:

Immune Globulin (previously known as ISG, gamma globulin, GG, gamma G.) contains antibodies commonly found in the serum of many persons. These antibodies may interfere with the replication of the virus in live virus vaccines. Replication of the virus is necessary for the vaccines to produce immunity to the disease. Thus, IG may prevent seroconversion following vaccination with live virus vaccines to which the general population is immune. Because replication is not necessary for killed vaccines and toxoids, and the amount of antibody in IG is small, killed vaccines and toxoids may be given following IG with no adverse effect on seroconversion.

Note: In certain unusual situations, (i.e., a disease outbreak) this policy may be temporarily suspended, but only on specific direction by the Regional Medical Director or OPH Medical Consultants.

For more information on administration of immune globulin preparations and vaccines see the appropriate table in the “Epidemiology and Prevention of Vaccine Preventable Diseases” manual.

POLICY REGARDING UNRULY AND RESISTING CHILDREN

Policy:

The parents of unruly or resisting children shall be asked to control and/or restrain the child. OPH staff are not permitted to use punitive physical force against a child regardless of provocation. OPH staff may assist parents with the restraint of a child during an immunization procedure as long as excessive force is not used.

Rationale:

Unruly or resisting children disrupt clinic activity, and may injure themselves or others.

Guidelines:

Recommendations for handling the resisting child for elective procedures are as follows:

Use a soothing tone of voice to tell the child that the injection is going to be given, where it is going to be given and that some pain will be felt for a short time only. Answer questions the child may have. If this is not successful, then:

1. Ask parents and child to return to the waiting room until the child is calm and quiet.

2. Try to carry out the procedure a second time.

3. If the child still resists to the point that the child or staff may be injured in the process of administering the required procedure, then:

> A. Inquire of the parent whether or not terms like "shots," "doctor," or "nurse" have been used as the threat for bad behavior or whether similar negative experiences have been common in the child's environment.
>
> B. Explain to the parent that the procedure may harm the child if given under present circumstances.
>
> C. Ask the parent and child to return to the next clinic, or if convenient, to return at a time when there is no clinic so that the atmosphere may be quieter and the child is less upset by others.
>
> D. During interval, suggest that the parent work with the child to develop more positive attitudes and behaviors.
>
> E. Record child's resistance and action taken on an appropriate record.

RECOMMENDED HANDLING OF THE RESISTING CHILD WHEN A PROCEDURE MUST BE DONE

1. Always explain to the parent and obtain prior approval in advance for the restraining procedure you intend to employ.

2. For immunizations, one effective means of holding the preschool child is as follow:

   A. Place the child in a sitting position on the lap of the parent or staff person, facing towards the parent's right side. The child's right arm is tucked under the parent's left arm. The parent then restrains the child's free left arm against the child's body with the parent's left arm. The parent restrains the legs across his/her lap with the right arm.

   B. If the thigh is the site chosen for administration of an injection, the parent's right hand/arm may be moved to just below the child's knee in order to more snugly restrain the legs. If the child is facing the parent's left side, the extremities will reverse. It may be necessary to have the child's legs held securely between the mother's legs to avoid injury to personnel, patient, or from kicking mother.

3. Record child's resistance and action taken on appropriate record.

POLICY ON THE MANAGEMENT OF EMERGENCY REACTIONS

Policy:

1. All nursing personnel involved in immunization activities shall be trained in the management of emergency reactions, including cardiopulmonary resuscitation (CPR) and other emergency procedures necessary to deal with reactions to vaccines or biologics.

2. All new nursing personnel will be trained as above within the first quarter of employment with the agency.

3. Refresher courses in management and emergency reactions must be conducted at least annually. The responsibility for coordinating and assuring adequate training rests with regional personnel, who should maintain a current listing.

4. Emergency equipment, and supplies, as outlined in the protocol on vaccine reactions and their management, must be maintained by each office. Maintenance includes renewal of medications as needed, testing of equipment and replacement of used or worn-out components. In order to assure proper maintenance it is suggested that an itemized sheet be used monthly to record dates that emergency equipment was checked.

PROTOCOL ON VACCINE REACTIONS AND THEIR MANAGEMENT

Introduction:

Modern vaccine administration is rarely complicated by serious adverse reactions. This protocol is not intended to replace information on contraindications, precautions or side effects contained on the appropriate product insert or vaccine information statement. Rather, this protocol is directed to the reactions which may occur within a short period after the vaccination. It is the responsibility of the parish health unit to ensure that in every setting in which immunizations are provided, the appropriate emergency equipment is available to handle serious reactions to vaccine.

Types of Reactions:

1. Local Reactions: slight bleeding, pain, swelling, and redness at the injection site.

2. Systemic Reactions:

A.“Pre-faint”: Refers to a feeling of weakness, nausea, sickness or feeling strange. This usually precedes an actual loss of consciousness by only a few seconds.

B.“Faint”: Fainting is due to a sudden, brief loss of crucial blood flow to the brain. It is usually caused by severe anxiety or pain - a “vasovagal” reaction. By causing the person who faints to collapse to the floor, the faint actually becomes a protective reaction, since blood flow to the brain resumes when the head is lowered to a level even with or below the heart. Other causes of fainting include severe blood loss, rapid assumption of a standing position (“orthostatic” faint) or cardiac arrhythmia or arrest with cessation of blood flow because the heart is pumping inefficiently or not at all).

C. Rashes and urticaria (hives): Allergic reactions mediated by the release of certain chemicals in the body, including histamine, can be caused by a reaction to substances to which the person has been sensitized and is allergic. Urticaria (hives) may occur alone or may be the first sign of anaphylaxis.

D. Anaphylaxis: Anaphylaxis is a life-threatening allergic reaction which may occur after injection or ingestion of a substance to which the person is sensitized. The mechanism of anaphylaxis is not related to the immune mechanism, which causes local reactions (even severe local reactions). Severe local reactions do not predispose individuals to anaphylactic reactions.

Anaphylaxis may begin with generalized itching, anxiety and sudden dramatic reddening of the skin with the development of hives (urticaria). Other early features may include swelling of the face and difficulty breathing. Without intervention, anaphylaxis can progress to bronchospasm, laryngeal edema, shock, respiratory arrest and cardiac arrest. It is a true medical emergency.

Cardiac Arrest: There are many causes of cardiac arrest, but diagnosis and initial management follows a standard pattern, regardless of cause.

Management of Reactions

The most important part of managing vaccine-related reactions is advance preparation for any emergency that may arise. The essential components of this preparedness include:

1. Understanding the basic emergency protocols;

2. Reviewing emergency procedures on a regular basis;

3. Rehearsing the management of emergencies;

4. Assuring that all necessary materials are present, intact, functional, and that medications and supplies have not passed the expiration date.

Besides equipment and medications, certain information must be determined in advance and made readily available. This includes emergency telephone numbers (ambulance, rescue squad, etc.) which should be taped on or near phones in patient care areas.

A copy of Emergency Protocols shall be kept with the Emergency Cart/Tray.

Standing Orders

See Policy Memorandum Number 119 (Revision 4), dated 7-1-2000, for Standing Orders.
For further information on Vaccine side effects, adverse reactions, contraindications, and precautions see MMWR 1996; 45(RR-12): 1-35 or www.cdc.gov/mmwr/preview/mmwrhtml/00046738.htm on the internet.

Cardio-pulmonary Resuscitation (CPR)

The techniques of cardio-pulmonary resuscitation (CPR) must be known by all nurses and used appropriately, if necessary. Refresher courses must be obtained annually from certified trainers or instructors.

Emergency Supplies and Equipment*

An emergency kit (cart) and an emergency supply of oxygen must be available in close proximity in each health unit or other OPH clinic facility. The cart must contain at all times, at a minimum, the following:

TOP OF CART
Box of gloves (latex and non-latex)
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 0.4mg/ml vial (2 vials)
- Benadryl 50 mg/cc (1 vial)
- Epinephrine solution 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 Start 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 and pediatric) (1 each)
Optional: Laryngoscope (adult, pediatric, curved, straight) with batteries and extra bulbs (1ea)
CPR mouth –to-mask emergency resuscitator (1 resuscitator)

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)

The assigned nurse is responsible for ensuring that the emergency tray is complete, that materials are checked routinely and outdated medications or broken equipment is immediately replaced, and that the tray is immediately available at any site where immunizations are being administered. The emergency tray must be present in the room where immunizations are being given, or if several rooms are involved, in a key central and immediately accessible location. All personnel involved in the operation of an immunization clinic must know where the tray is located.

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

CARDIAC ARREST PROTOCOL

The treatment of cardiac arrest, which may be caused by a wide variety of problems, requires knowledge of cardio-pulmonary resuscitation (CPR).

Nursing Assessment

It is vital to establish the presence of cardiac arrest before initiating treatment.

Check for a carotid pulse. If no carotid pulse, the presence of cardiac arrest is established.

Treatment:

Immediate reaction to this life-threatening emergency is needed.

1. Call for help. Have an ambulance called immediately and tell them it is a cardiac arrest. Note the time and record all pertinent events prior to their arrival.

2. Establish airway clearance.

3. Initiate CPR.

4. Transport patient to the nearest hospital emergency room that is capable of treating a critically ill patient.

5. Keep an accurate record of events for the medical record. Send a copy with the patient to the hospital. In the report, include information about the offending medication and the details leading up to the arrest, as well as the details of the resuscitation.

6. When the emergency has passed, complete the VAERS report form and notify Risk Management. The patient's immunization record and other medical records should indicate a contraindication to further immunization with the specific vaccine used. Inform the patient's regular medical provider of the occurrence and type of reaction.

ANAPHYLAXIS PROTOCOL

Anaphylaxis results from an exposure to an antigen to which the patient has been previously sensitized. The onset is characteristically sudden and dramatic. Anaphylaxis may cause shock, cardiac arrest, respiratory difficulties due to laryngeal edema and respiratory failure. The patient may describe a feeling of impending doom immediately before the onset of other symptoms. Anaphylaxis normally occurs within 30 minutes of exposure to the inciting antigen. Anaphylaxis may cause shock, cardiac arrest, or, most commonly, respiratory difficulties due to laryngeal edema.

Symptoms:

Generalized flush, coughing, urticaria, severe anxiety, dyspnea, wheezing, vomiting, cyanosis, shock

Treatment: TREATMENT MUST BE INITIATED IMMEDIATELY

Call for help. Notify Emergency Medical Services

Place the patient in recumbent position. Elevate legs. Remove dentures, if present.

Evaluate and maintain airway clearance, breathing, and circulation. Check Vital Signs (pulse, blood pressure, and respiratory rate).

Start Basic Life Support (cardiopulmonary resuscitation (CPR)), if necessary.

Give aqueous epinephrine solution (1:1000) subcutaneously. The dosage schedule for aqueous epinephrine is:

0.01 ml/kg/dose subcutaneously up to a maximum of 0.5 ml.

If the exact weight is not known, estimate weight and use the following guidelines for epinephrine solution (1:1000):

WEIGHT	DOSAGE
Less than 10 lbs.	0.05 ml
10-20 lbs.	0.05 - 0.1 ml
21-40 lbs.	0.1 - 0.2 ml
41-60 lbs.	0.2 - 0.3 ml
61-80 lbs.	0.3 - 0.4 ml
81-100 lbs.	0.4 - 0.5 ml
Greater than 100 lbs.	0.5 ml

Repeat the dose of aqueous epinephrine every ten minutes if there is no immediate improvement in pulse, respirations, or blood pressure. The dose can be repeated up to a total of 3 doses.

Oxygen may be given at a flow rate of 4-6 liters per minute.

Give normal saline by IV drip at a rate to keep the vein open.

If MD is present, give diphenhydramine (Benadryl) IV push or IM (if ordered by MD only) according to the weight of the patient (known or estimated). Benadryl dosage (50mg/ml) based on about 1 mgm/Kg or 0.5 mgm/lb body weight per dose.

If the exact weight is not known, estimate weight and use the following guidelines for diphenhydramine (Benadryl):

WEIGHT	DOSAGE
Less than 10 lbs.	0.08 ml
10-20 lbs.	0.1 - 0.2 ml
21-40 lbs.	0.2 - 0.4 ml
41-60 lbs.	0.4 - 0.6 ml
61-80 lbs.	0.6 - 0.8 ml
81-100 lbs.	0.8 - 1.0 ml
Greater than 100 lbs.	1.0 ml

Give copy of documentation to EMS upon arrival or transport the patient to the nearest hospital emergency room capable of treating a critically ill patient.

Keep a record of all events, including frequent vital signs and any drugs given or other treatment provided. Send a copy of this record with the patient. Include the name of the offending allergen (vaccine or drug).

When the emergency has passed, complete the VAERS report form and notify Risk Management. The patient's immunization record and/or other medical records should indicate a contraindication to further vaccination with the specific vaccine involved. Inform the patient's regular care provider of the occurrence of the reaction.

P.M. NO. 119 (Revision 5)

E M E R G E N C Y R E P O R T

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

PROTOCOL FOR BRONCHOSPASM

Definition:

A bronchospastic response is a focal allergic response occurring in the respiratory tract. This generally occurs in persons who are sensitized to the drug or vaccine involved. Persons with asthma may also exhibit this reaction if they are hypersensitive to a vaccine component.

Diagnosis:

The diagnosis relies on evidence of respiratory distress: shortness of breath, wheezing, gasping, stridorous respirations, etc.

Treatment:

1. Administer epinephrine, in the same dosage and schedule as for anaphylaxis (See Anaphylaxis Protocol).

2. Call an ambulance and transport the patient to the nearest hospital emergency room capable of caring for a very ill patient, or to a private physician's office if specifically requested by the attending physician in the clinic or by the patient.

3. Keep a record of frequent vital signs and all drugs given. Send a copy of this with the patient, including the name of the offending allergen (vaccine or drug).

When the emergency has passed, complete the VAERS report form and notify Risk Management. The patient's immunization record and/or other medical records should indicate a contraindication to further vaccination with the specific vaccine involved. Inform the patient's regular care provider of the occurrence of the reaction.

PROTOCOL FOR RASH AND URTICARIA

Rash and/or urticaria occurring relatively rapidly after injection of vaccine may represent an allergic reaction to the vaccine. There are two major issues at this point: 1) immediate treatment, 2) potential risk of more serious allergic reactions occurring later.

Diagnosis:

Rash is easily recognized, and may be local or generalized. Urticaria (hives) are notable for the severe pruritus (itchiness) associated with erythema and welts.

Treatment:

1. If the patient is not in distress, ask about allergies to drugs, eggs, and other substances. The nurses judgment, with or without medical consultation, will, in the long run, determine the final disposition and care for patient reactions.

2. Call the patient's physician or health unit clinician and indicate the findings. If the patient has their own physician, ask specifically if the physician would like the patient to come to his office, or be seen in the hospital emergency room.

3. If the patient experiences respiratory distress or shock, treat as for anaphylaxis. (See Anaphylaxis Protocol)

4. Record frequent vital signs every 5 minutes and each medication given. Send a copy of the record with the patient and name the suspected offending allergen (vaccine or drug).

5. When the emergency has passed, complete the VAERS report form. The patient's immunization record and/or other medical records should indicate a contraindication to further vaccination with the specific vaccine. Inform the patient's regular care provider of the occurrence of the reaction.

PROTOCOL FOR DIZZINESS AND FAINTING

Dizziness or fainting may occur in a clinic setting, mainly as a result of anxiety, hot weather, and occasionally, due to an underlying circulatory problem. Clinics must include facilities to accommodate those persons who either “feel faint” or actually lose consciousness (faint), including before, during, and immediately after immunization.

Diagnosis:

A person about to faint usually has a period of several seconds of warning. This may be expressed as feeling dizzy, weak, strange, sweaty, sick, or faint. The individual may also look pale, shaky or wet with perspiration. These warning symptoms are very brief, and must be considered as signs of a potentially dangerous event. By responding rapidly to a pre-faint situation, full faints may be prevented.

Treatment:

1. Pre-faint

If anyone expressed the warning symptoms of fainting, or appears very pale or shaky:

A. They must be immediately placed in a horizontal position. Lay them down and check vital signs.

B. The person should be moved, when practical, to a location that will not interfere with on-going clinic activities.

C. Encourage the person to remain in a horizontal position until they feel entirely normal, and then to get up very gradually over several minutes. Several minutes should pass before they sit from reclining and several more minutes before they attempt to stand from a sitting position.

D. If the immunization has not already been given, suggest that he/she be immunized at another time, or offer to give the immunization while the person is lying down.

2. Faint (This presumes that the person has lost consciousness.)

A. Place in a horizontal position and transport to a location where routine clinic activities will not be compromised, and in which the person will have some privacy. Check vital signs and record the results.

B. f the person does not recover consciousness rapidly after being placed in a horizontal position, call EMS for transport to a hospital.

C. Instruct someone to remain with the person and to report any difficulty with breathing, color, or signs of distress to the nurse immediately. If these events occur, a nurse must remain with the person and emergency transportation must be arranged. If blood pressure, pulse or respirations are compromised, monitor vital signs closely. This patient is at risk for cardiopulmonary or respiratory arrest. CPR may be necessary.

D. Mobilize slowly, giving several minutes with head and shoulders elevated prior to attempting to sit up, and several minutes more before attempting to stand.

1. Inform the patient's physician or health unit clinician. Ask the patient's physician specifically whether the person should be seen in the physician's office or emergency room.

2. If the person fell while fainting or struck any object, he/she must be seen and evaluated at either the private physician's office or a hospital emergency room. Consult Risk Management.

3. Obtain the person's name and telephone number for follow-up.

4. Record the event, including vital signs and drugs given, and the outcome of the case. Send a copy of this record with the patient to the physician.

EMPLOYEE VACCINATION POLICY

Introduction

A substantial decrease in vaccine preventable disease incidence has been achieved through the use of vaccines. Immunization of health care personnel is recommended for two purposes: to protect the employee potentially exposed to infectious diseases in their work, and to protect their patients from spread of disease in the health care setting.

Policy

1. Personnel working in Parish Health Units, Regional Offices, or Central Office who have contact with patients.

All personnel in the above category must have the following:

A. Rubella

1. Immunity to rubella is documented either by a prior rubella immunization (documented by written record), by a prior immune status determination (with written record demonstrating immunity to rubella), or by birth prior to 1957 (except for women of childbearing age). If the person is immune to rubella, no further action is needed.

2. This policy must be discussed with all prospective employees prior to hiring.

3. If documentation of immunity to rubella as outlined above is not available, the employee is to receive an injection of rubella vaccine (MMR) without testing. If the employee is pregnant or planning to become pregnant within the next 3 months, the MMR should be postponed until after delivery.

4. If the person is presumed to be susceptible to rubella, he/she must be vaccinated against rubella unless standard medical contraindications exist. A statement to applicants outlining specific contraindications is required. (See Refusal of Vaccination and Release from Responsibility form at the end of this chapter). Any case in which vaccination is not accepted must be referred to the respective regional administrator and the OPH Medical Consultant for discussion and review.

B. Measles

1. Immunity to measles is documented either by two previous doses of measles vaccine (documented by written record), prior immune status determination (with written record demonstrating immunity to measles), or by birth prior to 1957. If the person is immune to measles, no further action is needed.

2. This policy must be discussed with all prospective employees prior to hiring.

3. If documentation of immunity to measles as outlined above is not available, the employee is to receive one or two doses of measles vaccine (depending on prior immunization) without testing. If the employee is pregnant or planning to become pregnant within the next 3 months, the MMR should be postponed until after delivery.

4. If the person is presumed to be susceptible to measles, he/she must be vaccinated against measles unless standard medical contraindications exist. A statement from applicants outlining specific contraindications is required. (See Refusal of Vaccination and Release from Responsibility form at the end of this chapter). Any case in which vaccination is not accepted must be referred to the respective regional administrator and the OPH Medical Consultant for discussion and review.

C. Hepatitis B

1. All Category 1 DHH employees are required to be vaccinated against Hepatitis B. Category 1 Employees are personnel who, in an emergency, will be deployed to Regional field operations including Medical Special Needs Shelters, Transportation Triage, etc.

2. Immunity to Hepatitis B is documented either by three prior doses of hepatitis B vaccine (documented by written record) or by a prior immune status determination (with written record demonstrating immunity to hepatitis B). If the person is immune to hepatitis B, no further action is needed.

3. This policy must be discussed with all prospective employees prior to hiring.

4. If documentation of immunity to hepatitis B as outlined above is not available, the employee is to receive doses of Hepatitis B vaccine sufficient to complete a three dose series (including any prior doses). No testing is recommended prior to completing this three-dose series.

5. CDC's recommendations for post-vaccination antibody testing (antibody to Hepatitis B surface antigen) be drawn one month after the last dose of the initial series for employees who continue to have high risk blood exposure during their job activities. If the result of the antibody test is positive, the employee is immune. If the result is negative, the employee should repeat the three dose series. Do not administer further doses after two three-dose series have been completed. The immunity level may be so low that it is undetectable by standardized test, but may rise during exposure. There are also a very small percentage of people that will not seroconvert.

6. If the person is presumed to be susceptible to hepatitis B, he/she must be vaccinated unless standard medical contraindications exist. A statement to applicants outlining specific contraindications is required. (See Refusal of Vaccination and Release of Responsibility form at the end of this chapter). Any case in which vaccination is not accepted must be referred to the respective regional administrator and the OPH Medical Consultant for discussion and review.

D. Tetanus/diphtheria

1. Immunity to tetanus and diphtheria is documented by a written record of a booster within the

past ten years.

2. This policy must be discussed with all prospective employees prior to hiring.

3. If documentation of immunity to tetanus/diphtheria as outlined above is not available the employee is to receive one dose of either Td or Tdap vaccine.

4. If the person is found not to have been immunized against tetanus/diphtheria, he/she must be vaccinated (3-dose series) unless standard medical contraindications exist. A statement to applicants outlining specific contraindications is required. (See Refusal of Vaccination and Release from Responsibility form at the end of this chapter). Any case in which vaccination is not accepted must be referred to the respective regional administrator and the OPH Medical Consultant for discussion and review.

5. diphtheria-pertussis vaccine (Tdap) either as a booster dose or as one of the three dose Td series. There is no recommended minimal interval between Td and Tdap doses.

E. Varicella

1. Immunity to varicella is documented either by a history of chickenpox, or one prior dose of varicella vaccine (documented by written record), or by prior immune status determination (with written record demonstrating immunity to varicella). If the person is immune to varicella, no further action is needed.

2. This policy must be discussed with all prospective employees prior to hiring.

3. If documentation of immunity to varicella as outlined above is not available, the employee is to receive a series of two injections of varicella vaccine (Var) without testing. If the employee is pregnant or planning to become pregnant within the next 3 months, the Var should be postponed until after delivery.

4. If the person is presumed to be susceptible to varicella, he/she must be vaccinated against varicella unless standard medical contraindications exist. A statement to applicants outlining specific contraindications is required. (See Refusal of Vaccination and Release from Responsibility form at the end of this chapter). Any case in which vaccination is not accepted must be referred to the respective regional administrator and the OPH Medical Consultant for discussion and review.

F. Influenza

1. Influenza vaccine is recommended yearly for all LOPH employees annually, but especially those who have contact with high-risk patients. High-risk patients include adults age 50 and older, individuals with chronic lung or heart problems, adults and children with metabolic diseases such as diabetes, and those who are immune suppressed. Influenza is also recommended for employees who have any of these risk factors themselves. This vaccine is offered yearly during the fall and winter. Influenza immunization is given yearly because the specific strain of influenza changes slightly each year, requiring new vaccines to be developed annually.

Employees are strongly encouraged to use their health insurance and community providers to get an annual influenza vaccination. Employees who are high-risk, uninsured or underinsured are eligible for vaccine in the parish health unit, as would any uninsured or underinsured member of the public.

2. Laboratory Workers Who Have Possible Exposure to Rabies

A. Rabies

Laboratory workers and sanitarians (i.e., those who participate in handling brain tissue or involved in capturing/euthanizing the animal) who are at continual risk of exposure to rabies shall receive the primary course of the vaccine.

Pre-exposure rabies vaccination should be administered according to current CDC recommendations. Information about rabies immunization may be obtained from the Office of Public Health, Infectious Disease Epidemiology Section at 504-568-8313 of after hours at 800-256-2748.

Workers who decline rabies immunization shall do so in writing. (See Refusal of Vaccination and Release from Responsibility form at the end of this chapter).

State laboratory workers who conduct rabies tests should receive a primary course of vaccine with serologic testing done every 6 months. Booster vaccination should be given when the antibody level falls below an acceptable level. Sanitarians with continual risk of exposure for rabies should receive a primary course of vaccine and do not require routine serologic testing or boosters.

1. Parish Health Units that want to obtain rabies vaccine should do so through the OPH Pharmacy.

Methodology

A. Employees

1. Each regional administrator or their designee shall be responsible for ensuring their employee vaccinations are entered into the LINKS registry within his/her respective region by parish, name, sex, age, date of prior immunization, immunity test results, or date immunized.

2. It is the responsibility of each Regional Office Medical Director, Regional Administrator, or their designees to ensure that all existing and new employees are offered appropriate vaccinations. To ensure compliance with these guidelines, each supervisor should check the record of each employee under his or her supervision annually. Employees must have on file written verification from their own physician as to having the required immunization and/or tests, or enter the employee's immunization records in the LINKS registry, including date of administration and type of immunization given.

Refusal of Vaccination and Release from Responsibility

BE IT KNOWN that on this date, I, _____
(Name of employee)

have decided voluntarily to disregard the medical advice of the qualified health professionals attending me on behalf of the Department of Health and Hospitals.

I AM REFUSING TO RECEIVE VACCINATION AGAINST

_____.

I HAVE BEEN FULLY INFORMED BY

_____
(Name and Title)

of the possible and probable adverse consequences of my refusal. I understand that my health could be negatively affected and my life possibly endangered by this refusal. The reason for my refusal is
_____

_____

_____.

I declare myself to be a person of the full age of majority and to be mentally competent. I hereby assume full responsibility for any and all possible present or future results or complications of my condition due to this refusal.

I do further hereby now and forever free and release the Department of Health and Hospitals and all its agents, attending health care professionals, and other personnel from any and all legal or financial responsibility as a result of this refusal.

I certify that I have read (or had read to me) and that I fully understand this Refusal of Treatment and Release from Responsibility. All explanations were made to me and all blanks filled in before I signed my name. I have refused this vaccination of my own free will.

_____ _____ am/pm
Month Day Year Time

_____ _____
DHH Employee Refusing Witness

Vaccine Schedule

Policy:

1. Vaccinations given in OPH immunizations clinics will only be given according to the current edition of the Louisiana Office of Public Health - Immunization Schedule.

2. No variation from the schedule (dosage or vaccines) should occur without the approval of the OPH Immunization Program Medical Director.

Four Day Grace Period for Immunization Schedule

All vaccine doses administered less than or equal to four days before the required minimum interval age shall be considered valid doses when evaluating a student record for compliance with immunization requirements for schools and child care entry. The Advisory Committee on Immunization Practices (ACIP) continues to recommend that vaccine doses not be given at intervals less than the minimum intervals or earlier than the minimum age.

Rationale:

National public health immunization schedules occasionally conflict on minor points. To prevent unnecessary confusion or conflict at the parish health unit or regional level, only one schedule will be recognized and used in OPH immunization clinics.

DEPARTMENT OF HEALTH AND HOSPITALS
Immunization Program

LOUISIANA DEPARTMENT OF HEALTH AND HOSPITALS
OFFICE OF PUBLIC HEALTH

IMMUNIZATION SCHEDULE

2016 through 2017

Depending on the child's age, choose the appropriate initial set of immunizations.

RECOMMENDED SCHEDULE FOR IMMUNIZATION OF INFANTS AND CHILDREN	
AGE	
Birth	HBV
2 Months§	DTaP, Hib, IPV, HBV, PCV◊ , RV
4 Months	DTaP, Hib, IPV,PCV, RV
6 Months	DTaP, Hib, IPV, HBV, PCV, Flu, RV
12-15 Months	DTaP, Hib, MMR, Var, PCV, HAV
18-23 Months	HAV
4 Years Of Age Or Prior To School Entry	DTaP, IPV, MMR, Var
11-12 Years	Tdap, MCV4, HPV∞ (VAR, MMR, HBV If needed)
16 year	MCV4

ACCELERATED SCHEDULE FOR CHILDREN STARTING IMMUNIZATIONS LATE			
CHILDREN 4 MONTHS TO 7 YEARS OF AGE		CHILDREN 7-18 YEARS OF AGE	
1st Visit ‡	DTaP, Hib*,IPV,MMR,HBV,HAV, Var, Flu, PCV◊	1st Visit	Tdap, IPV, HBV, MMR, Var
2nd Visit (4 wks. after the 1st visit)	DTaP, Hib, HBV, IPV, PCV, Flu	2nd Visit (4 wks. after the 1st visit)	Td, IPV, HBV, MMR
3rd Visit (4 wks. after the 2nd visit)	DTaP, Hib, PCV	3rd Visit (6 mos. after the 2nd visit)	Td, IPV, HBV
4th Visit (6 mos. after the 3rd visit)	DTaP, Hib, HBV, IPV, PCV,HAV	11-12 Years	Td, MCV4, HPV ∞ (Var, MMR,HBV,IPV if needed)
4 Years Of Age †	DTaP, IPV, MMR (Var if needed) Or Prior To School Entry	16 Years	MCV4

VACCINE ABBREVIATIONS

HBV HEPATITIS B VACCINE, **HAV** HEPATITIS A VACCINE, **DTaP** DIPHTHERIA - TETANUS - ACELLULAR PERTUSSIS VACCINE, **Hib** HAEMOPHILUS INFLUENZA TYPE B VACCINE, **Td** ADULT TYPE TETANUS AND DIPHTHERIA VACCINE , **Tdap** TETANUS AND DIPHTHERIA TOXOIDS AND ACELLULAR PERTUSSIS VACCINE, **IPV** INACTIVATED POLIOVIRUS VACCINE, **RV** ROTAVIRUS VACCINE, **FLU** INFLUENZA VACCINE, **MCV4** MENINGOCOCCAL CONJUGATE VACCINE, **HPV** HUMAN PAPILLOMAVIRUS VACCINE **MMR** MEASLES - MUMPS - RUBELLA VACCINE, **VAR** VARICELLA VACCINE, **PCV** PNEUMOCOCCAL CONJUGATE VACCINE.

Individuals with altered immunocompetence, due to disease or medication must be evaluated by a physician prior to vaccination.

THE SCHEDULE ABOVE AND THE FOLLOWING GUIDELINES ARE SUMMARIES, FOR MORE DETAILED INFORMATION ON EACH VACCINE, REFER TO THE MANUFACTURERS' PRODUCT INSERT OR VIST THE NATIONAL IMMUNIZATION PROGRAM WEB SITE AT WWW.CDC.GOV/VACCINES OR CALL THE NATIONAL IMMUNIZATION HOTLINE AT 800-232-2522 (ENGLISH) OR 800-232-0233 (SPANISH).

§ • DTaP, IPV, HBV, PCV, RV and Hib can be administered as early as 6 weeks of age and simultaneously.

† • LOUISIANA STATE LAW requires prior to school entry: 2 doses of MMR, 3 Hepatitis B, 2 Varicella and booster doses of DTaP and Polio vaccines on or after the 4th birthday and prior to school entry. A preschool dose is not necessary if the 4th dose of DTaP and the 3rd dose of IPV (provided it is administered at least 6 months after dose 2) are administered after the 4th birthday. Sixth graders (11 -12 years of age) are required: 1 Tdap, 2 VAR, 2MMR, 3 HBV, 1 MCV. Entry for institutions of higher learning requires 2 doses of MMR, 1 Td/Tdap and 2 doses of MCV4 OR 1 dose, if first dose was given on or after age 16.

‡ • Depending on the child's age, choose the appropriate initial set of immunizations. Sometimes a scheduled dose of vaccine may not be given on time. If this occurs, the dose should be given at the next visit. It is not necessary to restart the series of any vaccine due to extended intervals between doses.

• see Hib section ∞ • see HPV section ◊ • see PCV section

Adolescents and post adolescents (11-18 yrs.) should be vaccinated with a second dose of MMR, Varicella (if no history of disease) and Hepatitis B if no history of previous vaccination.

HBV - Unimmunized infants should be given a first dose of Thimerosal-free HBV when first encountered, a second dose a minimum of 1 month later, and a third dose a minimum of 4 months after the first. Children aged 11 through 18 years of age who have not previously received 3 doses of Hepatitis B vaccine should be vaccinated. The 2nd dose should be administered at least 1 month after the 1st dose, and the 3rd dose should be administered at least 4 months after the 1st dose and at least 2 mos. after the 2nd dose. **The minimum age for dose #3 is 6 months. Hepatitis B vaccine is routinely recommended for all children up to 19 years of age.**

HAV – Routine Hepatitis A vaccination is recommended for all children 12 months through 18 years of age. The two doses in the series should be administered at least 6 months apart.

DTaP - DTaP vaccine is recommended and can be administered any time after 6 weeks of age. The 4th dose of DTaP vaccine should be given at least 6 months after the 3rd dose. Pediatric DT (Diphtheria-Tetanus) should be substituted for DTaP when Pertussis vaccine is contraindicated. Persons aged 7 and older who are fully immunized with DtaP should receive a Tdap at 11- 12 years in place of Td booster. Persons aged 7 years and older who are not fully immunized with DTaP vaccine should receive Tdap vaccine as 1 (preferably the first) dose in the catch-up series; if additional doses are needed, use Td vaccine. For children 7 through 10 years who receive a dose of Tdap as part of the catch-up series, an adolescent Tdap vaccine dose at age 11 through 12 years should NOT be administered. Td should be administered instead 10 years after the Tdap dose. Adolescents 13-18 years who missed the 11-12 year Td/Tdap booster should also receive a single dose of Tdap if they completed the recommended childhood DTaP series. No minimum interval required between giving doses of Td and Tdap. Subsequent routine Td boosters are recommended every 10 years.

Hib - Hib vaccine can be administered any time DTaP vaccine is given. If PRP-OMP (PedvaxHIB [Merck]) is administered at 2 and 4 mos. of age, a dose at 6 mos. is not required. Children who are 7 months of age or older at the time they receive the 1st Hib vaccination should be immunized as follows: 1) Unimmunized infants 7-11 months of age should receive a 3-dose regimen. A first dose should be given now, a second dose 1 month later, and a 3rd dose after 12 months of age, at least 2 months after the previous dose. (2) Unimmunized children 12-13 months of age should receive a primary series of one dose and a booster at age 15 months. (3) Unimmunized children 15 months of age or older who have not yet reached their 5th birthday should receive 1 dose.

PCV - All children should receive a 3 dose primary series and a booster if vaccination begun at ≤ 6 mos. of age; a 2 dose primary series and a booster if vaccination is begun between 7 and 11 months of age; a 2 dose series and no booster if vaccination is begun between 12 and 23 months of age. If vaccination is initiated at ≥ 24 months of age, the child should receive 1 dose of PCV. Children 24 through 59 months of age should receive a single dose of PCV13. Children with underlying medical conditions, a single supplemental PCV13 is recommended following primary series. High risk or presumed high risk for pneumococcal disease should be immunized with Polysaccharide Vaccine (PPSV) depending on the number of doses of PCV that they have received. PCV vaccination is required as part of the Daycare/HeadStart Immunization Requirement for children less than 24 months of age.

IPV - For infants, children and adolescents up to 18 years of age, the primary sequential series of IPV consists of four doses. The primary series is administered at 2 months, 4 months, 6-15 months and 4 years of age, or as age appropriate. A minimum of 6 month is required between the last two doses of IPV.

RV - Administer the first dose between 6 and 14 weeks, 6days of age. Maximum age for any dose is 8 months. Minimum interval between doses is 4 weeks. Monavalent RV1 is administered at 2 and 4 mos. of age, and then a dose at 6 mos. is not required. Pentavalent RV5 is administered at 2 months, 4 months and 6 – 8 months. If RV brand is unknown a total of three (3) doses are needed.

HPV - Administer the first dose of HPV vaccine between 11-12 years. Administer the second dose 2 months after the first dose and the third dose 6 months after the first dose. HPV catch up schedule: Four week minimum interval between dose 1and dose 2. A minimum interval of 12 weeks required between dose 2 and dose 3. The 3rd dose should be given at least 24weeks after the 1st dose.

MMR - Two doses of MMR vaccine after 12 months of age are required with a minimum of 28 days separating them. • If a child has received 2 doses of MMR vaccine after 12 months of age, another dose after the 4th birthday is not necessary. • Children 11-18 years of age not previously immunized with MMR should receive two doses. Individuals with one dose of MMR must receive an additional MMR Vaccination. • Students in schools of higher learning must receive 2 doses of MMR prior to registration.

MCV4 - Meningococcal conjugate vaccine should be administered to all children at age 11-12 years, a booster dose on/after 16 years. Meningococcal conjugate vaccine should be administered to all children at age 11-12 years, a booster dose on/after 16 years. The minimum interval between doses of MCV vaccine is 8 weeks. Only one (1) dose is needed if first dose given on or after age 16.

Var - All susceptible children who are at least 12 months old through 18 years of age are eligible. Administer the second dose of Varicella at age 4 – 6 years. Varicella Vaccine may be administered prior to 4-6 years, provided that ≥ 3 months have elapsed since the first dose and both doses are administered at ≥ 12 months. Susceptible persons aged ≥ 12 years should receive two doses at least 1 month apart. Parental history of having had chickenpox is acceptable. Physician documentation is not necessary at this time.

Flu - Routine annual influenza vaccination is recommended for all children 6 mos – 18 years. Two doses administered at least 1 month apart are recommended for children aged 6 mos – 8 yrs who are receiving the influenza vaccine for the 1st time, as well as, those who only received 1 dose in their previous year of vaccination, if applicable.

Four Day Grace Period: All vaccine doses administered less than or equal to four days before the required minimum interval or age shall be considered valid doses when evaluating a student record for compliance with immunization requirements for schools and child care entry. The Advisory Committee on Immunization Practices (ACIP) continues to recommend that vaccine doses not be given at intervals less than the minimum intervals or earlier than the minimum age.

SCHOOL ENTRY REQUIREMENTS IN ACCORDANCE TO R.S. 17:170 STUDENT IMMUNIZATIONS-SCOPE OF REQUIREMENT

Policy:

Any child 18 years or under, admitted to any day care center or residential facility shall have verification that the child has had all appropriate immunizations for age of the child according to the Office of Public Health schedule unless presenting a written statement from a physician stating that the procedure is contraindicated for medical reasons, or a written dissent from parents. The operator of any day care center shall report to the state health officer through the health unit of the parish or municipality where such day care center is located any case or suspected case of reportable disease. Health records, including immunization records, shall be made available during normal operating hours for inspection when requested by the state health officer. When an outbreak of a communicable disease occurs in a day care center or residential facility, the operator of said day care center or residential facility shall comply with outbreak control procedures as directed by the state health officer.

The current Louisiana Immunization Schedule shall be used by OPH personnel in cooperation with the responsible school nurse or other personnel to determine compliance with the Louisiana School Immunization Law. Appropriate immunizations for age for regulatory purposes shall be determined using the current immunization schedule from the Advisory Committee for Immunization Practice (ACIP) of the United States Public Health Service.

Louisiana State Law requires immunizations prior to school entry: 2 doses of MMR, 3 Hepatitis B, 2 Varicella and booster doses of DTaP and Polio vaccines on or after the 4th birthday and prior to school entry. A preschool dose is not necessary if the 4th dose of DTaP and the 3rd dose of IPV is administered after the 4th birthday. PCV vaccine is required for all children entering child care and pre-school up to 24 months of age.

Protocol:

Vaccination records for all children entering school or child care facilities are to be reviewed by the responsible school official (e.g. the school nurse) or child care manager. Children who are not in compliance with the schedule shall be immunized according to those schedules as specified by the law. Those who do not comply shall be excluded by the school.

The law in part, is as follows:

1. All children entering any school within the state for the first time, including kindergarten, at the time of registering or entering school, or licensed day care center, shall present satisfactory evidence of having been immunized against diphtheria, tetanus, whooping cough, poliomyelitis, measles, mumps, rubella, varicella and Hepatitis B and other communicable diseases, according to a schedule approved by the Office of Public Health. In addition, day-care and pre-school enterers must also be up to date on vaccination for Haemophilus influenzae, type b (Hib) which

causes such infections as meningitis and epiglottitis. –PCV13 is required for all children 2 years of age and younger for child care and pre-school entry.

2. A child transferring from another school system in or out of the state, shall submit either a certificate of immunization or a letter from his or her personal physician indicating immunization against the disease enumerated in subsection A, and other communicable diseases according to a schedule approved by the OPH, have been performed, or a statement that such immunizations are in progress.

If booster injections for the diseases enumerated in Subsection A hereof are advised by the parish health unit, such booster injections shall be administered before the child enters a school system within the state.

3. School principals and teachers of all schools, kindergartens or licensed day care centers within this state shall be responsible for checking students' records to see that the provisions of this Section are enforced.

4. No child seeking to enter any school system, kindergarten or licensed day care center of this state shall be required to comply with the provisions of this Section if the child or his parent or guardian submits either a written statement from a physician stating that the procedure is contraindicated for medical reasons, or a written dissent from the parents.

5. Act 152 and Act 342 was passed in legislation July 1, 2008 that as of the 2009-2010 school year, students shall provide satisfactory evidence of current immunizations against meningococcal disease and any other age appropriate vaccine as a condition for entry into the sixth grade. Further, any student who has attained the age of 11 years or who is entering a grade other than grade six shall provide satisfactory evidence of current vaccinations against meningococcal disease and any other age appropriate vaccine as a condition of entry into that grade. At the time of registration, students must show proof of immunizations of the following vaccines: Tetanus-diphtheria Acellular Pertussis vaccine (Tdap); two doses of Varicella vaccine; two doses of Measles-Mumps-Rubella vaccine; three doses of Hepatitis B vaccines; and one dose of meninogococcal vaccine. Also Act 573 states that the chief administrator of any city, parish, or other local public school or nonpublic school that educate students who are subject to the requirements of this law shall be responsible for checking students' records to ensure that the provisions of the law are enforced.

6. Since school year 2009-2010, two doses of varicella vaccine have been required in Louisiana schools for entry into Pre-K, Kindergarten, Daycare, and HeadStart programs for children aged 4 years and older. If a second dose of Varicella vaccine has been received at least 30 days after the first dose, no additional doses are required. In addition, prior to entry, these students must have documented proof of immunizations for: two doses of Measles-Mumps-Rubella vaccine; three doses of Hepatitis B vaccine; and booster doses of DTaP and Polio vaccines administered on or after their 4th birthday and prior to school entry.

A. All children aged less than 4 years of age enrolled in Pre-K, Daycare, HeadStart, etc should be vaccinated against and must show proof of immunizations for Diphtheria,

Tetanus, Acellular Pertussis vaccine (DTaP); Inactivated Poliovirus vaccine (IPV); Haemophilus Influenza Type B vaccine (Hib); Hepatitis B vaccine (HBV); Pneumococcal Conjugate Vaccine (PCV-13– for children less than 24 months of age); and one (1) dose of Varicella vaccine. If the child is not complete or up-to-date for age, he/she must present a record indicating that the child is in progress of receiving vaccines, and follow-up must be provided for compliance with the above requirements.

7. In addition, Act 210 requires city, parish and local public board the provision of information relative to the risks associated with human papillomavirus and cervical cancer. The Vaccine Information Statements regarding HPV at (http://www.cdc.gov/vaccines/hcp/vis/current-vis.html) can be used as an informative tool.

Remember: Louisiana State Law requires immunizations prior to school entry: 2 doses of MMR, 3 Hepatitis B, 2 Varicella and booster doses of DTaP and Polio vaccines on or after the 4th birthday and prior to school entry. A preschool dose is not necessary if the 4th dose of DTaP and the 3rd dose of IPV is administered after the 4th birthday. PCV13 is required for all children entering child care and pre-school up to 24 months of age.

POLICY ON ISSUANCE OF THE STATE OF LOUISIANA UNIVERSAL CERTIFICATE OF IMMUNIZATIONS FOR SCHOOL/ CHILD CARE - PRESCHOOL REGISTRATION

Policy:

The parish health unit shall issue the Universal Certificate of Immunizations for school attendance in public/non public school. This certificate will also be part of the Bureau of Licensing requirements for child care centers.

Rationale:

The issuance of the State of Louisiana Universal Certificate of Immunizations shall be given to demonstrate the student/child is in compliance with the Louisiana State Law immunization requirements for child care/preschool and school.

Instructions for the Universal Certificate of Immunizations:

1. When the student/child presents him/herself at the clinic, the immunization record shall be reviewed by a nurse/clerk prior to issuing the certificate. This can be accomplished by review of the immunization record if available in the LINKs registry or through other validated documentation of immunizations (Example: physician's record copy or parish health unit green card).

2. The student / child's immunization record must be entered in the LINKS registry. Login to the LINKS registry and enter the name of the student. You must complete a Search on the name and/or Add the patient to LINKS. Complete the demographic information on the student and enter the immunization dates in the Vaccination section. Any immunizations that the student/child may require to be considered up-to-date for age shall be administered at the time of the visit. Once the immunizations have been administered or recorded, proceed to the Reports section and select State Reports. Scroll down to the State of Louisiana Universal Certificate of Immunizations in order to print a certificate. Be sure the nurse has signed the form before issuance.

3. If a child is on schedule but has not completed all of his/her shots, the Certificate will reflect an expiration date of the certificate and will forecast the upcoming required immunizations that the student will need before the certificate expires. The nurse shall counsel the parents on the importance of returning to clinic to have the child complete the immunization series required.

4. If a patient of a private physician comes to the health unit for issuance of the Universal Certificate of immunizations for school attendance, transcribe immunization information and pertinent demographic information in the LINKS registry before issuance of the certificate.

5. No Universal Certificate shall be given if the child is not up-to-date with his or her immunizations.

GUIDELINES FOR EXCLUSION FROM SCHOOL OR DAYCARE

The daycare center director or school nurse shall exclude from the child care/school any child with the following illnesses or symptoms based on potential contagiousness of the disease. Periods may be extended beyond this depending upon individual conditions.

ILLNESS/SYMPTOM	EXCLUDE UNTIL
Meningococcal disease (Neisseria meningitidis)	Well & proof of non-carriage1
Hib disease (Haemophilus influenzae)	Well & proof of non-carriage1
Diarrhea (two or more loose stools, or over and above what is normal for that child)	Diarrhea resolved or is controlled (contained in diaper or toilet)
Fever of unknown origin (100°F oral or 101°F rectal or higher) and some behavioral signs of illness	Fever resolved or cleared by child's physician/health department
Chickenpox	Skin lesions (blisters) all scabbed over
Hepatitis A	One week after illness started and fever resolved
AIDS (or HIV infection)	Until child's healthy neurologic development, behavior, and immune status is deemed appropriate (on a case-by-case basis) by qualified persons, including the child's physician chosen by the child's parent or guardian and the center director 2
Undiagnosed generalized rash	Well or cleared by child's physician as non-contagious
Any child with a sudden onset of vomiting, irritability or excessive sleepiness	Evaluated and cleared by child's physician

1 Proof of non-carriage: Either by completion of appropriate drug regimen of Rifampin (two day course for meningococcal disease or 4 day course for Hib disease) or by a negative throat culture obtained after completion of treatment for meningitis.

2. These persons should include the child's physician and other qualified individuals such as the center director, a representative from the Office of Public Health, and a child development specialist, and should be able to evaluate whether the child will receive

optimal care in the specific program being considered and whether an HIV-infected child poses a potential threat to others.

With most other illnesses, children have either already exposed others before becoming obviously ill (e.g., colds) or are not contagious one day after beginning treatment (e.g. strep throat, conjunctivitis, impetigo, ringworm, parasites, head lice, and scabies). The waiting periods required after the onset of treatment vary with the disease.

Children who are chronic carriers of viral illnesses such as cytomegalovirus (CMV) and Herpes simplex can and should be admitted to day care centers and schools.

The parent or designated person shall be notified as soon as possible if a child develops symptoms of illness or suffers an accident while in care.

The Louisiana Sanitary Code 51 provides exclusion authority for non-compliant children to prevent the spread of contagious diseases. Immunization Consultants are responsible for the epidemiological investigation, follow-up and exclusion of those students found non-compliant with the Louisiana Immunization law or who may be susceptible due to inappropriate vaccination schedule. The Immunization Consultant is responsible for epidemiological investigations, surveillance, and outbreak control procedures for: measles, mumps, rubella and varicella.

POLICY ON IMMUNIZATION RECORDS UTILIZING LINKS

Policy:

The parish health unit and vaccine provider facilities shall utilize the LINKS registry system for all children receiving immunization services at that site including children who receive services for WIC only. All immunizations including those given by private physicians shall be noted in the LINKS record. A 'historical' notation (*) is made in the LINKS record next to the date for those immunizations obtained from another record.

Rationale:

The purpose of this policy is to establish a standardized Office of Public Health immunization record that can be maintained and permanently stored as well as allow accessibility to records statewide via the LINKS registry. This registry has the capacity to store immunization records, vaccine inventory as well as generate remainder/recall notices for clients who are due or past due immunizations. Reminder/Recall uses the CDC-approved ACIP schedule along with the patient and shot data stored in LINKS and associated business logic to determine who needs to be "reminded" of an upcoming shot that's due. This functionality is currently being used as an immunization strategy to improve immunization rates in Louisiana by reminding children and adults across the state that they are due shots and in addition to recall/reminders for Mass Vaccination Events. Reminder-recall systems leverage existing statewide immunization information systems (SIIS) as an adjunct to emergency public health operations. By recording administered vaccines or other therapeutic agents within the SIIS, it is possible to automate and greatly improve the speed and accuracy of reminding patients when and where they can receive required additional doses of a vaccine or therapeutic agent, or to recall patients if they miss re-administration dates or in circumstances where previously administered doses are found to be non-therapeutic for some reason (e.g. cold-chain not adhered to; contaminated lots; etc.). Such systems make possible the effective use of many automated communication and reporting features, as well as targeting and visualizing geographic distribution patterns.

LINKS Web Address: https://linksweb.oph.dhh.louisiana.gov/linksweb/main.jsp

linksweb.oph.dhh.louisiana.gov/linksweb/main.jsp
Links
Main
Home
Login
Patient
Vaccinations
Scheduled Reports
Job Queue
Change Password
Answers
iWeb
Version: 5.16.1.1
STC
Date: February 26, 2016
Welcome to the
Louisiana Immunization Network for Kids Statewide (LINKS)
Web Application
This web application allows enrolled users to conveniently search for patients in the LINKS Central Registry and to view the patients' vaccination record. In addition, authorized users can add and edit patient records and vaccination records, as well as maintain facility, physician, and lot number data.
Quick Access Links
Document Center
VOMS FAQ's
FAQ's
Meaningful Use
VOMS Transition Completed!
Remember Your Patient Needs Shots at: Birth, 2 Months, 4 Months, 6 Months, 12 Months and 4 Years!
"4" Sure! Ensure All Children Receive all DTaP Doses!
Polio Vaccination Reminder
LaChip Affordable Plan (LACHIP) and Louisiana Health Insurance Payment Plan (LAHIPP)
Vaccine for Children (VFC)
Vaccine Ordering Management System (VOMS) Documentation
Click Here
Contact LINKS User Services in your Region:
Metro Region 1

HIGHER LEARNING ENTRY REQUIREMENTS FOR STUDENTS IN LOUISIANA

Policy:

Students entering all colleges, universities, vocational-technical schools and proprietary schools in Louisiana will be required to show proof of immunity against measles, mumps, rubella, and to have had a booster dose of tetanus-diphtheria (Td) or Tdap vaccine within the past 10 years. Effective July 1, 2006, Louisiana has adopted legislation targeting freshmen college students living in dormitories to obtain MCV4 vaccine unless a vaccination waiver is provided.

Guidelines:

Students entering schools of higher learning in Louisiana born before January 1, 1957 will be exempt from showing proof of immunity against measles, mumps and rubella. A booster dose of tetanus-diphtheria vaccine (Td) or Tdap within the past 10 years will be required for those students and may be offered to anyone requesting it to comply with this recommendation.

Proof of immunity will be defined as two doses of measles vaccine, one administered on or after the first birthday and taken after 1967 without the simultaneous administration of immune globulin (known as gamma globulin or ISG). Those students who have documentation of receiving the first measles vaccine should receive a second dose before school entry. Students who cannot provide proof of receiving measles vaccine shall be given the first dose of MMR followed by a second dose given at least 28 days later. Documented history of disease, or serologic evidence of immunity, confirmed by a physician, may be accepted as evidence for waiver of requirement for measles immunization.

POLICY ON COMMUNICABLE DISEASE REPORTING

Policy:

In Louisiana, physicians are required by the Louisiana State Sanitary Code "to report to the State Health Officer […] any case or suspected case of reportable disease which he or she is attending, or has examined, or for which such physician has prescribed" (LAC 51:I.105A).

Guidelines:

There are a number of different ways to report communicable diseases to the Office of Public Health. Disease reports may be entered electronically into the Infectious Disease Reporting Information System (IDRIS), phoned in, mailed to the regional office in a sealed envelope marked "Confidential," or faxed. Electronic disease reporting is available for all communicable diseases through IDRIS. Please contact the IDEpi section at (504) 568-8313 to learn more about the system or to have an account created.

- Sexually Transmitted Diseases (STD) – cases of STDs may be reported using the STD-43 form. If you are reporting a case of syphilis with active lesions it must be reported by phone within one business day to (504) 568-7474.

- HIV/AIDS – any cases of HIV/AIDS should be reported by phone to (504) 568-7474. More information on this is available at www.hiv.dhh.louisiana.gov
.
- Tuberculosis (TB) – the CDC72.5 form may be used to report any cases of TB.

- Infectious Disease Epidemiology (IDEpi) – all other infectious diseases should be reported to the IDEpi section using the Confidential Disease Case Report form (EPI-2430).

The appropriate Surveillance Epidemiologist shall obtain all additional information necessary to complete the case investigation. The Regional Immunization Consultant will also be contacted regarding any measles, mumps, rubella, or varicella reports to ensure that outbreak control procedures are in place as soon as possible. The Immunization Consultant is responsible for outbreak control procedures for measles, mumps, rubella and varicella.

In the case that a condition must be reported immediately, physicians can utilize a 24-hour toll free telephone line to reach the IDEpi Section: 1-800-256-2748. An on-call epidemiologist is available 24 hours, 7 days a week. Any external partners who wish to report diseases by fax may send a secure fax to the IDEpi section at (504) 568-8290. All information obtained by the aforementioned methods will be shared with the appropriate regional and program area staff.

The Infectious Disease Epidemiology Section sends case notifications to CDC for nationally notifiable conditions on a daily basis through the CDC-developed NEDSS Base System (NBS).

Surveillance Epidemiologists ensure that external partners in their region(s) (e.g., hospitals,

clinics, physicians) have access to the most updated version of the Sanitary Code and know how to report any suspected communicable disease. Regional staff (Surveillance Epidemiologists and Immunizations Consultants) are to identify those external partners who are most likely to see patients with communicable diseases (family practice, internal medicine, obstetrics, pediatrics, infectious disease, and others) for this purpose.

Reporting inquiries are to be directed to the Infectious Disease Epidemiology Section at (504) 568-8313.

Mailing address: Infectious Disease Epidemiology
1450 Poydras St., Ste 2155
New Orleans, LA 70112

Additional guidance for the surveillance of vaccine preventable diseases can be found in CDC's Manual for the Surveillance of Vaccine Preventable Diseases available at: http://www.cdc.gov/vaccines/pubs/surv-manual/index.html

V. POLICY REGARDING SPECIFIC IMMUNIZATIONS

Policy on DTaP, DT, Td and Tdap Vaccinations

Policy:

Diphtheria, Tetanus Toxoid and acellular Pertussis Vaccine (DTaP) shall be given in OPH clinics to children 2 months through 6 years of age (up to seventh birthday) according to the current OPH schedule. Administration of the primary series may be initiated as early as 6 weeks of age. Subsequent doses can be administered at intervals of 4 to 8 weeks. The fourth dose of DTaP vaccine can be given as early as 12 months of age, as long as six months have elapsed since the third dose was administered. DTaP vaccines are recommended for all five doses in the vaccination schedule. Exceptions are outlined below.

Two acellular pertussis vaccines (Daptacel® and Infanrix® for all five doses) are licensed for the diphtheria, tetanus, and pertussis vaccination series. Four combination vaccines containing DTaP are licensed (Kinrix®, Pediarix®, Pentacel®, and Quadracel™). Kinrix® (DTaP – IPV) is licensed for the fifth dose of the vaccination series; it is not licensed for the first four doses. Pediarix® (DTaP – HepB – IPV) is licensed for the first three doses at 2, 4, and 6 months of age through 6 six years. It is not licensed for the fourth or fifth booster doses. Pentacel® (DTaP – IPV/Hib) is licensed for the first four doses at 2, 4, 6, and 15-18 months of age. Quadracel™ (DTaP – IPV) is licensed for the fifth dose in children 4 to 6 years of age. See chart below.

DTaP Product	Dose 1	Dose 2	Dose 3	Dose 4	Dose 5
Infanrix®	√	√	√	√	√
Daptacel®	√	√	√	√	√
Kinrix®					√*
Pediarix®	√	√	√		
Pentacel®	√	√	√	√	

†Kinrix® can be used can be used as a fifth dose for children 4 to 6 years of age who started the vaccination series with Infanrix® and/or Pediarix®.

Whenever feasible, the same brand of DTaP vaccine should be used for all doses of the vaccination series. However, the health unit may not be aware of the type of DTaP vaccine previously administered to a child. Under this circumstance, it should not present a barrier to administration of the vaccine and any of the licensed DTaP vaccines that may be used to complete the vaccination series. DTaP may also be used as a wound booster for the tetanus component.

The dose of all vaccines is 0.5 ml, administered intramuscularly. Fractional doses of DTaP vaccine are not to be administered by public health nurses in parish health units. Fractional doses are defined in two ways:

1. less than recommended doses of 0.5 ml.
2. giving the total dose over a period of time by administering a number of smaller doses of DTaP.

Preferred injection sites are the anterolateral aspect of the thigh and the deltoid muscle of the upper arm.

Acellular pertussis vaccine (DTaP) does not interfere with other routine childhood immunizations, and may be given simultaneously with IPV, MMR, PCV7, HAV, HBV, HiB, Influenza, Varicella and Rotavirus. Two vaccinations may be given in the same thigh, as long as different administration sites are used.

Diphtheria and Tetanus Toxoids, DT (pediatric), shall be used in OPH clinics for children 2 months through 6 years of age (up to seventh birthday) for whom pertussis vaccine is contraindicated. Contraindications must be reviewed by the regional or local medical director prior to giving DT. In the absence of a local or regional medical director, an order from a private physician is acceptable to administer DT (i.e., pertussis vaccine medically contraindicated). Medical contraindications must be documented in the patient's health unit clinic record and LINKS immunization record.

Tetanus and Diphtheria Toxoids (Td) or Tdap shall be used in OPH clinics for children 7 years of age and older and adults.

Tdap is recommended for children ages 7-10 years who are not fully vaccinated against pertussis. Use a single dose of Tdap for those not fully vaccinated. If additional doses of tetanus and diphtheria toxoid-containing vaccines are needed, then children aged 7 through 10 years should be vaccinated according to the catch-up schedule, with Tdap preferred as the first dose.

Tdap is routinely recommended as a single dose for those 11 through 18 years of age with preferred administration at 11 through 12 years of age. If adolescent was not fully vaccinated (see note 1) as a child, check the ACIP recommendations and catch-up schedule to determine what's indicated.

Any adult 19 years of age and older who has not received a dose of Tdap should get one as soon as feasible – to protect themselves and infants. This Tdap booster dose can replace one of the 10-year Td booster doses. Tdap can be administered regardless of interval since the previous Td dose. Shorter intervals between Tdap and last Td may increase the risk of mild local reactogenicity but may be appropriate if your patient is at high risk for contracting pertussis, such as during an outbreak, or has close contact with infants.

When feasible, Boostrix (GSK) should be used for adults 65 years and older; however, either vaccine product administered to a person 65 years or older provides protection and may be considered valid. Providers should not miss an opportunity to vaccinate persons aged 65 years and older with Tdap. Therefore, providers may administer the Tdap vaccine they have available.

Pregnant women should get a dose of Tdap during each pregnancy, preferably at 27 through 36 weeks gestation. By getting Tdap during pregnancy, maternal pertussis antibodies transfer to the newborn, likely providing protection against pertussis in early life, before the baby starts getting DTaP vaccines. Tdap will also help protect the mother at time of delivery, making her less likely to transmit pertussis to her infant. It is important that all family members and caregivers of the infant are up-to-date with their pertussis vaccines (DTaP or Tdap, depending on age) before coming into close contact with the infant. Tdap is recommended in the immediate postpartum period before discharge from the hospital or birthing center for new mothers who have never received Tdap before or whose vaccination status is unknown.

A single dose of Tdap is recommended for health care personnel who have not previously received Tdap as an adult and who have direct patient contact. Tdap vaccination can protect health care personnel against pertussis and help prevent them from spreading it to their patients. Priority should be given to vaccinating those who have direct contact with babies younger than 12 months of age.

Tdap can be administered regardless of interval since the previous Td dose. However, shorter intervals between Tdap and last Td may increase the risk of mild local reactogenicity.

No minimum interval is required between giving doses of Td and Tdap. According to the LA School Immunization Law, Tdap is required for all 11 year old children entering the 6th grade. Tdap may be substituted for any dose in a primary catch-up series or as a booster if age appropriate for Tdap. Subsequent routine Td boosters are recommended every 10 years thereafter using Td (not Tdap) vaccine. If a Tdap dose was given prior to 11 years of age, there is no need for an additional Tdap dose. At this time, Tdap is only recommended as a one-time vaccine dose.

Those never vaccinated against tetanus, diphtheria or pertussis or who have unknown vaccination status should receive a series of three vaccinations containing tetanus and diphtheria toxoids. The first of these three doses should be Tdap. For adults aged 65 years and older, ACIP has advised those who anticipate having close contact with an infant aged less than 12 months should receive a single dose of Tdap.

Pertussis vaccine shall not be given to children who have had any one of the following reactions after a previous dose of pertussis vaccine:

1. Previous anaphylactic response to a vaccine containing pertussis vaccine, i.e., fairly rapid onset after receiving the vaccine of hives, asthma, swelling of the mouth, difficulty breathing, hypotension, shock.

2. Encephalopathy occurring within 7 days of having received a DTP or DTaP immunization, including severe alterations in consciousness, e.g. comatose or semi-comatose state with generalized or focal neurologic signs, e.g. weakness, paralysis, seizures.

3. Fever of 105 degrees F. (40.5 degrees C) or greater within 48 hours of having received a previous DTP or DTaP immunization, unexplained by another cause.

4. Severe hypotonic-hyporesponsive episode, i.e., collapse or shock-like state within 48 hours of having received a previous DTP or DTaP immunization.

5. A screaming episode, abnormal and/or high-pitched crying or screaming, lasting at least three hours, occurring within 48 hours of having received a previous DTP or DTaP immunization.

6. A convulsion, or a series of convulsions, with or without fever occurring within 3 days (72 hours) of having received a DTP or DTaP immunization.

Td or DT or Tdap vaccine shall not be given in OPH clinics to persons who have had severe neurologic or anaphylactic reactions to previous doses of Td or DT vaccine.

Local reactions of DTaP, DT or Td are not a contraindication of further doses of the vaccine.

Inadvertent Administration of Tdap or Pediatric DTaP

To help prevent inadvertent administration of Tdap when pediatric DTaP is indicated or pediatric DTaP when Tdap is indicated, vaccine providers should review product labels before administering these vaccines. Whenever an inadvertent administration of vaccine occurs, you must inform the parent/guardian and address possible adverse events following vaccination. The following recommendations address inadvertent administration of vaccines and the process for continuation of the vaccine series.

1. If Tdap is inadvertently administered instead of pediatric DTaP to a child aged less than 7 years as any of the first three doses of the tetanus-diphtheria-pertussis vaccination series, the Tdap dose should NOT be counted as valid, and a replacement dose of pediatric DTaP should be administered. If this is discovered while the child is still in the office, the pediatric DTaP can be administered during the same visit. If the child has left the clinic, it is suggested to administer the replacement dose within 72 hours or administering it 4 weeks later to optimize the child's immune response to the antigens in pediatric DTaP. The remaining doses of DTaP should be administered on the routine schedule, with at least a 4 week interval between the replacement dose of pediatric DTaP and the next dose of pediatric DTaP.

2. If the Tdap is inadvertently administered as the fourth or fifth dose in the tetanus-diphtheria-pertussis vaccination series to a child aged less than 7 years, the Tdap dose should be counted as valid and does not need to be repeated; the child who received Tdap as the fourth dose should complete the pediatric DTaP schedule and the routine adolescent vaccination with Tdap would apply when this child becomes an adolescent. For example: if a child received Tdap as the fifth dose at age 5 years instead of pediatric DTaP should receive a second dose of Tdap at age 11-12 years.

3. If Tdap or pediatric DTaP is inadvertently administered to a child 7 – 9 years instead of Td as part of the catch-up vaccination or for wound management, this dose can be counted as the adolescent Tdap dose, or the child can later receive an adolescent booster dose of Tdap according

to the interval guidance used for Td or Tdap. In either case, the child should receive a dose of Td no longer than 10 years after the inadvertent Tdap or pediatric DTaP dose or according to the guidance for catch-up vaccination.

Wound Management

If a person presents with a clean, minor wound and has an unknown vaccination history or has had less than 3 doses of the tetanus toxoid, Td should be administered. Tdap can be substituted if the person is 10 years or older and has never received Tdap. If the person has had more than 3 doses of the tetanus toxoid, no Td is required unless it has been 10 or more years since their last dose. For all other wounds, Td and Tetanus immune globulin (TIG) should be administered if the person has an unknown vaccination history, or if they have had less than 3 doses of the tetanus toxoid. If the person has had more than 3 doses of the tetanus toxoid, no Td is required unless it has been 5 or more years since their last dose. Further, no TIG is required in these persons.

Disaster Relief

Health units may be involved in immunizing response workers, community members impacted, and the general public during disaster relief efforts. Guidance will be provided during those times based on the circumstances of the event if vaccinations are appropriate.

Rationale:
Diphtheria, tetanus, and pertussis: recommendations for vaccine use and other preventive measures: MMWR 1991; 40(RR-10): 1-28 or
www.cdc.gov/mmwr/preview/mmwrhtml/00041645.htm on the internet.

Preventing Tetanus, Diphtheria, and Pertussis Among Adolescents: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccines: MMWR 2006; 55(RR03);1-34 or
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5503a1.htm?s_cid=rr5503a1_e

POLICY ON THE ADMINISTRATION OF HAEMOPHILUS INFLUENZAE TYPE B CONJUGATE VACCINES

Introduction

Haemophilus influenzae type b (Hib) was a major cause of meningitis, cellulitis, and bacteremia in children, with peak incidence before the age of one year. With the introduction of vaccines against Hib, the disease has decreased from approximately 20,000 cases per year in the U.S. to less than 300 cases per year. Several conjugated Hib vaccines (HbOC, PRP-TT, and PRP-OMP) are available separately or in combination with other vaccine antigens for the primary series of vaccinations and booster doses.

Guidelines

1.All children should be immunized with Hib conjugate vaccine beginning at two months of age or as soon as possible thereafter. Hib vaccine should be given in a two or three dose primary series (depending on the specific product used) with doses given intramuscularly at two months, four months, and (possibly) six months of age. Administration of the primary series may be initiated as early as age six weeks, as is the case for the DTaP and polio series. The fourth dose (first booster) of Hib vaccine should be given at 12-15 months of age. For this booster dose, any conjugate Hib vaccine may be used. Hib vaccine should not be given prior to six weeks of age. Infants receiving Hib vaccine prior to six weeks of age have been reported to develop immunologic tolerance to the Hib antigen, which blocks development of antibodies to Hib, possibly permanently.

2. Immunization of children older than 2 months of age at the time of the first dose should be performed as follows (or See table at the end of this chapter):

> A. Unimmunized children between 3 and 6 months of age should receive a primary series of two to three doses (depending on the product used) given two months apart and a booster at age 12-15 months.
>
> B. Unimmunized children 7-11 months of age should receive a primary series of two doses given two months apart and a booster at age 12-15 months.
>
> C. Unimmunized children 12-14 months of age should receive a primary series of one dose and a booster two months later.
>
> D. Unimmunized children from 15 months until their fifth birthday should receive one dose of conjugate vaccine.

Please note: While most children can receive their last booster at age 12 months, those who do not receive their first Hib until age 12-14 months need one dose immediately and one booster two months later.

3. Children who initiate the vaccine series, fall behind on their schedule and then return for

completion of the vaccine series should be given the same number of additional doses that they would receive if they were initiating immunization at the time of the visit. The minimum interval between catch-up doses is one month. For example:

- a 12 month old child who received a dose of Hib vaccine at age 4 months and no dose for the next 8 months should be given two additional doses, one immediately and one at age 15 months;

- a 14 month old child who received two previous doses of Hib vaccine at ages 2 and 4 months and no doses for the next 10 months should receive two additional doses, one immediately and one at age 15 months;

- a 24 month old child who received a single dose of Hib vaccine at age 8 months and no doses for the next 16 months should be given one additional dose of vaccine.

4. Immunization records entered in the LINKS registry should indicate which type of Hib conjugate vaccine was given. For consistency with private providers and with other state immunization programs, OPH should use the following designations:

Designation in LINKS	Manufacturer	Trade Name	Used at < 15 mo
HIB-PRP-OMP	Merck	PedvaxHIB	Yes
HIB-PRP-T	Sanofi-Pasteur	ActHib, OmniHib	Yes
DTaP/HIB	Sanofi-Pasteur	TriHIBit	No*
DTaP/IPV/HIB	Sanofi-Pasteur	Pentacel	Yes

* Under the accelerated schedule, TriHIBit can be given as early as 12 months of age as a booster dose

5. All vaccines are approved for the primary series and may be used interchangeably. If PRP-T is used or if multiple vaccine types are used, the initial series will consist of three doses. If only PRP-OMP is used, only 2 doses are needed to complete the initial series. Any approved vaccine can be used for booster doses after the age of 15 months, regardless of the product(s) used for earlier doses.

6. Hib conjugate vaccines can and routinely should be given simultaneously with other scheduled vaccines, such as DTaP, IPV, MMR, PCV7, Varicella, HAV, influenza, Rotavirus and HBV. Hib conjugate vaccines should be administered intramuscularly in separate syringes and at separate sites from other immunizations, unless the Hib vaccine is part of a specifically approved vaccine combination. Children who require more than two simultaneous intramuscular vaccine injections may be given two vaccines in the same thigh, provided that separate syringes and separate injection sites are used.

7. Unimmunized children 5 years of age or older with chronic illnesses known to be associated with increased risk of Hib disease should be given a single dose of any licensed conjugate vaccine. These diseases are the following:

A. Sickle cell disease or any other hemoglobinopathy which may render a child functionally asplenic;
B. Cancer;
C. Anatomic asplenia, i.e. congenital asplenia or previous surgical splenectomy;
D. AIDS;
E. recipients of a hematopoietic stem cell transplant (HSCT).

8. Unimmunized children who experience invasive Hib disease when younger than 24 months of age should subsequently be immunized according to the age-appropriate recommendations. Children who developed Hib infections at 24 months of age or older do not need further Hib immunization.

9. Vaccination with a specific Hib conjugate vaccine is contraindicated in persons known to have experienced anaphylaxis following a prior dose of that vaccine.

10. Hib vaccine should not be given to pregnant females.

11. Adverse reactions to Hib conjugate vaccines are uncommon. Swelling, redness and/or pain have been reported in 5-30% of patients and usually resolve within 12-24 hours. Fever and irritability are infrequent.

Questions regarding Hib conjugate vaccine should be directed to the Immunization Program at (504) 838-5300.

Summary of Recommendations for Hib Conjugate Vaccine Use

Age at first dose (months)	Primary Series	Booster
2-6	2-3 doses (depending on product used), 2 months apart*	12-15 months
7-11	2 doses, 2 months apart*	12-18 months
12-14	1 dose	2 months later
15-59	1 dose	------

* Minimum interval between doses can be as early as 4 weeks

For further information on the recommendations for the use of Haemophilus b conjugate vaccines see MMWR 1991;40(RR-1): 1-7 or www.cdc.gov/mmwr/preview/mmwrhtml/00041736.htm on the internet.

POLICY ON HEPATITS A VACCINE

Policy:

Routine vaccination using Hepatitis A vaccine is the most effective way to reduce hepatitis A incidence nationwide over time. Vaccination of children living in states and communities with consistently elevated rates of hepatitis A to provide protection from disease was expected to reduce the overall incidence of hepatitis A. However, in 2005, another strategy was implemented to vaccinate children at 12 months of age as the next phase of the reduction of Hepatitis A morbidity allowing for its incorporation into the routine early childhood vaccination schedule.

Inactivated and attenuated hepatitis A vaccines currently licensed in the United States are the single-antigen vaccines HAVRIX® (manufactured by GlaxoSmithKline, Rixensart, Belgium) and VAQTA® (manufactured by Merck & Co., Inc., Whitehouse Station, New Jersey). TWINRIX®, manufactured by GlaxoSmithKline is a combination vaccine containing both HAV and HBV antigens and is indicated for active immunization of persons 18 years of age or older. All are inactivated vaccines. Caveat: This section on the administration of TWINRIX is in effect only when the Immunization Program has vaccine on hand for the age-appropriate group.

Guidelines:

The following recommendations for hepatitis A vaccination are intended to further reduce hepatitis A morbidity and mortality in the United States and make possible consideration of eventual elimination of HAV transmission. Hepatitis A vaccination is recommended routinely for children/adolescents, for persons who are at increased risk for infection, and for any person wishing to obtain immunity.

1. All children should receive hepatitis A vaccine at age 1 year (i.e., 12 months through 18 years). Vaccination should be completed according to the licensed schedules and integrated into the routine childhood vaccination schedule.

2. Persons at increased risk for HAV infection include:

> A. Persons traveling to or working in countries that have high or intermediate endemicity of infection – The first dose of hepatitis A vaccine should be administered as soon as travel is considered. Travelers who are administered vaccine can be assumed to be protected within 4 weeks after receiving the first vaccine dose.
>
> B. MSM (both adolescents and adults) should be vaccinated. Health-care providers in primary-care and specialty medical settings in which MSM receive care should offer hepatitis A vaccine to patients at risk.
>
> C. Vaccination is recommended for users of injection and noninjection illicit drugs.

D. Persons who have occupational risk for infection - Persons who work with HAV-infected primates or with HAV in a research laboratory setting should be vaccinated. Studies conducted among U.S. workers exposed to raw sewage do not indicate increased risk for HAV infection.

E. Persons with clotting-factor disorders - Susceptible persons who are administered clotting-factor concentrates, especially solvent-detergent–treated preparations, should receive hepatitis A vaccine.

F. Vaccination of persons with chronic liver disease - Susceptible persons with chronic liver disease should be vaccinated.

3. Two Hepatitis A vaccines are available in both pediatric and adult formulations - HAVRIX® and VAQTA®. Limited data indicate that vaccines from different manufacturers are interchangeable. The minimal interval between the first dose and booster dose of Hepatitis A vaccine is 6 calendar months.

4. Primary immunization with TWINRIX for high risk adults (18 years of age and older) consists of 3 doses given on a 0-, 1-, and 6 month schedule. Alternatively, an accelerated 4 dose schedule given on days 0-, 7 and 21-30 followed by a booster dose at month 12 may be used. The accelerated vaccination schedule may represent the preferred option for individuals at imminent risk for hepatitis A and hepatitis B.

NOTE: Twinrix vaccine for adults (18 years and older) is not available through the OPH Immunization Program for travelers to countries endemic for hepatitis A and hepatitis B, military personnel, health care workers, emergency care first responders to disaster areas other individuals who do ot meet the high-risk eligibility criteria. (see Policy on the Immunization of High Risk Adults, pg 133).

Recommended dosages of Hepatitis A Vaccines

Vaccine	Vaccine recipients Age	Dose	Volume (mL)	No. Doses	Schedule (mos) §
HAVRIX®•	12 mos – 18 years	720 EL.U	0.5	2	0, 6 – 12 mos
VAQTA®*	12 mos – 18 years	25 U	0.5	2	0, 6 – 18 mos

•Hepatitis A vaccine, inactivated, SmithKline Beecham Biologicals.
*Hepatitis A vaccine inactivated, Merck Co., Inc.

Recommended dosages of TWINRIX Vaccine

Vaccine	Vaccine recipients Age	Dose	Volume (mL)	No. Doses	Schedule (mos) §
TWINRIX	18 years and older	720 EL.U HAV 20 mcg HBV	1.0	3	1st dose @ day 0-, followed by 1 month and month 6
				Accelerated schedule for high risk 4	Days 0-, 7-, 21 to 30 followed by booster at month 12

Contraindications and Precautions:

Hepatitis A vaccine should not be administered to persons with a history of a severe allergic reaction to a previous dose of hepatitis A vaccine or to a vaccine component.

Route of Administration:
The vaccine should be administered intramuscularly into the deltoid muscle. A needle length appropriate for the person's age and size should be used. Simultaneous administration of hepatitis A vaccine can be given with diphtheria-tetanus-acellular pertussis (DTaP), Haemophilus influenzae type b (Hib), hepatitis B, MMR, Rotavirus, inactivated poliovirus vaccines, Varicella, PCV and/or influenza and does not affect the immunogenicity and reactogenicity of these vaccines. Among children, the most frequently reported side effects were feeding problems, headache, pain, soreness, tenderness and warmth at the injection site.

NOTE: On August 11, 2005, the Food and Drug Administration (FDA) approved an application of a pediatric/adolescent formulation of VAQTA® (hepatitis A vaccine, inactivated) (Merck & Co., Whitehouse Station, New Jersey) for use among persons aged 12 months--18 years. Previously, the pediatric/adolescent formulation of VAQTA was approved for use in persons aged 2--18 years. The formulation, dosage, and schedule for VAQTA have not changed. Each 0.5 mL dose of the pediatric/adolescent formulation of VAQTA contains approximately 25 units of formalin-inactivated hepatitis A virus antigen, adsorbed onto aluminum hydroxyphosphate sulfate, in 0.9% sodium chloride. The formulation does not contain a preservative.

On October 17, 2005, the Food and Drug Administration approved an application to allow use of the pediatric/adolescent formulation of Havrix® (hepatitis A vaccine, inactivated)

(GlaxoSmithKline Biologicals, Rixensart, Belgium) for persons aged 1 – 18 years. Previously, pediatric use of Havrix was approved for use in persons aged 2--18 years. The formulation, dosage, and schedule for Havrix were not changed. Each 0.5-mL dose of pediatric/adolescent Havrix contains 720 enzyme-linked immunosorbent assay units of formalin-inactivated hepatitis A viral antigen adsorbed onto aluminum hydroxide. The formulation contains 0.5% 2-phenoxyethanol as a preservative. The primary vaccination schedule utilizing either brand of Hepatitis A vaccines remains unchanged and consists of 2 doses, administered on a 0, 6-12 month schedule.

ACIP/MMWR Update October 2007: Clinical trials comparing Hepatitis A vaccine and Immune globulin (IG) for prevention of hepatitis A after exposure has generated new recommendations for postexposure prophylaxis (PEP). Persons who have been exposed to HAV and who have not previously received hepatitis A vaccine should be administered a single dose of single antigen vaccine or IG as soon as possible, preferably within 2 weeks of last exposure. For healthy persons, aged 12 months – 40 years, single antigen hepatitis A vaccine is preferred to IG because of vaccine advantages that include long-term protection and ease of administration. For persons aged > 40 years, IG is preferred because of the absence of information regarding vaccine performance and more severe manifestations of hepatitis A in this age group; vaccine can be used if IG cannot be obtained. IG should be used for children < 12 months, immunocompromised persons, persons who have had chronic liver disease diagnosed, and for persons for whom vaccine is contraindicated. The magnitude of the risk for HAV transmission from exposure should be considered in decisions to use IG or vaccine.

ADMINISTRATION OF IMMUNE SERUM GLOBULIN (ISG) PROPHYLAXIS OR HEPATITIS A VACCINE FOR HEPATITIS A CONTACTS

Policy:

In October 2007, the ACIP has changed the recommendations for Hepatitis A post-exposure prophylaxis (PEP). Within 2 weeks after last exposure, persons who have not previously received single antigen Hepatitis A vaccine should be administered a single dose of Hepatitis A vaccine for persons aged 12 months to 40 years. For persons > 40 years of age, ISG is preferred though vaccine can be given if ISG cannot be obtained. For clients who cannot receive the vaccine (e.g., children <12 months of age, persons with chronic liver disease, persons who are immunocompromised or vaccine contraindications) ISG should be used. These new recommendations reflect the new data on vaccine effectiveness postexposure.

Administration of ISG: ISG is a sterile solution for intramuscular use containing antibodies derived from human blood. When administered in the appropriate dose before or within 1-2 weeks after exposure to hepatitis A it may prevent illness in 80-90 percent of those exposed. ISG should be given as soon as possible after exposure since its prophylactic value is greatest when given early in the incubation period and decreases with time after administration. The use of ISG more than 2 weeks after exposure or after onset of clinical illness is not indicated. Because ISG may not suppress inapparent infection, long lasting natural immunity may result.

Currently the state will supply ISG to household contacts of hepatitis A cases and on specific occasions to hepatitis A associated child care center children and employees. (Consultation with the Infectious Disease Epidemiology Section should precede child care center children and employee vaccine administration.) The use of ISG is not normally recommended for school contacts, for routine prophylaxis to hospital personnel, or for persons exposed to a fellow worker with hepatitis A in the usual office and factory situation.

A diagnosis of hepatitis A can be confirmed by laboratories performing hepatitis A antibody tests (Anti-HAV IgM). This test is not available through the OPH Laboratory.

Contraindications for ISG:

- Should not be given to persons with isolated immunoglobulin A (IgA) deficiency.
- Should not be given to patients who have severe thrombocytopenia or any other coagulation disorder that would contraindicate intramuscular injection.
- Should not be given to persons who are known to have an allergic response to thimerosal.
- Should not be given to patients with a history of prior allergic reaction following the administration of ISG.

If the possibility exists that the person who is requesting ISG may have a contraindication as

listed, he or she must be referred to their private physician for evaluation. Persons who do not know if they are allergic to thimerosal may be considered non-allergic.

Precautions: Do not administer intravenously.

Reactions: Very rarely causes adverse reactions. Discomfort may occur at the site of injection. The risk of hypersensitivity is very small.

Administration: For household contacts of hepatitis A cases or for child care center contacts, a single intramuscular injection of .01 ml per pound (.02 ml/kg.) of body weight should be given.
Storage: Immune Globulin may be used up to the expiration date on the label if kept refrigerated at 36-46°F (2-8°C). It should not be frozen.

Recommendations for travelers: Travelers to high-risk areas, such as rural villages in the tropics, should be counseled about avoiding contaminated food or water and should be referred to their private physicians for administration of Hepatitis A vaccine or ISG (depending on their health status or ineligibility to receive HAV vaccine) when appropriate.

POLICY ON UNIVERSAL HEPATITIS B VACCINATION

Policy:

The Centers for Disease Control and Prevention (CDC) mandated strategy to eliminate hepatitis virus transmission includes the following: prevention of perinatal hepatitis B virus transmission, the routine vaccination of all infants and adolescents, and vaccination of children and adults in high-risk groups.

As part of this strategy, the CDC recommends the universal vaccination of infants to prevent hepatitis B virus transmission in early childhood and to protect adolescents and adults from infection. Routine vaccination is recommended for all children and adolescents through the age of 18 years. The first dose of hepatitis B vaccine should be administered before hospital discharge for every newborn, followed by the second dose at 1-2 months of age and then the third dose at 6-18 months of age with a minimum of 8 weeks after the second dose and 16 weeks after the first dose.

Routine Infant Hepatitis B Vaccine Schedule

Dose	Usual Age	Minimum Interval
Primary 1	Birth	---
Primary 2	1-2 months	4 weeks
Primary 3	6-18 months*	8 weeks**

* infants whose mothers are HBsAg-positive or whose HBsAg status is unknown should receive the third dose at 6 months of age
** at least 16 weeks after the first dose

Importance of the Hepatitis B Birth Dose

It is recommended that every newborn receives the first dose of hepatitis B vaccine at birth or before hospital discharge. This standard of care provides a safety net to prevent hepatitis B infection for at-risk newborns (including but not limited to, infants whose mothers were not identified due to no or little prenatal care, errors made by healthcare professionals in ordering, recording, or communicating lab test results determining the mother's hepatitis B status, and exposure to a family member who is a chronic carrier of hepatitis B).

Additional Considerations for Hepatitis B Vaccination

- For preterm infants weighing less than 2000 grams and whose mothers are hepatitis B-negative, delay the first dose of vaccine until infant is one month of age, due to potentially decreased immunogenicity.
- For infants whose mothers are HBsAg-positive at the time of delivery or whose mothers' HBsAg status is unknown, infants should receive the third dose at 6 months of age. Please see the following section, "Perinatal Hepatitis B Prevention Program", for additional information on infants born to HBsAg-positive women.

Vaccination Interruption and Delay

The catch-up schedule for vaccination of infants and children can begin at any point with a minimum interval of 4 weeks between the first and second dose and a minimum interval of 8 weeks between the second and third dose. Infants should not receive the third dose before 24 weeks of age. It is not necessary to add doses or restart the vaccine series if the series has already been started as long as the minimum intervals between doses have been achieved.

- If the series is interrupted after the first dose of vaccine, the second dose should be administered as soon as possible followed by the third dose administered at a minimum interval of 8 weeks after the second dose.
- If the series is interrupted after the second dose, the third dose should be administered as soon as possible and no sooner than 24 weeks of age (164 days).
- Booster doses of hepatitis B vaccine are not routinely recommended for persons with normal immune status who were vaccinated as infants, children, or adolescents.

It is recommended that all adolescents that have not been previously vaccinated be vaccinated at 11 or 12 years of age with the age-appropriate dose of vaccine or whenever possible. Vaccination is especially important for those in groups of increased risk of hepatitis B infection (for example, those who are sexually active). Vaccination of adults not previously vaccinated should be considered for those who are at increased risk of infection. For specific dose recommendations, see table below. For specific policy for adults, please reference the "Policy on the Immunization of High Risk Adults with Hepatitis Vaccine."

Vaccine Dosing and Administration

For infants and neonates, hepatitis B vaccine should be given intramuscularly in the anterolateral thigh. For older children and adults, hepatitis B vaccine should be given in the deltoid muscle. If the vaccine is administered at any site other than intramuscularly in the anterolateral thigh or deltoid muscle, this vaccine dose should not be counted as a valid dose and should therefore be repeated. The dosage of vaccine is dependent upon the age of the individual and the type of vaccine being given. Please see the following table as a guide.

	Single-Antigen Vaccine				Combination Vaccine			
	Recombivax HB		Engerix-B		Pediarix		Twinrix	
Age Group	Dose (mcg)*	Volume (mL)	Dose (mcg)*	Volume (mL)	Dose (mcg)*	Volume (mL)	Dose (mcg)*	Volume (mL)
Infants (<1 year)	5	0.5	10	0.5	10	0.5	N/A	N/A
Children (1-10 years)	5	0.5	10	0.5	10	0.5	N/A	N/A
Adolescents								
11-15 yrs	10┼	1.0	N/A	N/A	N/A	N/A	N/A	N/A
11-19 yrs	5	0.5	10	0.5	N/A	N/A	N/A	N/A
Adults (>20 years)	10	1.0	20	1.0	N/A	N/A	N/A	20
Hemodialysis patients and other immunocompro-mised persons								
<20 yrs[§]	5	0.5	10	N/A	N/A	N/A	N/A	N/A
>20 yrs	40[¶]	1.0	40[‡]	N/A	N/A	N/A	N/A	N/A

* Recombinant hepatitis B surface antigen protein dose.
┼ Adult formulation administered on a 2-dose schedule.
§ Higher doses might be more immunogenic, but no specific recommendations have been made.
¶ Dialysis formulation administered on a 3-dose schedule at 0, 1, and 6 months.
‡ Two 1.0 mL doses administered at one site, on a 4-dose schedule at 0, 1, 2, and 6 months.
** Not applicable.

Hepatitis B vaccine does not interfere with other childhood immunizations and may be given simultaneously with Rotavirus, DTaP, Tdap, Hib, PCV13, PPSV23, IPV, Influenza, MMR, Varicella, Hepatitis A, HPV and Meningococcal.

Different hepatitis B vaccine formulations contain different antigen content but are interchangeable to complete the vaccine series. For example, Recombivax HB may be used to complete a hepatitis B vaccine series that started with Engerix-B or vice-versa. Dosages must follow the correct schedule. However, Pediarix, the combination vaccine containing DTaP, hepatitis B and inactivated polio vaccines, can only be administered at 6 weeks of age or older. For this reason, Pediarix is not approved for the birth dose of the hepatitis B vaccine series but it is approved for 3 doses at 2, 4, and 6 months of age and can be given as such for infants who received the birth dose of hepatitis B vaccine. In addition, Pediarix is not approved for fourth or fifth doses of the DTaP or IPV series.

For hepatitis B vaccine storage and handling, please refer to the previous section, “Vaccine Storage Requirements.”

PERINATAL HEPATITIS B PREVENTION PROGRAM – SCREENING AND PREVENTION OF HEPATITIS B TRANSMISSION IN HIGH-RISK INFANTS

Rationale:

A hepatitis B positive mother may transmit virus to her infant at birth. Infants are exposed to the virus through contact with their mothers' blood during delivery. Up to 90 percent of infants less than 1 year of age who, in the absence of post-exposure prophylaxis, become infected with hepatitis B at birth will become chronically infected with hepatitis B virus. As such, perinatal transmission of hepatitis B among newborns is associated with significant morbidity and mortality. These children are more likely to experience additional health complications such as liver disease, cirrhosis, or hepatocellular carcinoma. For those infants who are not infected at birth, they remain at risk due to long-term exposure and contact with their positive mothers.

The purpose of the Louisiana Perinatal Hepatitis B Prevention Program is to ensure that infants born to hepatitis B-positive mothers are hepatitis B free after successful post-exposure prophylaxis at delivery, vaccination with the complete 3-dose series, and post-vaccination serologic testing.

Policy:

As part of the comprehensive strategy to eliminate hepatitis B virus transmission, it is recommended that all women be tested for hepatitis B surface antigen (HBsAg) during every pregnancy in order to effectively identify newborns that require proper post-exposure prophylaxis. Infants born to mothers who are HBsAg-positive or to mothers with unknown status should receive hepatitis B immune globulin (HBIG) and the first dose of hepatitis B vaccine within 12 hours of birth followed by the second dose at 2 months of age and the third dose at 6 months of age. Post-vaccination serologic testing should be completed to determine the vaccine response of the infant. Testing should be completed no sooner than 9-12 months of age or 1-2 months after completion of the 3-dose series. The Louisiana Perinatal Hepatitis B Prevention Program encourages all providers, especially obstetric and pediatric providers, to follow these recommended guidelines.

Guidelines:

<u>Screening and Reporting of HBsAg Status for All Pregnant Women</u>

- The Advisory Committee on Immunization Practices (ACIP), The American College of Obstetrics and Gynecologists (ACOG), and The American Academy of Pediatrics (AAP) recommend that **<u>all women be screened for HBsAg during every pregnancy</u>**. Testing should be performed during the first prenatal visit or at the time of delivery if the woman's status is unknown/ undocumented. For all women who are at high risk for infection (more than one sex partner in the last 6 months, recent history of STD, contact

with chronically HBV infected persons, and/ or injection-drug use) testing should be repeated at the time of delivery regardless of previous testing during the current pregnancy.

  - The standard screening test is NOT antibody to hepatitis B surface antigen (anti-HBs or HBsAb), antibody to hepatitis B core antigen (anti-HBc or HBcAb), HBeAg, anti-HBe, or HBV-DNA.

- Testing for hepatitis B should be completed regardless of whether or not the pregnant woman has been previously vaccinated or tested and even if the pregnant woman has previously been identified as being chronically infected with hepatitis B virus.
- If a pregnant woman is HBsAg-negative and is susceptible to hepatitis B virus infection (i.e. has never been vaccinated or infected), this individual can and should be vaccinated against hepatitis B during pregnancy (please reference CDC "Guidelines for Vaccinating Pregnant Women" at http://www.cdc.gov/vaccines/pubs/preg-guide.htm or contact the Immunization Program for additional information).
- If a pregnant HBsAg-positive woman is identified, it is required by The Sanitary Code for the State of Louisiana (LAC 51:II §105) that hepatitis B carriage during pregnancy be reported to the state Immunization Program and/ or to Infectious Disease Epidemiology within 1 business day.
  - Immunization Program: Phone 504-838-5300, Fax 504-838-5206
  - Infectious Disease Epidemiology: Phone 504-568-8313, 800-256-2748 (available 24/7), Fax 504-568-8290

  A copy of the Immunization Perinatal Hepatitis B Surveillance Form can be found below.
  - **Please note** that the requested information on the program surveillance form is required as part of the disease reporting of the positive mother and is not considered a violation of the confidential relationship between the practitioner and patient, as per the HIPAA Privacy Rule *45 CFR § 164.512(b)(1)(i)*.
- It is also recommended that pregnant HBsAg-positive women should be followed closely by their physician and referred for possible follow-up testing if not previously completed.
  - Pregnant HBsAg-positive women should also receive information on the following:
    - Modes of transmission
    - Advice that they may breast feed their infants upon delivery
    - Prevention of hepatitis B transmission to contacts, including the importance of post-exposure prophylaxis for newborn infants and hepatitis B testing (HBsAg and anti-HBs) and vaccination for household, sexual, and needle-sharing contacts
    - Substance abuse treatment, if appropriate
    - Medical evaluation and possible treatment of chronic hepatitis B.
  - For interpretation of hepatitis B serologic results, please see the table below.

- Maternal HBsAg status should be noted and flagged in the prenatal record in order to ensure proper post-exposure prophylaxis for infant(s) upon delivery.
- Please note that as part of the new ACOG-endorsed guidance for prenatal HBsAg tests available at commercial laboratories, pregnancy status should be included in laboratory test reports sent to the health department. Commercial laboratories (ARUP Laboratories, LabCorp, Mayo Medical Laboratories, and Quest Diagnostics) offer designated HBsAg tests for pregnant women as a standalone assay and/or as part of the prenatal/ obstetric panel.

Interpretation of Hepatitis B Serologic Tests

Tests	Results	Interpretation
HBsAg anti-HBc anti-HBs	Negative Negative Negative	Susceptible
HBsAg anti-HBc anti-HBs	Negative Negative Positive (≥10 mIU/mL)	Immune due to hepatitis B vaccination
HBsAg anti-HBc anti-HBs	Negative Positive Positive	Immune due to natural infection
HBsAg anti-HBc IgM anti-HBc anti-HBs	Positive Positive Positive Negative	Acutely infected
HBsAg anti-HBc IgM anti-HBc anti-HBs	Positive Positive Negative Negative	Chronically infected
HBsAg anti-HBc anti-HBs	Negative Positive Negative	Interpretation unclear; four possibilities: 1. Resolved infection (most common) 2. False-positive anti-HBc, thus susceptible 3. “Low-level” chronic infection 4. Resolving acute infection

Hepatitis B surface antigen (HBsAg): A protein on the surface of hepatitis B virus; it can be detected in high levels in serum during acute or chronic hepatitis B virus infection. The presence of HBsAg indicates that the person is infectious. The body normally produces antibodies to HBsAg as part of the normal immune response to infection.

Hepatitis B surface antibody (anti-HBs): The presence of anti-HBs is generally interpreted as indicating recovery and immunity from hepatitis B virus infection. Anti-HBs also develops in a person who has been successfully vaccinated against hepatitis B.

Total hepatitis B core antibody (anti-HBc): Appears at the onset of symptoms in acute hepatitis B and persists for life. The presence of anti-HBc indicates previous or ongoing infection with hepatitis B virus in an undefined time frame.

IgM antibody to hepatitis B core antigen (IgM anti-HBc): Positivity indicates recent infection with hepatitis B virus (≤6 mos). Its presence indicates acute infection.

Tracking of Infants Born to HBsAg-Positive Women

- In addition to documenting maternal HBsAg status on the prenatal record, mother's status should also be documented on infant's record.
- The Perinatal Hepatitis B Prevention Program (PHBPP) personnel work with OBGYN providers, delivery hospital staff, and pediatric providers to ensure that infants born to HBsAg-positive women are identified, followed, and receive the proper post-exposure prophylaxis consisting of the administration of the following within 12 hours of birth:
    - HBIG (0.5 mL)
    - First dose of hepatitis B vaccine.
- The PHBPP maintains a registry of all infants born to HBsAg-positive women. The program tracks and monitors infants throughout the completion of the 3-dose hepatitis B vaccine series and the completion of post-vaccination serologic testing, in order to ensure proper immunity to hepatitis B virus infection.

Vaccine Dosage, Administration, and Schedule for Infants Born to HBsAg- Positive Women

The following immunization schedule is recommended by the Advisory Committee on Immunization Practices (ACIP), the Centers of Disease Control and Prevention (CDC), the American Academy of Pediatrics (AAP), and adopted by the Louisiana Office of Public Health for all infants born to HBsAg-positive mothers and mothers of unknown status.

- HBIG (0.5 mL) and the first dose of hepatitis B vaccine should be administered in alternate anterolateral thigh muscles within 12 hours of birth.
    - There is a window of 7 days to administer HBIG if an infant born to an HBsAg-positive woman did not receive the dose of HBIG within 12 hours of delivery or before discharge from the hospital. The infant should then receive HBIG within 7 days.
- The second dose should be administered at 1-2 months of age followed by the third dose at 6 months of age. Infants may receive different formulations of the vaccine per manufacturer recommendations (Recombivax HB, Engerix-B, and Pediarix). Please see previous section on vaccine dosing and administration.
- Preterm infants weighing less than 2000 grams have a decreased response to the birth dose of hepatitis B vaccine prior to 1 month of age.
    - Administer the recommended post-exposure prophylaxis (HBIG and first dose of hepatitis B vaccine) within 12 hours of birth.
    - Repeat the first dose at 1 month of age to begin the complete 3-dose series, for a total of 4 doses, and continue to follow the recommended vaccine schedule.
    - The birth dose does not count as part of the complete 3-dose series.

- If interruption in vaccination occurs, the vaccine series does not need to be restarted. Please follow recommended schedule outlined in previous section for vaccination interruption and delay.

Post-Vaccination Serologic Testing (PVST) and Nonresponse

- Infants born to HBsAg-positive women or women of unknown HBsAg status should be tested for HBsAg (hepatitis B surface antigen) and antibody to HBsAg (anti-HBs or hepatitis B surface antibody) no sooner than 9-12 months of age or if vaccination has been delayed 1 to 2 months after receiving the final dose of the hepatitis B vaccine series (if the series is delayed).
    - Testing should not be performed before 9 months of age in order to avoid detection of passive anti-HBs from hepatitis B immune globulin administered at birth as well as to maximize the detection of late hepatitis B infection.
    - Low anti-HBs levels (<10 mIU/mL) is significantly associated with longer PVST intervals after receipt of the final hepatitis B vaccine dose, therefore it is optimal to test at 9-12 months of age.
    - Those who test with anti-HBs levels >10 mIU/mL at 9 months of age or 1-2 months after completing the vaccine series remain protected, even if the anti-HBs level decrease to <10 mIU/mL, presumably due to persistent cellular immunity.
- Please note that testing for anti-HBc (hepatitis B core antibody) in infants born to HBsAg-positive mothers is not recommended because passively acquired maternal anti-HBc might be detected through 24 months of age.
- Infants who test **HBsAg negative** and **anti-HBs positive** (≥10 mIU/mL) are considered to be immune and to be protected from hepatitis B infection.
- Infants who test **HBsAg negative** (<10 mIU/mL) and **anti-HBs negative** did not seroconvert and are not considered to be immune to the hepatitis B virus. It is recommended that the infant repeat the 3-dose vaccine series according to the recommended intervals and repeat serologic testing 1-2 months after the final dose of vaccine.
- Infants who do not respond to revaccination (those who test anti-HBs negative and HBsAg negative after an additional 3-dose vaccine series) should be considered susceptible to hepatitis B infection. Mothers, families, and primary caretakers should be counseled about the precautions to prevent hepatitis B infection.
- Infants who test **HBsAg positive** should receive appropriate follow-up and medical management.
- For additional information on the interpretation of hepatitis B lab results, please contact the Immunization Program.

Breastfeeding in Infants Born to HBsAg-Positive Women

- Infants born to HBsAg-positive women may breast feed beginning immediately after birth. There is no risk associated with breastfeeding.

References:

Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine Preventable Disease (Pink Book), CDC, 13th Edition, (2015) Washington, D.C.: Public Health Foundation.

Centers for Disease Control and Prevention. Hepatitis B Virus: A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States, Recommendations of the Advisory Committee on Immunization Practices (ACIP), Part 1: Immunization of Infants, Children, and Adolescent. *MMWR*, December 23, 2005, Vol. 54, No. RR-16, 1-32.

Centers for Disease Control and Prevention. Update: Shortened Interval for Postvaccination Serologic Testing of Infants Born to Hepatitis B-Infected Mothers. *MMWR*, October 9, 2015, Vol. 64, No. 30, 1118-1120.

Immunization Action Coalition. Ask the Experts: Disease & Vaccines: Hepatitis B. Saint Paul, MN. IAC, 2016. http://www.immunize.org/askexperts/experts_hepb.asp

Louisiana Department of Health and Hospitals
Office of Public Health

PERINATAL HEPATITIS B SURVEILLANCE FORM

Case#_____

SECTION I: PRENATAL CARE
Part A: Mother Information

1. Last Name _____ 2. First Name _____

3. Address _____ Address #2 _____

4. City _____ 5. Zip _____ 6. Parish _____

7. Phone _____ Alternate Phone _____

8. Age _____ 9. Date of Birth ___/___/___ (mo day yr) 10. Primary language _____

11. Race (check): ☐White ☐Black ☐Asian/Pacific Islander ☐Other _____ 12. Ethnicity: ☐Hispanic ☐Non-Hispanic

Part B: Medical Information (Mother)

1. Prenatal care received? ☐Yes ☐No 2. Health Insurance Status: ☐Medicaid ☐Private Insurance ☐Other _____

3. Name of prenatal care provider/clinic name _____ 4. Clinic Phone # _____
Clinic Fax # _____

5. Date hepatitis B labs collected ___/___/___ (mo day yr)

HBsAg test result (during this pregnancy) ☐Pos ☐Neg

PLEASE ATTACH A COPY OF THE PATIENT'S HEPATITIS B LAB RESULTS

6. Expected delivery date ___/___/___ (mo day yr)

7. Expected hospital of delivery _____

SECTION II: DELIVERY HOSPITAL CARE
Part A: Mother

1. Pregnancy outcome ☐ live birth ☐ stillborn ☐ miscarriage ☐pregnancy terminated

2. Hospital of delivery _____

Part B: Infant

1. Last Name _____ 2. First Name _____

3. Date of Birth ___/___/___ (mo day yr) 4. Birth time ___:___ (hr mn) am/pm 5. Birth weight _____

6. Sex Female ☐ Male ☐ 7. Health Insurance Status at Birth: ☐Medicaid ☐Private Insurance ☐Other _____

8. HBIG date ___/___/___ (mo day yr) HBIG time ___:___ (hr mn) am/pm

9. 1st dose HepB vaccine date ___/___/___ (mo day yr) 1st dose HepB vaccine time ___:___ (hr mn) am/pm

10. Name of pediatrician/clinic name _____ 11. Clinic Phone # _____
Clinic Fax # _____

Please fax or mail form to:

Louisiana Department of Health and Hospitals
Office of Public Health-Immunization Program
Attn: Hepatitis Program Manager
(504) 838-5300
(504) 838-5206 fax

For Office Use Only:

SECTION III: INFANT'S VACCINE RECORD

Part A: HBIG

1. HBIG date ____/____/____ (mo day yr) HBIG time ____:____ am/pm (hr mn)

Part B: Hepatitis B Vaccine

1. Dose #1 ____/____/____ (mo day yr) Dose #2 ____/____/____ (mo day yr) Dose #3 ____/____/____ (mo day yr)

2. Additional Dose of Hepatitis B Vaccine (if indicated) Explain _____

Dose #4 ____/____/____ (mo day yr) Dose #5 ____/____/____ (mo day yr) Dose #6 ____/____/____ (mo day yr)

Part C: Infant's 9-12 months Follow-up Serology:

1. Date ____/____/____ (mo day yr)

HBsAg	☐Pos	☐Neg	☐Not done
anti-HBs	☐Pos	☐Neg	☐Not done
anti-HBc IgM	☐Pos	☐Neg	☐Not done

2. Repeat Serology (if needed)

Date ____/____/____ (mo day yr)

HBsAg	☐Pos	☐Neg	☐Not done
anti-HBs	☐Pos	☐Neg	☐Not done
anti-HBc IgM	☐Pos	☐Neg	☐Not done

Section IV: CASE DISPOSITION

1. Date ____/____/____ (mo day yr)

☐Case completed
☐Lost to follow-up/ unable to locate
☐Parent/guardian non-compliant
☐Transfer out of state

Initials of person closing case _____

HEPATITIS B SURVEILLANCE AND FOLLOW-UP FORM

Please note that requested information on this surveillance form is required as part of the disease reporting of the positive mother and is not considered a violation of the confidential relationship between the practitioner and patient, as per the HIPAA Privacy Rule *45 CFR § 164.512(b)(1)(i)*.

SECTION I: Prenatal Care

Part A: Identifying Information – Mother

1-7. Enter the patient's name, mailing address, city, zip code and parish of residence, and primary telephone number.
8-9. Enter the patient's age and date of birth.
10-12. Enter patient's primary language if other than English.
Check the race and ethnicity of the patient. If the patient is neither Black, White, nor Asian/Pacific Islander, enter the race of the patient in the space provided.

Part B: Medical Information – Mother

1. Check whether or not the patient received prenatal medical care during current or most recent pregnancy.
2. Indicate the patient's health insurance type.
3. If the patient received prenatal care, enter the name of the physician and/ or clinic where the prenatal care is/ was received.
4. Enter the ten-digit prenatal clinic phone number and fax number.
5. Enter the date in which hepatitis B labs were collected from the patient *during the current pregnancy*. Indicate the HBsAg lab result (Positive or Negative).
Please fax a copy of the patient's hepatitis B labs (including the lab results for HBsAg/ hepatitis B surface antigen) to the Immunization Program at (504) 838-5206, Attn: Hepatitis B Program Manager
6. Enter the date that the patient is expected to deliver.
7. Enter the name of the hospital where the patient is expected to deliver.

SECTION II: Delivery Hospital Care

Part A: Mother

1. Check the outcome of the patient's pregnancy.
2. Enter the name of the hospital where the mother delivered her infant.

Part B: Infant

1-2. Enter the infant's first and last name (and middle name if available).
3-4. Enter the date and time that the infant was born.
5. Enter the infant's birth weight, either grams or pounds.
6-7. Check the sex of the infant and the insurance type at the time of delivery.
8. Enter the date and time that the infant received the HBIG (hepatitis B immune globulin).

9. Enter the date and time that the infant received the first dose of hepatitis B vaccine.

10-11. Enter the name, phone number, and fax number of the clinic where the infant is expected to receive pediatric medical care.

SECTION III & SECTION IV: Infant's Vaccine Record & Case Disposition

For office use only.

POLICY ON HUMAN PAPILLOMAVIRUS (HPV) VACCINES

Policy:

Human papillomavirus (HPV) is the most common sexually-transmitted infection in the U.S. For most women, the body's defense system will clear the virus and infected women do not develop health related problems. However, some HPV types can cause abnormal cells on the lining of the cervix that years later can turn into cancer. Other HPV types can cause genital warts. Three vaccines have been licensed by FDA recently – Gardasil (4vHPV, Merck), Cervarix (2vHPV, GSK) and Gardasil 9 (9vHPV, Merck). 2vHPV, 4vHPV and 9vHPV all protect against HPV types 16 and 18 which causes approximately 66% of cervical cancers. 4vHPV and 9vHPV also protect against types 6 and 11 which causes anogenital warts. 2vHPV vaccine offers protection against HPV types 16 and 18 only and is not approved for males or for the prevention of genital warts. Because the additional five types in 9vHPV account for a higher proportion of HPV-associated cancers in females compared with males and cause cervical precancers, the additional protection from 9vHPV will mostly benefit females. HPV vaccines are not protective against the diseases caused by all HPV types and will not treat existing disease caused by HPV types contained in the vaccine.

Guidelines:

CDC recommends that routine HPV vaccination be initiated at age 11 or 12 years. The vaccination series can be started beginning at age 9 years. 9vHPV, 4vHPV and 2vHPV can be used for routine vaccination of females aged 11 or 12 years and females through 26 years who have not been vaccinated previously or who have not completed the 3-dose series. 9vHPV or 4vHPV can be used for routine vaccination of males aged 11 or 12 years and males through 21 years who have not been vaccinated previously or who have not completed the 3-dose series.

2vHPV, 4vHPV and 9vHPV vaccines are administered as a 3-dose schedule. Individuals who may have been infected with HPV can still benefit from receiving HPV vaccine such that the vaccine can offer protection from other HPV types contained in the vaccine. Note that HPV vaccines are not intended to be used for treatment of HPV disease nor protect against diseases due to non-vaccine HPV types. Cervarix (2vHPV) is the not approved for vaccination of males.

Vaccination Schedule and Dosage:

HPV vaccines are given intramuscularly as a three injection series over a 6 month period. The first dose should be administered at 11-12 years of age followed by a second dose 1 to 2 months after the first dose. The third dose should be given 6 months after the first dose. Note: If the vaccine scheduled is interrupted, the vaccine series does not need to be restarted. If the series is interrupted after the first dose, the second dose should be given as soon as possible, and the second and third doses should be separated by an interval of at least 12 weeks. If the third dose is delayed, it should be given as soon as possible. If vaccination providers do not know or do not have available the HPV product previously administered, or are in settings transitioning to 9vHPV, any available HPV vaccine product may be used to continue or complete the series for

females for protection against HPV 16 and 18; 9vHPV or 4vHPV may be used to continue or complete the series for males.

The vaccine is can be administered at the same visit when other age appropriate vaccines are administered, such as Tdap, MCV4, and the second dose of varicella vaccine. Each single-use vial or prefilled syringe is for individual use only and should not be used for more than 1 individual. The full recommended dose of the vaccine should be used as supplied; no dilution or reconstitution is necessary.

Special situations and administration of HPV vaccines:
1) Immunocompromised persons, as a result of disease or medications, may receive HPV vaccines; however, the immune response to the vaccine might be less than that in persons who are immunocompetent.

2) HPV vaccine is not recommended for use in pregnancy. The vaccine has not been causally associated with adverse outcomes of pregnancy or adverse events to the developing fetus. However, data on vaccination in pregnancy are limited. If a woman is found to be pregnant after initiating the vaccination series, completion of the 3-dose regimen should be delayed until after the completion of pregnancy. If a vaccine dose is administered during pregnancy, there is no indication for intervention. Patients and providers can report an exposure to HPV vaccine during pregnancy to the Vaccine Adverse Event Reporting System (VAERS).
3) Either 9vHPV or 4vHPV vaccination is recommended through age 26 years for men who have sex with men and for immunocompromised persons (including those with HIV infection) who have not been vaccinated previously or have not completed the 3-dose series.

4vHPV and 9vHPV are contraindicated for those who are hypersensitive or have a severe allergic reaction to a vaccine component or to yeast. 2vHPV should not be used in persons with anaphylactic latex allergy. The vaccine is also contraindicated in recipients who have had an allergic reaction after getting a dose of the vaccine. The decision to administer or delay vaccination because of a current or recent febrile illness depends largely on the severity of symptoms and their etiology. Low-grade fever itself and mild upper respiratory infection are not generally contraindications to vaccination.

Side effects with HPV vaccines have been shown to be generally well tolerated in women and girls as young as 9 years of age. Syncope may follow vaccination with any vaccine resulting in falling with injury, especially in adolescents and young adults, therefore vaccinees should be observed for approximately 15 minutes following the administration of HPV vaccine.

NOTE: Vaccination does not substitute for routine cervical cancer screening. Females who receive HPV vaccine should be advised to continue cervical cancer screening. In addition, CDC recommends correct and consistent condom use may have a protective effect on HPV acquisition, reduce the risk for HPV-associated diseases, and mitigate the adverse consequences of infection with HPV.

Storage and Handling

HPV Vaccines must be stored refrigerated at 2 to 8°C (36 to 46°F) and should not be frozen. Protect from light. HPV vaccine will be supplied through the VFC program as either a carton of ten 0.5-mL single-dose vials or as 0.5-mL single-dose prefilled syringes in the package.

Vaccine Information Statement (VIS)

The Vaccine Information Statements (VIS) entitled "HPV Human Papillomavirus Vaccine - What You Need To Know" and "HPV Vaccine Gardasil-9 - What You Need To Know" are required to be provided to patients, guardians, or others with a need to know about the specific HPV immunization administered. The VIS forms are available at http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hpv-gardasil.html for 4vHPV or for 2vHPV (Cervarix) at http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hpv-cervarix.html or for 9vHPV at http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hpv-gardasil-9.html

POLICY ON INFLUENZA VACCINE

Policy:

Influenza vaccination shall be given in the Louisiana Office of Public Health (OPH) clinics in keeping with the ACIP and CDC recommendations. The OPH Immunization Program recommends, in accordance with CDC, universal immunization for all individuals > 6 months of age and older who do not have contraindications, in addition to those who are at high risk of serious illness or death from influenza. Vaccination to prevent influenza is particularly important for persons who are at increased risk for severe complications from influenza or at higher risk for influenza-related outpatient, ED, or hospital visits. Secondly, vaccination is important for those groups who typically serve as the "carrier" pool for influenza and tend to spread it to those at risk. While DHH-OPH vaccine supply is limited, vaccination efforts should focus on the following persons:

- all children aged 6 months through 59 months;
- all persons aged ≥65 years;
- adults and children who have chronic pulmonary (including asthma) or cardiovascular (except isolated hypertension), renal, hepatic, neurological, hematologic, or metabolic disorders (including diabetes mellitus);
- persons who have immunosuppression (including immunosuppression caused by medications or by HIV);
- women who are or will be pregnant during the influenza season;
- children and adolescents (aged 6 months--18 years) who are receiving long-term aspirin therapy and who might be at risk for experiencing Reye syndrome after influenza virus infection;
- residents of nursing homes and other long-term--care facilities;
- American Indians/Alaska Natives;
- persons who are morbidly obese (BMI ≥40).

Continued emphasis should be placed on vaccination of healthy persons who live with or care for persons at higher risk for influenza-related complications. Vaccination efforts should focus on delivering vaccination to persons at higher risk for influenza-related complications as well as these persons:

- HCP;
- household contacts (including children) and caregivers of children aged ≤59 months (i.e., aged <5 years) and adults aged ≥50 years; and
- household contacts (including children) and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza.

Groups potentially capable of nosocomial transmission of influenza to high risk persons (e.g. physicians, nurses and other persons who have extensive contact with high risk patients), and the general population are encouraged to see their own physicians for influenza vaccinations. While CDC does recommend influenza vaccination for all individuals, limited supplies of vaccine and

lack of public funding preclude OPH from serving all population groups as listed. **Groups not served by OPH should be encouraged to seek vaccination in their community, at their own physician or community pharmacies across the State.**

Because influenza viruses continually evolve and mutate, the influenza vaccine is different each year and is developed according to the predicted strain that will be prevalent during the season. Each year's influenza vaccine contains three virus strains (usually two type A and one type B) representing the influenza viruses that are likely to circulate in the United States in the upcoming winter. Quadrivalent influenza vaccines have been developed to include a second B strain for inclusion in the trivalent influenza vaccine to increase the likelihood of adequate protection against circulating influenza B strains. Please see the following changes to the various influenza vaccine formulations and denotation:

The former abbreviation TIV (Trivalent Inactivated Influenza Vaccine, previously used for inactivated influenza vaccines) has been replaced with the new abbreviation IIV (Inactivated Influenza Vaccine).

- IIVs as a class will include:

  egg-based and cell culture-based trivalent inactivated influenza vaccines (IIV3), and
  egg-based quadrivalent inactivated influenza vaccine (IIV4).

- RIV3 refers to recombinant hemagglutinin influenza vaccine, available as a trivalent formulation (RIV3);

IIV and RIV denote vaccine categories; numeric suffix specifies the number of antigens in the vaccine.

<u>In light of low effectiveness against influenza A(H1N1)pdm09 in the United States during the 2013–14 and 2015–16 seasons, for the 2016–17 season, ACIP makes the interim recommendation that LAIV4 should not be used. Because LAIV4 is still a licensed vaccine that might be available and that some providers might elect to use, for informational purposes, reference is made to previous recommendations for its use.</u>

For 2016-2017 flu season, healthy children aged 2 through 8 years who have no contraindications or precautions IIV is an appropriate option. An age-appropriate formulation of vaccine should be used. In the absence of data demonstrating consistent greater relative effectiveness of the current quadrivalent formulation of LAIV4, preference for LAIV4 over IIV is no longer recommended. ACIP will continue to review the effectiveness of influenza vaccines in future seasons and update these recommendations if warranted. The effectiveness or safety of LAIV4 is not known or is of potential concern for certain persons, and LAIV4 is not recommended for these persons.

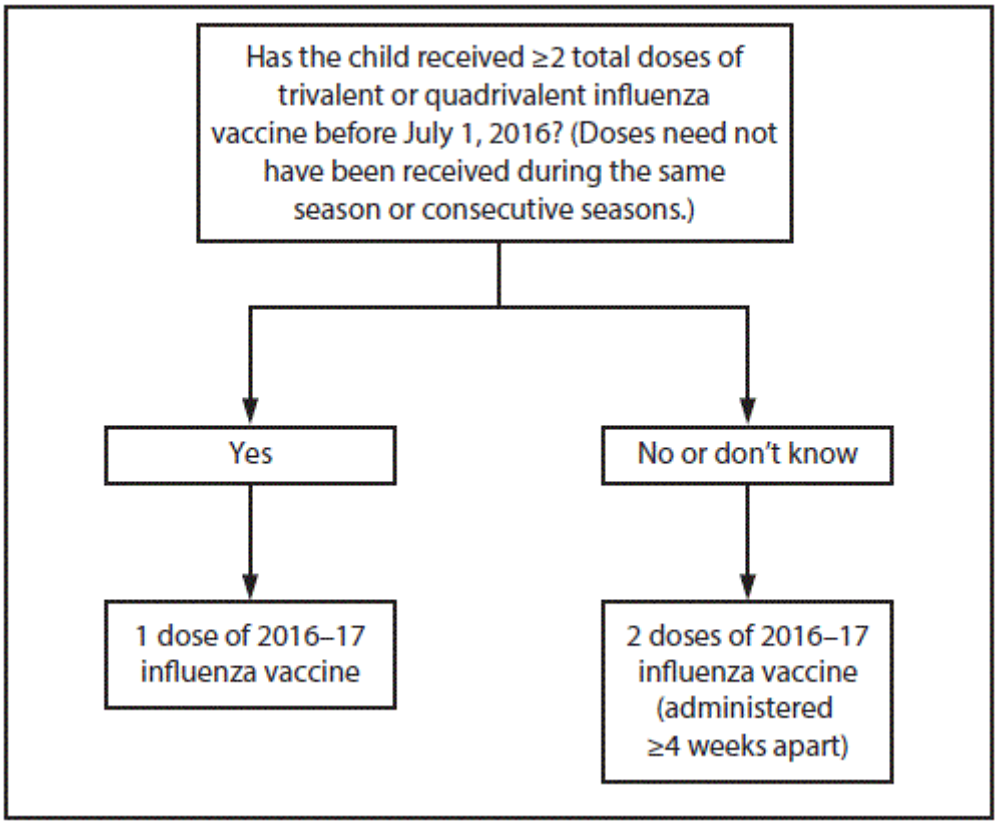
Do not administer LAIV4 to the following groups:

- Persons aged <2 years or >49 years;
- Persons with contraindications listed in the package insert:
- Children aged 2 through 17 years who are receiving aspirin or aspirin-containing products;
- Persons who have experienced severe allergic reactions to the vaccine or any of its components,
- or to a previous dose of any influenza vaccine;
- Pregnant women;
- Immunocompromised persons;
- Persons with a history of egg allergy;
- Children aged 2 through 4 years who have asthma or who have had a wheezing episode noted in the medical record within the past 12 months, or for whom parents report that a health care provider stated that they had wheezing or asthma within the last 12 months;
- Persons who have taken influenza antiviral medications within the previous 48 hours;
- In addition to the groups for whom LAIV4 is not recommended above, the "Warnings and Precautions" section of the LAIV4 package insert indicates that persons of any age with asthma might be at increased risk for wheezing after administration of LAIV4. The package insert also notes that the safety of LAIV4 in persons with other underlying medical conditions that might predispose them to complications after wild-type influenza virus infection (e.g., chronic pulmonary, cardiovascular [except isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders [including diabetes mellitus]), has not been established. These conditions, in addition to asthma in persons aged ≥5 years, should be considered precautions for the use of LAIV4; and
- Persons who care for severely immunosuppressed persons who require a protective environment should not receive LAIV4, or should avoid contact with such persons for 7 days after receipt, given the theoretical risk for transmission of the live attenuated vaccine virus to close contacts.

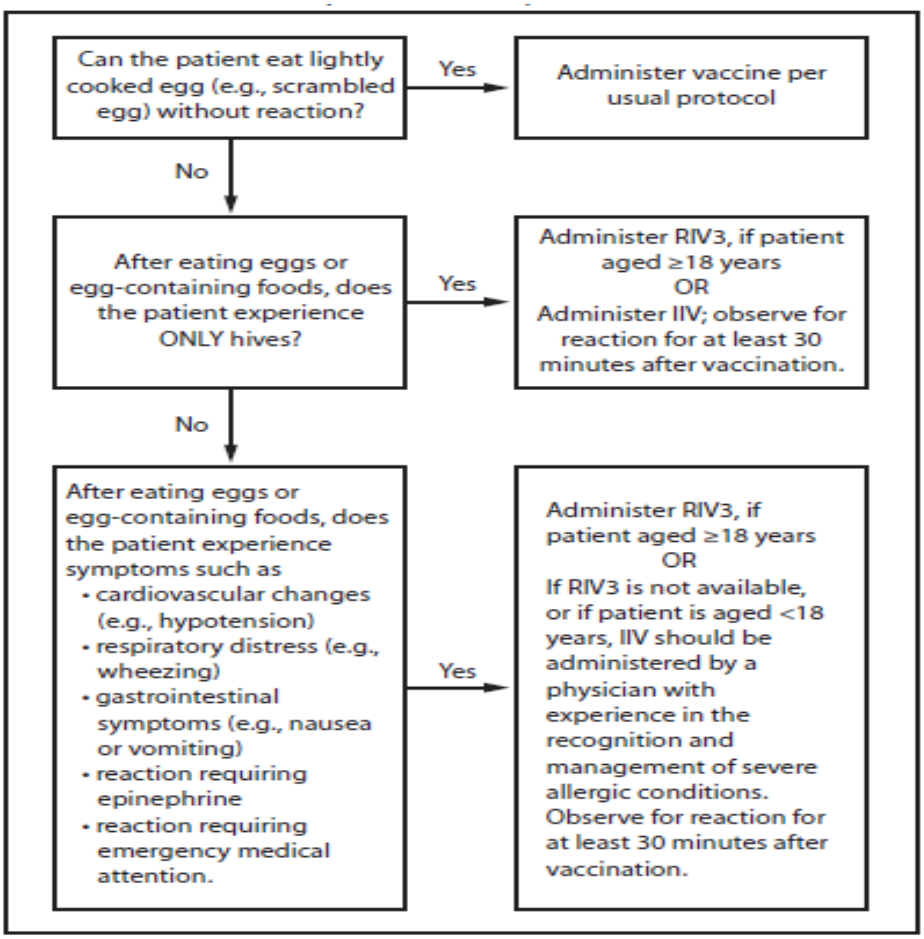
Recommended dosing by patient age and formulation:

For 2016–2017, ACIP recommends that children aged 6 months through 8 years who have previously received ≥2 total doses of trivalent or quadrivalent influenza vaccine before July 1, 2016, require only 1 dose for 2016–2017. The two previous doses need not have been given during the same season or consecutive seasons. Children in this age group who have not previously received a total of ≥2 doses of trivalent or quadrivalent influenza vaccine before July 1, 2016 require 2 doses for 2016–2017. The interval between the 2 doses should be at least 4 weeks.

See figure on dosing algorithm:



Recommendation regarding influenza vaccination of persons who report allergy to eggs - ACIP, 2016–2017 influenza season.



Persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine. Because relatively little data are available for use of LAIV4 in this setting, IIV or RIV should be used. RIV is egg-free and may be used for persons aged 18-49 years who have no other contraindications. However, IIV (egg- or cell-culture based) may also be used, with the following additional safety measures:

- Vaccine should be administered by a healthcare provider who is familiar with the potential manifestations of egg allergy;
- Vaccine recipients should be observed for at least 30 minutes for signs of a reaction after administration of each vaccine dose;
- Regardless of allergy history, all vaccines should be administered in settings in which personnel and equipment for rapid recognition and treatment of anaphylaxis are available;

- Persons who are able to eat lightly cooked egg (e.g., scrambled egg) without reaction are unlikely to be allergic. Egg-allergic persons might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy. Egg allergy can be confirmed by a consistent medical history of adverse reactions to eggs and egg-containing foods, plus skin and/or blood testing for immunoglobulin E directed against egg proteins;
- For persons with no known history of exposure to egg, but who are suspected of being egg-allergic on the basis of previously performed allergy testing, consultation with a physician with expertise in the management of allergic conditions should be obtained before vaccination. Alternatively, RIV3 may be administered if the recipient is aged ≥18 years; and
- A previous severe allergic reaction to influenza vaccine, regardless of the component suspected of being responsible for the reaction, is a contraindication to future receipt of the vaccine.

Persons who report having had reactions to egg involving such symptoms as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention may receive RIV3, if aged 18 through 49 years and there are no other contraindications. If RIV3 is not available or the recipient is not within the indicated age range, such persons should be referred to a physician with expertise in the management of allergic conditions for further risk assessment before receipt of vaccine.

2016-2017 Influenza Vaccines for different age groups:

TABLE. Influenza vaccines — United States, 2016–2017 influenza season*

Trade name	Manufacturer	Presentation	Mercury (from thimerosal) µg/0.5 mL	Ovalbumin µg/0.5 mL	Age indications	Latex	Route
Inactivated influenza vaccine, quadrivalent (IIV4), standard dose Contraindications*: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine. Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.							
Fluarix Quadrivalent	GlaxoSmithKline	0.5 mL single-dose prefilled syringe	—	≤0.05	≥3 yrs	No	IM†
FluLaval Quadrivalent	ID Biomedical Corp. of Quebec (distributed by GlaxoSmithKline)	5.0 mL multi-dose vial	<25	≤0.3	≥3 yrs	No	IM†

Fluzone Quadrivalent	Sanofi Pasteur	0.25 mL single-dose prefilled syringe 0.5 mL single-dose prefilled syringe 0.5 mL single-dose vial 5.0 multi-dose vial	— — — 25	§ § § §	6 through 35 mos > 36 mos > 36 mos > 6 mos	No No No No	IM† IM† IM† IM†
Fluzone Intradermal¶ Quadrivalent	Sanofi Pasteur	0.1 mL single-dose prefilled microinjection system	—	§	18 through 64 yrs	No	ID**
Inactivated influenza vaccine, trivalent (IIV3), standard dose Contraindications*: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine. Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.							
Afluria	bioCSL	0.5 mL single-dose prefilled syringe 5.0 mL multi-dose vial	— 24.5	<1 <1	≥9 yrs†† ≥9 yrs†† via needle; 18 – 64 yrs via jet injector	No No	IM† IM†
Fluvirin	Novartis Vaccines and Diagnostics	0.5 mL single-dose prefilled syringe 5.0 mL multi-dose vial	≤1 25	≤1 ≤1	≥4 yrs ≥4 yrs	Yes §§ No	IM† IM†
Fluzone	Sanofi Pasteur	5.0 mL multi-dose vial	25	§	≥6 mos	No	IM†
Inactivated influenza vaccine, cell-culture-based (ccIIV3), standard dose Contraindications*: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine. Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.							
Flucelvax	Novartis Vaccines and Diagnostics	0.5 mL single-dose prefilled syringe	—	¶¶	≥18 yrs	Yes §§	IM†

Inactivated influenza vaccine, trivalent (IIV3), high dose Contraindications*: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine. Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.							
Fluzone High-Dose***	Sanofi Pasteur	0.5 mL single-dose prefilled syringe	—	§	≥65 yrs	No	IM†
Recombinant influenza vaccine, trivalent (RIV3), standard dose Contraindications*: Severe allergic reaction to any vaccine component. Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.							
Flublok	Protein Sciences	0.5 mL single-dose vial	—	0	≥18 yrs	No	IM†
Live attenuated influenza vaccine, quadrivalent (LAIV4) Contraindications*: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine. Concomitant use of aspirin or aspirin-containing medications in children and adolescents. In addition, ACIP recommends LAIV4 not be used for pregnant women, immunosuppressed persons, persons with egg allergy, and children aged 2 through 4 years who have asthma or who have had a wheezing episode noted in the medical record within the past 12 months, or for whom parents report that a health care provider stated that they had wheezing or asthma within the last 12 months. LAIV4 should not be administered to persons who have taken influenza antiviral medications within the previous 48 hours. Persons who care for severely immunosuppressed persons who require a protective environment should not receive LAIV4, or should avoid contact with such persons for 7 days after receipt. Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine; asthma in persons aged 5 years and older; medical conditions which might predispose to higher risk for complications attributable to influenza.							
FluMist Quadrivalent†††	MedImmune	0.2 mL single-dose prefilled intranasal sprayer	—	<0.24 (per 0.2 mL)	2 through 49 yrs	No	IN

For table footnotes and more information on influenza, see MMWR Aug 26, 2016:65(5);1-54 or at http://www.cdc.gov/mmwr/volumes/65/rr/rr6505a1.htm

Vaccination and health care providers should check CDC's influenza website periodically for additional information http://www.cdc.gov/flu/professionals/index.htm

POLICY ON MEASLES VACCINATION

Policy:

1. A dose of measles (MMR) vaccine shall be given in OPH clinics to children 12 months of age and older followed by a booster dose at least a month apart. The MMR second dose should be routinely administered at 4 to 6 years of age, prior to school entry. The second dose may be given at any time 4 weeks or more after the first dose. Any MMR dose given after the first birthday and at least 4 weeks after the first dose can be counted as a valid second dose. Second doses should be given to older children who have not had one. The adolescent visit at 11 or 12 years of age should be used as a check point, to make sure that no child enters young adulthood without two doses of MMR.

2. Measles (MMR) vaccine shall not be given to women who are pregnant, state that they may be pregnant, or state that they intend to become pregnant within 3 months after being immunized.

3. Measles vaccine (MMR) shall not be given to persons who have had anaphylactic reactions to neomycin.

4. Measles (MMR) vaccine shall not be given to persons with diseases causing immune deficiency (including cancer) or persons receiving therapy (radiation, drugs) causing suppression of the immune mechanisms of the body. Measles vaccine may be given to asymptomatic HIV-infected individuals but should not be given to those who have severe immuno-suppression as evidenced by opportunistic infections or low CD-4 count (symptomatic AIDS).

A. A "routine" tuberculosis skin test is not required prior to measles immunization. If a TB skin test is needed as part of general care, it should be given simultaneously with the MMR or one month after the MMR.

B. A second dose of measles (MMR) vaccine is required for certain persons to comply with the school immunization law as outlined in the attached protocol. A second dose is required prior to school entry and is also required for admission to schools of higher learning.

C. Measles (MMR) vaccine may be given to children as young as 6 months under certain circumstances (outbreaks, international travel) but this can be done only after approval is obtained from the OPH Medical Consultants.

D. Measles (MMR) vaccine may be given to household contacts of persons with altered immunity or immune deficiency.

E. Combined MMR/Varicella (ProQuad) vaccine shall be used in accordance to the policies stated above for MMR use. At least 1 month should elapse between a dose of MMR and a dose of ProQuad. NOTE: ProQuad is indicated only for use in children 12 months to 12 years of age.

Rationale:

For more information on the prevention of Measles see MMWR 1989; 38(S-9): 1-13) or www.cdc.gov/mmwr/preview/mmwrhtml/00041753.htm on the internet.

POLICY ON MENINGOCOCCAL (Group A, C, Y and W-135) VACCINATION

Policy:

Two quadrivalent conjugate meningococcal vaccines (MCV4), MenactraTM, manufactured by Sanofi Pasteur and and (Menveo), MenACWY-CRM, manufactured by Novartis Vaccines and Diagnostics were approved for persons 2 through 55 years of age and licensed by the Food and Drug Administration. Both quadrivalent conjugate vaccines provide protection to the same four serogroups- A, C, Y, and W-135, as the previously licensed polysaccharide vaccine, MenomuneTM (MPSV4). As conjugate vaccines, both MCV4 and Menveo are expected to provide better and longer lasting protection than MPSV4, as well as a reduction in nasopharyngeal carriage of the vaccine serotypes.

The Advisory Committee on Immunization practices (ACIP) has issued recommendations for meningococcal conjugate vaccine (MCV4 and Menveo) for all adolescents aged 11-18 years old. Only medically high risk children should receive MCV4 prior to age 11 years.

Other populations at increased risk for meningococcal disease for which routine vaccination include:

Persons with functional or anatomic asplenia;
Persons with persistent complement component deficiency;
HIV infection;
Microbiologists who are exposed routinely to isolates of N. meningitidis;
Military recruits;
Persons who travel to, or reside in, countries in which N. meningitidis is epidemic or hyperendemic; and
College freshmen living in dormitories.

MenACWY-CRM or MCV4 may be used in persons aged 2 - 55 years, and are preferred to quadrivalent meningococcal polysaccharide vaccine (MPSV4). High risk persons aged 2--10 years who are recommended to receive a meningococcal vaccine should receive MCV4 or MenACWY-CRM, and persons aged >55 years should receive MPSV4. MPSV4 may continue to be used for persons 11-55 years if quadrivalent meningococcal conjugate vaccines are not available. MPSV4 (MENOMUNE) is not a VFC available vaccine. High risk children that have received meningococcal vaccine prior to 11 years of age should be re-vaccinated. Administer quadrivalent meningococcal conjugate vaccines to persons less than 11 years of age who received MPSV4 > 3 years previously and remain at increased risk for meningococcal disease.

Re-vaccination with MCV vaccine has been recommended for persons aged 11 through 18 years of age and certain risk groups including persistent complement component deficiency, anatomic or functional asplenia, and persons with HIV infection. According to the LA School Immunization Law, all 11 or 12 year old children must be vaccinated with meningococcal conjugate vaccine as part of the adolescent immunization schedule. Adolescents at age 11 or 12 years should routinely receive the first MCV vaccine dose followed by a booster dose at age 16

years. For adolescents who received the first MCV dose at age 13 through 15 years, a one-time booster dose should be administered preferably at age 16 through 18 years. Revaccination does not apply to persons who previously received a primary dose of MCV vaccine on or after 16 years of age. Vaccination of persons in the select risk groups aged 2 through 55 years of age should receive a 2-dose MCV primary series administered two months apart followed by a booster dose every 5 years. Adolescents aged 11- 18 years with HIV infection should be routinely vaccinated with a 2-dose primary series. Children vaccinated prior to 11 years of age that do not meet the high risk criteria will need to be re-vaccinated with MCV when the child becomes 11- 12 years of age. The minimal interval between doses of MCV vaccine is 8 weeks. All other persons at increased risk for meningococcal disease (e.g., microbiologists or travelers to an epidemic or highly endemic country) should receive a single dose.

ADMINISTRATION:

Quadrivalent meningococcal conjugate vaccines (MCV4 or Menveo) should be administered as a single 0.5 ml injection intramuscular route, preferably in the deltoid region and can routinely be given with other scheduled vaccines including MenB, Varicella, IPV, Td, MMR, HBV, and Influenza.

POLICY ON MENINGOCOCCAL DISEASE (MenB) SEROGROUP B VACCINATION

Meningococcal group B disease (MenB) is a bacterial infection that is one of five of the primary forms of the bacteria that cause meningococcal disease in adolescents and young adults in the US. It is a rare but serious bacterial infection. On average, the disease is fatal for one in ten persons who develop meningococcal group B disease.

The new MenB vaccine is not a replacement for the ACIP recommended and Louisiana school required MCV4 vaccination. MCV4 protects against meningococcal groups A, C, Y and W-135. The new MenB vaccine protects against serogroup B meningococcal disease. Vaccination with MCV4 should continue as usual. MenB and MCV4 may be administered with other vaccines indicated for this age, but at a different anatomic site, if feasible.

The Advisory Committee on Immunization Practices (ACIP) recommends the routine use of Meningococcal B vaccines among certain groups of persons aged > 10 years who are at increased risk for serogroup B meningococcal disease. Individuals at risk include:

- Individuals with persistent complement component deficiencies;
- Individuals with anatomic or functional asplenia, including sickle cell disease; and
- Individuals identified to be at increased risk because of a serogroup B meningococcal disease outbreak.

ACIP states “decisions to vaccinate adolescents and young adults aged 16 through 23 years of age against serogroup B meningococcal disease should be made at the discretion of the administrating provider”. While the ACIP guidance is for individuals 16 through 23 years of age, the MenB vaccine offered by the VFC Program may be administered to eligible individuals 16 through 18 years of age only.

MenB vaccine is available as either the 2-dose series of Men B-4C (Bexsero by Novartis) or a 3-dose series of Men B-FHbp (Trumenba by Wyeth). The same vaccine product must be used for all doses in the series. PHUs will provide the Men B-4C vaccine, Bexsero by Novartis.

POLICY ON MUMPS VACCINATION

Policy:

1. One dose of mumps (MMR) vaccine shall be given in OPH clinics to children 12 months of age and older followed by a booster dose at least a month apart. The MMR second dose should be routinely administered at 4 to 6 years of age, prior to school entry. The second dose may be given at any time 4 weeks or more after the first dose. Any MMR dose given after the first birthday and at least 4 weeks after the first dose can be counted as a valid second dose. Second doses should be given to older children who have not had one. The adolescent visit at 11 or 12 years of age should be used as a check point, to make sure that no child enters young adulthood without two doses of MMR.

2. Mumps vaccine shall not be given in OPH clinics to females who are pregnant or suspect that they are pregnant, or who state they intend to become pregnant within 3 months after being immunized.

3. Mumps (MMR) vaccine shall not be given in OPH clinics to persons with a history of anaphylactic reactions to neomycin (see measles protocol).

4. Mumps (MMR) vaccine shall not be given in OPH clinics to persons who have diseases that cause immune deficiency (including cancer) or are receiving therapy (drugs or radiation) that suppress its immune system. Mumps vaccine may be given to asymptomatic HIV-infected individuals but should not be given to those who have severe immuno-suppression as evidenced by opportunistic infections or low CD-4 count (symptomatic AIDS).

5. Mumps (MMR) vaccine may be given to household contacts of persons with altered immunity.

6. Children needing only mumps vaccine may be safely immunized with MMR.

Rationale:

For more information on Mumps prevention see MMWR 1989; 38(22): 388-392, 397-400) or www.cdc.gov/mmwr/preview/mmwrhtml/00001404.htm on the internet.

POLICY ON PNEUMOCOCCAL CONJUGATE VACCINE (PCV)

Policy:

The Office of Public Health Immunization Program follows recommendations from the Advisory Committee on Immunization Practices (ACIP) of the U.S. Public Health Service to immunize children at least six weeks of age through 59 months old with Pneumococcal Conjugate Vaccine (PCV) and for children 60-71 months with underlying medical conditions that increase their risk for pneumococcal disease or complications. In February 2010, Prevnar13, (Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer, Inc.) was licensed by FDA for the prevention of invasive pneumococcal disease caused by 13 pneumococcal serotypes covered by the vaccine and for prevention of otitis media caused by serotypes in the 13-valent pneumococcal conjugate vaccine formulation (PCV13).

Guidelines:

CDC recommends PCV13 for all children 2 through 59 months of age and for children 60 through 71 months of age who have underlying medical conditions that increase their risk of pneumococcal disease or complications.

1. Infants and children who have not previously received PCV7 or PCV13

The recommendation for use of PCV13 and the immunization schedules for infants and toddlers 2 through 59 months of age who have not received any prior PCV7 or PCV13 doses are the same as those previously published for PCV7 with PCV13 replacing PCV7 for all doses (MMWR 2000; 49 (RR-9).

2. Infants 2 through 6 months of age

PCV13 is recommended as a 4-dose series at 2, 4, 6, and 12 through 15 months. Infants receiving their first dose at age <6 months should receive 3 doses of PCV13 at intervals of approximately 8 weeks (the minimum interval is 4 weeks). Minimum age for administration of first dose is 6 weeks. The fourth dose is recommended at age 12 through 15 months and should be given at least 8 weeks after the third dose (Table 1).

3. Unvaccinated children 7 months of age and older

Infants 7 through 11 months of age

> A. Three doses are recommended. The first 2 doses should be given with an interval of at least 4 weeks between doses. The third dose should be given at age 12 through 15 months, at least 8 weeks after the second PCV13 dose (Table 1).

4. Children 12 through 23 months of age

A. Two doses are recommended, with an interval of at least 8 weeks between doses (Table 1).

B. Children 24 months of age and older

1. Unvaccinated healthy children 24 through 59 months of age should receive a single dose of PCV13. Unvaccinated children 24 through 71 months of age with underlying medical conditions should receive 2 doses of PCV13 with an interval of at least 8 weeks between doses (Table 2). Children incompletely vaccinated with PCV7 or PCV13.

5. Children <24 months of age

Infants and children < 24 months of age who have received one or more doses of PCV7 should complete the immunization series with PCV13 (Table 1).

6. Children >24 months of age

A. A single dose of PCV13 is recommended for all healthy children 24 through 59 months of age with any incomplete PCV schedule (PCV7 or PCV13) (Table 2).

B. For children 24 through 71 months of age with underlying medical conditions who have received any incomplete schedule of <3 doses of PCV (PCV7 or PCV13), 2 doses of PCV13 are recommended. For children with underlying medical conditions who have received 3 doses of PCV (PCV7 or PCV13), a single dose of PCV13 is recommended through 71 months of age (Table 2). The minimum interval between doses is 8 weeks.

7. Children completely vaccinated with PCV7

A. A single supplemental dose of PCV13 is recommended for all children 14 through 59 months of age who have received 4 doses of PCV7 or other age-appropriate, complete PCV7 schedule (fully vaccinated with PCV7) (Tables 1 and 2).

B. For children who have underlying medical conditions, a single supplemental PCV13 dose is recommended through 71 months of age (Table 2). This includes children who have previously received the 23-valent pneumococcal polysaccharide vaccine (PPSV23). PCV13 should be given at least 8 weeks after the last dose of PCV7 or PPSV23.

8. Children 6 through 18 years of age with high risk conditions

A. A single dose of PCV13 may be administered for children 6 through 18 years of age who are at increased risk for invasive pneumococcal disease because of sickle cell disease, HIV-infection or other immunocompromising condition, cochlear implant or cerebrospinal fluid leaks, regardless of whether they have previously received PCV7 or PPSV23.

Use of PPSV23 among children 2 through 18 years of age who are at increased risk for invasive pneumococcal disease

In addition to receiving PCV13, children with underlying medical conditions should receive PPSV23 at age 2 years or as soon as possible after the diagnosis of chronic illness is made in children >2 years.

Doses of PCV13 should be completed before PPSV23 is given.

The minimum interval is at least 8 weeks after the last dose of PCV13.
However, children who have previously received PPSV23 should also receive the recommended PCV13 doses.

A second dose of PPSV23 is recommended 5 years after the first dose of PPSV23 for children who have sickle cell disease, or functional or anatomic asplenia, HIV infection, or other immunocompromising condition

No more than two PPSV23 doses are recommended.

Table 1. **Recommended schedules for administering doses of PCV13 to children < 24 months of age by PCV vaccination history and age**

Age at examination (mos)	Vaccination history: total number of PCV7 and/or PCV13 doses received previously	Recommended PCV13 Regimen1
2 through 6 mos	0 doses	3 doses, 8 weeks apart; fourth dose at age 12–15 mos
	1 dose	2 doses, 8 weeks apart; fourth dose at age 12–15 mos
	2 doses	1 dose, 8 weeks after the most recent dose; fourth dose at age 12-15 mos
7 through 11 mos	0 doses	2 doses, 8 weeks apart; third dose at 12-15 mos
	1 or 2 doses before age 7 mo	1 dose at age 7–11 mos, with a second dose at 12–15 mos, ≥ 8 weeks later
12 through 23 mos	0 doses	2 doses, ≥ 8 weeks apart
	1 dose before age 12 mo	2 doses, ≥ 8 weeks apart
	1 dose at ≥12 mo	1 dose, ≥ 8 weeks after the most recent dose2

	2 or 3 doses before age 12 mo	1 dose, ≥ 8 weeks after the most recent dose2
	4 doses of PCV7 or other age-appropriate, complete PCV7 schedule	1 supplemental dose, ≥ 8 weeks after the most recent dose*

1 Minimum interval between doses is 8 weeks except for children vaccinated at age <1 year, for whom minimum interval between doses is 4 weeks.
2 No additional PCV13 doses are indicated for children 12 through 23 months of age who have received 2 or 3 doses of PCV7 before age 12 months and at least 1 dose of PCV13 at age 12 months or older.
* For children who have underlying medical conditions, a supplemental PCV13 dose is recommended through 71 months of age. For list of conditions, see MMWR 2010;59:9 or Table 3 below.

Table 2. **Recommended schedules for administering doses of PCV13 to children >24 months of age by PCV vaccination history and age**

Age at examination (mos)	Vaccination history: total number of PCV7 and/or PCV13 doses received previously	Recommended PCV13 Regimen1
Healthy children 24 through 59 mos	Unvaccinated or any incomplete schedule	1 dose, ≥ 8 weeks after the most recent dose
	4 doses of PCV7 or other age-appropriate, complete PCV7 schedule	1 supplemental dose, ≥ 8 weeks after the most recent dose*
Children 24 through 71 mos with underlying medical conditions	Unvaccinated or any incomplete schedule of <3 doses	2 doses, one ≥ 8 weeks after the most recent dose and another dose ≥ 8 weeks later
	Any incomplete schedule of 3 doses	1 dose, ≥ 8 weeks after the most recent dose
	4 doses of PCV7 or other age-appropriate complete PCV7 schedule	1 supplemental dose, ≥ 8 weeks after the most recent dose*

1 Minimum interval between doses is 8 weeks.
* For children who have underlying medical conditions, a supplemental PCV13 dose is recommended through 71 months of age. For list of conditions, see MMWR 2010;59:9 or Table 3 below.

Table 3. **Underlying medical conditions that are indicators for pneumococcal vaccine among children, by risk group, ACIP, US, 2010**

Risk group	Condition
Immunocompetent children	Chronic heart disease*
	Chronic lung disease†
	Diabetes mellitus
	Cerebrospinal fluid leaks
	Cochlear implant
Children with functional or anatomic asplenia	Sickle cell disease and other hemoglobinopathies Congenital or acquired asplenia, or splenic dysfunction
Children with immunocompromising conditions	HIV infection
	Chronic renal failure and nephrotic syndrome
	Diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease; or solid organ transplantation
	Congenital immunodeficiency§

* Particularly cyanotic congenital heart disease and cardiac failure.
† Including asthma if treated with prolonged high-dose oral corticosteroids.
§ Includes B- (humoral) or T-lymphocyte deficiency; complement deficiencies, particularly C1, C2, C3, and C4 deficiency; and phagocytic disorders (excluding chronic granulomatous disease).

Vaccine information Statement:

The "Vaccine Information Statement (VIS)" entitled "Pneumococcal Conjugate Vaccine: What you need to know" PCV (12/08) must be provided to patients, parents, or guardians of children being immunized with PCV.

Rationale:

For more information on 13-Valent Pneumococcal Conjugate Vaccine see MMWR 2010; 59(No.9): 258-61 or www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm on the internet.

POLICY ON PNEUMOCOCCAL POLYSACCHARIDE VACCINE (PPSV)

Policy

Streptococcus pneumoniae (pneumococcus) remains a leading infectious cause of serious illness, including bacteremia, meningitis, and pneumonia, among older adults in the United States. Use of a 7-valent pneumococcal conjugate vaccine (PCV7) since 2000 and PCV13 since 2010 among children in the United States has reduced pneumococcal infections directly and indirectly among children, and indirectly among adults. By 2013, the incidence of invasive pneumococcal disease (IPD) caused by serotypes unique to PCV13 among adults aged ≥65 years had declined by approximately 50% compared with 2010, when PCV13 replaced PCV7 in the pediatric immunization schedule. However, in 2013 an estimated 13,500 cases of IPD occurred among adults aged ≥65 years. Approximately, 20%–25% of IPD cases and 10% of community-acquired pneumonia cases in adults aged ≥65 years are caused by PCV13 serotypes and are potentially preventable with the use of PCV13 in this population

The presence of certain underlying medical conditions increases the risk for pneumococcal disease and its complications. The risk for IPD is greatest among persons who have congenital or acquired immunodeficiency, abnormal innate immune response, human immunodeficiency virus (HIV) infection, or functional or anatomic asplenia (e.g., sickle cell disease or congenital or surgical asplenia). Alaska Native children and children among certain American Indian populations also have higher rates of IPD. Among Alaska Native and American Indian adults, the majority of IPD cases occur in persons with underlying medical conditions or other risk factors (e.g., heavy alcohol use or smoking) that are associated with increased risk for IPD in the general population.

In 2014, CDC recommended 2 pneumococcal vaccines for all adults 65 years or older. For those who have never received any pneumococcal vaccines, a dose of PCV13 should be administered first, followed by a dose of the PPSV23, ideally 6 to 12 months later. For any adult who has already received any doses of PPSV23, a dose of PCV13 should be given at least 1 year after receipt of the most recent PPSV23 dose. If the adult has already received a dose of PCV13 at a younger age, another dose of PCV13 is not recommended. Adults who received PPSV23 before age 65 years for any indication, should receive another PPSV23 dose at age 65 years or later if at least 5 years have passed since their previous dose. Those who receive PPSV23 at or after age 65 years should receive only a single dose.

Guidelines

NOTE: PPSV and PCV13 vaccine is available for eligible, high risk individuals (uninsured, underinsured whose insurance does not cover the particular antigen, Medicaid or migrant/refugees) listed in this policy that attends the Office of Public Health clinics. All other groups should be encouraged to see their primary care physicians for PPSV and PCV.

Pneumococcal Polysaccharide Vaccine (PPSV) contains polysaccharide antigen from 23 types of pneumococcal bacteria that cause 88% of bacteremic pneumococcal disease. Pneumoccocal

vaccine is indicated for
1. people 65 and older, people with special health problems such as heart and/or lung disease, kidney failure, diabetes, Human Immunodeficiency Virus (HIV) infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, or nephrotic syndrome, those receiving immunosuppressive chemotherapy (including corticosteroids), and those who received an organ or bone marrow transplant. In addition, ACIP concluded that asthma is an independent risk factor for IPD and should be included in the group of chronic pulmonary diseases (e.g., COPD and emphysema) that are indications for PPSV23 and for adults who smoke cigarettes are at significantly increased risk for IPD and recommended that persons aged 19--64 years who smoke cigarettes should receive a single dose of PPSV23 and smoking cessation guidance.

2. Persons aged two and older who have chronic illness, such as long term illnesses that are associated with high risk of getting pneumococcal infections or its complications, specifically children whose spleens have been surgically removed, as well as those who have sickle cell disease, or cerebral spinal fluid leaks. Also children with immunosuppression, including asymptomatic or symptomatic HIV, should be vaccinated. (see Policy on Pneumococcal Conjugate Vaccine (PCV) for additional at-risk groups for children, pg 143).

Presently there are two approved types of Pneumococcal Polysaccharide Vaccine (PPSV). They are Pneumovax 23 by Merck & Co. and Pnu-Immune 23 by Lederle Laboratories. The vaccine may be administered either intramuscularly or subcutaneously preferably in the deltoid muscle or lateral mid-thigh. A needle length appropriate for the vaccine recipient's age and size should be used. For information on PCV13, see Policy on Pneumococcal Conjugate Vaccine (PCV)/

Vaccination Schedule and Dosage

Persons with uncertain or unknown PPSV or PCV vaccination status should be vaccinated with PCV13 and PPSV23. Adults with specified immunocompromising conditions who are eligible for pneumococcal vaccine should be vaccinated with PCV13 and PPSV series schedule during their next pneumococcal vaccination opportunity.

Simultaneous Vaccine Administration

Pneumococcal Polysaccharide Vaccine (PPSV23) and PCV13 do not interfere with other routine childhood/adult immunizations and may be given simultaneously with IPV, OPV, DTaP, DT, Tdap, Td, MMR, HBV, HAV, HIB, VAR, MMR/VAR, MCV4 and Influenza.

Vaccine Information Statement (VIS)

The Vaccine Information Statement (VIS) entitled "Pneumococcal Polysaccharide Vaccine What you need to know before you or your child gets the vaccine" must be provided to patients, guardians, or others with a need to know about the immunization.

Rationale:

For more information on PPSV23, see MMWR 63(37); 822-25 or go to http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm on the Internet.

POLICY ON POLIOMYELITIS VACCINATION

Policy:

Polio vaccine (IPV) shall be given in OPH Clinics to children 2 months to 18 years of age in accordance with the Louisiana Office of Public Health - Immunization Schedule as outlined below.

IPV may be given in OPH clinics to women who are pregnant.

IPV may be given in OPH clinics to persons who have diseases that cause immune deficiency including cancer and HIV infection or receiving therapy (radiation, drugs that cause immune suppression).

IPV may be given to household contacts of persons with diseases that cause immune deficiency or receiving therapy that cause immune suppression.

IPV shall be given according to the schedule given in the protocol section that follows.

Rationale:

For more information on Poliomyelitis prevention see MMWR 1997; 46(RR-3): 1-25 or www.cdc.gov/mmwr/preview/mmwrhtml/00046568.htm on the internet.

Polio Schedules and Recommendation

The currently approved vaccine for childhood Polio vaccination is to use only Inactivated Polio Vaccine (IPV) which minimizes the disadvantages and side effects of the live virus polio vaccination given previously.

The advantage of using Inactivated polio vaccine includes its lack of spread to others, which protects immunodeficient household members from infection with the vaccine virus, and its inability to cause paralytic disease, since there is no live virus in the vaccine. Disadvantages of IPV are the lack of intestinal immunity, which can allow an individual to become an asymptomatic carrier and the uncertainty about the need for later booster doses.

1. **Schedule**:

IPV schedule

Dose Number	Age of Child	Minimum Interval
1	2 months	6 weeks of age
2	4 months	1 month
3	12 months	6 months
First booster	4-6 years	------
Subsequent boosters	Unknown	------

2. Boosters

Booster doses may be necessary for the schedule which uses only IPV vaccine, but the need for further booster doses has not yet been established.

3. Simultaneous Administration

IPV should be administered simultaneously with other routine childhood immunizations, including DTaP, MMR, Hib, influenza, PCV7, Varicella, HAV, HBV and Rotavirus vaccine. Two vaccinations may be given in the same thigh or extremity, if necessary, using different sites of injection.

4. Non-Simultaneous Administration

Polio vaccine may be given simultaneously with other live virus vaccines, such as MMR or Varicella, or at any time in relation to them. There is no need to wait for a specific interval between doses of MMR or Varicella and polio if they are not given simultaneously.

5. Adult Immunization

If adults were to be vaccinated in special circumstances, IPV should be used.

Minimal Dosing Interval for IPV

The first dose of IPV may be given as early as 6 weeks of age. The minimum interval between subsequent doses of polio vaccine is one month. See schedule tables above for other dose-specific minimums.

POLICY ON ADMINISTRATION OF RABIES VACCINATION

The following information is provided for informational purposes only. Rabies vaccine and products are not available through the Immunization Program and may require consultation with the Infectious Disease Epidemiology Section and purchase through the State Pharmacy.

Rabies immunizing agents

Two types of rabies immunizing products are available in the United States.

1. Rabies vaccines induce an active immune response that includes the production of neutralizing antibodies. This antibody response requires approximately 7-10 days to develop and usually persists for greater than or equal to 2 years.

2. Rabies immune globulin (RIG) provides a rapid, passive immunity that persists for only a short time (half-life of approximately 21 days). In all postexposure prophylaxis regimens, except for persons previously immunized, both products should be used concurrently.

Vaccines Licensed for Use in the United States

Three cell culture rabies vaccines are licensed in the United States: human diploid cell vaccine (HDCV, Imovax® Rabies, Sanofi Pasteur), purified chick embryo cell vaccine (PCECV, RabAvert®, Novartis Vaccines and Diagnostics), and rabies vaccine adsorbed (RVA, Bioport Corporation). Only HDCV and PCECV are available for use in the United States. When used as indicated, all three types of rabies vaccines are considered equally safe and efficacious. The potency of one dose is greater than or equal to 2.5 international units (IU) per 1.0 mL of rabies virus antigen, which is the World Health Organization recommended standard. A full 1.0-mL dose can be used for both preexposure and postexposure prophylaxis. Rabies vaccines induce an active immune response that includes the production of virus neutralizing antibodies. The active antibody response requires approximately 7--10 days to develop, and detectable rabies virus neutralizing antibodies generally persist for several years. A vaccination series is initiated and completed usually with one vaccine product. No clinical trials were identified that document a change in efficacy or the frequency of adverse reactions when the series is initiated with one vaccine product and completed with another.

The passive administration of RIG is intended to provide an immediate supply of virus neutralizing antibodies to bridge the gap until the production of active immunity in response to vaccine administration. Use of RIG provides a rapid, passive immunity that persists for a short time (half-life of approximately 21 days). Two antirabies immune globulin (IgG) formulations prepared from hyperimmunized human donors are licensed and available for use in the United States: HyperRab™ S/D (Talecris Biotherapeutics) and Imogam® Rabies-HT (Sanofi Pasteur). In all postexposure prophylaxis regimens, except for persons previously vaccinated, HRIG should be administered concurrently with the first dose of vaccine.

Human Diploid Cell Vaccine (HDCV)

HDCV is prepared from the Pitman-Moore strain of rabies virus grown on MRC-5 human diploid cell culture, concentrated by ultrafiltration, and inactivated with beta-propiolactone. HDCV is formulated for intramuscular (IM) administration in a single-dose vial containing lyophilized vaccine that is reconstituted in the vial with the accompanying diluent to a final volume of 1.0 mL just before administration. One dose of reconstituted vaccine contains <150 µg neomycin sulfate, <100 mg albumin, and 20 µg of phenol red indicator. It contains no preservative or stabilizer.

Purified Chick Embryo Cell Vaccine (PCEC)

PCEC became available in the United States in 1997. It is prepared from the fixed rabies virus strain Flury LEP grown in primary cultures of chicken fibroblasts. The virus is inactivated with betapropiolactone and further processed by zonal centrifugation in a sucrose density gradient. It is formulated for IM administration only. PCEC is available in a single-dose vial containing lyophilized vaccine that is reconstituted in the vial with the accompanying diluent to a final volume of 1.0 mL just before administration. One dose of reconstituted vaccine contains <12 mg polygeline, <0.3 mg human serum albumin, 1 mg potassium glutamate, and 0.3 mg sodium EDTA. No preservatives are added.

Rabies Immune Globulin Licensed for Use in the United States

The two RIG products, HyperRabTM S/D and Imogam Rabies-HT, are an antirabies immunoglobulin (IgG) preparation concentrated by cold ethanol fractionation from plasma of hyperimmunized human donors.

Rabies neutralizing antibody, standardized at a concentration of 150 IU per mL, is supplied in 2-mL (300 IU) vials for pediatric use and 10-mL (1,500 IU) vials for adult use; the recommended dose is 20 IU/kg body weight. Both RIG preparations are considered equally efficacious when used.

These products are made from the plasma of hyperimmunized human donors that, in theory, might contain infectious agents. Nevertheless, the risk that such products will transmit an infectious agent has been reduced substantially by screening plasma donors for previous exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses. No transmission of adventitious agents has been documented after administration of HRIGs licensed in the United States.

TABLE 1. Currently available rabies biologics — United States, 2008

Human rabies vaccine	Product name	Manufacturer	Dose	Route	Indications
Human diploid cell vaccine	Imovax® Rabies*	sanofi Pasteur Phone: 800-822-2463 Website: http://www.vaccineplace.com/products/	1 mL	Intramuscular	Pre-exposure or postexposure†
Purified chick embryo cell vaccine	RabAvert®	Novartis Vaccines and Diagnostics Phone: 800-244-7668 Website: http://www.rabavert.com	1 mL	Intramuscular	Pre-exposure or postexposure†
Rabies immune globulin	Imogam® Rabies-HT	sanofi pasteur Phone: 800-822-2463 Website: http://www.vaccineplace.com/products/	20 IU/kg	Local§	Postexposure only
	HyperRab™ S/D	Talecris Biotherapeutics Bayer Biological Products Phone: 800-243-4153 Website: http://www.talecris-pi.info	20 IU/kg	Local§	Posteexposure only

* Imovax rabies I.D., administered intradermally, is no longer available in the United States.
† For postexposure prophylaxis, the vaccine is administered on days 0, 3, 7, 14 and 28 in patients who have not been previously vaccinated and on days 0 and 3 in patients who have been previously vaccinated. For pre-exposure prophylaxis, the vaccine is administered on days 0, 7 and 21 or 28.
§ As much of the product as is anatomically feasible should be infiltrated into and around the wound. Any remaining product should be administered intramuscularly in the deltoid or quadriceps (at a location other than that used for vaccine inoculation to minimize potential interference).

Vaccine and immunoglobulin Availability

Vaccine and immunoglobulin are available in some large pharmacies and in LSU Medical Center pharmacies.

Primary or Preexposure Vaccination

Preexposure prophylaxis is administered for several reasons. First, although pre-exposure vaccination does not eliminate the need for additional therapy after a rabies exposure, it simplifies therapy by eliminating the need for RIG and decreasing the number of doses of vaccine needed -- a point of particular importance for persons at high risk for being exposed to rabies in areas where immunizing products might not be available or where they might be at high risk for adverse reactions. Second, pre- exposure prophylaxis might protect persons whose postexposure therapy is delayed. Finally, it might provide protection to persons at risk for inapparent exposures to rabies.

Preexposure vaccination should be offered to persons in high-risk groups, such as veterinarians and their staff, animal handlers, rabies researchers, and certain laboratory workers. Preexposure vaccination also should be considered for other persons whose activities bring them into frequent contact with rabies virus or potentially rabid bats, raccoons, skunks, cats, dogs, or other species at risk for having rabies. In addition, international travelers might be candidates for preexposure vaccination if they are likely to come in contact with animals in areas where dog rabies is enzootic and immediate access to appropriate medical care, including biologics, might be limited. Routine preexposure prophylaxis for the general U.S. population or routine travelers to areas where rabies is not enzootic is not recommended.

Primary Vaccination

Three 1.0-mL injections of HDCV or PCEC should be administered intramuscularly (deltoid area) -- one injection per day on days 0, 7, and 21 or 28. Vaccine preparations for ID

administration are no longer available in the United States.

Preexposure Booster Doses of Vaccine

Persons who work with rabies virus in research laboratories or vaccine production facilities (continuous risk category are at the highest risk for inapparent exposures. Such persons should have a serum sample tested for rabies antibody every 6 months. An IM booster dose of vaccine should be administered to maintain a serum titer corresponding to at least complete neutralization at a 1:5 serum dilution by the RFFIT. The frequent-risk category includes other laboratory workers (e.g., those performing rabies diagnostic testing), spelunkers, veterinarians and staff, and animal-control and wildlife officers in areas where animal rabies is enzootic. Persons in this group should have a serum sample tested for rabies antibody every 2 years; if the titer is less than complete neutralization at a 1:5 serum dilution by the RFFIT, the person also should receive a single booster dose of vaccine. Veterinarians, veterinary students, and animal-control and wildlife officers working in areas where rabies is uncommon (infrequent exposure group) and certain at-risk international travelers who have completed a full pre-exposure vaccination series with licensed vaccines and according to schedule do not require serologic verification of detectable antibody titers or routine preexposure booster doses of vaccine. If they are exposed to rabies in the future, they a re considered immunologically primed against rabies and simply require postexposure prophylaxis for a person previously vaccinated (i.e., days 0 and 3 vaccination).

For postexposure prophylaxis for previously vaccinated persons, administration of RIG is unnecessary and should not be administered to previously vaccinated persons because the administration of passive antibody might inhibit the relative strength or rapidity of an expected anamnestic response. For previously vaccinated persons who are exposed to rabies, determining the rabies virus neutralizing antibody titer for decision-making about prophylaxis is inappropriate for at least three reasons. First, several days will be required to collect the serum and determine the test result. Second, no "protective" titer is known. Finally, although rabies virus neutralizing antibodies are important components, other immune effectors also are operative in disease prevention.

Postexposure Management

Postexposure antirabies vaccination should always include administration of both passive antibody and vaccine, with the exception of persons who have ever previously received complete vaccination regimens (pre-exposure or postexposure) with a cell culture vaccine or persons who have been vaccinated with other types of vaccines and have previously had a documented rabies virus neutralizing antibody titer. These persons should receive only vaccine (i.e., postexposure for a person previously vaccinated). The combination of HRIG and vaccine is recommended for both bite and nonbite exposures reported by persons who have never been previously vaccinated for rabies, regardless of the interval between exposure and initiation of prophylaxis. If postexposure prophylaxis has been initiated and appropriate laboratory diagnostic testing (i.e., the direct fluorescent antibody test) indicates that the exposing animal was not rabid, postexposure prophylaxis can be discontinued.

Rabies IgG Use. HRIG is administered only once (i.e., at the beginning of antirabies prophylaxis) to previously unvaccinated persons to provide immediate, passive, rabies virus-neutralizing antibody coverage until the patient responds to HDCV or PCECV by actively producing antibodies. If HRIG was not administered when vaccination was begun (i.e., day 0), it can be administered up to and including day 7 of the postexposure prophylaxis series. Beyond the seventh day, HRIG is not indicated because an antibody response to cell culture vaccine is presumed to have occurred. Because HRIG can partially suppress active production of antibody, the dose administered should not exceed the recommended dose. The recommended dose of HRIG is 20 IU/kg (0.133 mL/kg) body weight. This formula is applicable to all age groups, including children. If anatomically feasible, the full dose of HRIG should be thoroughly infiltrated in the area around and into the wounds. Any remaining volume should be injected IM at a site distant from vaccine administration. This recommendation for HRIG administration is based on reports of rare failures of postexposure prophylaxis when less than the full amount of HRIG was infiltrated at the exposure sites. HRIG should never be administered in the same syringe or in the same anatomical site as the first vaccine dose. However, subsequent doses of vaccine in the 5-dose series can be administered in the same anatomic location where the HRIG dose was administered, if this is the preferable site for vaccine administration (i.e., deltoid for adults or anterolateral thigh for infants and small children).

Vaccine Use

Two rabies vaccines are available for use in the United States; either can be administered in conjunction with HRIG at the beginning of postexposure prophylaxis. A regimen of 5 one-mL doses of HDCV or PCECV should be administered IM to previously unvaccinated persons. The first dose of the 5-dose course should be administered as soon as possible after exposure. This date is then considered day 0 of the postexposure prophylaxis series. Additional doses should then be administered on days 3, 7, 14, and 28 after the first vaccination. For adults, the vaccination should always be administered IM in the deltoid area. For children, the anterolateral aspect of the thigh is also acceptable. The gluteal area should never be used for HDCV or PCECV injections because administration of HDCV in this area results in lower neutralizing antibody titers.

Deviations from Recommended Postexposure Vaccination Schedules

Every attempt should be made to adhere to the recommended vaccination schedules. Once vaccination is initiated, delays of a few days for individual doses are unimportant, but the effect of longer lapses of weeks or more is unknown. Most interruptions in the vaccine schedule do not require reinitiation of the entire series. For most minor deviations from the schedule, vaccination can be resumed as though the patient were on schedule. For example, if a patient misses the dose scheduled for day 7 and presents for vaccination on day 10, the day 7 dose should be administered that day and the schedule resumed, maintaining the same interval between doses. In this scenario, the remaining doses would be administered on days 17 and 31. When substantial deviations from the schedule occur, immune status should be assessed by performing serologic testing 7--14 days after administration of the final dose in the series.

Management and Reporting of Adverse Reactions to Rabies Biologics

Once initiated, rabies prophylaxis should not be interrupted or discontinued because of local or mild systemic adverse reactions to rabies vaccine. Usually, such reactions can be successfully managed with anti-inflammatory, antihistaminic, and antipyretic agents.

When a person with a history of hypersensitivity to rabies vaccine must be revaccinated, empiric intervention such as pretreatment with antihistamines might be considered. Epinephrine should be readily available to counteract anaphylactic reactions, and the person should be observed carefully immediately after vaccination.

Although serious systemic, anaphylactic, or neuroparalytic reactions are rare during and after the administration of rabies vaccines, such reactions pose a serious dilemma for the patient and the attending physician. A patient's risk for acquiring rabies must be carefully considered before deciding to discontinue vaccination. Advice and assistance on the management of serious adverse reactions for persons receiving rabies vaccines can be sought from the state or local health department or CDC.

All clinically significant adverse events occurring following administration of rabies vaccine should be reported to VAERS, even if causal relation to vaccination is not certain. Although VAERS is subject to limitations common to passive surveillance systems, including underreporting and reporting bias, it is a valuable tool for characterizing the safety profile of vaccines and identifying risk factors for rare serious adverse reactions to vaccines (94). VAERS reporting forms and information are available at http://www.vaers.hhs.gov or by telephone (800-822-7967). Web-based reporting is available and health-care providers are encouraged to report electronically at https://secure.vaers.org/VaersDataEntryintro.htm. Clinically significant adverse events following HRIG administration should be reported to the Food and Drug Administration's MedWatch. Reports can be submitted electronically to http://www.fda.gov/MedWatch.

POLICY ON LIVE, ORAL ROTAVIRUS VACCINATION

Policy:

Rotavirus is the leading cause of gastroenteritis and death worldwide among infants and young children. Four prevalent serotypes which accounted for more than 80% of cases of human rotavirus disease worldwide are G1P[8], G2P[4], G3P[8], and G4P[8]. A recent strategy to prevent rotavirus was through vaccination which induced immunity against rotavirus gastroenteritis. The first rotavirus vaccine licensed in 1998 was recommended for routine immunization of infants in the United States. Shortly thereafter, an association between the use of the vaccine and intestinal intussusception was recognized and the vaccine was voluntarily withdrawn in October 1999.

Two rotavirus vaccines have been approved by the FDA. RotaTeq® (RV5) manufactured by Merck & Co and licensed in 2006 is a live, oral pentavalent human-bovine (WC3) reassortant rotavirus vaccine that has demonstrated its potential benefit in preventing rotavirus gastroenteritis with no significant increased risk of intussusception.

Rotarix® (RV1) manufactured by GSK was licensed in April 2008 and is indicated for the prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (G3, G4, and G9) when administered as a 2-dose series. ROTARIX® is a live, attenuated oral rotavirus vaccine derived from the human 89-12 strain which belongs to G1P[8] type.

These two products differ in composition and schedule of administration. Both vaccines significantly reduced the need for hospitalization, emergency department visits, and office visits associated with rotavirus gastroenteritis, underscoring the potential public health benefits of a universal vaccination program. There is no precedence for use with either vaccine.

Vaccination Schedule and Dosage:

RotaTeq® vaccine is indicated for the prevention of rotavirus gastroenteritis in infants and children caused by serotypes G1, G2, G3, and G4 when administered in a 3-dose series to infants between the ages of 6 to 32 weeks. The first dose should be administered at a minimum age of 6 weeks; the maximum age for dose 1 of rotavirus vaccine is 14 weeks and 6 days with subsequent minimum interval doses administered at 4 week intervals with completion of the 3-dose series by 8 months and 0 days. The RotaTeq® vaccine series consists of three ready-to-use liquid doses of vaccine administered orally and each dose is supplied in a squeezable plastic, latex-free dosing tube with a twist-off cap allowing for direct oral administration. RotaTeq® vaccine should be provided during the 2, 4 and 6 months of age schedule and can routinely be given simultaneously with other scheduled vaccines, such as DTaP, IPV, PCV, HIB, and HBV.

Rotarix® vaccine is to be administered as a 2-dose series with doses given at age 2 and 4 months. The vaccination series consists of two 1-mL doses administered orally. The first dose should be administered to infants beginning at 6 weeks of age. There should be an interval of at least 4 weeks between the first and second dose. The 2-dose series should be completed by 24

weeks of age.

Guidelines:

Rotavirus vaccine should not be administered to infants who have a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of rotavirus vaccine or to a vaccine component. Latex rubber is contained in the RV1 oral applicator, so infants with a severe (anaphylactic) allergy to latex should NOT receive RV1. The RV5 dosing tube is latex-free. Based on recommendations from CDC and ACIP, practitioners should consider the potential risks and benefits of administering rotavirus vaccine to infants who have altered immunocompetence (e.g., blood dyscrasias, leukemia, hematopoietic transplantation, HIV/AIDS) or to infants with a previous history of intussusception.

NOTE: The first dose of rotavirus vaccine should be administered from ages 6 weeks through age 14 weeks 6 days (the maximum age for the first dose is 14 weeks 6 days). Vaccination should NOT be initiated for infants of age 15 weeks 0 days or older because of insufficient data on safety of dose 1 of rotavirus vaccine in older infants. The minimum interval between doses of rotavirus vaccine is 4 weeks; no maximum interval is set. All doses should be administered by 8 months 0 days.

Interchangeability of vaccines:

ACIP recommends that the rotavirus vaccine series be completed with the same product whenever possible. However, vaccination should not be deferred if the product used for previous doses is unavailable or is unknown. In this situation, the provider should continue or complete the series with the product available. If ANY dose in the series was RV5 or the product is unknown for any dose in the series, a total of 3 doses of rotavirus vaccine should be given.

While these vaccines are orally administered, if for any reason an incomplete dose of rotavirus vaccine is administered (e.g., infant spits or regurgitates the vaccine), a replacement dose is NOT recommended and should continue to receive any remaining doses in the recommended series. There are no restrictions on the infant's consumption of food or liquids, including breast milk, either before or after vaccination. Rotavirus vaccine may be administered at any time before, concurrent with, or after administration of any blood product, including antibody-containing products, following the routinely recommended schedule for rotavirus vaccine among infants who are eligible for vaccination. Rotavirus vaccine can be given to premature infants if they a) are at least 6 weeks of age, b) are being or have been discharged from the hospital nursery, and c) are clinically stable.

Vaccine Information Statement (VIS):
The Vaccine Information Statement (VIS) entitled "Rotavirus Vaccine: What You Need to Know" must be provided to patients, guardians, or others with a need to know about the immunization. The VIS forms will be available at the Division of Administration Forms Management Warehouse.

Rationale:

For more information on Rotavirus vaccine, see MMWR or http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5802a1.htm on the internet.

POLICY ON RUBELLA VACCINATIONS

Policy:

1. One dose of rubella (MMR) vaccine followed by a booster dose at least a month apart will be given in OPH clinics to children 12 months of age and older, adolescents, health care personnel regardless of sex, and women of childbearing age who lack documentation of previous vaccinations or adequate immunity except as outlined below. The MMR second dose should be routinely administered at 4 to 6 years of age, at school entry. The second dose may be given at any time 4 weeks or more after the first dose. Any MMR dose given after the first birthday and at least 4 weeks after the first dose can be counted as a valid second dose. Second doses should be given to older children who have not had one. The adolescent visit at 11 or 12 years of age should be used as a check point, to make sure that no child enters young adulthood without two doses of MMR.

2. Rubella vaccine is not given to women who know or suspect they are pregnant.

3. Rubella vaccine is not given to persons with known anaphylactic allergy to neomycin (see measles protocol).

4. Women who are not pregnant when given rubella vaccine are advised that they should not become pregnant for 3 months following vaccination.

5. Rubella vaccine is not given to persons with disease that results in immune deficiency (including cancer) and persons who are receiving therapy including radiation that suppresses the immune system. Rubella vaccine may be given to asymptomatic HIV-infected individuals, but should not be given to those who have severe immuno-suppression as evidenced by opportunistic infections or low CD-4 count (symptomatic AIDS).

6. Rubella vaccine shall not be given as a single antigen. If rubella vaccine is required, MMR may be used.

7. Rubella vaccine may be given to household contacts of person with altered immunity.

Rationale:

For more information on Rubella prevention see MMWR 1990; 39(RR-15): 1-18 or www.cdc.gov/mmwr/preview/mmwrhtml/00001893.htm on the internet.

POLICY ON VARICELLA, ZOSTAVAX AND MMRV COMBINATION VACCINATION

Introduction:

The Office of Public Health Immunization Program follows recommendations from the Advisory Committee on Immunization Practices (ACIP) of the U.S. Public Health Service to immunize children age 12 months and older against varicella (chickenpox). All individuals > 13 years of age without evidence of immunity should be vaccinated with 2 doses of Varicella vaccine at an interval of 4-8 weeks.

Varicella (chickenpox) is a highly contagious disease caused by varicella zoster virus (VZV). There are two vaccines approved by FDA that can be utilized to offer protection against varicella – Varivax, which is a specific single antigen vaccine and secondly, ProQuad, which is a combination of measles, mumps, rubella and Varicella (MMRV). These licensed varicella vaccines provide 70-90% protection against infection with varicella zoster virus, and 95% protection against severe disease. The vaccine contains live, attenuated virus grown in human or guinea pig cells. No chicken or duck egg proteins are present in the vaccine. Vaccination with varicella vaccine is contraindicated in individuals with a history of anaphylactic reactions to gelatin or neomycin.

Guidelines:

The dosage of varicella or MMRV vaccine is 0.5 ml to be given subcutaneously only. For record keeping purposes, the identifying designation for varicella vaccines are Var or MMRV.

All children < 13 years of age should be administered routinely 2 doses of Varicella-containing vaccine, with the first dose administered at 12-15 months of age and the second dose at 4 – 6 years of age. The second dose can be administered at an earlier age provided the interval between the first and second dose is at least 3 months. However, if the second dose is administered at least 28 days following the first dose, the second dose does not need to be repeated.

Two postlicensure studies and other related data support the conclusion that use of MMRV vaccine among children aged 12--23 months results in a higher risk for fever and febrile seizures during the 5--12 days after the first dose compared with the use of MMR vaccine and varicella vaccine at the same visit. Although data regarding the risk for febrile seizures after administration of the first dose of MMRV vaccine are available only for children aged 12--23 months, the increased risk for febrile seizures during the 5--12 days postvaccination is likely to be present among children aged ≤47 months because that is the biologic window of vulnerability for febrile seizures in children (approximately 97% of febrile seizures occur in children aged <4 years). Results from postlicensure studies do not suggest that children aged 4--6 years who receive the second dose of MMRV vaccine have an increased risk for febrile seizures after vaccination compared with children the same age who receive the second dose of MMR vaccine and varicella vaccine at the same visit.

Use of MMRV vaccine has the benefit of requiring one less injection than the alternative of MMR vaccine and varicella vaccine. The decision-making process must include provision of specific information to parents and caregivers about the risk for febrile seizures associated with receipt of the first dose of MMRV vaccine compared with the first dose of MMR vaccine and varicella vaccine. The following CDC update and recommendations as of May 2010 pertaining to MMRV vaccine include:

The routinely recommended ages for measles, mumps, rubella and varicella vaccination continue to be age 12--15 months for the first dose and age 4--6 years for the second dose.

For the first dose of measles, mumps, rubella, and varicella vaccines at age 12--47 months, either measles, mumps, and rubella (MMR) vaccine and varicella vaccine or MMRV vaccine may be used. Providers who are considering administering MMRV vaccine should discuss the benefits and risks of both vaccination options with the parents or caregivers. Unless the parent or caregiver expresses a preference for MMRV vaccine, CDC recommends that MMR vaccine and varicella vaccine should be administered for the first dose in this age group.

For the second dose of measles, mumps, rubella, and varicella vaccines at any age (15 months--12 years) and for the first dose at age ≥48 months, use of MMRV vaccine generally is preferred over separate injections of its equivalent component vaccines (i.e., MMR vaccine and varicella vaccine). Considerations should include provider assessment, patient preference, and the potential for adverse events.

A personal or family (i.e., sibling or parent) history of seizures of any etiology is a precaution for MMRV vaccination. Children with a personal or family history of seizures of any etiology generally should be vaccinated with MMR vaccine and varicella vaccine.

A second dose catch-up Varicella vaccination is recommended for children, adolescents, and adults who previously had received one dose, to improve protection against Varicella and for more rapid impact on school outbreaks. Catch-up second dose can be administered at any interval longer than 3 months after the first dose. According to the LA Immunization School law, 2 doses of Varicella and MMR or MMRV are required for entry in kindergarten as well as required for adolescents 11 years of age who will be entering middle school. At least one dose of varicella and MMR or MMRV is required for entry in child care and Headstart facilities.

HIV-infected children > 12 months of age in CDC clinical class N, A, or B, with CD4+ T-lymphocyte counts > 15% and without evidence of Varicella immunity should receive 2 doses of single antigen Varicella vaccine at a minimum interval of 3 months. Varicella vaccine was recommended previously for asymptomatic or mildly symptomatic HIV-infected children with age-specific CD4+ T-lymphocyte counts > 25%. Because data are not available on safety, immunogenicity or efficacy of MMR/VAR vaccine in HIV-infected children, MMR/VAR should not be administered as a substitute for the component vaccines when vaccinating HIV infected children.

Combined MMR/Var (ProQuad) vaccine shall be used in accordance to the policies as stated for

MMR and Varicella use. At least 1 month should elapse between a dose of MMR and a dose of ProQuad. However, if for any reason a second dose of varicella-containing vaccine is required, at least 3 months should elapse before administration of the 2 dose.

NOTE: ProQuad is indicated only for use in children 12 months to 12 years of age.

Women should be asked if they are pregnant and advised to avoid pregnancy for three months following each dose of varicella vaccine. This vaccine should not be administered to a pregnant woman. Upon completion or termination of their pregnancies, women who do not have evidence of Varicella immunity should receive the first dose of Varicella vaccine before discharge from the healthcare facility. The second dose should be administered 4 – 8 weeks later.

Herpes Zoster

Both chickenpox and shingles are caused by the same virus, the varicella zoster virus (VZV). After a person has had chickenpox, the virus rests in the body's nerves permanently. Approximately 30% of all people who have been infected with chickenpox will later develop herpes zoster, commonly known as zoster or shingles.

Shingles usually starts as a rash with blisters that scab after 3 to 5 days. The most frequently mentioned symptom is pain. Both the rash and pain usually occur in a band on one side of the body or clustered on one side of the face.

The rash clears within 2 to 4 weeks. Complications from shingles include pneumonia, hearing problems, blindness, scarring, brain inflammation (encephalitis) or death. One out of five persons will develop post-herpetic neuralgia (PHN) even after the rash has cleared. Treatment for shingles includes antiviral medicine and should be given as soon as the rash appears and is most effective if given within 24 to 72 hours of rash onset.

Transmission of shingles is not passed from person-to-person unless the exposed individual has never had chickenpox disease or never been vaccinated against chickenpox (if they have direct contact with the rash). This exposed person would develop chickenpox and not shingles.

Zoster vaccine (ZOSTAVAX® Merck & Co., Inc.) was licensed in 2006 and is a live, attenuated vaccine recommended for adults 60 years (per ACIP) of age and older as a single one-time dose administered subcutaneously. The most commonly reported side effects include redness, pain or tenderness, swelling and itchiness at the injection site. Zoster vaccine is contraindicated for those individuals who are allergic to neomycin or any component of the vaccine (including gelatin) and for those who have weakened immune system caused by treatments such as radiation or corticosteroids, or due to conditions such as HIV/AIDS, cancer of the lymph, bone or blood. Transmission of the chickenpox virus from a person who has received shingles vaccine has never been documented.

Simultaneous vaccine administration:

Varicella and Zostavax vaccine and MMR/VAR combination vaccine do not interfere with other

routine childhood/adult immunizations. There is a theoretical risk that non-simultaneous administration of multiple live virus vaccines (MMR and varicella) within less than 28 days of one another will result in a suboptimal immune response. Until further information becomes available, specific antigen MMR and varicella vaccines should be given at least 4 weeks apart, if they are not given on the same day. If MMRV combination vaccine is used, appropriate spacing of doses must be considered depending on the specific live vaccine that has been used previously.

Two vaccinations may be given in the same thigh, using different administration sites, if necessary.

Storage, handling, and ordering:

Varicella vaccine, Zostavax and MMRV combination vaccine are less stable than other vaccines that are routinely handled. All vaccines must be protected from light and they are more temperature sensitive than other routine vaccines. Varicella and MMRV vaccine should only be stored in freezers or refrigerator/freezers with separate doors and compartments. (Exception: Zostavax should be stored only in freezers). Dormitory style refrigerators, usually smaller, are not acceptable for the storage of any varicella-containing vaccine.

Reconstituted Vaccine

Do not store reconstituted vaccine. Varicella, Zostavax vaccine and MMRV vaccine should be administered immediately after reconstitution, to minimize loss of potency. Discard if the reconstituted vaccine is not used within 30 minutes. Under no circumstances should a single Varicella dose be mixed with an MMR dose.

Rationale:
For more information on Varciella prevention see MMWR 1996; 45(RR-11): 1-36 or www.cdc.gov/mmwr/preview/mmwrhtml/00042990.htm or MMWR 2010;59(RR03);1-12. For Prevention of Herpes Zoster see MMWR 2008; 57(RR-5): 1-30 or http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5705a1.htm

Inquiries concerning Varicella or Zostavax vaccine or MMRV vaccine may be directed to the Immunization Program at (504) 838-5300.

POLICY ON THE IMMUNIZATION OF ADOLESCENTS

Policy:

This policy emphasizes vaccination of adolescents 11-12 years of age (from the 11th birthday to the day before the 13th birthday) and is retroactive to May 1, 1996. Specifically, this policy recommends vaccination of unimmunized adolescents with varicella virus vaccine, hepatitis B, meningococcal conjugate vaccine (MCV4), and/or the second dose of the measles, mumps and rubella (MMR) vaccine in addition to providing a booster dose of tetanus diphtheria toxoid and acellular pertussis (Tdap) if at least five years have lapsed since the last vaccine booster.

Note: Children who received a second dose of MMR at school entry or who received two doses of MMR after one year of age do not need to be re-vaccinated with MMR vaccine at 11-12 years of age. Varicella vaccine should be given to 11-12 year old adolescents if they have no history of chicken pox. If the child is deficient in either MMR or Varicella, the MMR/VAR combined vaccine may be used. MCV4 should be given to all 11-18 year old children with a booster dose at age 16. Hepatitis B should be given to 11-12 year old adolescents if they have not previously completed a 3 dose series. If they have had a partial series, the series should be completed. Tdap should be only administered once in the routine Td series throughout adulthood.

This policy also emphasizes the vaccination of all children up to 19 years of age at a high risk of HBV infection. This includes children and adolescents who are developmentally disabled, on hemodialysis, those who have bleeding disorders who receive clotting factor concentrates, sexually active, users of illicit injectable drugs, or those who have sexual or regular household contact with a person who is hepatitis B surface antigen positive. In addition, children born since October 1983 to women from areas of high hepatitis B endemicity are also eligible.

Vaccine dosage, schedule and administration:

All vaccinations should be given according to the current OPH schedule. Dosages and further guidelines for each vaccine can be found in the corresponding policies for Varicella/MMR-VAR, Hepatitis B, Measles-Mumps-Rubella, and Tetanus and diphtheria toxoid and acellular pertussis.

Simultaneous vaccine administration:

Routine immunizations can and may be given simultaneously including Varicella, IPV, OPV, Td, Tdap, MMR, MMR-VAR, HBV, and Influenza. There is a theoretical risk that non-simultaneous administration of multiple live virus vaccines (MMR and varicella) within less than 28 days of one another will result in a suboptimal immune response. For this reason, MMR and Var should be given at least 4 weeks apart if they are not given on the same day. Refer to Policy on Varicella and MMR/VAR Combination Vaccine section for further instructions on scheduling doses. Two vaccinations may be given in the same arm, using different administration sites.

For further information on the Immunization of Adolescents see MMWR 1996; 45(RR-13): 1-16 or www.cdc.gov/mmwr/preview/mmwrhtml/00044572.htm on the internet.

POLICY ON THE IMMUNIZATION OF HIGH RISK ADULTS WITH HEPATITIS VACCINE

Policy:

This policy describes the procedure for identification, referral, screening, vaccination and monitoring of persons considered at high risk for exposure to the hepatitis viruses. The procedures are designed primarily for prevention of transmission and the severity of burden of hepatitis A, B, and C in Louisiana. The policy will help increase vaccination coverage in Louisiana by prompting providers to administer immunizations to high-risk individuals.

Note: This policy is in effect only when the STD, HIV/AIDS Program have vaccine on hand for the age-appropriate group. However, the dosage schedule can be used as a guide in any event where vaccination of HAV would be required.

Guidelines:

1. Identification and Referral

An adult at high risk or possible high-risk of hepatitis B or hepatitis C infection should be offered hepatitis A and B vaccine. Persons at high risk include:

- Injection drug user (past or present)
- Sex partner of injection drug user
- Sex partner of an individual known to be chronically infected with hepatitis
- Female commercial sex worker
- Men who have sex with men
- Received a blood transfusion or other blood products prior to 1992

2. Screening and Vaccination

Pre-screening is not required. At the initial visit, the first dose of Hepatitis A and B vaccine should be given, and follow – up appointments made for the second and third dose of vaccine (one and six months later respectively). However, if serological screening is an option, hepatitis B Core Antibody (anti-HBc) and anti Hepatitis C Virus (anti-HCV) testing is recommended. If the patient was exposed to hepatitis B (anti-HBC positive), he/she should be notified that the second and third doses of vaccine are not necessary.

If the patient is susceptible to hepatitis B (anti-HBC negative), then encourage the patient to keep appointments for the second and third doses.

Every patient of the clinic should be offered the hepatitis B vaccine. In addition, hepatitis A vaccine should be offered to patients who meet the following criteria:

- Men who have sex with men
- Injection drug user (past or present)
- Any individual who is chronically infected with HBV or HCV

3. Vaccine Dosage, Schedule and Administration

The following immunization schedule is recommended by the Advisory Committee on Immunization Practices (ACIP) to the Centers for Disease Control and adopted by Louisiana Office of Public Health (OPH). Administer Hepatitis A and B vaccines intramuscularly (IM) in the deltoid muscle (1", 23 gauge needle is preferred). The amount of each dose is shown in the tables below. Two doses given when using the hepatitis A vaccine single dose and three doses when using hepatitis B vaccine single dose or Twinrix (the combination vaccine A&B). Primary immunization with TWINRIX for high risk adults (18 years of age and older) consists of 3 doses given on a 0-, 1-, and 6 month schedule.

Alternatively, an accelerated 4 dose Twinrix schedule given on days 0-, 7 and 21-30 followed by a booster dose at month 12 may be used. The accelerated vaccination schedule may represent the preferred option for individuals at imminent risk for hepatitis A and hepatitis B. These include travelers to countries endemic for hepatitis A and hepatitis B, prison inmates, military personnel, emergency care first responders to disaster areas, persons with high-risk sexual behavior, and intravenous drug users.

Recommended dosages of Hepatitis A Vaccines

Vaccine	Vaccine recipients Age (yrs)	Dose	Volume (mL)	No. Doses	Schedule (mos) §
HAVRIX®*	2 -18	720 EL.U	0.5	2	0,6 - 12
	> 18	1,440 EL.U	1.0	2	0, 6 – 12
VAQTA®**	2 – 18	25 U	0.5	2	0, 6 – 18
		50 U	1.0	2	0, 6

* Hepatitis A vaccine, inactivated, SmithKline Beecham Biologicals.
**Hepatitis A vaccine inactivated, Merck Co., Inc.

Recommended dosages of Single Antigen (hepatitis B vaccine)

Vaccine	Vaccine recipients age (yrs)	Dose (µg)ï	Volume (mL)	No. Doses	Schedule (mos)§
Engerix B®*	Infants and children <19	10	0.5	3	0, 1, 6
	≥ 20	20	1.0	3	0, 1, 6
	Dialysis patients &other compromised persons	40ug	2.0	4	0, 1, 2, 6
Recombivax®*	Infants and children <19	5	0.5	3	0, 1, 6
	≥ 20	10	1.0	3	0, 1, 6
	Dialysis patients & other compromised persons	40ug	1.0	3	0, 1, 6

• Hepatitis B vaccine, inactivated, SmithKline Beecham Biologicals.
ï micrograms.
§ 0 months represents timing of the initial dose; subsequent numbers represent months after the initial dose
Þ Special formulation for dialysis patients.

Recommended dosages of Twinrix®

Vaccine Recipients age (yrs)	Dose (EL.U and µg†	Volume (mL)	No. Doses	Schedule (mos) §
>18	720 (hepatitis A) 20 (hepatitis B)	1.0	3	0, 1, 6
Accelerated schedule > 18	720 (hepatitis A) 20 (hepatitis B)	1.0	4	Days 0-, 7-, 21 to 30 days followed by booster dose at month 12

† Each dose of Twinrix contains 720 EL.U of hepatitis A vaccine (equivalent to a pediatric dose of Havrix), and 20 µg of hepatitis B surface antigen protein (equivalent to an adult dose of Engerix-B®)
§ 0 months represents timing of the initial dose; subsequent numbers represent months after the initial dose.

Schedule Containing Both Twinrix and Single Antigen Vaccines

Dose 1	Dose 2	Dose 3
Twinrix	Adult Hepatitis A vaccine Adult Hepatitis B vaccine	Adult Hepatitis A vaccine* Adult Hepatitis B vaccine
Twinrix	Twinrix	Adult Hepatitis A vaccine Adult Hepatitis B vaccine
Adult Hepatitis A vaccine Adult Hepatitis B vaccine	Twinrix	Adult Hepatitis A vaccine* Adult Hepatitis B vaccine
Adult Hepatitis A vaccine Adult Hepatitis B vaccine	Adult Hepatitis A vaccine* Adult Hepatitis B vaccine	Adult Hepatitis B vaccine**

*Separated from prior Hepatitis A vaccine dose by ≥5 months
**May use Twinrix for this dose

4. Interruption in the Vaccine Schedule

If the second dose of hepatitis A vaccine is delayed, the second dose should be administered as soon as possible. There is no need to repeat the first dose. The hepatitis B vaccine is still effective when given at intervals longer than those recommended; therefore persons whose schedule is interrupted do not need to have the vaccine series restarted. If the vaccine series is interrupted after the first dose, the second and third doses should be given separated by an interval of 3-5 months. If the vaccine series is interrupted after the second dose, the third dose should be given as soon as practical.

5. Follow-up of patients who do not come for vaccination

The amount of effort to be spent in locating a patient should depend on the patient's risk and on the likelihood, that he/she will complete the series. Those at the highest risk should be encouraged to complete the series.

6. Post- vaccination Testing

No post – vaccination serologic testing will be done for adult patients.

7. Tracking

Information about the patients may be maintained in both the central office (Immunization Program LINKS System) and in the Health Care Provider's Office.

POLICY ON USAGE OF COMBINATION VACCINES

An increasing number of new vaccines to prevent childhood diseases have been licensed. Combination vaccines represent one solution to the issue of increased numbers of injections during a single clinic visit. To minimize the number of injections children/infants receive, parenteral combination vaccines should be used as licensed and indicated for patient's age, instead of their equivalent component vaccines. Prior to administration, the healthcare provider should review the patient's immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions to allow an assessment of benefits and risk.

Immunization providers should stock sufficient types of combination and monovalent vaccines needed to immunize children against all diseases for which vaccines are recommended. When patients already have received the recommended immunizations for some of the components in a combination vaccine, administering the extra antigens in the combination vaccine is permissible. Several combination vaccines have been licensed for use by FDA and utilized in the VFC program. Specific indications and instructions should be reviewed for each licensed vaccine and the interchangeability with other vaccines.

Pediarix (DTaP-Hep B-IPV)

On December 2002, the U.S. Food and Drug Administration (FDA) licensed a combined diphtheria and tetanus toxoids and acellular pertussis adsorbed (DTaP), hepatitis B (HepB) (recombinant) and inactivated poliovirus vaccine (IPV), DTaP-HepB-IPV (Pediarix™, SmithKline Beecham Biologicals, Rixensart, Belgium). Pediarix is approved as a 3-dose primary series, generally beginning at 2, 4, and 6 months of ages. It is licensed for children 6 weeks through 6 years of age. The DTaP-HepB-IPV combination is not approved for the fourth dose of IPV or the fourth and fifth dose of DTaP. If there are no documented doses of DTaP, IPV, or hepatitis B vaccines, then Pediarix can be used for the first 3 doses of these vaccines as long as the child is at least 6 weeks of age and younger than 7 years of age.

DTaP-HepB-IPV and HepB vaccine from a different manufacturer are interchangeable for HepB vaccination. DTaP-HepB-IPV and IPV from a different manufacturer are interchangeable for poliovirus vaccination. DTaP-HepB-IPV combination can be administered with Hib and PCV vaccines at separate injection sites.

A birth dose of single-antigen vaccine is preferred for all infants but must be administered to infants who are born to women who are HBsAg-positive or whose HBsAg status is unknown. The birth dose can then be followed by 3 doses of Pediarix™ at ages 2, 4, and 6 months. Second, the third dose of Pediarix™ should be administered at least 16 weeks after the first dose and at least 8 weeks after the second dose but not before age 6 months.

Kinrix (DTaP-IPV)

KINRIX (GSK) vaccine contains 4 vaccines to protect against diphtheria, tetanus, pertussis and

poliomyelitis. The vaccine is indicated for the fifth DTaP and fourth dose IPV in 4 to 6 year olds whose previous DTaP vaccine doses have been with Infanrix and/or Pediarix or individual component vaccines. It was licensed by the FDA on June 24, 2008, DTaP-IPV (Kinrix™) combination vaccine is approved for the booster dose for children ≥ 4 years to <7 years of age. Kinrix is available as a single-dose vial and prefilled syringe containing a 0.5 ml suspension for injection of diphtheria and tetanus toxoids, acellular pertussis antigens and inactivated poliovirus types 1, 2 and 3. The vaccine is to be administered as a 0.5-ml dose by intramuscular injection. Do not administer this product intravenously, intradermally, or subcutaneously.

Common adverse events were injection-site reactions (pain, redness, swelling or increase in arm circumference), drowsiness, fever, and loss of appetite. Previous hypersensitivity to any component of Kinrix, including neomycin and polymixcin B, is a contraindication. Encephalopathy within 7 days of administration of a previous pertussis-containing vaccine or progressive neurologic disorder is a contraindication. The tip cap and the rubber plunger of the needleless, prefilled syringes contain dry natural latex rubber and may cause allergic reactions in latex sensitive individuals. The vial stopper is latex-free.

Pentacel (DTaP-IPV-Hib)

Pentacel is a combination vaccine that contains DTaP, IPV and Hib vaccines. Pentacel is supplied as single-dose vial, 5 doses to a package. A single dose of liquid DTaP-IPV vaccine is use to reconstitute a single-dose vial of lyophilized ActHIB vaccine. Pentacel can be administered to any child 6 weeks through 4 years of age, without a contraindication to any component, for whom DTaP, IPV and Hib vaccines are indicated. The recommended schedule for Pentacel is functionally the same as for DTaP and ActHIB with doses at 2, 4, 6, and 15 though 18 months of age.

Pentacel may be used whenever any component(s) of the combination is indicated and no other component of the vaccine is contraindicated. This means that Pentacel can be used when a child needs one or two components, but does not need the others. Contraindications and precautions for Pentacel are the same as those for DTaP, IPV, and Hib vaccines.

Pentacel Schedule for Administration

Parameter	Age/interval
Minimum age for any dose	6 weeks
Minimum interval for doses 1 and 2	4 weeks
Minimum age for dose 2	10 weeks
Minimum interval for doses 2 and 3	4 weeks
Minimum age for dose 3	14 weeks
Minimum interval for dose 3 and 4	6 months (determined by DTaP component; minimum interval for dose 3-4 is two months for HIB and four weeks for IPV)

Minimum age for dose 4	12 months (determined by DTaP and HIB components). Note that both the minimum interval AND age must be met for the fourth dose of DTaP or HIB (as Pentacel or any other formulation) to be counted as valid
Maximum age for any dose	4 years, 364 days (i.e., do not administer at age 5 years or older)

Sample Vaccination Schedules for Using Pentacel®* for Hep B, Hib, IPV, & DTaP
In the Event of Hib Shortage*

Table 1. Using Pentacel* for All Doses

Birth	2 Months	4 Months	6 Months	12 Months	4 – 6 years
Hep B	Hep B		Hep B		
				DTaP	DTaP
					IPV
	Pentacel*	Pentacel*	Pentacel*		

Sample Vaccination Schedules for Using Pentacel®* for Hep B, Hib, IPV, & DTaP in the Event of Hib Shortage* (cont.)

Table 2. Using Single Anitgen Vaccines for First Dose and Pentacel* for Remainder of Doses

Birth	2 Months	4 Months	6 Months	12 Months	4 -6 years
Hep B	Hep B		Hep B		
	Hib*				
	DTaP			DTaP	DTaP
	IPV				IPV
		Pentacel*	Pentacel*		

Table 3. Using Single Antigen Vaccines for First and Second Doses and Pentacel* for Third Dose

Birth	2 Months	4 Months	6 Months	12 Months	4 -6 years
Hep B	Hep B		Hep B		
	Hib*	Hib*			
	DTaP	DTaP		DTaP	DTaP
	IPV	IPV			IPV
			Pentacel*		

Table 4. Using Pediarix* for First Dose and Pentacel* for Remainder of Doses

Birth	2 Months	4 Months	6 Months	12 Months	4 -6 years
Hep B			Hep B		
	Hib*			DTaP	DTaP

		Pentacel*	Pentacel*		IPV
	Pediarix*				

Table 5. Using Pediarix* for First and Second Doses and Pentacel* for Third Dose

Birth	2 Months	4 Months	6 Months	12 Months	4 -6 years
Hep B			Hep B		
	Hib*	Hib*			
				DTaP	DTaP
					IPV
			Pentacel*		
	Pediarix*	Pediarix*			

In general, ACIP recommends the same brand of DTaP be used for all doses of the series. However, different brands can be used if the provider does not know or have available the brand of DTaP used for prior doses.**
*Hib Shortage Guidelines: “Updated Hib Interim Schedule”

MenHibrix
(Hib-MenCY-TT [MenHibrix, GlaxoSmithKline Biologicals])

MenHibrix is a vaccine indicated for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroups C and Y and Haemophilus influenzae type b. MenHibrix is approved for use in children 6 weeks of age through 18 months of age at increased risk for meningococcal disease. These include infants with recognized persistent complement pathway deficiencies and infants who have anatomic or functional asplenia including sickle cell disease. MenHibrix can be used in infants ages 2 through 18 months who are in communities with serogroup C and Y meningococcal disease outbreaks. Four doses (0.5 mL each) should be administered by intramuscular injection at 2, 4, 6, and 12 through 15 months of age. The first dose may be given as early as 6 weeks of age. The fourth dose may be given as late as 18 months of age. MenHibrix may be administered to infants to complete the routine HIB series.

If an infant at increased risk for meningococcal disease is behind on his or her Hib vaccine doses, MenHibrix may be used following the same catch-up schedule used for Hib vaccine.

However, if the first dose of MenHibrix is given at or after 12 months of life, 2 doses should be given at least 8 weeks apart to ensure protection against serogroups C and Y meningococcal disease. For infants at increased risk for meningococcal disease who have received or are going to receive a different Hib vaccine product, ACIP recommends a 2-dose series of MenACWY-D if they are aged 9 through 23 months or either of the two quadrivalent meningococcal vaccine products after age 23 months. MenHibrix may be co-administered with other routine infant vaccinations, including 13-valent pneumococcal conjugate vaccine.

MenHibrix should not be co-administered with other Hib-containing vaccines.Infants and children who received Hib-MenCY-TT and are travelling to areas with high endemic rates of meningococcal disease such as the "meningitis belt" are not protected against serogroups A and

W-135 and should receive a quadrivalent meningococcal conjugate vaccine licensed for children aged ≥9 months before travel.

Do not administer this product intravenously, intradermally, or subcutaneously. After reconstitution, administer MenHibrix immediately. Rates of local injection site pain, redness, and swelling ranged from 15% to 46% depending on reaction and specific dose in schedule. Commonly reported systemic events included irritability (62% to 71%), drowsiness (49% to 63%), loss of appetite (30% to 34%), and fever (11% to 26%) (specific rate depended on the event and dose in the schedule).

Example of "Shots for Tots By One" Schedule Using Pediarix & TriHIBit

Vaccine/Age	Birth	2 mos	4 mos	6 mos	12 mos	Total
Hep B	Hep B	Pediarix	Pediarix	Pediarix		
DTaP		Pediarix	Pediarix	Pediarix	TriHIBit	
Hib		Hib	Hib	Hib	TriHIBit	
IPV		Pediarix	Pediarix	Pediarix		
PCV		PCV	PCV	PCV	PCV	
MMR					MMR	
Varicella					Varicella	
# of injections	1	3	3	3	4	14

PROCEDURES FOR VACCINE PROTECTION AND HURRICANE/DISASTER PREPAREDNESS

When there is a reasonable cause to believe that emerging conditions will disrupt vaccine operations, emergency procedures should be implemented well in advance of the event to protect the vaccine inventory and minimize the potential monetary loss from natural disasters or other emergencies.

In advance of the emergency, all providers should ensure the following:

If the facility does not have a backup generator, identify an alternative storage facility (i.e., hospital, packing plant, state depot, fire or police station, etc.), with back-up power (generator), where the vaccine can be properly stored and monitored for the duration of the storm. Make arrangements with the site to store your vaccine if your vaccine storage equipment malfunctions or there is a power outage; the availability of staff to pack and move the vaccine; the use of appropriate packing materials and containers, and cold packs and/or portable freezer (for Varicella and/or MMR/VAR vaccine) and the availability of resources for transportation of the vaccine to a secure storage facility.

In situations where a location with a backup generator cannot be identified within a reasonable distance, preparations should be made to obtain use of a refrigerated truck or purchase coolers, frozen ice packs and/or portable freezer to temporarily store vaccine.

NOTE: It is appropriate for providers to suspend vaccinations BEFORE weather conditions deteriorate. Sufficient time must be allowed for packing and transporting vaccine BEFORE the storm adversely affects local conditions.

There are other precautions and appropriate measures one can take to protect vaccine inventories using the emergency procedures described below. The following includes some HELPFUL HINTS AND REFERENCE INFORMATON.

I. EMERGENCY PROCEDURES

A. List emergency phone numbers, companies, and points of contact for:

1. Electrical power company:
2. Refrigeration repair company:
3. Temperature alarm monitoring company:
4. Perimeter alarm repair company:
5. Perimeter alarm monitoring company:
6. Backup storage facility:
7. Transportation to backup storage:

8. Emergency generator repair company:
9. National weather service:
10. Vaccine Manufacturers:

a. Merck: www.merckvaccines.com or 1- 877-829-6372

b. Sanofi Pasteur: www.sanofipasteur.us or 1-800-VACCINE (800-822-2463)

c. GlaxoSmith Kline: www.gsk.com or 1-866-475-8222

d. Pfizer: www.pfizer.com or 1-800-879-3477

e. Novartis: www.novartis.com or 1-877-683-4732

f. MedImmune: www.medimmune.com or 1-877-633-4411

B. State/project assistance to providers in possession of vaccine

1. Identify hospitals, health departments or other facilities that could serve as emergency vaccine storage facilities and communicate this information. This might also be done at the regional or parish level and/or with the assistance of Bioterrorism or Emergency Preparedness Units.

2. Prioritize assistance and communication to target providers in areas at highest risk, e.g., low lying coastal or floodprone areas.

C. Entering vaccine spaces/facility floor plan - Describe, when necessary, how to enter the building and vaccine storage spaces in an emergency if closed or after hours. Include a floor diagram and the locations of:

1. Storage units
2. Doors
3. Flash lights
4. Spare batteries
5. Light switches
6. Keys
7. Locks
8. Alarms
9. Circuit breakers
10. Packing materials

D. Identify who to call for the following assistance:

1. Equipment problems
2. Backup storage

3. Backup transportation
4. Security

E. Identify what vaccines to pack first in an emergency and while the power is still working:

1. Pack the refrigerated vaccines first with an adequate supply of cold packs.

2. Remove and pack the Varicella or MMR-VAR vaccine and place in a portable freezer with calibrated thermometer. Document time, temperature and date prior to and after safe storage.

F. Pack and transport all vaccines or if that is not possible, determine the types and amounts to save: e.g., save only the most expensive vaccines to minimize dollar loss or save some portion of all vaccines to ensure a short term, complete supply for resuming the vaccination schedule. We would suggest the first priority be given to those vaccines which would be the most expensive to replace.

G. Follow vaccine packing procedures for transport to backup storage facilities:

1. Open refrigerated units only when absolutely necessary and only after you have made all preparations for packing and moving the vaccine to alternative storage sites.

2. Use properly insulated containers.

3. Record vaccine type(s), quantity, date, time and originating facility on the container.

H. Move vaccine to backup storage according to pre-arranged plans.

1. How to load transportation vehicle

2. Routes to take

3. Time en route

4. Ensure vaccine containers are stored properly in the emergency storage facility (Varicella or MMR-VAR in freezer, refrigerated vaccines in refrigerator, adequate circulation, functional temperature monitoring device, etc)

I. Once the vaccines have been safely transported to another location and if there are plans to distribute vaccines from that site, assure that there is an inventory process to maintain accountability throughout the duration of time while at the temporary vaccine storage site.

J. Impact of Severe Weather Conditions on Biological Products

Vials of biological products in contact with flood waters should not be used given the possibility of contamination and the likelihood of significant exposure to temperatures outside of those recommended for cold chain storage.

Vaccines Requiring Refrigeration or Frozen Storage – Most refrigerated vaccines are relatively stable at room temperature for limited periods of time, although certain vaccines are temperature-sensitive. Products stored in a closed refrigerator (or freezer, if appropriate) during a power outage may maintain their potency unless the power outage is of such duration that the refrigerator's (or freezer's) internal temperature rises significantly. It is recommended that thermometers be located in the refrigerator and freezer section so that temperatures can be read when power resumes to see if excursions outside of the recommended temperatures have occurred.

1. If Power Goes Out – Persons responsible for storing refrigerated or frozen biological product should take the following actions to reserve cold storage conditions during a power outage:

a. Note the time of power outage and do not open freezers/refrigerators until power is restored to help keep the temperature low for a longer period of time.

1. For refrigerator-stored vaccines, do not open the refrigerators to check temperatures during a power outage, as many products will maintain their potency for a few days in the relative cool of a closed refrigerator.

2. For vaccines requiring freezer storage, remove them from the freezer (if the power outage continues) and place in another freezer if possible. If the vaccines are not cold to the touch upon removal from the freezer, the vaccine should be isolated and not be used. Contact the Immunization Program for further guidance

b. When Power is Restored – Record the temperature in the refrigerator or freezer as soon as possible after power is restored and before the temperature has begun to drop again. Continue to record the temperature at periodic intervals until it reaches the temperature range indicated on the product labeling as appropriate for product storage. Record the duration of increased temperatures exposure.

c. If a flood is Expected – When a flood is anticipated, facilities should take steps to raise stored products out of range of anticipated flood waters. For products stored in refrigerators at floor level, elevate refrigerators on wheels or platforms to the extent possible.

Many immune globulin products are licensed for storage at 36 to 46 degrees Fahrenheit, and some products may be stored at room temperatures for all or part of the time before expiration. Because storage temperatures and times are specific to each product, you should follow the package insert recommendations for Immune Globulin (IGIV), intramuscular IG (IG) and subcutaneous IG (IGSC) products. Products requiring lower temperatures can be stored on wet ice. All of these products should not be frozen.

K. Refer to the Emergency Response Plan and Worksheet (included in this section) and post near or on outside of vaccine storage equipment:

EMERGENCY RESPONSE PLAN & WORKSHEET (Part 1)

Post near or on outside of refrigerator for all staff

Provider Name:	VFC PIN#
Primary Person Responsible:	Phone:
Secondary Person Responsible:	Phone:
Person with 24-hour access:	Phone:

For a Power Outage: If you do not have a generator, identify at least one location with a generator (hospital, 24-hour store, public health unit etc.). Before transporting, call the back-up location site to ensure that their generator is working.

#1.Location & Contact's Name Ph#_____

#2.Location & Contact's Name Ph#_____

How will you be notified of an outage?

Vaccines must be transported in an insulated cooler with a barrier separating the vaccines from the ice/cold packs.
Varicella, MMRV and zoster must be transported using a portable freezer.

If your emergency back-up location is more than 30 minutes away and you have a large quantity of vaccine, consider renting a refrigerated truck to transport your vaccine.
Refrigeration Company Phone #

OTHER RESOURCES:
Public Health Unit:
_____
Ph#_____
_____

PREVENT LOSS FROM EXPIRED VACCINES

Check and rotate your stock to assure shortest dated vaccine is used first and in front of vaccines with longer expiration dates. Designate a staff person to verify rotation and documentation. (Post vaccine expiration table.)

Notify the Louisiana Immunization Program (504-838-5300) if vaccines are going to expire within 3-6 months.

CHECK AND RECORD REFRIGERATOR AND FREEZER TEMPERATURES TWICE A DAY

Once in the am when the practice opens.
Once in the afternoon to allow for adjustments prior to the time the practice closes.

What to do if a power failure occurs, the refrigerator door was left open, the temperature was too cold, the refrigerator plug was pulled, or any other situation which would cause improper storage conditions:

1. Determine the cause of improper vaccine temperatures (i.e., mechanical failure, power outage, natural disaster, human error). Close the door and/or plug in the refrigerator/freezer.
2. Store the vaccines at appropriate temperatures. Determine if vaccine should be moved and move if appropriate.
3. Record the current temperature of the refrigerator/freezer.
4. Mark the vaccine so that the potentially compromised vaccines can be easily identified.
5. Collect essential data on the Emergency Vaccine Response Worksheet. (see part 2 of this sheet.)
6. Notify the Louisiana Immunization Program at (504-838-5300).

Practice Name: _____ VFC PIN: _____

EMERGENCY RESPONSE WORKSHEET (Part 2)

1. Date of Event: _____
2. Current temperature of refrigerator: Max/min temperature reached:
3. Current temperature of freezer: Max/min temperature reached:
4. Amount of time temperature was outside normal range:
   refrigerator freezer:

Refrigerator

Vaccine and Manufacturer	Lot Number	Expiration Date	Amount of Vaccine Action Taken

Freezer

Vaccine and Manufacturer	Lot Number	Expiration Date	Amount of Vaccine Action Taken

Vaccine Manufacturers

Manufacturer	Telephone Number Recommendations
Sanofi Pasteur www.sanofipasteur.us	1-800-822-2463
Merck www.merckvaccines.com	1-877-829-6372
GlaxoSmithKline www.gsk.com	1-866-475-8222
Pfizer www.pfizer.com	1-800-879-3477
Novartis www.novartis.com	1-800-244-7668
MedImmune www.medimmune.com	1-877-633-4411
Manufacturer	**Telephone Number Recommendations**
Sanofi Pasteur www.sanofipasteur.us	1-800-822-2463
Merck www.merckvaccines.com	1-877-829-6372
GlaxoSmithKline www.gsk.com	1-866-475-8222
Pfizer www.pfizer.com	1-800-879-3477
Novartis www.novartis.com	1-800-244-7668
MedImmune www.medimmune.com	1-877-633-4411

IMMUNIZATION GUIDELINES FOR DISPLACED CHILDREN - POST-NATURAL DISASTER

Determining immunization status among post natural disaster displaced children, adolescents.
Situation: a child's record is assumed to be lost, and can not be recovered from a provider's office, a daycare, school, or the parent has no record of immunization then several determinations should be attempted.
Question- Based upon what the parent is saying about medical visits, is it probable that the child has had age appropriate immunization? Answer: Possibly.
Question: Can you accept that the history given can be relied upon? Was the child probably up-to-date at the last medical visit? Answer: To meet enrollment requirements the Immunization Program will accept historical data of primary series, and does not recommend the starting of the immunization series. But enrollees must receive age appropriate boosters prior to entering school.
Question: Has the child already been enrolled in the school system? If so, then it should be assumed that the child had complied with the immunization requirements at the time of enrollment. Answer: Yes. To meet enrollment requirements the Immunization Program will accept historical data of primary series, and does not recommend the starting of the immunization series. But enrollees must receive age appropriate boosters prior to entering school.
Question: If the child is four years of age, what vaccines are needed to be in compliance with age appropriate vaccination? Answer: A four year old child should have or receive a DTaP, IPV, MMR, Var (or history of disease), HBV
Question: If the child is 7 years of age what does he needs? Answer: The child should have or receive a Td, IPV, MMR, HBV, Varicella (or history of disease) in order to be in compliance with Louisiana's state immunization law.
Question: If an adolescent age 14 years enrolls in schools does she need any immunization or is she age appropriate vaccinated? Answer: If she received her last booster dose on or after 4 th birthday or prior to school entry, she is considered in need of a Td vaccination (a minimum of five (5) years from the last dose). While you are checking her status, see if she needs Varicella, MMR, and HBV.
Question: How can I get historical immunization information on a patient from New Orleans ? Answer: For patients or parents who are requesting copies of their immunization records: A . Search for the patient in LINKS by entering the first initial of their first name and date of birth. If patient is located, print, sign and send copy of record to patient. B . If the patient was not in LINKS but attended one of the City of New Orleans clinics that used LINKS: Ida Hymel, Edna

Pilsbury, Helen Levy, Katherine Benson, Mandeville-Detiege Health Clinics or the Wellness Shop, call (504) 658-2510 . The City of New Orleans staff may be able to assist them. If the patient attended the St. Bernard-Gentilly Health Clinic, this clinic did not use LINKS, but the City of New Orleans Health Department may be able to assist. C. The New Orleans Health Corporation Clinics were not LINKS users. Those records would probably not be in LINKS. D. If the patient is on Medicaid , call 1-800-259-4444 and request a History of Immunization Claims. E. If the patient had private insurance, they can call their insurance company and request an "Entire Claims History".
Question: What immunizations should be given to Katrina/Rita Evacuees with no past immunization history? Answer: 2 Years of Age – If child had shots at one year of age or after – Nothing is needed until age four. 4 Years of Age - (and up through age 6) – DTaP, IPV, MMR, HBV, Varicella (or history of disease). 7 - 10 Years of Age – If it cannot be determined that the child received the vaccines for school entry at 4 – 6 years of age, he/she should receive Td, IPV, MMR, HBV and Varicella (or history of disease). 11 Years and Up – Tdap, IPV, MMR, HBV, VAR (or history of disease) MCV4 if 11-12 years, 15 years or through age 18 living in dormitory and must be VFC eligible.
- Rule of Thumb: Any Katrina/Rita impacted student must show proof of age appropriate immunizations dated on or after August 29, 2005. This up to date status will expire five years after date of issue.
Inquiries may be directed to the Immunization Program at 504-838-5300.

CHECK YOUR VIALS: Is It Tdap, DTaP, or Td?

VACCINES FOR CHILDREN (VFC) DISCREPANCY OR MISUSE POLICY

Policy
The purpose of this procedures document is to outline the Louisiana Immunization Program responsibilities when discrepancies, misuse, or suspected health care provider activities which are not consistent with the Vaccines for Children Program (VFC) are discovered.

DEFINITIONS:

Discrepancy occurs when accountability data and other pieces of information indicate that vaccine may have been used for purposes, other than the intended use (sold, traded, discarded, etc).

Misuse occurs when vaccine is knowingly given to patients for whom it is not intended or given inappropriately. For example: giving DT to adults, using PCV-7 for fully insured children, etc.

The severity or the degree of the discrepancy and/or misuse may lead to further investigation by other agencies for fraud and/or abuse.

Fraud, as it is defined in 42 CFR 455.2, is "an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself/herself, or some other person".

Abuse is defined as provider practices that are inconsistent with sound fiscal, business, or medical practices. Consequently these practices result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet the professionally recognized standard for health care.

The Centers for Disease Control and Prevention (CDC) grant mandates that states prevent fraudulent use of vaccines purchased with public funds. The federal grant further states that: Immunization programs also have a prime responsibility to assure appropriate use of public vaccine and to vigorously enforce measures to prevent fraud and abuse of public vaccine at the provider level, and Louisiana must immediately report to CDC instances of possible fraudulent use of vaccine purchased with federal funds. Louisiana must work closely with Medicaid in VFC fraud investigations and complete a preliminary investigation within five working days of the initial report.

POSSIBLE ORIGINS OF SUSPECTED DISCREPANCIES AND/OR MISUSE:

1. Outside call reporting a suspected discrepancy and/or misuse situation. For example:
   A. A concerned patient or provider staff member may call Louisiana Immunization Program VFC.
2. Vaccine Administered Report (VAR) reviews. For example:
   A. Provider VARs document PCV-7 given to ineligible patients.
   B. VAR review suggests a pattern of non-simultaneous vaccine administration.

C. Provider not submitting monthly report to VFC Program Office.

3. Vaccine Orders. For example:

A. Order Entry unit notices that provider is ordering amounts inconsistent with usual ordering patterns and/or reported patient population distribution per funding source.

4. Routine VFC Site Visits. A minimum of 50 records review.

A. Interview staff regarding administration fees and other charges.
B. Interview staff regarding simultaneous vaccine administration.
C. Patient chart review for documentation of VFC Screening and eligibility.
D. Comparing patient chart review data with VAR data.
E. During site visit, Immunization Consultant compares recent VAR to patient record to ensure proper documentation of eligibility.
F. Excessive staff turnover
G. Vaccine administration errors.
H. Vaccine storage and handling. Temperatures repeatedly documented outside the recommended range.

ACTIONS TO BE TAKEN:

Unintentional Discrepancies and/or Misuse of Louisiana Immunization Program, Vaccines for Children Program Policy and Vaccines.

If regional and/or central office staff determines the discrepancy or misuse to be unintentional and originating from lack of program knowledge, education is generally the reasonable course of action. If directed by the Vaccines Procurement Manager and/or AFIX Coordinator, follow up by regional and/or central office staff in 30 to 90 days is generally recommended.

Education Efforts Include but are not limited to:

- Provide education at time of contact (i.e. during VFC site visit, per telephone conversation)
- If a discrepancy or misuses are noted during VFC site visit, a Provider Improvement Plan (PIP) report needs to be written by the Consultant and returned to the VFC Program Office within 30 days of visit. The PIP should clearly state the actions being taken by the provider to adhere to the Louisiana Immunization Vaccines For Children Program (LIVFCP) contract.
- Need for a follow-up visit or phone call will be determined on a case-by-case basis.

Determinants for a follow-up may include:

- Failure to return a completed, signed PIP within 30 days.
- The severity of original misconduct
- Recommendations from the Immunization Management
- Suspicions that documented changes will not be implemented by provider.
- Low performers will be placed on VFC site visit list for following year.

Intentional Discrepancies and/or Misuse of VFC Policy and Vaccines

All DHH-OPH employees should immediately report any suspected discrepancies and/or misuse of VFC policy or vaccines situations to the Vaccines Procurement and Management Office (VPMO) and/or AFIX Coordinator (AC).

1. The origin of the suspected discrepancy and/or misuse should be documented.
2. The VPMO and/or AC will review the situation and if he/she deems it necessary will relay the information to the Immunization Program Office.
3. The Immunization Program Office will determine if the situation warrants further investigation.
4. If it is deemed necessary, the VFC-AFIX Immunization Consultant or other appropriate Immunization Program staff will follow-up with the provider. Areas of concern will be further investigated. The VFC-AFIX Immunization Consultant will conduct a site visit and submit a report to the Immunization Program Office summarizing his/her findings and recommendations.

REFERRALS TO MEDICAID

Situations may occur where no further follow-up or other intervention beyond referral to the Medicaid Office exist. The Medicaid Office has several branches within their organization that work on suspected fraud and/or abuse situations. The Immunization Program would immediately report suspected discrepancies and/or misuse to the Medicaid Office if Medicaid regulations are in possible jeopardy. The immunization Program will make referrals to Medicaid in writing. Such communiqué will include as much information as possible. The letter will go to the attention of:

Department of Health and Hospitals
Medicaid Program Operations Program Integrity
543 Spanish Town Road, Baton Rouge, La 70802

Fraud hotline is 1- 800- 488-2917
Program Unit telephone (225) 219-4152

Or

The fraud hotline number is 1-866-Fraud05 (1-866-372-8305).

If deemed appropriate the Public Health Advisor would report to CDC's National Immunization Program (NIP) any cases of suspected intentional discrepancies and/or misuse.

Referrals to the Insurance Commissioner

Situations may occur where no further follow up or other interventions beyond the referral to the Insurance Commission exist. For example:

Louisiana Insurance Commissioner
1702 North Third Street
Baton Rouge, La 70802
Telephone (225) 342-5900

If deemed appropriate by the Immunization Program, the Public Health Advisor would report to CDC's National Immunization Program (NIP) cases of suspected intentional discrepancies and/or misuse.

Annual Activities by the State Immunization Program

The Immunization Program will contact Medicaid and ask to be routinely informed of individuals enrolled in Medicaid and are also enrolled in VFC and are being investigated for alleged malfeasance, and /or misfeasance.

Continue regular meetings with Medicaid.

Ensure Medicaid is up to date on Louisiana Immunization Program - Vaccines For Children changes.

The Louisiana Department of Health and Hospital –Office of Public Health Immunization Program will contact the Insurance Commission to see if there are any other activities we could collaborate on to ensure Louisiana Immunization Program – Vaccines For Children compliance, Update CDC/NIP on Louisiana Immunization Program – Vaccines For Children activity in this area.

FOREIGN-BORN PERSONS AND IMMUNIZATIONS WITH FREQUENTLY ASKED QUESTIONS

Policy

Immunization recommendations for immigrants, refugees, migrants, foreign exchange students, and internationally adopted children living in Louisiana are the same as for any person born in the United States.

Vaccines at Parish Health Units are available for any uninsured or underinsured persons, regardless of immigration status. Parish Health Units routinely provide MMR, Tdap, varicella and seasonal influenza vaccinations to uninsured or underinsured persons applying for immigration. Louisiana's foreign-born persons include:

A. Refugees: Persons lawfully admitted to the U.S. who cannot return to their countries of origin because of well-founded fear of persecution because of race, religion, membership in a particular social group, or political opinion.

B. Immigrants: Persons lawfully admitted for permanent residence in the U.S.

C. Migrants: (Documented/un-documented) generally, foreign-born persons (and their families) who are seasonally employed in Louisiana.

D. Internationally Adopted Children: Children from foreign countries who are adopted by U.S. families.

E. Foreign Students: Persons from outside the U.S. who are studying in this country.

As a general policy, the CDC and The U.S. Department of Justice strongly encourage all health departments to immunize foreign-born persons when ever possible. The Frequently Asked Questions about Immunizations and Foreign-Born Persons address some of the unique challenges such as:

- How do you communicate with someone who does not speak English?
- What are those strange shots listed on some of your patients' records?
- Where can you find a list of foreign language vaccine-preventable disease terms?
- Where can you get translated patient education materials (i.e., VIS)?
- What is a Supplemental I-693 form?

Frequently Asked Questions about Immunizations and Foreign-Born Persons

Question: Are immunization requirements and/or recommendations different for foreign-born persons than people born in the United States?

Answer: No. Immunization requirements and/or recommendation for immigrants, refugees, foreign exchange students, migrants, and internationally adopted children living in Louisiana are the same as for any person born in the United States. Assess the immunization status of foreign-born persons and determine needed vaccines based upon the Louisiana childhood and adult immunization schedules.

Question: Do immunizations given overseas count?

Answer: Immunizations given outside the United States are valid only if they were given at the appropriate age recommended by the official Louisiana Department of Health and Hospital, Office of Public Health, Immunization Program childhood or adult schedule.

Question: What are these foreign vaccines on vaccination record card?

Answer: See the links on how to interpret foreign vaccines at the end of this section and Vaccines and Biologics Used in U.S. and Foreign Markets.

Question: What schedule should we use to "catch up" our foreign-born patients?

Answer: Use the same schedule you would use to catch up any patient. The catch-up schedules are located with the childhood and adult immunization schedules. Be sure to use the most current year schedules.

Question: What if a foreign-born patient has no written documentation of his/her immunization record?

Answer: If no written documentation exists, the individual is to be considered unvaccinated and should receive age-appropriate vaccinations. Use the catch up schedule on the most current Louisiana childhood and adult schedules.

Question: Should we start a series over again if there has been a long delay between doses?

Answer: No. No matter how long it has been since the previous dose, a vaccine series never needs to be started over again. You just pick up where the patient left off and give the remaining doses.

Question: What are the immunization requirements for refugees?

Answer: Refugees are not required to show proof of vaccination when applying for entrance to the U.S. However, they must satisfy age-appropriate immunization requirements when they apply for adjustment of their status, which they can do no less than one year after their admission to the U.S. Refugees may have had vaccinations in their country of origin, but due to the circumstances of their departure are unlikely to have vaccination documentation.

Immunization assessment is a component of the Refugee Health Assessment and many refugees who have received this assessment have also received the first doses of their needed immunization series. Ask individuals if they have completed this medical assessment. If they have, and they do not present with an immunization record card, contact the provider who did the medical assessment.

Question: What are the immunization requirements for immigrants?

Answer: Immigrants are required to have received some immunizations prior to leaving their country of origin. Be sure to ask if the individual has immunization documentation when they are enrolling in school, seeking medical care, or preparing to apply to adjust their status.

Question: What is a supplemental I-693 Form?

Answer: All refugees and immigrants applying to change their immigration status or to apply for their "green cards" must show proof of age-appropriate immunizations. This information may be completed by any public or private provider on the Supplemental I-693 Form and it then must be signed by a U.S. Civil Surgeon.

Question: What are the immunization requirements for foreign students?

Answer: Students enrolling in a Louisiana school must meet the Louisiana School Immunization Law requirements.

Question: What are the immunization recommendations for families adopting children from other countries?

Answer: Providers should make sure that families traveling to other countries to pick up their adopted children receive all the recommended immunizations for international travel.

Question: How can I be sure the immunization record of my internationally adopted patient is accurate?

Answer: If you have reason to believe that you cannot reasonably determine your patient's level of protection against vaccine-preventable disease based on his or her record--vaccinate. When in doubt, vaccinate!

Question: What about varicella, measles, mumps, rubella, polio and Mantoux tests?

Answer: Assessing patients for varicella, MMR, and other vaccines is often confusing. The following "tips" on assessing foreign-born persons also apply to persons born in the United States.

Varicella, measles, mumps, rubella, polio, and Mantoux tests

Varicella: A patient's self-report of varicella disease is acceptable.

Caution: Some patients may confuse chickenpox and smallpox diseases/symptoms.If patient has no history of "chicken pox" then provide varicella immunization.

Measles and mumps: Acceptable evidence of immunity includes a positive serologic test for antibody for each disease; a physician diagnosis of disease; patient's birth before 1957; or written documentation of vaccination. If not, vaccinate.

Rubella: Only serologic evidence of disease or documented vaccination should be accepted as proof of immunity. If not, vaccinate.

Polio and Foreign-born adults: All persons 18 and older (foreign-born and non-foreign born) do not need polio vaccine unless they are traveling to a country where polio is endemic.

Mantoux / live vaccines: A Mantoux test (PPD) can be administered simultaneously with a live or inactivated vaccine. However, if the patient received a live vaccine (e.g., MMR or varicella) the previous day or earlier, the Mantoux test must be delayed for at least four weeks; if the Mantoux test was administered earlier, there is no need to wait before administration of a live vaccine (e.g., MMR or varicella). The OPH TB Program performs PPDs on children under 2 or those with indeterminate blood assay (IGRA) tests. Please check with the Tuberculosis Program if there are questions

Vaccine Information Statements (VISs) in languages other than English

Federal law requires that you give patients the appropriate Vaccine Information Statement (VISs) for each vaccine to be given before you immunize them. VISs are available in at least 26

different languages and are an excellent source of vaccine information for patients. Try to provide your patient with a VISs in his/her primary language. Find VISs translated into other languages at http://www.immunize.org/vis/

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, 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.

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!

VACCINATION OF HEMATOPOIETIC CELL TRANSPLANT RECIPIENTS

A hematopoietic cell transplant (HCT) results in immunosuppression because of the hematopoietic ablative therapy administered before the transplant, drugs used to prevent or treat graft-versus-host disease, and, in some cases, from the underlying disease process necessitating transplantation. HCT involves ablation of the bone marrow followed by reimplantation of the person's own stem cells or stem cells from a donor. Antibody titers to vaccine-preventable diseases (e.g., tetanus, poliovirus, measles, mumps, rubella, and encapsulated bacteria) decrease 1--4 years after autologous or allogeneic HCT if the recipient is not revaccinated. HCT recipients of all ages are at increased risk for certain vaccine-preventable diseases, including diseases caused by encapsulated bacteria (i.e., pneumococcal, meningococcal, and Hib infections). As a result, HCT recipients should be revaccinated routinely after HCT, regardless of the source of the transplanted stem cells. Most inactivated vaccines should be initiated 6 months after the HCT. Below are recommendations for specific vaccines:

Influenza vaccine - Life-long seasonal influenza vaccination is recommended for all HCT candidates and recipients, beginning during the influenza season before HSCT and resuming >6 months after HCT. HCT recipients <6 months after HCT should receive chemoprophylaxis with amantadine or rimantadine during community or nosocomial influenza A outbreaks. These drugs are not effective against influenza B. Inactivated influenza vaccine should be administered beginning at least 6 months after HCT and annually thereafter for the life of the patient. A dose of inactivated influenza vaccine can be given as early as 4 months after HCT, but a second dose should be considered in this situation. A second dose is recommended routinely for all children receiving influenza vaccine for the first time.

Pertussis vaccine - Revaccination to prevent pertussis should involve a primary series of DTaP followed by a Tdap booster.

Pneumococcal vaccine - Three doses of pneumococcal conjugate vaccine (PCV-13) is recommended, beginning 3--6 months after the transplant, followed by a dose of PPSV.

HIB vaccine - Although no data regarding vaccine efficacy among HCT recipients were found, Hib conjugate vaccine should be administered to HCT recipients at 12, 14, and 24 months after HCT. This vaccine is recommended because the majority of HCT recipients have low levels of Hib capsular polysaccharide antibodies >4 months after HCT, and allogeneic recipients with chronic GVHD are at increased risk for infection from encapsulated organisms (e.g., Hib). HCT recipients who are exposed to persons with Hib disease should be offered rifampin prophylaxis according to published recommendations. A 3-dose regimen of Hib vaccine should be administered beginning 6 months after transplant; at least 1 month should separate the doses.

MMR vaccine - MMR vaccine should be administered 24 months after transplant if the HCT recipient is immunocompetent.

Varicella vaccine - Because of insufficient experience using varicella vaccine among HCT recipients, physicians should assess the immune status of each recipient on a case-by-case basis

and determine the risk for infection before using the vaccine. If a decision is made to vaccinate with varicella vaccine, the vaccine should be administered a minimum of 24 months after transplantation if the HCT recipient is presumed to be immunocompetent.

Household and other close contacts of HCT recipients and healthcare providers who care for HCT recipients should be appropriately vaccinated, particularly against influenza, measles, and varicella.